

**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, 2021

or

**Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number: 001-36715

**NEVRO CORP.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

56-2568057  
(I.R.S. Employer  
Identification No.)

1800 Bridge Parkway  
Redwood City, California 94065  
(Address of principal executive offices and zip code)

(650) 251-0005  
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, par value \$0.001 per share	NVRO	New York Stock Exchange

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act of 1934 (the "Exchange 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 Exchange Act 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 during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or 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.

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

As of June 30, 2021, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$5,695 million based on the closing sale price for the registrant's common stock on The New York Stock Exchange on that date of \$165.79 per share.

As of February 16, 2022, there were 35,049,108 shares of the registrant's Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement for the registrant's 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K to the extent stated herein. The Proxy Statement will be filed within 120 days of the registrant's fiscal year ended December 31, 2021.

Auditor Firm Id: 238

Auditor Name: PricewaterhouseCoopers LLP

Auditor Location: San Jose, California

**NEVRO CORP.**  
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## PART I

### ITEM 1. BUSINESS

#### Overview

We are a global medical device company focused on delivering comprehensive, life-changing solutions that continue to set the standard for enduring patient outcomes in chronic pain treatment. We have developed and commercialized the Senza® spinal cord stimulation (SCS) system, an evidence-based neuromodulation platform for the treatment of chronic pain, with the Senza® Omnia™ platform being our latest addition to the Senza family of products. Our proprietary, paresthesia-free 10 kHz Therapy, delivered by our Senza system, was demonstrated in our SENZA randomized controlled trial (RCT) to be superior to traditional SCS therapy, with 10 kHz Therapy being nearly twice as successful in treating back pain and 1.5 times as successful in treating leg pain when compared to traditional SCS therapy. In addition to the original approval of our therapy in back and leg pain, we received approval of unilateral or bilateral pain, associated with painful diabetic neuropathy (PDN) in July 2021 and we received expanded labeling in non-surgical refractory back pain (NSRBP) in January 2022. Our SENZA-RCT study, along with our SENZA-PDN clinical study, SENZA-NSRBP clinical study and European studies, represents what we believe is the most robust body of clinical evidence for any SCS therapy. We believe the superiority of 10 kHz Therapy over traditional SCS therapies will allow us to capitalize on and expand the approximately \$2.3 billion global SCS market by treating patients with debilitating chronic pain, including back and leg pain, NSRBP and PDN.

We launched Senza commercially in the United States in May 2015, after receiving a label from the U.S. Food and Drug Administration (FDA) supporting the superiority of our 10 kHz Therapy over traditional SCS. The Senza system has been commercially available in certain European markets since November 2010 and in Australia since August 2011. We have experienced significant revenue growth in the United States since commercial launch. Senza is currently reimbursed by all of the major insurance providers. In early 2017, we commenced a controlled commercial launch of our family of surgical leads, marketed as the Surpass surgical lead, and in April 2020 received FDA approval for our reduced-size Surpass-C surgical lead. In January 2018, we received FDA approval of our next generation Senza II SCS system. In the fourth quarter of 2019, we received FDA approval of our next generation product platform, Senza Omnia, which we launched in the United States in the fourth quarter of 2019. Additionally, we received approval to commercially launch Senza Omnia in Europe during the second quarter of 2020 and in Australia in July 2020. In the first quarter of 2021, we received FDA approval for our first Senza Omnia upgrade, Omnia™ Powered by HFX Connect™, and our next generation trial stimulator. In July 2021, we received FDA approval of our 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN. This approval is specific to our unique 10 kHz stimulation, and the Senza system was the first spinal cord stimulation system approved by the FDA with a specific indication to treat certain forms of pain associated with PDN.

The tables below set forth our revenue from U.S. and international sales the past three years on a quarterly basis and total revenue for each of the past five years.

<u>Revenue from:</u>	<u>Q1 2019</u>	<u>Q2 2019</u>	<u>Q3 2019</u>	<u>Q4 2019</u>	<u>Q1 2020</u>	<u>Q2 2020</u>	<u>Q3 2020</u>	<u>Q4 2020</u>	<u>Q1 2021</u>	<u>Q2 2021</u>	<u>Q3 2021</u>	<u>Q4 2021</u>
(in millions)												
U.S. sales	\$ 65.8	\$ 78.1	\$ 84.2	\$ 97.9	\$ 75.3	\$ 51.0	\$ 90.9	\$ 94.6	\$ 74.7	\$ 85.0	\$ 78.1	\$ 88.4
International sales	16.3	15.5	16.0	16.5	12.2	5.4	17.5	15.1	13.9	17.3	15.2	14.3
Total revenue	<u>\$ 82.1</u>	<u>\$ 93.6</u>	<u>\$ 100.2</u>	<u>\$ 114.4</u>	<u>\$ 87.5</u>	<u>\$ 56.4</u>	<u>\$ 108.5</u>	<u>\$ 109.7</u>	<u>\$ 88.6</u>	<u>\$ 102.3</u>	<u>\$ 93.2</u>	<u>\$ 102.8</u>

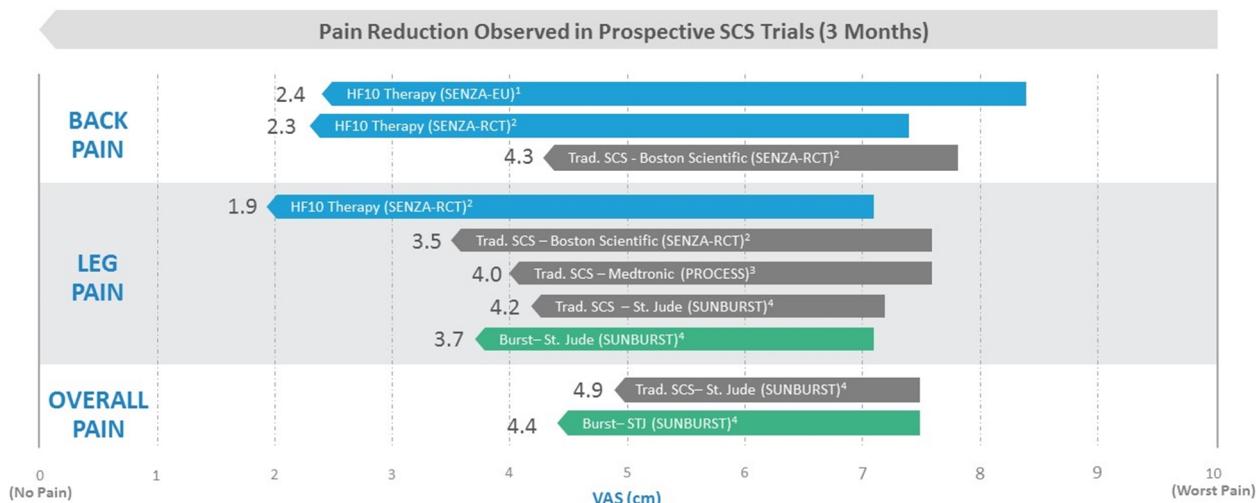
<u>Revenue from:</u>	<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>
(in millions)					
U.S. sales	\$ 263.5	\$ 321.8	\$ 326.0	\$ 311.9	\$ 326.2
International sales	63.2	65.5	64.3	50.2	60.7
Total revenue	<u>\$ 326.7</u>	<u>\$ 387.3</u>	<u>\$ 390.3</u>	<u>\$ 362.0</u>	<u>\$ 386.9</u>

The 2021 global market for SCS therapy was estimated to be approximately \$2.3 billion. Throughout 2021, the COVID-19 pandemic negatively impacted the global SCS therapy market, which we estimate decreased by approximately 5% to 10%. We believe the superiority of 10 kHz Therapy over traditional SCS therapies will allow us to capitalize on the addressable trunk and limb chronic pain market, which is estimated to be approximately 14% penetrated in the United States, as well as expand the SCS market by treating other pain-related indications, such as PDN and NSRBP, among others. The United States represents approximately 80% of this global market due in part to governmental reimbursement restraints in international markets. We believe that due to factors such as an aging population, an increasing number of failed back surgeries and an increasing prevalence of diabetes, there is continuing opportunity for an SCS therapy that effectively treats back pain to increase the size of the existing SCS market over time.

We believe that we will continue to both take share of and expand the SCS therapy market due to the unique benefits of 10 kHz Therapy, as well as the broad therapy versatility of our product platform. 10 kHz Therapy is paresthesia-free therapy and has demonstrated superior efficacy when compared to traditional SCS therapies. Traditional SCS therapy generates paresthesia, a sensation typically experienced as tingling, numbness and buzzing, which overlaps the pain area. Paresthesia is often considered unpleasant or uncomfortable. Compared to traditional SCS therapy, which typically operates at 50 Hz to 60 Hz, 10 kHz Therapy delivers spinal cord stimulation at a lower amplitude and a higher frequency waveform of 10,000 Hz. In addition, 10 kHz Therapy relies on consistent anatomical placement of the stimulation leads across patients, thus reducing procedure variability relative to traditional SCS therapy which requires individualized lead placement to properly map paresthesia coverage. We believe the ability of 10 kHz Therapy to deliver pain relief without paresthesia provides a substantial benefit over traditional SCS therapy to patients and physicians. However, despite its shortcomings traditional SCS therapy has a long track record of safety and, together with our product platform, can be made available to the subgroup of patients who do not receive adequate relief with 10 kHz Therapy alone.

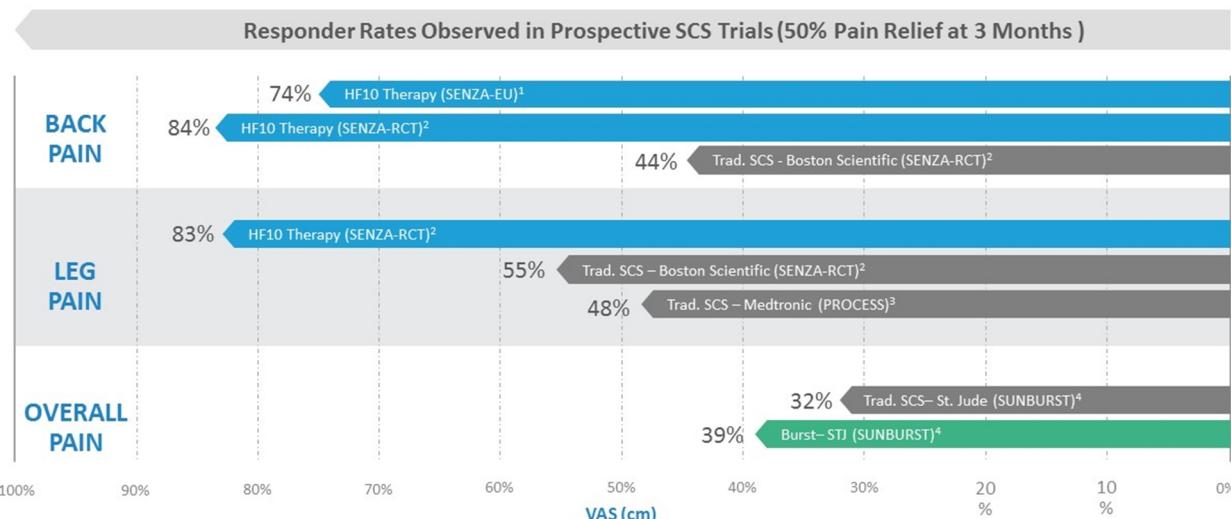
We believe the clinical results from our SENZA-RCT study, along with our European studies, position us with superior and compelling efficacy data. The following charts provide a comparison of 10 kHz Therapy in both pain reduction and responder rates against the other prospective Level 1 studies conducted.

## Comparison of Pain Relief Across Prospective, Level I SCS Studies



1. Al-Kaisi A, et. al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med*. 2014;15:347-354. Internal data on file.
2. Kapural, Leonardo et. al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. *Anesthesiology* Vol. 123 No 4. October 2015.
3. Kumar K et al., Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome, *Pain* (2007), doi:10.1016/j.pain.2007.07.028. 6-month data shown.
4. St. Jude Medical Proclaim™ Implantable Pulse Generator Clinician's Manual, Models 3660, 3662, 3665, 3667. Published on www.sjm.com October 2016.

## Comparison of Responder Rates Across Prospective, Level I SCS Studies



1. Al-Kaisi A, et. al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med.* 2014;15:347-354. Internal data on file.
2. Kapural, Leonardo et. al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. *Anesthesiology* Vol. 123 No 4. October 2015.
3. Kumar K et al., Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome, *Pain* (2007), doi:10.1016/j.pain.2007.07.028. 6-month data shown.
4. St. Jude Medical Proclaim™ Implantable Pulse Generator Clinician's Manual, Models 3660, 3662, 3665, 3667. Published on www.sjm.com October 2016.

We believe we have built competitive advantages through our proprietary technology, clinical evidence base, strong track record of execution with approximately 80,000 patients implanted with Senza systems, extensive intellectual property and a proven management team with substantial medical device experience. With the well-demonstrated superior efficacy of our 10 kHz Therapy, we aim to continue to drive adoption and penetration in the U.S. market, which represents the largest opportunity in SCS, and expand patient access to 10 kHz Therapy by investing in the development of evidence for new indications such as chronic painful neuropathies (including PDN) and NSRBP. On this front, we conducted two randomized controlled trials, SENZA-PDN and SENZA-NSRBP, which are evaluating 10 kHz Therapy for the treatment of PDN and NSRBP, respectively.

The SENZA-PDN study is one of the largest randomized controlled trials (RCT) conducted in the field of spinal cord stimulation with 216 randomized patients. The study is evaluating paresthesia-free SCS 10 kHz Therapy among patients diagnosed with PDN and refractory to conventional medical management (CMM). Patients were randomized one to one to CMM alone or CMM with 10 kHz Therapy. We presented the complete six-month and preliminary twelve-month data in January 2021 at the North American Neuromodulation Society (NANS) conference. The primary outcome was a composite endpoint of safety and efficacy, specifically including greater than or equal to 50% pain relief and no worsening in neurological deficit versus the baseline. Eighty-six percent (86%) of patients in the 10 kHz Therapy plus CMM arm met the three-month endpoint, compared with 5% in the CMM only arm. At six months, patients in the 10 kHz Therapy plus CMM arm had a response rate of 85%, compared with 5% in the CMM only arm. In April 2021, the six-month data were published online in *JAMA Neurology*. In June 2021, the complete 12-month data, including the six-month crossover patient data, was presented at the American Diabetes Association 81st Scientific Sessions. These 12-month results, including six-month crossover data, demonstrated significantly improved and sustained outcomes with 10 kHz Therapy, including substantial, sustained pain relief and improved health-related quality of life measures. In November 2021, the 12-month results and six-month crossover data were published online in *Diabetes Care*. In July 2021, the FDA approved the Senza System for the treatment of chronic intractable pain of the lower limbs, including unilateral and bilateral pain, associated with PDN. This approval is specific to Nevro's unique 10 kHz stimulation, and the Senza system was the first spinal cord stimulation system approved by the FDA with a specific indication to treat PDN. The study continues such that future follow-ups will be utilized for publication and expanded reimbursement payor coverage. In January 2022, we announced that UnitedHealthcare will provide coverage for our 10 kHz Therapy for the treatment of PDN for dates of service on or after March 1, 2022.

At the 2021 NANS conference we also presented our three-month primary endpoint data of SENZA-NSRBP study, which includes patients with chronic back pain but, based on an assessment from a spine surgeon, are not surgical candidates. The study compares patients receiving 10 kHz Therapy plus CMM to patients receiving CMM alone. At the three-month primary endpoint, patients who received 10 kHz Therapy plus CMM had a response rate of 80.9% compared to 1.3% for the CMM alone group. In January 2022, the FDA approved the Senza System as an aid in the management of NSRBP (intractable back pain without prior surgery and not a candidate for back surgery). We expect that the 12-month follow-up data will be utilized for publications and to seek expanded payor coverage for this patient cohort.

Additionally, at the 2022 NANS conference we presented the complete 18-month results, including the 12-month crossover patient data, for our SENZA-PDN study. Key findings at 18 months included significant and sustained outcomes with 10 kHz SCS. In addition, analysis of healthcare resource utilization through the first 12 months of the SENZA-PDN trial showed reduced spending associated with 10 kHz Therapy, particularly for hospitalizations. We also presented our 12-month results, including six-month crossover patient data, for our SENZA-NSRBP study. Key findings at 12 months showed profound improvements in pain relief, function, quality of life measures, awareness of positive change and reduction in daily opioid use in NSRBP patients receiving 10 kHz Therapy at 12-months post-implant. Results also included comparable improvements for patients that crossed over from CMM to 10 kHz after 6 months. In February 2022, the SENZA-NSRBP 12-month results were published online in the *Journal of Neurosurgery: Spine*. Patients in the SENZA-PDN and SENZA NSRBP studies will be followed for 24 months.

## Market Overview

### ***Existing Treatments for Chronic Pain and Limitations***

Chronic pain has been defined as pain that lasts longer than the time required for tissues to heal, which is often considered to be three months. Patients who present with chronic pain are typically placed on a treatment progression plan. Initial medical management typically includes behavioral modification, exercise, physical therapy and over-the-counter analgesics and non-steroidal anti-inflammatory drugs. When early-stage medical management is not sufficient for the treatment of chronic leg and back pain, patients may progress to interventional techniques including steroid injections or nerve blocks. Patients who do not respond to these more conservative treatments are considered candidates for more advanced therapies. These more advanced therapies include spine surgery, treatment with oral opioids and SCS. Spine surgery, while a common invasive procedure, can result in complications such as Failed Back Surgery Syndrome (FBSS) a condition where pain persists despite the procedure, and spinal surgery often fails to treat certain types of chronic pain such as severe neuropathic back pain. Oral opioids, while reducing the patient's perception of pain, lack clinical evidence to support long-term usage and can cause multiple complications and side-effects including nausea, vomiting and dizziness. Further, opioids present a high risk of addiction and abuse.

### ***Traditional Spinal Cord Stimulation and Limitations***

SCS is a type of neuromodulation technology that utilizes an implantable, pacemaker-like device to deliver electrical impulses to the spinal cord to treat chronic pain. Traditional SCS therapy is designed to induce paresthesia, a sensation typically experienced as tingling, numbness and buzzing, which overlaps the area of pain with the intent of masking pain perception. The electrical pulses are delivered by small electrodes on leads that are placed near the spinal cord and are connected to a battery-powered generator implanted under the skin. Traditional SCS therapy is currently indicated as a treatment for chronic pain of the trunk and limbs in patients who failed CMM. Traditional SCS therapy is considered to be a minimally invasive and reversible therapy that may provide greater long-term benefits over more invasive surgical approaches or opioids. The most common use for traditional SCS therapy is for neuropathic pain conditions such as FBSS.

Traditional SCS therapy generally consists of two phases, an evaluation period, also called the trial period, which typically lasts several days, followed by a permanent implant for those patients who experience a successful trial period. The trial period involves a percutaneously placed insulated wire, called a lead, which a physician implants near the spinal cord using a needle. During the trial period, a temporary external system is used by patients and physicians for evaluating whether traditional SCS therapy is effective. If the trial period is successful, a permanent system is implanted in the patient. The success criterion is typically an approximate 50% reduction in

pain during the evaluation period. For those patients that proceed to the permanent implant procedure, we believe that approximately 30% to 40% of U.S. procedures are completed using surgical leads and the remaining are completed using percutaneous leads.

A key part of the permanent system is the implantable pulse generator (IPG) which is a miniaturized version of the external stimulator. The IPG should provide the patient with multiple years of use and can be either rechargeable or non-rechargeable (primary cell). Due to payor constraints in certain European countries, the transition from primary cell IPGs to rechargeable IPGs has been slow in those markets. In the United States and Australia, the majority of IPGs implanted are rechargeable.

Traditional SCS products have required paresthesia to provide pain relief, and consequently, paresthesia coverage has been used as a surrogate metric for successful pain relief. Paresthesia, however, is often considered unpleasant or uncomfortable and is sometimes made worse by a shocking or jolting sensation with changes in posture. Unpleasant sensations can be caused by lead movement closer to the spinal cord or away from it as the patient moves, resulting in variation in paresthesia intensity. Paresthesia is also a constant reminder of the patient's chronic condition. These limitations of paresthesia-based therapy are particularly true for PDN patients, who are already suffering from paresthesia-like symptoms. Due to the distraction of paresthesia, patients with traditional SCS devices are instructed not to drive or operate machinery when the device is active. Medtronic plc (Medtronic) has released a survey showing that 71% of patients find paresthesia uncomfortable at times. As such, innovation in the SCS market has historically focused on technologies that optimize traditional SCS therapy's ability to create more precise paresthesia fields. Even with successful paresthesia coverage, patients still may not receive pain relief or often lose pain relief after a period of time.

Traditional SCS procedures also require physicians to perform the complex and often time-consuming process of paresthesia mapping. This mapping process requires a patient to be sedated for the lead placement, then awakened and repeatedly questioned in order for the physician to assess paresthesia coverage over the patient's area of pain and reposition and reprogram the leads to redirect the paresthesia. This process creates variability in the procedure and a complicated anesthesia management process, impacting the physician's schedule and patient comfort. The primary objective of traditional SCS therapy is to create a stimulation program that covers the areas of pain without creating paresthesia beyond the pain areas, given that this can be uncomfortable and difficult to tolerate.

Traditional SCS technology involves the delivery of low frequency electrical impulses, or waveforms, to the spinal cord. Recent developments in traditional SCS have resulted in alternative waveforms, some of which are variations of low frequency waveforms, some at sub-threshold amplitudes aimed at reducing the reliance on paresthesia. Abbott Laboratories has developed a SCS system that offers an alternate low frequency waveform called BurstDR. Medtronic is promoting a programming approach called DTM™ (Differential Target Multiplexed) which involves frequencies up to 1,200 Hz. Additionally, Boston Scientific is now offering sub-threshold therapy at frequencies below 1.2 kHz.

## Our Solution for Chronic Pain

### **10 kHz Therapy**

Our 10 kHz Therapy is designed to deliver innovative neuromodulation solutions for treating chronic pain based on what we believe to be the best clinical evidence available. By overcoming many of the limitations of traditional SCS therapy, our 10 kHz Therapy offers superior efficacy for patients and provides significant advantages to physicians and hospitals. We believe the advantages of our proprietary 10 kHz Therapy over traditional SCS include:

- **Demonstrated superior efficacy data for both leg and back pain:** In our SENZA-RCT pivotal study, 10 kHz Therapy was demonstrated to provide significant and sustained back pain relief in addition to leg pain relief. 10 kHz Therapy was shown in both number of patients that respond and in treatment efficacy to be superior to traditional SCS therapy as it was nearly twice as successful in treating back pain and 1.5 times as successful in treating leg pain. Our SENZA-RCT study, along with the previously completed European studies, represent what we believe is the most robust body of clinical evidence for any SCS therapy. We believe that the superior efficacy results and robust data provided in our pivotal

clinical trials will drive increased adoption of our 10 kHz Therapy among patients, payors and providers and may enable us to gain significant market share in the approximately \$2.3 billion global SCS back and leg pain market. In addition, we believe our efficacy data in back pain will allow us to expand the SCS market under current reimbursement regimes by meeting demand from back pain patients who are largely untreated by traditional SCS therapies.

- **FDA-approved for use in PDN and NSRBP patients:** In our SENZA-PDN and SENZA-NSRBP studies, 10 kHz Therapy provided significant and sustained pain relief to patients suffering from PDN and NSRBP compared to CMM. Based on this evidence, we received FDA approval for specific indications to treat PDN and NSRBP patients in July 2021 and January 2022, respectively. We believe that the results and robust data provided in our SENZA-PDN and SENZA-NSRBP clinical trials will support increased adoption of our 10 kHz Therapy among patients, payors and providers and may enable us to gain significant market share in the PDN and NSRBP markets. In addition, we believe our efficacy data in back pain will allow us to expand the SCS market under current reimbursement regimes by meeting demand from back pain patients who are largely untreated by traditional SCS therapies. For example, in January 2022, we announced that UnitedHealthcare will provide coverage for our 10 kHz Therapy for the treatment of PDN for dates of service on or after March 1, 2022.
- **Paresthesia free pain relief for patients:** 10 kHz Therapy offers the notable benefit to patients of achieving significant and sustained pain relief without paresthesia, thus enabling our patients to avoid the uncomfortable shocking or jolting sensations commonly associated with paresthesia, and removing a major barrier for many patients who may otherwise benefit from SCS therapy. This is particularly true for PDN patients who are already suffering from uncomfortable paresthesia-like symptoms.
- **Anatomical lead placement for physicians.** Since 10 kHz Therapy relies on consistent anatomical lead placement, it removes the cumbersome process of paresthesia mapping that is required by traditional SCS therapy, reducing variability in the operating procedure and offering a significant benefit to both physicians and hospitals by reducing variability of procedures.
- **Ability to treat a broader group of chronic pain patients:** Our 10 kHz Therapy is a platform technology that we believe can provide treatment benefits for a broader group of chronic pain indications. Based on analysis from our SENZA-RCT and European studies, as well as our SENZA-PDN and SENZA-NSRBP RCTs, we believe 10 kHz Therapy may be an attractive treatment option for patients. Due to the removal of paresthesia, we believe 10 kHz Therapy may also be an effective therapy for patients with chronic upper limb and neck pain as it does not create the intense discomfort that traditional SCS generates for patients with chronic upper limb and neck pain when leads are placed in the cervical spine. We are currently investigating the use of 10 kHz Therapy to address chronic pain conditions such as chronic upper limb and neck pain.

## Our Growth Strategy

By combining the brightest talent with the strongest foundation of clinical evidence, our mission is to deliver comprehensive, life-changing solutions that continue to set the standard for enduring patient outcomes in chronic pain treatment.

To accomplish this objective we intend to:

- **Earn market share through leveraging the Senza Omnia platform:** Senza Omnia offers the most versatile platform in SCS as it includes the broadest frequency range, the most waveform capabilities and the unique ability to offer 10 kHz Therapy. In 2022, we will continue to expand our commercialization of Omnia and our HFX Connect platform and continue to position Omnia as the most versatile product available in the market, and we believe that it will have broad appeal to clinicians offering SCS.
- **Expand the existing SCS market by treating back pain and PDN:** We believe we are expanding the existing SCS market by delivering a system that provides meaningful treatment for chronic back pain, including NSRBP, and PDN, which we believe represents a significant opportunity in the global SCS market. With traditional SCS therapy, patients who experience predominant back pain are often

associated with lower levels of treatment success. Consequently, patients with back pain are typically not recommended for treatment with traditional SCS therapy due to the difficulty of achieving and maintaining pain coverage. We are also currently running the SENZA-NSRBP study, which has been shown to demonstrate significant pain relief for patients suffering from back pain when that patient is not a candidate for spine surgery. In contrast to traditional SCS therapy, we believe 10 kHz Therapy is positioned to help continue expanding the existing SCS market by effectively treating back pain in addition to leg pain. With respect to PDN, our SENZA-PDN study demonstrated significantly improved and sustained outcomes with 10 kHz Therapy for patients suffering from PDN. This data was used to support our PDN label expansion and will be used to expand payor coverage for, and the broader adoption of, 10 kHz Therapy in treating PDN patients.

- **Communicate the clinically demonstrated, superior efficacy of 10 kHz Therapy to patients, physicians and payors globally:** Given our robust clinical evidence that demonstrates the superior efficacy of our 10 kHz Therapy, we believe we will be able to position our therapy with patients, providers and payors in a differentiated way. Given that our SENZA-RCT pivotal study has demonstrated superiority for both back and leg pain in a head-to-head comparison with traditional SCS, we are able to differentiate 10 kHz Therapy by communicating its superior clinical benefits and advantages to patients, physicians and payors.
- **Invest in research and development to drive innovation:** We are extending our novel and proprietary technologies into a series of product enhancements with the goal of improving the treatment of chronic pain. We also expect to continue developing enhancements to Senza to further increase performance and introduce new benefits including next generation IPGs, enhanced software, updated accessories and enhanced MRI capabilities. We believe that further product enhancements if and when completed will drive continued adoption of our technology platform and further validate the advantages and benefits of our 10 kHz Therapy.
- **Scale our business to achieve cost and production efficiencies:** We plan to improve the efficiency of our manufacturing processes, which we believe will lower our per unit manufacturing cost. We expect to continue to scale our manufacturing operations as we expand Senza sales volumes in the United States. For example, in the third quarter of 2020, we made the strategic decision to vertically integrate the assembly of IPG's, peripherals and various other manufacturing related activities to mitigate our reliance on third-party manufacturers and improve our long-term gross margins. We plan on conducting these manufacturing activities in a facility in Costa Rica. The integration process is expected to be completed in mid-2022. Even after this integration process is completed, we expect that we will continue to rely on third-party manufacturers to provide key components to support the assembly process. We may incur significant capital expenditures and implementation costs to initiate the manufacturing operations in Costa Rica.

### ***Growth Opportunities in Other Chronic Pain Indications***

We plan to use our platform technology to generate evidence on 10 kHz Therapy for use in other chronic pain indications and painful neuropathies. There can be no assurance that we will be successful in generating evidence for 10 kHz Therapy in other indications or in receiving additional regulatory approvals and reimbursement coverage to promote Senza and 10 kHz Therapy for use in other indications. Below are two areas where results have been successful:

#### ***Non-Surgical Back Pain***

One of the most common uses for SCS is for neuropathic pain conditions such as FBSS. The incidence of patients that will develop FBSS following lumbar spinal surgery is estimated to be within the range of 10% to 40%. However, in addition to having applicability for treating FBSS patients, there is a potential for SCS to provide benefit for patients suffering from chronic pain who are not surgical candidates. 10 kHz Therapy could provide an attractive treatment option for these patients, as a subset analysis of non-surgical patients from our SENZA-RCT and European studies, respectively, found a decrease in back pain VAS scores from 7.2 to 2.6 (12 months, n=12) and 8.1 to 3.4 (24 months, n=14), as well as a decrease in leg pain VAS scores from 7.2 to 2.8 (12 months, n=12) and 7.4 to 2.3 (24 months, n=11). More recent results in patients who were not candidates for major spine surgery and treated

with 10 kHz Therapy in a study led by Dr. Adnan Al-Kaisy demonstrated similar promising results. In this study, patients experienced reduced back pain VAS and Oswestry Disability Index (ODI) scores from baseline of 87% and 63% respectively at 36 months (n=17). In addition to pain reduction and reduced disability, a reduction in opioid use was observed with 90% of the patients using opioids at the start of the study compared to 12% at the end of the study. The results of this study led to the initiation of the SENZA-NSRBP RCT, which compares 10 kHz Therapy delivered in conjunction with CMM to CMM alone in NSRBP patients. At the 2021 NANS conference, we presented our three-month primary endpoint data of SENZA-NSRBP study. The study compares patients receiving 10 kHz Therapy plus CMM to patients receiving CMM alone, among those suffering from chronic back pain who are not surgical candidates based upon an assessment from a spine surgeon. At the three-month primary endpoint patients who received 10 kHz Therapy plus CMM had a response rate of 80.9% compared to 1.3% for the CMM alone group. In June 2021, we presented our six-month data for the SENZA-NSRBP study at the American Society of Interventional Pain Physicians. At the NANS conference in January 2022, we presented our 12-month data for the SENZA-NSRBP study at the 2022 NANS conference, which demonstrated profound improvements in pain relief, function, quality of life measures, awareness of positive change and reduction in daily opioid use in NSRBP patients receiving 10 kHz Therapy at 12-months post-implant. Results also included comparable improvements for patients that crossed over from CMM to 10 kHz after 6 months.

### *Painful Neuropathies*

The American Chronic Pain Association estimates that more than 15 million people in the United States and Europe have some degree of neuropathic pain. More than two out of every 100 people are estimated to have peripheral neuropathy, with the incidence rate increasing to eight in every 100 for people aged 55 or older. The diminished quality of life and increased disability associated with peripheral neuropathy results in significant workforce and healthcare costs. Various treatments currently exist, but have limited efficacy. As such, we have initiated an initial study to determine if 10 kHz Therapy could help this patient group. Results of a prospective, multicenter feasibility study treating chronic intractable pain of the limbs from peripheral polyneuropathy using 10 kHz Therapy demonstrated a decrease in mean VAS pain score from 7.5 at baseline (N=18) to 1.9 at three months post-implant (the primary endpoint), 2.8 at twelve months and 1.4 at twenty-four months. Subject deemed responders was 78% at three months, 69% at twelve months and 88% at twenty-four months (presented at NANS in January 2019). The results from this study led to the initiation of the SENZA-PDN RCT.

In 2020, we presented the preliminary outcome data from SENZA-PDN which demonstrated greater than or equal to 50% pain relief and no worsening in neurological deficit versus baseline was achieved, with 86% of patients in the 10 kHz Therapy plus CMM arm reaching the endpoint, compared with 5% in the CMM only arm at three months. At the 2021 NANS conference, we presented the six-month data, which showed that patients in the 10 kHz Therapy plus CMM arm had a response rate of 85%, compared with 5% in the CMM only arm. The response rate and level of pain relief was maintained through twelve months in the 10 kHz Therapy plus CMM arm. At the American Diabetes Association 81st Scientific Sessions in June 2021, we presented the complete 12-month data, including the six-month crossover data, which showed the response rate and level of pain relief was maintained in the 10 kHz Therapy plus CMM arm and in the crossover arm. The 12-month outcomes in our SENZA-PDN study were published in *Diabetes Care* in November 2021, which showed that 86% of participants in the 10 kHz SCS study arm reported pain relief >50%, while the average pain relief was 77.1% (% reduction of VAS from baseline). After six months with 10 kHz SCS therapy, 84% of participants in the crossover arm reported pain relief >50%, and average pain relief was 70.3% (% reduction of VAS from baseline). At the NANS conference in January 2022, we presented the 18-month data, which included significant and sustained outcomes with 10 kHz SCS. In addition, analysis of healthcare resource utilization through the first 12 months of the trial indicated reduced spending associated with 10 kHz SCS treatment, particularly for hospitalizations. We expect to publish our 24-month data as it becomes available.

## **Clinical Data**

### *Back Pain*

To support development of our proprietary 10 kHz Therapy, the technology was evaluated in preclinical studies and further studied in prospective clinical trials, some of which have been published. Key highlights of our SENZA-RCT pivotal study are as follows:

- Our SENZA-RCT study results demonstrated the superiority of 10 kHz Therapy to traditional SCS therapy on all primary and secondary endpoints through 24 months.
- 10 kHz Therapy was nearly twice as successful in treating back pain as traditional SCS therapy, with 84.3% of patients receiving 10 kHz Therapy reporting 50% or more pain relief at three months, as compared to 43.8% of patients receiving traditional SCS therapy. The superiority of 10 kHz Therapy for treating back pain was maintained through the 24-month follow-up period of the study.
- 10 kHz Therapy was 1.5 times as successful in treating leg pain as traditional SCS therapy, with 83.1% of patients receiving 10 kHz Therapy, as compared to 55.5% of patients receiving traditional SCS therapy, reporting 50% or more pain relief at three months, results that were superior. The superiority of 10 kHz Therapy for treating leg pain was maintained through the 24-month follow-up period of the study.
- 10 kHz Therapy provided a 69.2% reduction in back pain as measured by VAS, versus 44.2% for traditional SCS therapy, at three months, results that were superior. The superiority of 10 kHz Therapy for reducing back pain was maintained through the 24-month follow-up period of the study. 10 kHz Therapy provided a 72.8% reduction in leg pain as measured by VAS, versus 51.5% for traditional SCS therapy, at three months, results that were superior. The superiority of 10 kHz Therapy for reducing leg pain was maintained through the 24-month follow-up period of the study. Superiority of 10 kHz Therapy to traditional SCS therapy demonstrated for both back and leg pain at each designated study endpoint throughout 24 months.
- Patients receiving 10 kHz Therapy did not report paresthesia or uncomfortable stimulation at three months. In comparison, 46.5% of patients receiving traditional SCS therapy reported uncomfortable stimulation at three months.
- Two-thirds of 10 kHz Therapy patients had a VAS pain score of less than or equal to 2.5 on a scale of 0 to 10 for back pain at three months (which we define as achieving remitter status), which is nearly twice the number of traditional SCS therapy patients (35%) with a VAS pain score of less than or equal to 2.5, results that were statistically superior. The superiority of 10 kHz Therapy for achieving remitter status for back pain was maintained through the 24-month follow-up period of the study.
- Two-thirds of 10 kHz Therapy patients had a VAS pain score of less than or equal to 2.5 on a scale of 0 to 10 for leg pain at three months, a much greater number than traditional SCS therapy patients (40%) with a VAS pain score of less than or equal to 2.5, results that were statistically superior. The superiority of 10 kHz Therapy for achieving remitter status for leg pain was maintained through the 24-month follow-up period of the study.
- Safety outcomes were consistent across the treatment groups, with the exception of uncomfortable paresthesia in traditional SCS patients, which was not in 10 kHz Therapy patients.

The results from the clinical studies have been consistent across studies and across outcome measures. Our initial prospective multicenter European clinical study (the EU study) were consistent with our subsequent findings in our prospective, comparative, randomized, controlled U.S. pivotal study (SENZA-RCT study). In the two-year follow up of the EU study, average back pain VAS was reduced from 8.4 at baseline to 2.8 at 12 months to 3.3 at 24 months. Average leg pain was reduced from 5.4 VAS pain level at baseline to 2.0 at 12 months to 2.3 at 24 months. Additionally, for responder rates, 60% of the implanted patients had at least 50% back pain relief and 71% had at least 50% leg pain relief. Disability as measured by Oswestry Disability Index (ODI) improved by an average of 15 points at 24 months, a clinically and statistically significant improvement. The following table summarizes key outcomes for implanted subjects in our EU and SENZA-RCT studies.

	Month 3		Month 6		Month 12		Month 24	
	EU	RCT	EU	RCT	EU	RCT	EU	RCT
<b>Back pain responders</b>								
10 kHz Therapy (%)	82.9	84.3	73.6	76.4	70.1	78.7	60.0	76.5
Traditional SCS (%)		43.8		52.5		51.3		49.3
Superiority p-value		<0.001		0.001		<0.001		<0.001
<b>Leg pain responders</b>								
10 kHz Therapy (%)	82.9	83.1	86.0	80.9	65.0	80.9	71.1	72.9
Traditional SCS (%)		55.0		55.0		50		49.3
Superiority p-value		<0.001		<0.001		<0.001		<0.001
<b>Back pain reduction from Baseline</b>								
10 kHz Therapy (%)	71.3	69.2	67.7	62.4	64.9	66.4	59.6	66.9
Traditional SCS (%)		44.2		44.3		44.7		41.1
Superiority p-value		<0.001		<0.001		<0.001		<0.001
<b>Leg pain reduction from Baseline</b>								
10 kHz Therapy (%)	75.3	72.8	73.4	66.9	61.6	69.5	61.6	65.1
Traditional SCS (%)		51.5		49.9		48.0		46.0
Superiority p-value		<0.001		0.002		<0.001		0.002

Our SENZA-RCT pivotal study was a prospective, randomized, multi-center study, conducted across 11 U.S. clinical trial sites, comparing the safety and effectiveness of Senza delivering 10 kHz Therapy, which we refer to as the test to Boston Scientific's FDA-approved Precision Plus system, delivering traditional SCS therapy, which we refer to as the control. Each included patient was required to have a leg and back pain VAS score of at least 5. Among the 198 chronic pain patients who were randomized for treatments, 171 had a successful therapy evaluation phase, or trial phase, and were implanted with an SCS system. The study was designed as a non-inferiority trial and met its primary and secondary endpoints. Statistical analysis also demonstrated the superior efficacy of 10 kHz Therapy over traditional SCS therapy for all primary and secondary endpoints.

The 12-month outcomes for 10 kHz Therapy in our SENZA-RCT pivotal study were published in *Anesthesiology* and are consistent with the outcomes from our European clinical study, the two year results of which have been published in the *Pain Medicine* journal of the American Academy of Pain Medicine. The 24-month SENZA-RCT results were presented in December 2015 at the annual meeting of the North American Neuromodulation Society, showing sustained superiority of 10 kHz Therapy compared with traditional SCS in treating both back and leg pain over the 24-month follow-up period. The 24-month outcomes in our SENZA-RCT pivotal study were published in *Neurosurgery*.

Patients with chronic pain are generally classified by physicians based on the location of their pain, for example whether their worst pain is predominant back, predominant leg, mixed back and leg, upper limb, neck or other. The adoption of SCS to date has been driven primarily by the treatment of patients whose worst pain is in their legs and for whom other treatment approaches have failed. We believe that broader utilization of traditional SCS therapy has been restrained by the lack of prospective randomized clinical evidence supporting SCS broadly and, in particular, demonstrating an ability to treat back pain.

#### Safety Data (EU and RCT Studies)

Safety results of our SENZA-RCT pivotal study were generally consistent between the test and control groups. Study-related serious adverse events (SAEs) occurred in 4.0% of 10 kHz Therapy subjects (n=4) compared with 7.2% of traditional SCS therapy subjects (n=7;  $p = 0.37$ ). In addition to the SAEs described above, there were two deaths, one of which was study-related and resulted from a myocardial infarction of a subject randomized to traditional SCS therapy that occurred during the implant procedure. The other death occurred outside the study period in the test group and resulted from a malignant hepatic neoplasm. The most common study-related AEs were implant site pain (in 11.9% of 10 kHz Therapy and 10.3% of traditional SCS therapy subjects) and uncomfortable paresthesia (in 11.3% of traditional SCS therapy subjects and in no 10 kHz Therapy subjects). Lead migration leading to revision occurred in 3.0% of 10 kHz Therapy and 5.2% of traditional SCS therapy participants.

Importantly, neurological assessment revealed no stimulation-related neurological deficits in either treatment group. Also, there were no stimulation-related SAEs in either arm.

Safety results of our EU study demonstrated no evidence of neurologic deficit or dysfunction attributable to prolonged delivery of 10 kHz Therapy. Further, investigators reported that adverse events were similar in nature and frequency to those seen with traditional SCS therapy. The most common adverse events in both arms of the study were implant site pain, infection and lead migration.

#### *Painful Diabetic Neuropathy*

Our SENZA-PDN study is a prospective, randomized, multi-center study, comparing 10 kHz SCS plus CMM to CMM alone in 216 patients at 18 centers in the United States. The primary endpoint of the study is a composite endpoint that includes the difference in proportion of treatment responders without deterioration of neurological deficits at three-month follow-up. Subjects could opt to crossover to the other treatment arm if they had insufficient pain relief (<50%), were dissatisfied with treatment, and were appropriate to proceed as determined by their physician. At six months, 82% of patients who met criteria in the CMM arm elected to crossover, vs none in the 10 kHz SCS + CMM treatment arm. Study participants continue to be followed out to 24 months.

The 12-month outcomes for 10 kHz Therapy in our SENZA-PDN study were presented at the American Diabetes Association 81<sup>st</sup> Scientific Sessions in June 2021 and were published in *Diabetes Care* in November 2021. The SENZA-PDN RCT 12-month data demonstrated the following benefits of 10 kHz SCS:

- At 12 months, 86% of participants in the 10 kHz SCS study arm reported pain relief  $\geq 50\%$ , while the average pain relief was 77.1% (% reduction of VAS from baseline).
- After six months with 10 kHz SCS therapy, 84% of participants in the crossover arm reported pain relief  $\geq 50\%$ , and average pain relief was 70.3% (% reduction of VAS from baseline).
- 5 of 154 permanent SCS devices were explanted for a 3.2% explant rate (all explants were due to infection).
- At 12 months, 68% of the 10 kHz SCS treatment group had observed improvement upon an investigator-assessed neurological examination, which included testing lower limb motor strength, sensory function, and reflexes.
- After six months with 10 kHz SCS therapy, 62% of the crossover arm had observed improvement upon an investigator-assessed neurological examination, which included testing lower limb motor strength, sensory function, and reflexes.

Data from the SENZA-PDN trial supported the FDA's July 2021 approval of the Senza System for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN.

## **Non-Surgical Refractory Back Pain**

Our SENZA-NSRBP study is a prospective, randomized, multi-center study, comparing 10 kHz SCS plus CMM to CMM alone in 159 randomized patients at 15 study centers. The primary endpoint of the study is responder rate ( $\geq 50\%$  pain relief) at three months. Subjects could opt to crossover to the other treatment arm if they had insufficient pain relief ( $< 50\%$ ), were dissatisfied with treatment, and were appropriate to proceed as determined by their physician. At six months, 75% of patients who met criteria in the CMM arm elected to crossover and were implanted; no one in the 10 kHz SCS + CMM treatment arm elected to stop 10 kHz Therapy. Study participants continue to be followed out to 24 months.

The 12-month outcomes for 10 kHz Therapy in our SENZA-NSRBP study were presented at the NANS meeting in January 2022 and were published in the *Journal of Neurosurgery: Spine* in February 2022. The SENZA-NSRBP RCT 12-month data demonstrated the following benefits of 10 kHz SCS:

- At 12 months, 78.2% of participants in the 10 kHz SCS study arm reported pain relief  $\geq 50\%$ , while the average pain relief was 72.1% (% reduction of VAS from baseline).
- After 6 months with 10 kHz Therapy, 78.2% of participants in the crossover arm reported pain relief  $\geq 50\%$ , and average pain relief was 70.4% (% reduction of VAS from baseline).
- 3 of 145 permanent SCS devices were explanted for a 2.1% explant rate (all explants were due to wound complications).
- There were no explants due to loss of efficacy.
- The average score on the Oswestry Disability Index (ODI) at baseline indicated severe disability, while post-implant the scores improved to borderline minimum/moderate disability (an average 20 point reduction).
- Three-quarters of the subjects receiving 10 kHz Therapy had clinically significant improvement ( $\geq 10$  points) in ODI or were in the minimally disabled category at the end of 12 months of follow-up for the 10 kHz SCS group (6 months post-implant for the crossover group).
- Despite no specified opioid weaning protocol, usage in this study declined by 46% on average in subjects receiving treatment, while increasing among subjects receiving CMM alone. The changes were significant even with the high variation in prescribed opioid dose across subjects in both groups.

Data from the SENZA-NSRBP trial supported the company FDA January 2022 approval of the 10 kHz Senza System for the management of for NSRBP (back pain without prior surgery and not a candidate for back surgery). Nevro is the only SCS company with a product having an approved indication for treating patients with NSRBP.

## **Our HFX Solution**

HFX is a comprehensive solution that includes a Senza spinal cord stimulation system and support services for treatment of chronic pain and is approved to deliver a versatile range of waveforms. HFX delivers traditional low frequency therapies and our proprietary 10 kHz Therapy, and is the only SCS solution with the ability to pair high and low frequencies and multiple waveforms and mechanisms of action.

The HFX solution includes all necessary components that enable physicians to place leads and conduct SCS trials, as well as permanent implants of the Omnia implantable pulse generator, and enable patients to interact with the system. Below is a depiction of our Omnia powered by HFX Connect IPG, the patient remote control and the wireless trialing system.



**Omnia™** Powered by **HFX** | **Connect™**

**Implantable Pulse Generator (IPG):** The rechargeable IPG delivers electrical pulses to the lead. It can connect to one or two leads, and up to 16 electrodes. The programming of this device is customizable for each patient and their appropriate pain area. The IPG is placed surgically under the skin, usually above the buttock or the abdomen. The Senza, Senza II and Omnia SCS IPGs are all approved with a 10-year battery life.



**Surpass Surgical Leads:** The Surpass and Surpass-C surgical leads are Nevro's surgical lead options when appropriately needed. Our Surpass surgical leads received initial approval from the FDA in late 2016 with a further approval received in January 2017. In April of 2017, the surgical lead was certified by our notified body (the British Standards Institution, or BSI), allowing us to apply the CE mark and to market our products in the European Union and received TGA approval in Australia. We believe the Surpass leads give us access to up to approximately 30% to 40% of the U.S. SCS market that we previously did not address without a surgical lead. In 2020, we also launched our Surpass-C surgical lead, designed for patients who have a compact epidural space that cannot be addressed by other lead options. Our Surpass-C surgical lead is currently approved in the United States, Europe and Australia, where it will be available starting in late first quarter of 2022.



**Percutaneous Leads:** Nevro also offers multiple lengths of percutaneous leads to accommodate patient anatomy. These are available in the United States, Europe and Australia.



**Trial Stimulator:** The trial stimulator is an external device that is worn around the waist during an evaluation period (SCS trial) that typically lasts five to seven days. Nevro's wireless trial stimulator uniquely offers both low and high frequencies and is available in the United States and Europe. It will be available in Australia pending regulatory approval.

**Programmer:** The clinician laptop programmer contains proprietary software that allows for customized patient therapy programming of the IPG. It can non-invasively interrogate the IPG and transmit programming information as well as download diagnostic information. With the Nevro HFX solution, the patient's IPG can be wireless updated with new programming without the need for additional surgery.

**Patient Remote Control:** The patient remote control is a handheld device that allows patients to turn their stimulation on and off and change programs uploaded to their IPG.

**Charger:** The charger recharges the IPG from outside the body. The charger is mobile and can be worn around the waist using a belt, so that the patient can perform various tasks while charging. The Nevro IPG has patented rapid recharge coil technology designed for convenient charging that delivers the fastest charge rates in the market.

**Surgical Tools:** Surgical tools include percutaneous insertion needles used to introduce the lead into the epidural space, a variety of stylets that give physicians the ability to steer and deliver the lead to the desired location, anchors to secure the leads and tunneling tools that provide access from the lead insertion site to the location of the IPG.

In addition to the Nevro HFX product portfolio, Nevro also has both in-person and remote teams of representatives to support procedures and patient therapy. The remote HFX Coach™ team consists of patient support representatives who are trained to help patients change their therapy program remotely, according to a proprietary algorithm, to optimize programming for patient pain relief when they need it, without the need for an in-clinic visit.

### **Third-Party Coverage and Reimbursement**

In the United States, the primary purchasers of Senza are hospitals, outpatient surgery centers and physician offices. These purchasers bill various third-party payors, such as Medicare, Medicaid and private health insurance plans for the healthcare services associated with the SCS procedure. Government agencies and private payors determine whether to provide coverage for specific procedures. In the United States, the Centers for Medicare & Medicaid Services (CMS) administers the Medicare and Medicaid programs (the latter, along with applicable state governments). As the single largest payor, this program has a significant impact on other payors' payment systems.

Generally, reimbursement for services performed are reported using billing codes issued by the American Medical Association (AMA) known as Current Procedural Terminology (CPT) codes. Physician reimbursement under Medicare generally is based on a fee schedule that is set annually by CMS. Hospital outpatient services, reported by CPT codes, are assigned to clinically relevant Ambulatory Payment Classifications (APCs) used to determine the Medicare payment amount for services provided.

In the United States, although CMS initially approved a transitional pass-through payment for High-Frequency Stimulation under the Medicare hospital outpatient prospective payment system effective January 1, 2016 through December 31, 2017, healthcare providers who purchase our products currently do not receive separate reimbursement for our products and rely on third-party payors, including Medicare, Medicaid and private health insurance plans, to reimburse for the procedure under their payment methodologies, many of which are bundled fee schedules and include both the device, supplies and facility overhead. Accordingly, the additional cost associated with the use of our products can impact the profit margin of the hospital or surgery center where the surgery is performed. Medicare reimbursement rates for the same or similar procedures vary due to geographic location, nature of the facility in which the procedure is performed (i.e., hospital outpatient department or outpatient surgery centers) and other factors.

Although private payors' coverage policies and reimbursement rates can differ significantly from payor to payor, the Medicare program is frequently used as a model for how private payors and other governmental payors develop their coverage and reimbursement policies for healthcare items and services, including SCS procedures. For example, certain regional Blue Cross Blue Shield plans previously denied coverage for Senza on the basis that high-frequency neuromodulation is investigational and/or experimental. We continue to engage in efforts to educate such payors on the advantages of 10 kHz Therapy. However, there can be no assurances that we are successful in overturning any negative coverage decisions by private health insurance plans, should they arise. In addition, payors continually review new technologies for possible coverage and can deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. In January 2022, we announced that UnitedHealthcare will provide coverage for our 10 kHz Therapy for the treatment of PDN for dates of service on or after March 1, 2022.

Outside the United States, reimbursement levels vary significantly by country, and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Some countries will require us to gather additional clinical data before granting broader coverage and reimbursement for our products. It is our intent to complete the requisite clinical studies and obtain coverage and reimbursement approval beyond what we have today in countries where it makes economic sense to do so.

### **Product Development and Research Development**

Our objective is to continue to improve patient outcomes and further expand patient access to 10 kHz Therapy through enhancements to Senza and the development of new indications. Research and development (R&D) expenses were \$59.0 million, \$45.6 million and \$47.7 million, for the years ended December 31, 2019, 2020 and 2021, respectively.

Since the launch of the initial Senza system, we have introduced a number of product enhancements. These include a short-tip version of the lead, new lengths of the lead, a surgically placed paddle lead, an active anchor with

improved performance over silicon anchors, a second generation active anchor with smaller volume, lead adaptors that allow use of competitor leads already implanted in patients, upgraded clinician programmer software, a number of next generation IPGs which are conditionally safe for MRI scans anywhere on the body, our Surpass surgical lead to complement our percutaneous lead, and our recent Omnia upgrade powered by HFX Connect, and a new trial stimulator. We also expect to continue developing enhancements to further increase performance and introduce new benefits including next generation IPGs and enhanced MRI capabilities. There can be no assurance that we will be successful in these efforts or in receiving any required regulatory approvals.

## **Sales and Marketing**

### ***United States***

In 2021, we maintained the overall size of our U.S. sales organization, which represents our main channel to communicate with our customers. Our sales representatives target physician specialties involved in SCS treatment decisions, including neurosurgeons, physiatrists, interventional pain specialists and orthopedic spine surgeons. In addition, our commercial team plans to continue to create demand for Senza among additional stakeholders involved in the SCS treatment decision, including third-party payors, hospitals administrators and SCS patients and their families. We have also developed a clinical support team and HFX coaches in order to provide ongoing support to physicians and patients for the use of Senza.

Additionally, in 2021, we established a new sales organization to support the launch of our PDN indication in the U.S. This sales organization targets physician specialties involved in PDN treatment decisions, including primary care physicians, endocrinologists, internal medicine and podiatrists, to create awareness of 10 kHz Therapy to treat PDN patients.

### ***International***

We sell Senza in Europe and Australia through a combination of our direct sales force and a network of sales agents and independent distributors. We began our direct sales operations in the United Kingdom in late 2010 and to date have expanded our direct sales operations to Austria, Australia, Belgium, Germany, Luxembourg, Netherlands, Norway, Sweden and Switzerland. We utilize sales agents and independent distributors to sell in other countries.

## **Competition**

We compete in the SCS market for chronic pain. We also compete with spine surgeries, in particular re-operations. Currently, our major competitors are Medtronic, Boston Scientific and Abbott Laboratories, who have obtained regulatory approval for SCS systems. We believe that the primary competitive factors in the market are:

- Sales force experience and access
- Published clinical efficacy data
- Product support and service
- Effective marketing and education
- Company brand recognition
- Clinical research leadership
- Technological innovation, product enhancements and speed of innovation
- Pricing and reimbursement
- Product reliability, safety and durability
- Ease of use
- Physician advocacy and support

Many of our competitors have greater capital resources, more established operations, longer commercial histories and more extensive relationships with physicians. They also have wider product offerings within neuromodulation and in other product categories, providing them with greater supplier power and with more opportunities to interact with stakeholders involved in purchasing decisions. We also face competition to recruit and retain qualified sales and other personnel.

We expect our competitors to periodically launch new products and release additional clinical evidence. For example, Abbott Laboratories received FDA approval for a SCS system that offers an alternate low frequency waveform called BurstDR, and in February 2016, the company gained approval for a neuromodulation system that stimulates the dorsal root ganglion for treatment of focal pain and complex regional pain syndrome, in each case, using pivotal clinical studies for each therapy to support the FDA approval process. Medtronic gained FDA approval for the Intellis™ spinal cord stimulator in September of 2017, and in January of 2020 announced the purchase of a company called Stimgenics, which includes a proprietary SCS waveform called Differential Target Multiplexed (DTM). Medtronic also gained FDA approval for its Intellis™ and Vanta™ spinal cord stimulators for the treatment of chronic pain associated with diabetic peripheral neuropathy in January 2022. Additionally, Boston Scientific broadly launched the WaveWriter™ SCS system in January 2019, the WaveWriter™ Alpha SCS system and its Fast Acting Sub-perception Therapy (FAST™) in January 2021, and also promotes the results of a sub-threshold therapy through their WHISPER, COMBO and HALO studies. Additionally, there are a number of emerging competitors at various stages of development. Stimwave has developed and is commercializing a minimally invasive stimulation system that employs an externally worn power source and radio frequency transmitter. Nalu Medical, Inc. (Nalu Medical) and Neuspera Medical Inc. (Neuspera Medical) are also pursuing a similar approach as well. Saluda is developing and testing a low frequency closed loop system for the treatment of chronic pain that currently has approval in Europe and Australia.

## **Intellectual Property**

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, which includes seeking and maintaining patents covering our technology and products, proprietary processes and any other inventions that are commercially or strategically important to the development of our business. We also rely upon trademarks to build and maintain the integrity of our brand, and we seek to protect the confidentiality of trade secrets that may be important to the development of our business. For more information, please see “Risk Factors—Risks Related to Intellectual Property.”

### ***Patents, Trademarks and Proprietary Technology***

As of December 31, 2021, we owned 257 issued patents globally, of which 155 were issued U.S. utility patents, two were issued U.S. design patents, 53 were issued Australian utility patents, five were Australian design patent, 19 were issued European utility patents, seven were European design patents, four were issued Japanese patents, two were issued Korean utility patents, one was an issued Korean design patent, two were issued Chinese utility patents, three were issued Chinese design patents, two were Canadian utility patents and one was a United Kingdom utility patent. In general, our patents cover SCS systems that are configured to generate non-paresthesia producing therapy signals at frequencies between 1,500 Hz to 100,000 Hz, as well as additional aspects, algorithms and components of the Senza system and 10 kHz Therapy. As of December 31, 2021, we held 123 patent applications pending globally, of which 58 were patent applications pending in the United States, and 65 were PCT patent applications or patent applications pending across Europe, Australia, Canada, Japan, China, Costa Rica, India and Korea. We also have an exclusive license from the Mayo Foundation to two U.S. issued patents and one U.S. pending patent application. All of our current issued patents are projected to expire between 2028 and 2041.

As of December 31, 2021, our trademark portfolio contained 109 trademark registrations, of which there were nine U.S. trademark registrations, 16 Australian trademark registrations, 13 European trademark registrations, 24 U.K. trademark registration, eight Japanese trademark registrations, six Norwegian trademark registration, eight Swiss trademark registration, 14 Kuwaiti registration, three Canadian registrations and eight Turkish trademark registrations. Our trademark portfolio also contained 112 pending applications, of which 12 are pending U.S. trademark applications and 100 are pending foreign trademark applications.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional or priority patent application. We cannot assure that patents will be issued 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. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or proprietary technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using Senza, any of which could severely harm our business.

We also rely upon trade secrets, know-how and continuing technological innovation, and may rely upon licensing opportunities in the future, to develop and maintain our competitive position. We seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information, under which they are bound to assign to us inventions made during the term of their employment.

### ***The Mayo License***

In October 2006, we entered into a license agreement (the Mayo License) with the Venturi Group, LLC (VGL) and the Mayo Foundation for Medical Education and Research (the Mayo Foundation) pursuant to which the Mayo Foundation committed to confer with us exclusively to develop products for the treatment of autonomic and peripheral nervous system disorders, including pain, using devices to modulate nerve signaling, and non-exclusively to test such devices, and VGL committed to confer with us non-exclusively to develop such devices, and exclusively to test such devices. These commitments to confer expired in January 2011. We were granted a worldwide license to make, use, sell, offer for sale, and import products incorporating or using the know-how developed for and provided to us by the Mayo Foundation or VGL in the course of such development and testing activities, exclusively for product development and non-exclusively for product testing. Pursuant to the Mayo License, we are obligated to pay royalties in the low single digits to the Mayo Foundation, on a country-by-country and product-by-product basis, based on a percentage of net sales of licensed products, subject to reduction under certain circumstances. We are also required under the Mayo License to use commercially reasonable efforts to research, develop and commercialize licensed products.

The Mayo License terminates upon the expiration of (1) the last to expire of the licensed patents or (2) our obligation to pay royalties, whichever is later. As of Jan. 1, 2021, we do not have an existing obligation to pay royalties under the Mayo License. Such obligations may be subject to change if: (1) additional relevant patents issue that are subject to the Mayo License; or (2) we launch an SCS product, which is subject to the Mayo License, in another country. We, the Mayo Foundation or VGL may terminate the Mayo License upon 60 days' notice of a party's material breach if such breach remains uncured after such 60-day period.

### **Manufacturing and Supply**

We rely upon third-party suppliers for the manufacture and assembly of our Senza SCS system and its components, some of which are single- or sole-sources of the relevant product component. We are in the process of identifying and qualifying second-source alternatives for several of our critical single-source suppliers. Thus, in the event that our relationship with any of our single- or sole-source suppliers terminates in the future, we feel confident that sufficient production capacity is available to build products at the standards we require. We believe that existing third-party facilities will be adequate to meet our current and anticipated manufacturing needs.

In the third quarter of 2020, we made the strategic decision to vertically integrate the assembly of IPG's, peripherals and various other manufacturing related activities to mitigate our reliance on third-party manufacturers and improve our long-term gross margins. We plan on conducting these manufacturing activities in a facility in Costa Rica. The integration process is expected to be completed in the mid-2022. Even after this integration process is completed, we expect that we will continue to rely on third-party manufacturers to provide key components to support the assembly process. We may incur significant capital expenditures and implementation costs to initiate the manufacturing operations in Costa Rica.

We believe our manufacturing operations, and those of our suppliers, are in compliance with regulations mandated by the FDA. Manufacturing facilities that produce medical devices or their component parts intended for distribution world-wide are subject to regulation and periodic unannounced inspection by the FDA and other domestic and international regulatory agencies. For products distributed in the United States, we are required to manufacture any products that we sell in compliance with the FDA's Quality System Regulation (QSR) which covers the methods used in, and the facilities used for, the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. In international markets, we are required to obtain and maintain various quality assurance and quality management certifications. We have obtained the following international certifications: Quality Management System ISO13485, Full Quality Assurance Certification for the design and manufacture of spinal cord stimulator systems and accessories and a Design Examination certificate for Implantable Pulse Generator and Accessories. We are required to demonstrate continuing compliance with applicable regulatory requirements to maintain these certifications and will continue to be periodically inspected by international regulatory authorities for certification purposes.

Our material supply contracts are as follows:

#### ***Pro-Tech Design and Manufacturing***

In July 2014, we entered into a supply agreement with Pro-Tech Design and Manufacturing, Inc. (Pro-Tech) pursuant to which Pro-Tech, as a single-source supplier, conducts the inspection, labeling, packaging and sterilization of our Senza SCS system. In June 2020, we entered into an amendment to extend the terms of our original agreement and to provide for automatic one-year annual renewals, unless if a notice of termination is provided 30 days prior to the expiration of the then current term.

#### ***Stellar (Cirtec) Technologies***

On July 1, 2009, we entered into a manufacturing agreement with Stellar Technologies, Inc. (Stellar) our single-source supplier of our percutaneous leads, percutaneous lead extenders and surgical leads for our neurological stimulator products. On June 30, 2014, the agreement's initial term expired, and the agreement automatically renewed for the first time. On July 1, 2014, we entered into a first amendment to the manufacturing agreement with Stellar, which provides for an additional five-year term commencing from the date of the amendment, after which the agreement automatically renews for successive one-year terms unless either party provides written notice of intent not to renew at least 30 days before the expiration of the then-current term. On January 28, 2016, we entered into a second amendment to this agreement, which provides for the purchase of certain supplementary products pursuant to the agreement. We refer to the manufacturing agreement as amended by the first and second amendments as the Stellar Agreement.

Either we or Stellar may terminate the Stellar Agreement at will upon one year's advance notice, subject to certain remaining rights and payment obligations, including an early cancellation fee payable by us to Stellar. We may also terminate the Stellar Agreement if Stellar is unable to perform its obligations under the Stellar Agreement for 60 days or more, or if Stellar is unwilling to perform its obligations under the Stellar Agreement and does not cure such defect within 60 days of our providing written notice to cure. Stellar may terminate the Stellar Agreement in the event of our default of certain specified obligations, including our payment obligations, material violation of a warranty or law, our material breach, and our insolvency.

### **CCC Supply Agreement**

We rely upon C.C.C. Del Uruguay S.A. (CCC), a subsidiary of Integer Holdings Corporation (formerly Greatbatch Ltd.), as one of our manufacturers of our IPGs. We currently have a multi-year supply agreement with CCC with regard to the manufacture and supply of our IPGs. The agreement was effective as of November 11, 2016. On April 30, 2019, we entered into the first amendment to the supply agreement with CCC, incorporating new product models and adjusting unit cost.

The agreement continues for ten years unless terminated earlier. The term of the agreement automatically renews for additional two-year terms unless one party provides the other party with written notice of termination at least one year prior to the end of the initial term or the applicable renewal period. In the event of a change of control of CCC, the agreement may be terminated by us upon three years' written notice to CCC, provided that such notice period shall be one year in the event CCC is acquired by certain competitors to us. In addition, the agreement may be terminated by mutual agreement of the parties, or by either party, with written notice, upon the other party's cessation of business or other termination of its business operations, uncured material breach or insolvency of the other party. Upon termination of the agreement, CCC shall, subject to certain exceptions and unless otherwise agreed to by the parties, fulfill all purchase orders placed by us and accepted by CCC prior to the effective date of termination.

The agreement contains, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property created during the term of the agreement, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions.

### **EaglePicher Medical Power Supply Agreement**

In April 2009, we entered into a product supply and development agreement with EaglePicher Medical Power LLC (EaglePicher) our single-source supplier of the batteries and related products for our IPG. Pursuant to the agreement, EaglePicher must use its best efforts to supply these batteries and related products in sufficient quantity to meet our demand. The agreement also provides that, upon our written request, EaglePicher will conduct development of a modified version of these products to our specifications, if we so desire. The initial term of our supply agreement with EaglePicher expired in November 2010, and the term had been automatically renewing for successive one-year periods.

In March 2015, we entered into a first amendment to the product supply and development agreement with EaglePicher. The amendment committed us to specified minimum purchase amounts until the end of 2017 and adjusts EaglePicher's production capacity and facilities commitments under the agreement as well as certain pricing, purchasing, delivery and cancellation terms. The amendment also extends the term of the agreement to December 31, 2019, with an additional two-year automatic renewal period unless we or EaglePicher provide notice of intent not to renew prior to the commencement of such renewal term. The amendment further provides us with the right to place a final order with EaglePicher following termination of the agreement, as amended and modifies certain warranty and assignment terms and the parties' limitations of liability.

In November 2015, we entered into a second amendment to the agreement, which increased our pre-existing specified minimum purchase amounts and increased EaglePicher's production capacity commitments under the agreement, as well as specifying certain purchasing and purchase order protocols. The amendment obligated EaglePicher to establish and qualify an additional battery production operation and commits us to fund approximately \$1.0 million of such production operation paid in three milestone installments. The amendment also establishes EaglePicher as our exclusive battery supplier through the initial five-year term of the agreement, ending December 31, 2019.

In September 2017, we entered into a third amendment to the agreement, which changed the renewal term of the agreement such that the agreement will automatically renew for a period of one year unless we or EaglePicher provides notice of intent to terminate the agreement six months prior to the commencement of such renewal term. In 2019, we notified EaglePicher of our intent to not renew the agreement upon its expiration on December 31, 2019. We are currently in discussions with EaglePicher on a revised agreement.

### **Vention (Nordson) Supply Agreement**

In December 2015, we entered into a Manufacturing and Supply Agreement with Vention Medical Design and Development, Inc. (Vention) pursuant to which Vention agreed to manufacture and supply our IPGs. We are obligated to purchase from Vention specified minimum purchase quantities of IPGs for the duration of the Vention agreement.

The agreement continues for five years unless terminated earlier. The term of the agreement automatically renews for additional one-year terms unless one party provides the other party with written notice of termination at least one year prior to the end of the applicable renewal period. The agreement may be terminated by us for any reason upon 180 days' written notice to Vention. In addition, the agreement may be terminated by mutual agreement of the parties, or by either party, with written notice, upon uncured material breach or insolvency of the other party. Upon termination of the agreement, Vention shall, upon our request, manufacture an additional 24 months of continuous supply of IPGs based on the preceding forecast average or such other amount as agreed upon by the parties.

In September 2017, we entered into a first amendment to the Manufacturing and Supply Agreement with Vention, which changed the unit costs of the products supplied by Vention. In April 2018, we entered into a second amendment to the Manufacturing and Supply Agreement, which acknowledged that Vention changed its name to Nordson MEDICAL Design and Development, Inc (Nordson) and which changed the unit cost of the products supplied by Nordson. In August 2021, we terminated the agreement with Vention with an effective date of December 31, 2021, as we continue to receive IPGs from one of our alternative suppliers and as we transition IPG manufacturing to our Costa Rica manufacturing facility.

### **Other Suppliers**

We also have other suppliers, including some sole-source suppliers, for certain of our components, with whom we do not have agreements.

### **Product Liability and Insurance**

The manufacture and sale of our products subjects us to the risk of financial exposure to product liability claims. Our products are used in situations in which there is a risk of serious injury or death. We carry insurance policies which we believe to be customary for similar companies in our industry. We cannot assure you that these policies will be sufficient to cover all or substantially all losses that we experience.

We endeavor to maintain executive and organization liability insurance in a form and with aggregate coverage limits that we believe are adequate for our business purposes, but our coverage limits may prove not to be adequate in some circumstances.

### **Government Regulations**

#### **United States**

Our products and operations are subject to extensive and rigorous regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA) and its implementing regulations, guidance, and standards. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution, and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA also regulates the export of medical devices manufactured in the United States to international markets. Any violations of these laws and regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, if there is a change in law, regulation or judicial interpretation, we may be required to change our business practices, which could have a material adverse effect on our business, financial condition and results of operations.

Under the FFDCA, 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 control needed to ensure safety and effectiveness.

Class I devices are those for which safety and effectiveness can be assured by adherence to 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 appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries, and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. A legally marketed device is defined by statute to mean a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another commercially available, similar device that was cleared through the 510(k) process. 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 much more rigorous premarketing requirements in the form of a premarket approval (PMA).

A Class III device includes devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to a device that has a new intended use or utilizes advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by general and special controls. These devices almost always require formal clinical studies to demonstrate safety and effectiveness. Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process.

### **PMA Approval**

The Senza SCS system is a Class III device subject to review and approval through the PMA pathway. PMA applications must be supported by, among other things, valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. A PMA application must also include, among other things, a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device and proposed labeling. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees.

The FDA has 45 days from its receipt of a PMA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has 180 days to review a PMA application that has been filed by the FDA, although the review of an application more often occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. 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 conduct a pre-approval inspection of the applicant and/or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval order or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and the data is then submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. In May 2015, we received approval for our PMA application for the Senza SCS system.

Approval by the FDA of new PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. Certain other changes to an approved device also 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. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data.

### **Clinical Studies**

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. In the United States, human clinical trials intended to support medical device clearance or approval require compliance with the FDA's investigational device exemption (IDE) regulations. For a device that presents a "significant risk" to human health, the device sponsor is required to file an IDE application with the FDA and obtain IDE approval prior to commencing the human clinical trial, as well as obtain approval of an Institutional Review Board (IRB) at each institution where the study will be conducted. If the device is considered a "non-significant risk," IDE approval from FDA is not required. Instead, only approval from the IRB overseeing the investigation at each clinical trial site is required, though the sponsor must still comply with abbreviated IDE requirements, such as protection of human subjects and informed consent. Human clinical studies are generally required in connection with approval of Class III devices and may be required for Class I and II devices. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

If an IDE application is approved by the FDA, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Submission of an IDE application for review does not guarantee that the FDA will approve the IDE and permit the conduct of clinical trials and, even if the IDE 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.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to

FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

### ***Continuing Regulation***

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include: compliance with the QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk of health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur. Manufacturers are also required to register and list their devices with the FDA, based on which the FDA will conduct inspections to ensure continued compliance with applicable regulatory requirements.

The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters; fines; injunctions; consent decrees; civil penalties; repairs, replacements or refunds; recalls, corrections or seizures of products; total or partial suspension of production; the FDA's refusal to grant future premarket clearances or approvals; withdrawals or suspensions of current product applications; and criminal prosecution. If any of these events were to occur, they could have a material adverse effect on our business, financial condition and results of operations.

### ***International***

Our international sales are subject to regulatory requirements in the countries in which our products are sold. The regulatory review process varies from country to country and may in some cases require the submission of clinical data. In addition, the FDA must be notified of, or approve the export to certain countries of devices that require a PMA, and not yet approved in the United States.

#### *Regulation of Medical Devices in the European Union*

The European Union (EU) has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices and implantable active medical devices were respectively regulated by Council Directive 93/42/EEC (the EU Medical Devices Directive) and Council Directive 90/385/EEC (the EU Active Implantable Medical Devices Directive, or the EU AIMD) (together the Medical Devices Directives), which have been repealed and replaced by Regulation (EU) No 2017/745 (the EU Medical Devices Regulation). Our current certificates have been granted under the EU AIMD whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directives with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation when our current certificates expire.

#### *Active Implantable Medical Devices Directive*

Under the EU AIMD, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the EU AIMD, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or

the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I EU AIMD, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and that any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical investigations conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical investigations in the EU is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the EU member states in which the investigation takes place and the requirement to obtain a positive opinion from a competent ethics committee.

A conformity assessment procedure with the essential requirements generally requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. The assessment of the conformity of Senza has been certified by our notified body (the British Standards Institution, or BSI).

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

#### *Medical Devices Regulation*

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directives, the EU Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU.

The EU Medical Devices Regulation became effective on May 26, 2021. The Regulation among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the EU Medical Devices Directives) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

Devices lawfully placed on the market pursuant to the EU Medical Devices Directives prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below.

The EU Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier (UDI) database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier (UDI-DI) specific to a device, and a production identifier (UDI-PI) to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions (FSCAs) must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directives continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical

device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

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

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

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

#### *Brexit*

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) has become the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA (but manufacturers were given a grace period of four to 12 months to comply with the new registration process) before being placed on Great Britain market. The MHRA only registers devices where the manufacturer or their United Kingdom (UK) Responsible Person has a registered place of business in the UK. Manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA in line with the grace periods. By July 1, 2023, in Great Britain, all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU notified bodies will remain valid until this time. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

An MHRA public consultation was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive, the EU AIMD and the EU In Vitro Diagnostic Medical Devices Directive 98/79/EC), in particular to create a new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform in vitro diagnostic medical devices regulation, and foster sustainability through the reuse and remanufacture of medical devices. The regime is expected to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The

consultation indicated that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

In addition, the Trade Deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization-related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

### ***Other Regulations***

We are also subject to healthcare fraud and abuse regulation in the jurisdictions in which we will conduct our business. These laws include, without limitation, applicable anti-kickback, false claims, physician sunshine and data privacy and security laws and regulations.

*Anti-Kickback Statute:* The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The federal Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term “remuneration” includes kickbacks, bribes, or rebates and also has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the federal Anti-Kickback Statute. These statutory exceptions and safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they may not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more applicable statutory exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Penalties for violations of the Anti-Kickback Statute include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs, and the curtailment or restructuring of operations.

*Federal Civil False Claims Act:* The federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim to, or the knowing use of false statements to obtain payment from or approval by, the federal government. In addition, private individuals have the ability to bring actions under the civil False Claims Act in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. Manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Penalties for a federal civil False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and criminal liability.

*Health Insurance Portability and Accountability Act of 1996:* The federal Health Insurance Portability and Accountability Act (HIPAA) created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or

attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute 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. 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.

In addition, HIPAA and its implementing regulations established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

*EU Data Protection Laws:* We are subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure and security of personal information that identifies or may be used to identify an individual, such as names, contact information and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.

For example, the EU General Data Protection Regulation (GDPR) became applicable on May 25, 2018, implementing more stringent operational requirements for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, mandatory data breach notification requirements, more robust rights for individuals over their personal data and higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are subject to evolving EU and EEA laws on data export, as we may transfer personal data from the EU and EEA to other jurisdictions, for example, in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. The GDPR also provides that EU and EEA member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition.

Following Brexit, we have to comply with the GDPR and the UK GDPR, with each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear and it is unclear how UK data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data.

In recent years, U.S. and European lawmakers and regulators have expressed concern over electronic marketing and the use of third-party cookies, web beacons and similar technology for online behavioral advertising. In the EU, informed consent is required for the placement of a cookie on a user's device. The current EU laws that cover the use of cookies and similar technology and marketing online or by electronic means are under reform. A draft of the new ePrivacy Regulation is currently going through the European legislative process. Unlike the current ePrivacy Directive, the ePrivacy Regulation will be directly implemented into the laws of each of the EU member

states, without the need for further enactment. When implemented, it is expected to alter rules on third-party cookies, web beacons and similar technology for online behavioral advertising and to impose stricter requirements on companies using these tools. The current provisions of the draft ePrivacy Regulation also extend the strict opt-in marketing rules to business-to-business communications, and significantly increase penalties. While the text of the draft ePrivacy Regulation is still under development, a recent European court decision and regulators' recent guidance are driving increased attention to cookies and tracking technologies. If regulators start to enforce the strict approach in recent guidance, this could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, increase costs and subject us to additional liabilities.

Any failure or perceived failure by us to comply with privacy or security laws, policies, legal obligations or industry standards or any security incident that results in the unauthorized release or transfer of personally identifiable information may result in governmental enforcement actions and investigations including by European Data Protection Authorities, fines and penalties (for example, of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher) under the GDPR and draft ePrivacy Regulation, and £17.5 million or 4% of the total worldwide annual turnover for breaches of the UK legislation), litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers to lose trust in us, which could have an adverse effect on our reputation and business. Such failures could have a material adverse effect on our financial condition and operations. If the third parties we work with violate applicable laws, contractual obligations or suffer a security breach, such violations may also put us in breach of our obligations under privacy laws and regulations and/or could in turn have a material adverse effect on our business.

*The Federal Physician Payments Sunshine Act:* The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members.

*Analogous State and Foreign Law Equivalents:* We may be subject to state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other "transfers of value" to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For example, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

*Healthcare Reform:* In March 2010, the Affordable Care Act (the ACA) was signed into law, which has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and

significantly impact the medical device industry. The ACA impacted existing government healthcare programs and resulted in the development of new programs.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 (MACRA), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

Any regulatory or legislative developments in domestic or foreign markets that eliminates or reduces reimbursement rates for procedures performed with our products could harm our ability to sell our products or cause downward pressure on the prices of our products, either of which would affect our ability to generate the revenues necessary to support our business.

*The Foreign Corrupt Practices Act:* The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

*The UK Bribery Act.* The UK Bribery Act prohibits giving, offering or promising bribes (which includes anything of value) to any person, including private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies which carry on a business or part of a business in the UK, as we do, may be held liable not only for bribes given, offered, promised, requested or accepted to any person, including private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company, but also for failing to prevent the bribe in the first place. Liability for the offence of failing to prevent bribery is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the UK Bribery Act there is no exception for facilitation payments.

## **Employees and Human Capital**

As of December 31, 2021, we had 945 employees globally. We believe the success of our business depends, in part, on our ability to attract and retain qualified personnel. We are committed to developing our employees and providing them with opportunities to contribute to our growth and success. Our employees are not subject to a collective bargaining agreement, and we believe that we have good relations with our employees.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We strive to attract and retain the most talented employees in the industry by offering competitive compensation and benefits that support their health, financial and emotional

well-being. The principal purposes of our compensation plans are to attract, retain and motivate selected employees and directors. We use a combination of fixed and variable compensation including base salary, cash-based performance bonuses and stock-based compensation awards.

## **About Us**

We were incorporated in Minnesota in March 2006 and reincorporated in Delaware in October 2006. We completed the initial public offering of our common stock in November 2014. Our common stock is currently listed on the New York Stock Exchange (NYSE) under the symbol “NVRO.” Our principal executive offices are located at 1800 Bridge Parkway, Redwood City, California 94065. Our telephone number is (650) 251-0005. Our website address is [www.nevro.com](http://www.nevro.com). The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, or Annual Report, or any other filings we make with the U.S. Securities and Exchange Commission, or SEC.

## **Available Information**

We make available on or through our website certain reports and amendments to those reports that we file with, or furnish to, the SEC in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. This information is also available by writing to us at the address on the cover of this Annual Report. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at [www.sec.gov](http://www.sec.gov). The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report or any other filings we make with the SEC.

## **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, including our financial statements, 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 harm our business, financial condition, results of operations and growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.*

### **Risk Factor Summary**

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” and should be carefully considered together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission (SEC) before making investment decisions regarding our common stock:*

- The COVID-19 pandemic has harmed and continues to affect our business, financial condition, results of operations, and growth.
- We are substantially dependent on continued market acceptance in the United States for our 10 kHz Therapy, and the failure of our 10 kHz Therapy to continue to gain market acceptance would negatively impact our business.
- Our success depends on our ability to grow the SCS market by generating awareness and demonstrating the benefits of our therapy for treating PDN and NSRBP.
- We must educate physicians and demonstrate to them the merits of our 10 kHz Therapy compared to those of our competitors.
- If our competitors, who are large, well-established companies with substantially greater resources than ours and a long history of competing in the SCS market, are better able to develop and market neuromodulation products (including for new indications, such as PDN) that are safer, more effective, less costly, easier to use or otherwise more attractive than our Senza systems, our business will be adversely impacted.
- We have a history of significant losses. If we do not achieve and sustain profitability, our financial condition could suffer.
- If third-party payors do not provide adequate coverage and reimbursement for the use of Senza, our revenue will be negatively impacted.
- We currently are, and may in the future become, involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.
- If we fail to maintain FDA approval or foreign approval or certification to market and sell Senza, or if such approval or certification is impacted in the future, we will be unable to commercially distribute and market Senza in the United States and abroad. Further, we may not be able to obtain required regulatory approvals or certifications to expand the indications for which we may market and sell Senza.
- We are in the process of developing internal manufacturing capabilities for our products, but expect to remain dependent upon third-party manufacturers and suppliers, in some cases sole- or single-source suppliers, making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business.
- If we fail to receive access to hospital facilities, our sales may decrease.
- If clinical studies for future indications do not produce results necessary to support regulatory clearance, approval or certification in the United States or elsewhere, we will be unable to commercialize our products for these indications.

- We are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.
- Senza is subject to extensive governmental regulation, both in the United States and in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.
- We may be subject to federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.
- Our stock price has experienced significant volatility and may continue to be volatile. As a result, our stockholders may not be able to resell shares of our common stock at or above the price they paid and such volatility may also adversely impact the value of the 2025 Notes.

## Risks Related to our Business

***Our business, financial condition, results of operations and growth have been harmed by the effects of the COVID-19 pandemic and the pandemic continues to affect our business.***

We are subject to risks related to the global pandemic associated with COVID-19, as well as similar future public health crises. The COVID-19 outbreak has negatively impacted, and continues to negatively impact our operations and revenues and overall financial condition as demand for elective procedures remains unpredictable and the number of Senza trials and permanent system implant procedures has not recovered to pre-pandemic levels. The magnitude of the risks and uncertainties are unpredictable and could be further aggravated by the spread of new variants of the COVID-19 virus such as the Delta and Omicron variants, which may be more contagious and/or virulent. During the initial stages of the pandemic, the number of Senza systems procedures performed, similar to other elective surgical procedures, decreased significantly as health care organizations globally prioritized the treatment of patients with COVID-19. For example, in the United States in the first half of 2020 and more recently in connection with the spread of the Omicron variant, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments, be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. Additionally, overall patient willingness to pursue elective procedures has decreased due to the pandemic. Throughout 2021, the COVID-19 pandemic negatively impacted the global SCS therapy market, which we estimate decreased by approximately 5% to 10%. These challenges may arise again at any time throughout the duration of the pandemic, which is uncertain, and could reduce our revenue while the pandemic continues.

Notably, the predictability of trial and permanent implant procedures continues to be challenging to forecast in light of the ongoing pandemic and recent surges in cases caused by the Delta and then Omicron variants. Even if the severity of the pandemic subsides, we are unable to predict the timing that demand for Senza system procedures may return to historic levels as prospective patients may decide to delay their procedures. As a result of the spread of more contagious and virulent variants, the COVID-19 pandemic could continue to result in a meaningful delay in patients seeking to have a Senza system trial. Further, we anticipate that the substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions will result in patients seeking to have Senza system trials or implant procedures performed having to navigate limited provider capacity, due to, among other reasons, a growing trend of labor shortages with nurses and other healthcare facility staff. We believe these factors may have an adverse effect on the recovery of the global SCS therapy market and, as a result, the amount of time we predict for our sales to recover following the end of the pandemic.

Further, numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Multiple times in 2020, the governor of California, where our headquarters are located, issued “shelter-in-place” or “stay at home” orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or

restrictions resulted in our headquarters closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on our personnel and personnel of partners to travel and access customers for training and case support; delays in approvals or certifications by regulatory authorities and notified bodies; delays in product development efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our Senza systems. For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the Medical Devices Regulation (EU) No 2017/745 (the EU Medical Devices Regulation). While several notified bodies have been designated, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation as a consequence of which review times have lengthened. This situation could impact our ability to grow our business in the EU and EEA. In addition, even after the lift of “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19, we continue to experience disruptions to our business as a result of patients and customers continuing to be cautious in restarting elective procedures in light of the continued risk posed by the virus.

Global and domestic supply chains and the timely availability of raw materials and products may be materially disrupted by quarantines, factory slowdowns or shutdowns, border closings and travel restrictions resulting from the COVID-19 pandemic. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future activities.

While the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity, including our ability to repay our 2.75% convertible senior convertible notes due 2025 (the 2025 Notes). We expect any further shelter-in-place policies and restrictions on elective surgical procedures worldwide to have a substantial impact on our revenue. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. During the COVID-19 pandemic, our customers, including hospitals, ASCs and physician offices, have experienced financial hardship and some of them may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for bankruptcy or being acquired by larger health systems, leading to reduced procedures and/or additional pricing pressure on our products. The COVID-19 pandemic has also resulted in a significant increase in unemployment in the United States, Europe and Australia, which may continue even after the pandemic. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of Senza systems sold after the pandemic has ended.

***We are substantially dependent on continued market acceptance in the United States for our 10 kHz Therapy, and the failure of our 10 kHz Therapy to continue to gain market acceptance would negatively impact our business.***

Since our inception, we have devoted substantially all of our efforts to the development and commercialization of Senza and 10 kHz Therapy for the treatment of chronic leg and back pain. We have expanded our commercial efforts since our initial PMA in May 2015, however, we are still in the early stages of our overall commercialization efforts. For example, in July 2021, we received the first FDA approval for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with painful diabetic neuropathy (PDN) utilizing SCS therapy, and we just recently initiated our commercial rollout. In addition, in January 2022, we received FDA approval of our 10 kHz Therapy for the management of non-surgical refractory back pain (NSRBP) (intractable back pain without prior surgery and not a candidate for back surgery), for which we intend to initiate a commercial rollout. The expansion of our commercial efforts, particularly into the PDN indication, is at a very early stage. While we believe the market for SCS in PDN is substantial, it is undeveloped and will require substantial marketing and education efforts by our sales force to develop this market, the success of which is very uncertain. We have incurred significant costs, including costs to continue to build our sales force in the United States, and we expect these costs to continue as we initiate our commercial rollout for the PDN and NSRBP markets. If we are unable to achieve significant market acceptance in the United States, our results of operations will be adversely affected as the United States is the principal market for Senza. If we are unsuccessful in our continuing efforts to commercialize our products or are unable to market our products as a result of a quality

problem, failure to maintain or obtain additional regulatory approvals or certifications, unexpected or serious complications or other unforeseen negative effects related to our 10 kHz Therapy or the other factors discussed in these risk factors, we would lose our only source of revenue, and our business will be materially adversely affected.

We may be unable to gain broader market acceptance for a number of reasons, including due to the below and as a result of other factors set forth herein:

- established competitors with strong relationships with customers, including physicians, hospitals and third-party suppliers;
- limitations in our ability to demonstrate differentiation and advantages of our product compared to competing products and the relative safety, efficacy and ease of use of our product;
- the limited size of our sales force and the learning curve required to gain experience selling our product;
- difficulties and challenges in developing and addressing the PDN and NSRBP markets as the first neuromodulation therapy approved for these indications, some of which may be difficult to predict or foresee until later in the commercial rollout;
- the inability to obtain sufficient supply of the components for our Senza systems or secure second-source suppliers if our main suppliers are unable to fulfill our orders;
- insufficient financial or other resources to support our commercialization efforts necessary to reach profitability; and
- the introduction and market acceptance of new, more effective or less expensive competing products and technologies.

Moreover, physicians and hospitals may not perceive the benefits of our products and may be unwilling to change from the SCS devices they are currently using. Communicating the benefits of Senza and the 10 kHz Therapy to these physicians and hospitals requires a significant commitment by our marketing team and sales organization. Physicians and hospitals may be slow to change their practices because of perceived risks arising from the use of new products. Physicians may not recommend or use Senza until there is more long-term commercial experience to convince them to alter their existing treatment methods, or until they receive additional recommendations from other physicians that our product is effective. We cannot predict when, if ever, physicians and hospitals may adopt use of our product. If we are unable to educate physicians and hospitals about the advantages of our 10 kHz Therapy, do not continue to gain market acceptance of our product, or fail to significantly grow our market share, we will not be able to grow our revenue and our business and financial condition will be adversely affected.

***We must educate physicians and demonstrate to them the merits of our 10 kHz Therapy compared to those of our competitors.***

Physicians play a significant role in determining the course of a patient's treatment and the type of product that will be used to treat a patient. An important part of our sales process includes the education of physicians on the safe and effective use of our 10 kHz Therapy and our Senza systems, particularly because Senza and high-frequency neuromodulation treatment is relatively new as compared to existing low-frequency traditional SCS systems, and is the first non-drug product approved for use in the management of certain types of chronic pain associated with PDN, as well as being the only SCS therapy for the management of NSRBP. As a result, our ability to address, develop and grow the markets for our 10 kHz Therapy and, ultimately our success, depends, in large part, on effectively educating physicians about our 10 kHz Therapy, including the results of our pivotal clinical studies.

In order for us to sell our products, we must successfully demonstrate to physicians the merits of our 10 kHz Therapy compared to our competitors' products. Acceptance of our 10 kHz Therapy depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of Senza as compared to our competitors' products, as well as in new indications such as those we have received with respect to PDN and NSRBP, and then communicating to physicians the proper application of our 10 kHz Therapy. Physicians typically need to perform several procedures to become comfortable using 10 kHz Therapy and Senza. If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to

continue to use our product or to recommend it to other physicians. As a result, educating physicians on the proper use of Senza is critical to the success of our commercialization efforts. If we are not successful in educating physicians and convincing them of the merits of our 10 kHz Therapy or educating them on the use of Senza, they may not use our Senza systems and we may be unable to increase our sales, sustain our growth or achieve profitability.

In addition, we believe receiving support of our products from physicians is essential for market acceptance and adoption. If we do not receive support from physicians or long-term data does not show the benefits of using our 10 kHz Therapy, physicians may not use Senza. In such circumstances, our results of operations would be materially adversely affected. It is also important for our growth that these physicians advocate for the benefits of our products in the broader marketplace. If physicians misuse or ineffectively use our products, it could result in unsatisfactory patient outcomes, patient injuries, negative publicity or lawsuits against us, any of which could have an adverse effect on our business.

***Our competitors are large, well-established companies with substantially greater resources than we have and have a long history of competing in the SCS market.***

Our most significant competitors are publicly traded, or are divisions of publicly traded, major medical device companies that have substantially greater financial, technical, sales and marketing resources than we have. The 2019 global SCS market, before the COVID-19 pandemic, was estimated to be approximately \$2.5 billion, with the United States comprising approximately 80% of the market at that time. Given the size of the existing and potential market in the United States, we expect that as we work to increase our market position and penetration in the United States our competitors will take aggressive action to protect their current market position. For example, in May 2015, a unit of Boston Scientific, one of our principal competitors, filed with the USPTO two petitions for *inter partes* review challenging the validity of our U.S. Patent No. 8,359,102 (the ‘102 patent), which the Patent Trial and Appeals Board (PTAB) at the USPTO denied in November 2015, and, in December 2016 and April 2018, filed lawsuits against us in the U.S. District Court for the District of Delaware alleging that we infringed their patents covering technology related to stimulation leads, batteries and telemetry units, and alleging theft of trade secrets and tortious interference with contract. We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States.

In addition, we face a particular challenge overcoming the long-standing practices by some physicians of using the neuromodulation products of our larger, more established competitors. Physicians who have completed many successful implants using the neuromodulation products made by these competitors may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try and subsequently adopt our product, then our revenue growth will slow or decline.

Further, a number of our competitors are currently conducting, or we anticipate will be conducting, clinical studies to demonstrate the results of their SCS systems. The results of these studies may be equivalent to, or potentially better than, the results of our pivotal U.S. trial.

***If our competitors are better able to develop and market neuromodulation products that are safer, more effective, less costly, easier to use or otherwise more attractive than our Senza systems, our business will be adversely impacted.***

The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to establish a competitive position in the neuromodulation market by securing broad market acceptance of our 10 kHz Therapy and our Senza systems for the treatment of approved chronic pain conditions. Any product we develop that achieves regulatory clearance, approval or certification will have to compete for market acceptance and market share. We believe that the primary competitive factors in the neuromodulation market are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects, pricing and contracting, and salesforce experience and relationships. We face significant competition in the United States and internationally, which we believe will continue to intensify. For example, our major competitors, Medtronic, Boston Scientific and Abbott Laboratories, each has approved neuromodulation systems in at least the United States, Europe, and Australia and have been established for several years. Further, since the launch of our product, these major competitors have all launched new SCS systems:

Medtronic launched the Intellis system, Boston Scientific launched the Spectra WaveWriter SCS system, the WaveWriter Alpha SCS system and the Fast-Acting Sub-perception Therapy, and Abbott Laboratories launched the Proclaim system. We believe these competitors will continue to launch new products, waveforms, and datasets to remain competitive. For example, in early 2020 Medtronic announced the acquisition of Stimgenics, a company that has developed a specific waveform (DTM) with a purported mechanism of action, and the results of an RCT which had superior results versus traditional SCS. The DTM waveforms have been launched, and launches such as these could result in a reduction of our differentiation in the marketplace. In addition, in January 2022, Medtronic announced that it had received FDA approval of its Intellis rechargeable neurostimulator and Vanda recharge-free neurostimulator for the treatment of chronic pain associate with diabetic peripheral neuropathy, which will directly compete with Senza in the new PDN market.

In addition to these major competitors, we also face competition from companies such as Stimwave, Saluda, Mainstay Medical and Nalu Medical, and may face competition from Neuspera Medical and Biotronik in the future. These companies are becoming more active in the SCS market. For instance, in the first quarter of 2019, Stimwave received FDA clearance for 10 kHz stimulation, expanding their previous clearance for low frequency therapy, Nalu Medical received FDA clearance in the first quarter of 2019 for their SCS system, and Saluda Medical received certification in the European Union (EU) in the third quarter of 2019 for their SCS system, were added to the Prostheses List for the same system in Australia in July of 2020 and could potentially launch their SCS system in the United States as early as the end of 2021. Additionally, there are other emerging competitors with active neuromodulation system development programs that may emerge in the future. Many of the companies developing or marketing competing products either enjoy or may develop several advantages over us, including:

- more experienced sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;
- earlier regulatory approval or certification;
- long established relationships with physicians and hospitals;
- the ability to offer competitive products at a lower price;
- significant patent portfolios, including issued U.S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third-party suppliers and distributors;
- the ability to acquire and integrate our competitors and/or their technology;
- demonstrated ability to develop product enhancements and new product offerings;
- established history of product reliability, safety and durability;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- greater financial and human resources for product development, sales, and marketing; and
- greater experience in and resources for conducting R&D, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance, approval or certification for products and marketing approved or certified products.

Our competitors may develop and patent processes or products earlier than we do, obtain patents that may apply to us at any time, obtain regulatory clearances, approvals or certifications for competing products more rapidly than we do or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified sales, scientific, and management personnel, establishing clinical studies sites and enrolling patients in clinical studies. If our competitors are more successful than we are in these matters, our business may be harmed.

**We have a history of significant losses. If we do not achieve and sustain profitability, our financial condition could suffer.**

We have experienced significant net losses, and have no assurance that we will achieve profitability. We expect to continue to incur losses as we build our U.S. commercial operations and continue to investigate the use of our 10 kHz Therapy to treat other chronic pain conditions. We incurred net losses of \$131.4 million, \$83.1 million and \$103.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, our accumulated deficit was \$624.2 million. Our prior losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. If our revenue grows more slowly than we anticipate, or if our operating expenses are higher than we expect, we may not be able to achieve profitability and our financial condition could suffer. Our patent infringement lawsuits with Boston Scientific Corporation have caused us to, and may continue to cause us to, incur substantial legal expenses. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

***Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit manufacturing cost of our products.***

Currently, the gross profit generated from the sale of our Senza systems is not sufficient to cover our operating expenses. To achieve our operating and strategic goals, we will, among other things, need to reduce the per-unit manufacturing cost of Senza. This cannot be achieved without increasing the volume of components that we purchase in order to take advantage of volume-based pricing discounts, improving manufacturing efficiency or increasing our volume to leverage manufacturing overhead costs. While we made the strategic decision in the third quarter of 2020 to reduce our reliance on third party manufacturers by initiating a plan to establish manufacturing operations in Costa Rica, which is, at least in part, intended to improve our long-term gross margin, there can be no assurance such actions will be successful or not ultimately result in us incurring more costs. If we are unable to improve manufacturing efficiency and reduce manufacturing overhead costs per unit, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes is dependent upon a corresponding increase in sales. The occurrence of one or more factors that negatively impact the manufacturing or sales of Senza or reduce our manufacturing efficiency may prevent us from achieving our desired reduction in manufacturing costs, which would negatively affect our operating results and may prevent us from attaining profitability.

***If third-party payors do not provide adequate coverage and reimbursement for the use of Senza, our revenue will be negatively impacted.***

Our success in marketing our products depends and will depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations adequately cover and reimburse customers for the cost of our products.

In the United States, we expect to derive nearly all our revenue from sales of our products to hospitals and outpatient medical facilities who typically bill various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, to cover all or a portion of the costs and fees associated with our products and bill patients for any applicable deductibles or co-payments. Access to adequate coverage and reimbursement for SCS procedures using Senza (and our other products in development) by third-party payors is essential to the acceptance of our products by our customers.

We believe that SCS procedures using our products are adequately described by existing CPT, HCPCS II and ICD-10-CM codes for the implantation of spinal cord stimulators and related leads performed in various sites of care, although such codes generally do not specifically describe procedures using either low-frequency or high-frequency stimulation. In the United States, although CMS approved a transitional pass-through payment for High-Frequency Stimulation under the Medicare hospital outpatient prospective payment system effective as of January 1, 2016 through December 31, 2017, our customers currently do not receive separate reimbursement for our products. In addition, effective July 1, 2021, Medicare now requires Prior Authorization for certain hospital outpatient procedures, including SCS procedures.

Accordingly, we believe that some of our target customers may be unwilling to adopt Senza over more established or lower-cost therapeutic alternatives already available or that may subsequently become available. Further, any decline in the amount payors are willing to reimburse our customers for SCS procedures using Senza could make it difficult for new customers to adopt Senza and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. For our traditional chronic back and leg pain market, we believe that favorable coverage and reimbursement of procedures using our products from Medicare and certain commercial payors, such as Aetna, Cigna, Humana, Blue Cross Blue Shield and Kaiser, have contributed to our increase in revenue to date, while we continue to engage in efforts to educate payors on the advantages of 10 kHz Therapy. However, there can be no assurance that all private health insurance plans will cover procedures using the product. We currently have more limited coverage and reimbursement for use of our therapy in PDN and NSRBP patients and are working to expand payor coverage to include the use of our 10 kHz Therapy in this patient population. This effort could be costly and could take many years to gain broad acceptance, and there can be no guarantee that it will be successful. A significant number of negative coverage and reimbursement decisions by private insurers may impair our ability or delay our ability to grow our revenue. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

***We are currently, and may in the future become, involved in lawsuits to protect or enforce our intellectual property, which are expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively grow sales of our Senza systems or commercialize future products, if any. If we are unable to obtain, maintain, protect, and enforce our intellectual property, our business will be negatively affected.***

The market for medical devices is subject to rapid technological change and frequent litigation regarding patent and other intellectual property rights. It is possible that our patents or licenses may not withstand challenges made by others or protect our rights adequately.

Our success depends in large part on our ability to secure effective patent protection for our products and processes in the United States and internationally. We have filed and intend to continue to file patent applications for various aspects of our technology and trademark applications to protect our brand and business. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products or services that misappropriate our technology and/or infringe our intellectual property to compete with our products. We are currently involved in, and in the future may become involved in additional, lawsuits and/or proceedings to protect and enforce our intellectual property rights. These lawsuits and proceedings are expensive and require substantial attention of management.

However, we face the risks that:

- We may fail to secure necessary patents, potentially permitting competitors to market competing products and make, use or sell products that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete.
- Patents may not issue from any of our currently pending or future patent applications.
- Our already-granted patents and any future patents may not survive legal challenges, including challenges in the ongoing lawsuit with Boston Scientific, to their scope, validity or enforceability, or provide significant protection for us, and they may be re-examined or invalidated, and/or may be found to be unenforceable or not cover competing products.
- Even if our patents are determined by a court to be valid and enforceable, they may not be drafted or interpreted broadly enough to prevent others from marketing products and services similar to ours. Similarly, others may simply design around our patents. For example, third parties may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO, to determine priority of invention in the United States. There may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.
- Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.
- Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' products and services. For example, we filed a lawsuit in November 2016 against Boston Scientific Corporation in order to enforce certain of our patents, we filed a lawsuit in February 2019 for patent infringement and false advertisement against Stimwave, we filed a lawsuit in February 2020 for patent infringement against Nalu Medical, and we filed another lawsuit in February 2021 for patent infringement against Boston Scientific. We may in the future seek to enforce our patents or other proprietary rights against other potential infringements. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar

technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, including interferences, derivation proceedings, re-examination proceedings, post-grant review, *inter partes* review, third-party submissions, oppositions, nullity actions, or other patent proceedings. We may also need to initiate infringement claims or litigation. Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

- We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and/or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.
- We may also be forced to enter into cross-license agreements with competitors in order to manufacture, use, sell, import and/or export products or services that are covered by our competitors' intellectual property rights. If we need to use our intellectual property to enter such cross-license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, import and/or export our patented technology.

For additional information regarding risks related to our intellectual property, see "Risks Related to Intellectual Property."

***If we fail to develop and retain an effective direct sales force in the United States, our business could suffer.***

As we increase our commercial and marketing efforts, we will need to retain, develop and grow the number of direct sales personnel that we employ. We continue to make a significant investment in recruiting and training sales representatives and clinical representatives. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products often requires or benefits from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, or if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. For example, during the first half of 2018, we hired sales personnel at a slower rate than we had expected, which, among other factors, caused us to lower our expectations for full year 2018 worldwide revenue. Also, to the extent we hire personnel from our competitors, our new sales representatives will usually be subject to restrictive covenants with their former employers, including non-competition, non-solicitation and/or confidentiality provisions. As a result, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. We and certain of our new sales representatives have been, continue to be, and may in the future be, subject to allegations that these new hires have violated the non-competition clauses, been improperly solicited or divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business.

***If we fail to maintain FDA approval or foreign approval or certification to market and sell Senza, or if such approval or certification is impacted in the future, we will be unable to commercially distribute and market Senza in the United States and abroad. Further, we may not be able to obtain required regulatory approvals or certifications to expand the indications for which we may market and sell Senza.***

We and our products are subject to extensive regulation in the U.S. and elsewhere, including by the FDA and its foreign counterparts.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and foreign regulatory authorities enforce these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA or foreign regulatory authorities inspections. For example, while we have received FDA approval of our Senza PMA application, there can be no assurance that approval will be maintained. For example:

- we may not be able to maintain to the FDA's satisfaction that our product is safe and effective for its intended use;
- we may fail to comply with the guidelines required by FDA and other agencies to maintain our PMA approval; and
- the manufacturing processes and facilities we and our vendors use may not meet applicable requirements to maintain our PMA approval.

In addition, we may suffer from product liability or other issues that impact our ability to continue to market the Senza systems in the United States.

Failing to maintain FDA approval or foreign approval or certification could result in unexpected and significant costs for us and consume management's time and other resources. The FDA or foreign regulatory authorities or notified bodies could ask us to improve or augment manufacturing processes, collect and provide data on the quality or safety of our product or issue us warning letters relating to matters that may result in removal of our product from the market. Additionally, we will be required to obtain FDA approval or notified body certification prior to making any modification to the device, and the FDA or foreign regulatory authorities may revoke the approval or certification or impose other restrictions if post-market data demonstrates safety issues or lack of effectiveness. If we are unable to obtain and maintain the necessary regulatory approvals or certifications, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited. Further, the failure to obtain approval or certification for new products and new indications, such as painful diabetic neuropathy, on existing products could have an adverse effect on our business, financial condition or results of operations.

***Modifications to our products may require us to obtain new PMA approvals or approvals of a PMA supplement, or any similar approval or certification and if we market modified products without obtaining necessary approvals or certifications, we may be required to cease marketing or recall the modified products until required approvals or certifications are obtained.***

Certain modifications to a PMA-approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to the FDA. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices in the future that we believe do not require approval of a new PMA or PMA supplement. If the FDA disagrees with our determination and requires us to submit a new PMA or PMA supplement for modifications to our previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. With respect to PMA-approved devices, any changes to the manufacturing processes, including manufacturing site changes such as the planned change to assemble our Senza systems at our Costa Rica facility when completed, may require prior approval of a PMA supplement before such

changes may be implemented. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

In the EU, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the European Economic Area (EEA) (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland), of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation.

***Our growth and success depends on physicians' use of our 10 kHz Therapy to treat chronic back pain, as well as the development and success in the PDN and NSRBP markets.***

Our growth and success is dependent on physicians' acceptance and use of our 10 kHz Therapy to treat chronic back pain and our development and success in the markets for our newest indications, PDN and NSRBP. We believe a significant limitation of current neuromodulation systems is the limited evidence supporting efficacy of traditional SCS products. Senza utilizes high-frequency stimulation technology capable of delivering waveform of up to 10,000 Hz for spinal cord stimulation that has been shown to be effective in the treatment of both leg and back pain and the management of chronic pain associated with PDN and NSRBP. However, we may face challenges convincing physicians, many of whom have extensive experience with competitors' SCS products and established relationships with other companies, to appreciate the benefits of the 10 kHz Therapy and, in particular, its ability to treat back pain as well as leg pain, and adopt it for treatment of their patients. If Senza is unable to gain acceptance by physicians for the treatment of PDN, NSRBP or other pain indications for which its use is approved or certified, our potential to expand the existing neuromodulation market will be significantly limited and our revenue potential will be negatively impacted.

***Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.***

As of December 31, 2021, we sell Senza directly in the Netherlands, Austria, Switzerland, United Kingdom, Sweden, Australia, Belgium, Luxembourg, Norway and Germany and through distributors and agents located in Spain, Italy, Slovakia, Turkey and Kuwait. The sale and shipment of Senza across international borders, as well as the purchase of components from international sources, subject us to United States and foreign governmental trade, import and export and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors, or any of our third-party suppliers;
- reduced or varied protection for intellectual property rights in some countries;
- pricing pressure that we may experience internationally;

- foreign currency exchange rate fluctuations;
- a shortage of high-quality sales people and distributors;
- third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of Senza;
- relative disadvantages compared to competitors with established business and customer relationships;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- virus epidemics and pandemics such as the COVID-19 outbreak;
- changes in duties and tariffs, license obligations and other non-tariff barriers to international trade, including any retaliatory tariffs or other actions taken by foreign countries in response to the U.S. tariffs imposed and threatened by the United States presidential administration;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities that could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and
- the imposition of new trade restrictions.

If we experience any of these risks, our sales in non-U.S. jurisdictions may be harmed and our results of operations would suffer.

***We are in the process of developing internal manufacturing capabilities for our products, but expect to remain dependent upon third-party manufacturers and suppliers, in some cases sole- or single-source suppliers, making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business.***

We do not currently operate manufacturing facilities for our products, and to date, have outsourced all our manufacturing operations to third parties. We are in the process of developing our first in-house manufacturing capabilities in our new product manufacturing facility in Costa Rica, which we expect, if successfully completed, will enable us to partially reduce our reliance on our third-party manufacturers and improve our long-term gross margins. In order to develop internal manufacturing expertise, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to effectively manage our planned manufacturing operations and we may not achieve the operating efficiencies that we anticipate from developing these capabilities, which may negatively affect our product manufacturing processes or result in difficulties in maintaining compliance with applicable regulatory requirements. Further, we have never developed or conducted any manufacturing activities in-house, and as a result, our inexperience could exacerbate the likelihood and/or impact of any of the above factors occurring. Any such problems could seriously harm our business. Even if we are

successful in developing our internal manufacturing capabilities, we will continue to rely on a limited number of suppliers who manufacture and assemble certain components of our products.

The facilities used by us and third-party manufacturers to manufacture our products must be approved by the FDA and any comparable foreign regulatory authority or notified body pursuant to inspections or audits that will be conducted after we submit a PMA to the FDA or any comparable filing to a foreign regulatory authority or notified body. We do not control the manufacturing process of, and are completely dependent on, any third-party manufacturers we utilize for compliance with current Good Manufacturing Practice (cGMP) requirements or similar foreign requirements for manufacture of our products. If we or our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority or notified body, we or they will not be able to secure and/or maintain regulatory approval or certification for use of these manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority or notified body does not approve or certify these facilities for the manufacture of our products or if it withdraws any such approval or certification in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval or certification for or market our products. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals or certifications, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

In addition, our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our suppliers may also encounter problems sourcing key components due to supply shortages. For example, in 2021, there is a global shortage of microchips. Should this shortage continue, our ability to produce and sell goods could be significantly impacted. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain adequate supplies from one or more vendors in a timely manner or on commercially reasonable terms;
- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our products, impacting our ability to maintain our PMA approval or similar foreign approval or certification, or cause delays in shipment, impacting our ability to meet demand in the United States or international markets;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers, including our planned vertical integration of certain manufacturing capabilities at our new Costa Rica facility, may require product redesign and possibly submission to FDA, notified bodies or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;
- we may incur additional costs in switching from certain existing suppliers in connection with our planned build-out of our Costa Rica manufacturing facility;
- one or more of our sole- or single-source suppliers may be unwilling or unable to supply components of our products, or may supply products that do not meet our product requirements;

- other customers may use fair or unfair negotiation tactics and/or pressures to impede our use of the supplier;
- the occurrence of epidemic or pandemics, such as the COVID-19 outbreak, which may cause one or more of our suppliers to close their operations either temporarily or permanently;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or alternative suppliers for commercialization in the United States if necessary, in part because we may need to undertake additional activities to qualify such suppliers as required by the regulatory approval process. Similar risk may exist in foreign jurisdictions. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain single-source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available.

***We rely upon third-party, single-source, and in certain cases sole-source, suppliers for many of the components and materials used in our products, and for critical manufacturing and packaging services, and the loss of any of these suppliers could harm our business.***

A number of the critical components used in our products are supplied to us from single-source, or in certain cases sole-source, suppliers, including leads, lead extenders, surgical leads, neurostimulator components and telemetry modules. Our ability to supply our products commercially depends, in part, on our ability to obtain a supply of these components that have been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. In some cases, we have not entered into manufacturing, supply or quality agreements with our single-source and sole-source suppliers, some of which supply components critical to our products. We are not certain that our single-source or sole-source suppliers will be able to meet our demand for their products and services, either because of the nature of our agreements with those suppliers, or our limited experience with those suppliers, or due to our relative importance as a customer to those suppliers or otherwise. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to the needs of their other customers.

Establishing additional or replacement suppliers for the components or processes used in Senza systems, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory authority approval or certification, which could result in further delay. While we seek to maintain adequate inventory of the single-source or sole-source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders. In addition, from time to time, certain of our suppliers experience interruptions and variances in their manufacturing processes, including suppliers of our leads and batteries. Because we are reliant on these single source suppliers, we are particularly susceptible to supply shortages and, if one of our suppliers were to experience an ongoing or continued manufacturing problem, and, in particular, our leads and battery suppliers, our ability to meet our forecasted commercial demand could be materially and negatively impacted.

If our third-party suppliers fail to deliver the required commercial quantities of materials, or the level of services we require, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued commercialization of Senza would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

***If we fail to properly manage our anticipated growth, our business could suffer.***

To achieve our revenue goals, we must successfully increase manufacturing output to meet expected customer demand. In the future, we may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenue.

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure.

In order to manage our operations and growth we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

***If we fail to receive access to hospital facilities, our sales may decrease.***

In the United States, in order for physicians to use Senza, the hospital facilities where these physicians treat patients typically require us to enter into purchasing contracts. The process of securing a satisfactory contract can be lengthy and time-consuming and require extensive negotiations and management time. In the EU, from time to time, certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may stagnate or decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

***We rely in part on a small group of third-party distributors to effectively distribute our products in certain countries outside the United States.***

We depend in part on medical device distributors for the marketing and sales of our products in certain territories in Europe. We depend on these distributors' efforts to market our products, yet we are unable to control their efforts completely. These distributors typically sell a variety of other, non-competing products that may limit the resources they dedicate to selling Senza. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell Senza in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offering requires time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed.

***We may face product liability claims that could result in costly litigation and significant liabilities.***

Manufacturing and marketing Senza, and clinical testing of our 10 kHz Therapy, may expose us to product liability and other tort claims. Although we have, and intend to maintain, liability insurance, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. For example, in 2014, the U.S. Supreme Court declined to hear an appeal where the U.S. Court of Appeals for the Ninth Circuit ruled that the Medical Device Amendments of 1976 to the FFDCA did not preempt state laws in a product liability case involving a medical device

company. If other courts in the United States adopt similar rulings, we may be subject to increased litigation risk in connection with our products. Product liability claims could negatively affect our reputation, continued product sales, and our ability to obtain and maintain regulatory approval for our products.

***If clinical studies for future indications do not produce results necessary to support regulatory clearance, approval or certification in the United States or elsewhere, we will be unable to commercialize our products for these indications.***

Clinical studies are necessary to support PMA applications or similar foreign applications or submissions and may be necessary to support PMA supplements or similar foreign applications or submissions for modified versions of our marketed device products. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical study. Adverse outcomes in the post-approval studies could also result in restrictions or withdrawal of approval of the PMA or similar foreign approval or certification. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals, clearances or certifications of new product lines, or for the approval or certification of the use of our products in some foreign countries. For example, we are currently conducting clinical studies for Senza to explore the potential for 10 kHz Therapy to treat certain chronic pain conditions, including chronic upper limb and neck pain and non-surgical refractory back pain. We will likely need to conduct additional clinical studies in the future to support regulatory approval or certification for the use of our products to treat some of these new indications. Clinical testing can take many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, Institutional Review Boards (IRBs), Ethics Committees, competent authorities of the EU member states or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products and similar risk exists in foreign jurisdictions;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our products such as the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or perform in a manner inconsistent with the investigator agreement, clinical study protocol, good clinical practices, other FDA, IRB or Ethics Committee requirements, and other foreign regulations governing clinical studies;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim or final results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;

- the study design is inadequate to demonstrate safety and efficacy; or
- the statistical endpoints are not met.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical studies. Clinical failure can occur at any stage of the testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or non-clinical studies in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of any of our devices would prevent receipt of regulatory clearance, approval or certification and, ultimately, the commercialization of that device or indication for use.

We could also encounter delays if the FDA or foreign regulatory authorities concludes that our financial relationships with investigators results 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 equity-based awards 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 or foreign regulatory authorities 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 FDA or foreign regulatory authorities or notified bodies refusing to accept the data as support for our future applications. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

Even if our products are approved in the United States, Australia and certified in the EEA, comparable regulatory authorities of additional foreign countries and/or notified bodies must also approve the manufacturing and marketing of our products in those countries. Approval or certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, Australia or the EEA, including additional preclinical studies or clinical studies. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Even though we may generate positive data to support the use of our therapy and products for market expansion opportunities, and receive approval or certification to expand our indications for use to include additional indications, internal and external factors may make it more difficult for these additional indications and market expansion opportunities, or any other indications or other market expansion opportunities we may pursue in the future, to be commercially successful.***

Even if we get approval or certification to expand our indications for use or generate positive data to support the use of our therapy and products for other market expansion opportunities, internal and external factors may make it more difficult for such expanded indications or uses to be commercially successful. These factors include, among others, the following:

- the perceived efficacy and safety of our therapy and products for such additional indications or uses by healthcare professionals;
- the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team, for such new additional indications or uses;
- our ability to offer our therapy and products for such additional indications or uses for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- education and awareness of patients, treating physicians and referring physicians concerning the use of our therapy and products for such additional indications or uses;

- sufficient third-party coverage or reimbursement for such additional indications or uses;
- natural disasters, including pandemics such as the COVID-19 pandemic, and political unrest that could inhibit our ability to promote such new indications or uses and can negatively affect product demand by creating obstacles for patients to seek treatment and undergo elective procedures; and
- the ability of our competitors to obtain similar approvals, such as Medtronic's recent PDN approval, and to more successfully commercialize on such market expansion opportunities.

For example, even though we have received approval for 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN and the management of NSRBP (intractable back pain without prior surgery and not a candidate for back surgery), we will still be required to educate patients and healthcare professionals of the benefits of our therapy and products for the treatment of PDN and NSRBP. If we are unable to successfully educate patients and healthcare professionals, including referring physicians, we will not be able to establish our 10 kHz Therapy as a viable treatment option for eligible PDN and NSRBP patients. Further, we will also be required to either engage and build, or to otherwise contract, a salesforce network to market 10 kHz Therapy for the treatment of PDN. Any such effort could be costly and time-consuming, and there can be no guarantee that it will be successful. In addition, we will also need to establish payor acceptance of 10 kHz Therapy as a treatment option within the PDN and NSRBP patient communities, a process that may not be successful and could take many years to gain broad acceptance. In addition to the foregoing factors, for our therapy for patients with NSRBP to be commercially successful it will require physicians who treat chronic back pain patients with back surgery to refer those patients to other physicians to perform an SCS procedure.

As a result of the above factors, any future indications or uses of our therapy and products we may pursue may not be successfully commercialized and as a result, our business and operating results may be harmed.

***If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely effected while we attract other highly qualified personnel.***

Our future success depends, in part, on our ability to continue to retain our executive officers and other key employees, and recruit and hire new employees. All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business.

In addition, many of our employees have become, or will soon become, vested in a substantial amount of our stock or be able to exercise a substantial number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate.

Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and other employees in the neuromodulation and medical device industry are subject to strict non-competition, non-solicitation and/or confidentiality agreements with their employers, including our main competitors Medtronic plc, Boston Scientific and Abbott Laboratories. Our competitors may allege breaches of, and seek to enforce, such non-competition, non-solicitation and/or confidentiality agreements or initiate litigation based on such agreements, particularly now that we have entered the U.S. market. Such litigation, whether or not meritorious, may impede our ability to attract, hire or utilize executive officers and other key employees who have been or are currently employed by our competitors.

## Risks Related to Intellectual Property

*We currently are, and may in the future become, involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.*

Our success depends in part on not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical industry. Whether merited or not, it is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. For example, on December 9, 2016, Boston Scientific filed a patent infringement lawsuit alleging our manufacture, use and sale of the Senza system infringes certain of Boston Scientific's patents covering technology related to stimulation leads, batteries and telemetry units. On April 27, 2018, Boston Scientific filed a second lawsuit alleging patent infringement, theft of trade secrets, and tortious interference with contract.

Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and/or export our products. For example, our major competitors, Medtronic, Boston Scientific and Abbott Laboratories, each have significant patent portfolios covering systems, sub-systems, methods, and manufacturing processes. These competitors may have one or more patents for which they can threaten and/or initiate patent infringement actions against us and/or any of our third-party suppliers. Our ability to defend ourselves and/or our third-party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages and/or attorneys' fees. From time to time and in the ordinary course of business, we may develop non-infringement and/or invalidity positions with respect to third-party patents, which may or not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;

- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for prior FDA authorization;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; and/or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

From time to time, we may be subject to legal proceedings and claims with respect to intellectual property. For more information regarding our ongoing litigation with Boston Scientific, see the section titled “Legal Proceedings” included under Part I, Item 3 of this Annual Report. 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 technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, that we do not control. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock and the value of the 2025 Notes. Additionally, because we often do not control the timing of the public announcements, there is the potential for these announcements to be made during market hours, necessitating a halt in the trading of our common stock for periods of time. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the neuromodulation industry grows, the possibility of intellectual property infringement claims against us increases.

In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods, and/or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers, or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers, or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. An unfavorable outcome in these or any other such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all.

We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. For example, two of our competitors, Boston Scientific and Medtronic, have filed oppositions in the EU with respect to certain of our patents. Boston Scientific has filed an entitlement action against us in the German courts. In addition, an anonymous petitioner has filed an opposition before the China National Intellectual Property Administration against one of our patents in China (which was dismissed, but for which the anonymous petitioner has filed an appeal). Defending our position in proceedings such as these will require management’s time and attention, as well as financial costs. Given the competitive environment in which we operate, we expect additional

challenges to our intellectual property portfolio as we continue commercialization of Senza in the United States and abroad. An unfavorable outcome in these or any other such proceedings could cause us to lose valuable intellectual property rights and/or be unable to enforce our intellectual property rights, which could invite increased competition thereby materially harming our business.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.***

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and may affect patent litigation. The changes also switched the United States patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith 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, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. In addition, many of our executive officers and key employees have worked for our major competitors (or companies acquired by these competitors), which include Boston Scientific, Medtronic and Abbott Laboratories. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. For example, in April 2018, Boston Scientific filed such suit against us, claiming trade secret misappropriation. While we believe the Boston Scientific claim lacks merit, even if we are successful in defending against the Boston Scientific claim or any other such claims, litigation necessarily results in substantial costs and could be a distraction to management. If our defense to litigation claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or

prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

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

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors, or our former or current employees. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection.

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

## Risks Related to our Financial and Operating Results

***Our operating results may vary significantly from quarter to quarter, which may negatively impact our stock price in the future.***

Our quarterly revenue and results of operations may fluctuate from quarter to quarter due to, among others, the following reasons:

- effects of the ongoing COVID-19 pandemic, including, among others, surges of cases related to new variants, suspensions of non-essential or elective procedures to reduce non-critical hospitalizations, reduced demand for elective procedures and delays in trials and permanent implants;
- physician and payor acceptance of our products and 10 kHz Therapy;
- our success in initiating patient trials for the 10 kHz Therapy and converting those trials into permanent implants;
- our ability to develop and grow the SCS market by convincing physicians and patients to use our therapy to treat PDN and NSRBP, and convincing payors to cover such procedures;
- the effectiveness of the development of new markets for SCS, including PDN and NSRBP;
- fluctuations in our expenses associated with inventory buildup or write-downs from analyzing our inventory for obsolescence or conformity with our product requirements;
- fluctuations in the average sales prices of our products, in particular due to pricing pressure from competitors;
- fluctuations in the expenses related to initiating, pursuing and defending lawsuits;
- buying patterns of our customers;
- the timing, expense and results of our commercialization efforts in the United States and elsewhere, R&D activities, clinical studies and regulatory approvals or certifications;
- the introduction of new products and technologies by our competitors;
- the productivity of our sales representatives;
- difficulties in collecting receivables related to our sales in the United States;
- fluctuations in expenses as a result of expanding our commercial operations and operating as a public company;
- supplier, manufacturing or quality problems with our products;
- changes in our pricing policies or strategies or in the pricing policies or strategies of our competitors;
- changes in coverage amounts or government and third-party payors' reimbursement policies; and
- market volatility impacted by the COVID-19 pandemic

Because of these and other factors, it is likely that in some future period our operating results will not meet investor expectations or those of public market analysts.

Any unanticipated change in revenues or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could cause a decline in our stock price.

***We may choose, or need, to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.***

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we continue to build a commercial sales force in the United States, including for our recently

approved indications of PDN and NSRBP, investigate the use of our 10 kHz Therapy for the treatment of other chronic pain conditions, continue to otherwise grow our business, including potentially acquiring other businesses or technologies, manage the maturity of the 2025 Notes, and continue to operate as a public company. In particular, we believe that we will continue to expend substantial resources for the foreseeable future on the commercialization of Senza in the United States, as well as the growth of our sales and marketing efforts and sales representative training, seeking additional foreign regulatory approvals or certifications, the preparation and submission of regulatory filings and the clinical development of any other product candidates or indications we may choose to pursue. These expenditures will also include costs associated with manufacturing and supply as well as marketing and selling Senza in the United States and elsewhere, and any other future products approved for sale, R&D, conducting preclinical studies and clinical studies and obtaining regulatory approvals or certifications.

We believe that our growth will depend, in part, on our ability to fund our commercialization efforts, particularly in the United States, and our efforts to develop our Senza systems and 10 kHz Therapy for the treatment of additional chronic pain indications and develop technology complementary to our current product. In order to further enhance our R&D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to seek additional funds. If we are unable to raise funds on favorable terms, or at all, the long-term growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the costs of commercializing our products in the United States and elsewhere, including costs associated with product sales, marketing, manufacturing and distribution;
- our ability to maintain the average sales price of our products, in particular if we face pricing pressure from competitors' products;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including, in particular, the costs of enforcing our patent rights in the action we filed against Boston Scientific and in defending against Boston Scientific's action against us;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- 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 market acceptance of our products in the United States and elsewhere;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- 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.

To finance these activities, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, or at all.

The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If we borrow additional funds or issue debt securities, these securities could have rights superior to holders of our common stock and the 2025 Notes, and could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates, or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively and the growth of our business will be harmed.

***We are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.***

As a result of the need to maintain substantial levels of inventory, we are subject to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges. Our products consist of a substantial number of individual components. In order to market and sell Senza effectively, we often must maintain high levels of inventory. In particular, as we continue to market and sell Senza in the United States, we intend to maintain our high levels of inventory in order to meet our estimated demand and, as a result, incur significant expenditures associated with such levels of inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or underestimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of inventory obsolescence comparatively, and we would be required to record an impairment charge, as we did in the first quarter of 2019 and the second quarter of 2020. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire and its value would become impaired. We have also experienced inventory write-downs as a result of inventory that did not meet our product requirements. In addition, as we release later generations of products that contain advancements or additional features, the earlier generations may become obsolete. If our estimates of required inventory are too high, we may be exposed to further inventory obsolescence risk. In the event that a substantial portion of our inventory becomes obsolete or expires, or in the event we experience a supply chain imbalance as described above, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

***The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results.***

Our revenue fluctuates on a seasonal basis, which affects the comparability of our results between periods. For example, due to the seasonality of buying patterns and implant volumes of distributors, hospitals and clinics, the industry generally experiences lower revenues in the first and third quarters of the year and higher revenues in the fourth quarter. We have experienced these industry trends to a greater degree than in our initial U.S. commercial launch phase, although normal purchasing patterns have been disrupted since the COVID-19 pandemic. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable, which introduce additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales.

***We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.***

A portion of our business is located outside the United States and, as a result, we generate revenue and incur expenses denominated in currencies other than the U.S. dollar, a majority of which is denominated in Euros, British Pounds and Australian Dollars. As a result, changes in the exchange rates between such foreign currencies and the U.S. dollar could materially impact our reported results of operations and distort period to period comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-U.S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common stock and the value of the 2025 Notes could be adversely affected.

In the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations.

***Our ability to use our net operating losses and tax credits to offset future taxable income and taxes may be subject to certain limitations.***

In general, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating loss (NOL) carryforwards and other tax attributes, such as research and development tax credits, to offset post-change taxable income and taxes.

As a result of our June 2015 underwritten public offering, we have experienced a Section 382 “ownership change.” We currently believe that this “ownership change” will not inhibit our ability to utilize our NOLs prior to expiration. However, we may experience additional ownership changes as a result of subsequent changes in our stock ownership, some of which changes may be outside our control. As a result, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability and generate sufficient taxable income in the future. If we are limited in our ability to use our NOLs and tax credits in future years as a result of ownership changes, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits. This could materially and adversely affect our results of operations. As of December 31, 2021, we had federal NOLs of \$588.4 million, of which \$329.4 million was generated in fiscal year 2018 and thereafter, which can be carried forward indefinitely under the Tax Cuts and Jobs Act (the 2017 Tax Act), as well as state NOLs of \$336.5 million, of which \$54.3 million may be carried forward indefinitely. If not utilized, the remaining federal NOLs will begin to expire in 2026 and the state NOLs will begin to expire in 2022.

**Risks Related to Regulation of our Industry**

***Senza is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer.***

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the competent authorities of the EU member states. The FDA and other U.S. and foreign governmental agencies and authorities and notified bodies regulate and oversee, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical studies;
- product safety;
- marketing, sales and distribution;
- pre-market regulatory clearance, approval and certification;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Our failure to comply with U.S. federal and state regulations or other foreign regulations applicable in the countries where we operate could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance, approvals or certifications, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facilities are possible. If any of these risks materialize, our business would be adversely affected.

***Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to expand the potential indications for which Senza is approved or certified or introduce new or improved products.***

Our products must comply with regulatory requirements imposed by the FDA in the United States and similar agencies or bodies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes or notified bodies review processes, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include:

- FFDCA and the FDA's implementing regulations (Title 21 CFR);
- EU legislation on medical devices;
- Medical Device Quality Management System Requirements (ISO 13485:2016);
- Occupational Safety and Health Administration requirements; and
- California Department of Health Services requirements.

Government regulation may impede our ability to conduct clinical studies and to manufacture and sell our existing and future products. Government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities. Foreign regulatory agencies or notified bodies may not approve or certify Senza and any of our future products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals or certifications could negatively impact our marketing of any future products and reduce our product revenues.

Our products remain subject to strict regulatory controls on manufacturing, marketing and use. We may be forced to modify or recall a product after release in response to regulatory action or unanticipated difficulties encountered in general use. Any such action could have a material effect on the reputation of our products and on our business and financial position.

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our R&D programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the 2020 Presidential election may impact our business and industry. Namely, the previous presidential administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these Executive Orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of an incoming presidential administration are unknown and could materially impact the regulations governing our products.

For instance, the EU landscape concerning medical devices recently evolved. On May 25, 2017, the EU Medical Devices Regulation entered into force, which repeals and replaces the EU Medical Devices Directive and the EU Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive or EU Active Implantable Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation with regard to registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance requirements.

Non-compliance with the EU Medical Devices Regulation may affect our business or the way we intend to conduct our business in the EU.

The aforementioned EU rules are generally applicable in the EEA. Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

***Senza is subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.***

Subject to the transitional provisions and in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces EU Medical Devices Directive and the EU Active Implantable Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the European Conformity (CE) mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

Following a national referendum and enactment of legislation by the government of the United Kingdom (UK), the UK formally withdrew from the EU and ratified a trade and cooperation agreement governing its relationship with the EU. The EU–UK Trade and Cooperation Agreement (TCA) was applied provisionally as of January 1, 2021 and entered into force on May 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that sought to mirror the EU Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in Great Britain (England, Scotland and Wales) continues to be based on the requirements derived from previous EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation going forward. CE markings will continue to be recognized in the UK, and certificates issued by EU-recognized notified bodies will be valid in the UK, until June 30, 2023. For medical

devices placed on the market in Great Britain after this period, the UK Conformity Assessed (UKCA) marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified bodies will not be recognized on the EU market. Additionally, UK-based notified bodies, which were designated to independently assess the conformity of certain products requiring CE marking before being placed on the EU market, are no longer established in the EU, and accordingly, the conformity assessments carried out by such UK notified bodies, including those assessments carried out prior to 1 January 2021, are no longer valid for the EU compliance regime. Manufacturers whose products currently rely on third-party conformity assessments carried out by UK notified bodies require new conformity assessments to be carried out by EU-based notified bodies in order to ensure continuing compliance with the EU regime and to continue to place those products on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the “rules of origin” criteria will need to be reviewed. Depending on which countries products will be ultimately sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain.

In order to continue to sell Senza in Europe, we must maintain our certification and continue to comply with EU legislation and also the UK legislation. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EU member states or the MHRA, could result in enforcement actions against us, including refusal, suspension or withdrawal of our certificates issued by our notified bodies, which could impair our ability to market products in the Europe in the future.

In addition, we are subject to the EU General Data Protection Regulation (GDPR), which imposes obligations on companies that operate in our industry with respect to the processing of personal data of individuals within the EEA and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. Data privacy laws in the EU are developing rapidly and, in July 2020, the Court of Justice of the EU limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. Further, from January 1, 2021, companies have had to comply with the GDPR and the GDPR as incorporated into the UK national law, with each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear and it is unclear how UK data protection laws and regulations will develop in the medium to longer term. These changes may lead to additional costs and increase our overall risk exposure. On June 28, 2021, the European Commission adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from member states in the EU to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission renews or extends that decision and remains under review by the Commission during this period.

In the EU, according to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. We are also subject to Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EU member state legislation governing the advertising and promotion of medical devices. EU member state legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products and may impose limitations on our promotional activities with healthcare professionals.

The aforementioned EU rules are generally applicable in the EEA. Non-compliance with the above requirements would also affect our business in these three countries.

***The misuse or off-label use of our product may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in off-label promotion.***

Senza has been approved for marketing in the United States, certified in the EU and approved by the TGA in Australia for specific treatments and anatomies. We may only promote or market the Senza SCS system for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our product off-label, when in the physician’s independent professional medical judgement he or she deems the use of the product in the non-approved indication as appropriate. There may be increased risk of injury to patients if physicians attempt to use our product off-label. Furthermore, the use of our product for indications other than those approved or certified by the applicable regulatory authority or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our product or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management’s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA or foreign regulatory authorities determines that our promotional materials, training or physician support activities constitute promotion of an off-label use, it could request that we modify our training, promotional materials or physician support activities or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Further, regulators or legislators may also enhance the enforcement of, and attempt to curtail, any off-label use by physicians of medical devices in the future. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

***Our products may in the future be subject to notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results.***

The FDA, competent authorities of the EU member states and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use, or if a deficiency in a device is found or suspected. A government-mandated recall or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. Recalls, which include certain notifications and corrections as well as removals, of Senza could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation with customers, and reduce our ability to achieve expected revenue.

In addition, the manufacturing of our products is subject to extensive post-market regulation by the FDA and foreign regulatory authorities, and any failure by us or our contract manufacturers or suppliers to comply with regulatory requirements could result in recalls, facility closures, and other penalties. We and our suppliers and contract manufacturers are subject to the Quality System Regulation (QSR), and comparable foreign regulations which govern the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, and servicing of medical devices. These regulations are enforced through periodic inspections or audits of manufacturing facilities. Any manufacturing issues at our or our suppliers’ or contract manufacturers’ facilities, including failure to comply with regulatory requirements, may result in warning or untitled letters, manufacturing restrictions, voluntary or mandatory recalls or corrections, fines,

withdrawals of regulatory clearances, approvals or certifications, product seizures, injunctions, or the imposition of civil or criminal penalties, which would adversely affect our business results and prospects.

***We are required to report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA medical device reporting regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EU are legally bound to report serious incidents and Field Safety Corrective Actions (FSCAs) involving devices they produce or sell to the relevant authorities of the EU member states, in whose jurisdiction the incident occurred.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

***A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.***

The FDA and similar foreign governmental authorities such as the relevant authorities of the EU member states have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

***We may be subject to federal, state and foreign healthcare and data privacy and security laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.***

We are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, as well as data privacy and security laws and regulations that govern the collection, use, disclosure and protection of personal information, including health-related information, which could significantly impact our business. In the United States, the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. 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;
- federal civil and criminal false claims laws, including the False Claims Act, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to

pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters submitted for payment. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA; and
- federal and state laws and regulations governing the collection, use, disclosure and protection of health-related and other personal information that could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g. Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information. For example, the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and the CPRA may increase our compliance costs and potential liability. Similar laws have been passed in Virginia and Colorado and proposed at the federal level and in other states. The legislative and regulatory landscape for privacy and

data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

***Healthcare legislative reform measures may have a material adverse effect on us.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the ACA was signed into law, which included, among other things, comparative effectiveness research initiatives and payment system reforms, including shared savings pilots and other provisions. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payor insurance plans could impact demand for our product.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012, was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 (MACRA), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

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

***Our future success depends on our ability to develop, receive regulatory clearance, approval or certification for, additional chronic pain indications for Senza and introduce new products or product enhancements that will be accepted by the market in a timely manner.***

It is important to our business that we build a pipeline of product offerings for treatment of chronic pain. As such, our success will depend in part on our ability to expand the chronic pain indications for which our products may be used and/or develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance, approval or certification for expanded indications or product enhancements, or new products, or these products may not be accepted by physicians or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical and clinical studies;
- obtain the necessary regulatory clearances, approvals or certifications for new products or product enhancements;
- comply fully with FDA and foreign regulations on marketing of new devices or modified products;
- provide adequate training to potential users of our products; and
- receive adequate coverage and reimbursement for procedures performed with our products.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer.

## Risks Related to Our Securities

***Our stock price has experienced significant volatility and may continue to be volatile. As a result, our stockholders may not be able to resell shares of our common stock at or above the price they paid and such volatility may also adversely impact the value of the 2025 Notes.***

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this “Risk Factors” section of this Annual Report and others such as:

- achievement of expected product sales and profitability, including the effects of seasonality on our results of operations, as well as adjustments to our sales forecasts;
- the ongoing COVID-19 pandemic, see “—Risks Related to our Business—Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic”;
- delays or setbacks in the commercialization of Senza or the expansion of indications for which Senza is approved;
- announcements of new products by us or our competitors;
- announcements or developments in any intellectual property infringement actions in which we may become involved, including our lawsuits with Boston Scientific;
- manufacture, supply or distribution shortages;

- fluctuations in our expenses associated with inventory buildup or write-downs from analyzing our inventory for obsolescence or conformity with our product requirements;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- our operating results;
- results from, or any delays in, clinical trial programs relating to our product candidates;
- changes or developments in laws or regulations applicable to our products;
- any adverse changes in our relationship with any manufacturers or suppliers;
- the success of our efforts to acquire or develop additional products;
- announcements concerning our competitors or the medical device industry in general;
- actual or anticipated fluctuations in our operating results;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- changes in financial estimates or recommendations by securities analysts, as well as publications from research analysts associated with short selling;
- trading volume of our common stock;
- trading activity in our common stock by the option counterparties to our convertible note hedge transactions to unwind or modify their hedge positions;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the United States equity markets, including as a result of volatility related to the recent coronavirus outbreak and related health concerns; and
- the loss of any of our key management personnel.

Because the 2025 Notes are convertible into shares of common stock, volatility or depressed market prices of our common stock could have a similar effect on the value of the 2025 Notes. Holders who receive shares of our common stock upon conversion of the 2025 Notes will also be subject to the risk of volatility and depressed market prices of our common stock. Similarly, the liquidity of the trading market in the 2025 Notes, and the market price quoted for the 2025 Notes, may be adversely affected by changes in the overall market for this type of security and by changes in our financial performance or prospects or in the prospects for companies in our industry generally.

In addition, the stock markets in general, and the markets for medical device stocks in particular, have experienced volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock and the value of the 2025 Notes. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

***Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.***

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the 2025 Notes, or to make cash payments in connection with any conversion of the 2025 Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our

debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

***Regulatory actions and other events may adversely affect the value and liquidity of the 2025 Notes.***

We expect that many investors in, and potential purchasers of, the 2025 Notes will employ, or seek to employ, a convertible arbitrage strategy with respect to the 2025 Notes. Investors would typically implement such a strategy by selling short the common stock underlying the notes and dynamically adjusting their short position while continuing to hold the 2025 Notes. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of or in addition to short selling the common stock.

The SEC and other regulatory and self-regulatory authorities have implemented various rules and taken certain actions, and may in the future adopt additional rules and take other actions, that may impact those engaging in short selling activity involving equity securities (including our common stock). Such rules and actions include Rule 201 of SEC Regulation SHO, the adoption by the Financial Industry Regulatory Authority, Inc., or FINRA, and the national securities exchanges of a “Limit Up-Limit Down” program, the imposition of market-wide circuit breakers that halt trading of securities for certain periods following specific market declines, and the implementation of certain regulatory reforms required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, the notes to effect short sales of our common stock, borrow our common stock or enter into swaps on our common stock could adversely affect the trading price and the liquidity of the 2025 Notes.

***We may incur substantially more debt or take other actions which would intensify the risks discussed above.***

We and our subsidiaries may incur substantial additional debt in the future, subject to the restrictions contained in any debt instruments we may have, some of which debt may be secured debt. We are not restricted under the terms of the indenture governing the 2025 Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the 2025 Notes that could have the effect of diminishing our ability to make payments on these notes when due.

***If we are unable to maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock and the value of the 2025 Notes could be adversely affected.***

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. Further, the Sarbanes-Oxley Act also requires that our internal control over financial reporting be attested to by our independent registered public accounting firm.

If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. The process of designing and implementing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock and the value of the 2025 Notes could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

***The accounting method for convertible debt securities that may be settled in cash, such as the 2025 Notes, could have a material effect on our reported financial results.***

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options (“ASC 470-20”), an entity must separately account for the liability and equity components of the convertible debt instruments (such as the 2025 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer’s economic interest cost. The effect of ASC 470-20 on the accounting for the 2025 Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders’ equity on our consolidated balance sheet, and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the 2025 Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2025 Notes to their face amount over the respective terms of the 2025 Notes. We will report lower net income (or larger net losses) in our financial results because ASC 470-20 will require interest to include both the current period’s amortization of the debt discount and the instrument’s non-convertible interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the notes.

In addition, under certain circumstances, convertible debt instruments (such as the 2025 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the 2025 Notes are not included in the calculation of diluted earnings per share except to the extent that the respective conversion values of the 2025 Notes exceeds their respective principal amounts. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued.

In August 2020, the FASB issued a new standard that proposes to change the accounting for the convertible debt instruments described above. Under the new standard, an entity may no longer be required to separately account for the liability and equity components of convertible debt instruments. This could have the impact of reducing non-cash interest expense, and thereby increasing net income (or decreasing net losses). Additionally, the treasury stock method for calculating earnings per share will no longer be allowed for convertible debt instruments whose principal amount may be settled using shares. Rather, the if-converted method may be required, which could decrease our diluted earnings per share. The new standard is effective for fiscal years beginning after December 15, 2021 and interim periods within that year, with early adoption permitted, and can either be adopted on a modified retrospective or full retrospective basis.

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price and the value of the 2025 Notes 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 and the value of the 2025 Notes may decline.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price and the value of the 2025 Notes to fall.***

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for issuance upon the exercise of stock options, upon the vesting of restricted stock units, upon conversion of the 2025 Notes, upon exercise of the warrants in the warrant transactions we entered into in connection with the offering of the 2021 Notes and 2025 Notes. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the trading price of the notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock and the value of the 2025 Notes could decline. As of December 31, 2021, we had outstanding a total of approximately 35.0 million shares of common stock, and approximately 9.4 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock and the value of the 2025 Notes could decline.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

***We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.***

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, our stockholders are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders have purchased it.

## **General Risk Factors**

***Changes in tax laws, tax rulings or trade policies may have a material adverse effect on our business, financial condition and results of operations.***

Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations.

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws or tax rulings, or changes in interpretations of existing laws, could materially affect our financial position, results of operations, and cash flows. Recently enacted legislation and associated regulations have significantly changed U.S. federal income tax laws, with potential impact to state and local taxation. Further, many countries in Europe have recently proposed or recommended changes to existing tax laws or have enacted new laws that may increase our tax obligations in those countries.

In addition, changes in U.S. trade policies could materially and adversely impact our effective tax rate, increase our costs and reduce the competitiveness of our products.

***Failure to protect our information technology infrastructure, and those of our third-party service providers, against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.***

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing and distribution. We use enterprise information technology systems to record, process and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, “phishing” attacks, attacks by computer hackers, unauthorized access, natural disasters, terrorism, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and

patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

***We may not be able to adequately protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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 in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights 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, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and if we do prevail, the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have registered trademarks similar and identical to our trademarks in foreign jurisdictions, and may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

***If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. For example, in the fourth quarter of 2020, a research analyst associated with short selling activity published a report that resulted in short term volatility in our stock. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We incur significantly increased costs and devote substantial management time as a result of operating as a public company.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), and the Dodd-Frank Act, as well as rules and regulations subsequently implemented by the SEC and the NYSE, including the

establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly.

In addition, our management and other personnel divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. We continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we will incur in order to remain compliant with our public company reporting requirements or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our corporate headquarters and R&D facilities are located in Redwood City, California, where we lease and currently occupy approximately 50,740 square feet of office and laboratory space. In December 2016, we amended the original lease for our corporate headquarters in order to increase the space we occupy by approximately 49,980 square feet of office space adjacent to our corporate headquarters. Our obligations under the amended lease for the new space commenced on June 1, 2018. The term of the lease for our corporate headquarters and the new adjacent space ends on May 31, 2025. In April 2017, we entered into a second amendment to the original lease for a temporary space of approximately 8,171 square feet of office space for the period from May 2017 until June 1, 2018, the commencement of the term for the additional adjacent space. We believe our current headquarters, together with our additional adjacent space, is sufficient for our current and foreseeable business needs. We also lease a small storage facility in Australia and a small amount of warehouse space in San Carlos, California. In August 2020, we entered into a lease for approximately 35,411 square feet of manufacturing space to begin in April 2021 and to last through June 2031 at a facility in Costa Rica. We plan to use this facility to build-out certain manufacturing capabilities so that we can vertically integrate the assembly of IPG's, peripherals and various other manufacturing related activities for products that we currently purchase from third-parties.

For additional information, see Note 7, *Commitments and Contingencies*, of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

#### **ITEM 3. LEGAL PROCEEDINGS**

The legal proceedings information set forth in Note 7 *Commitments and Contingencies*, of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report is incorporated herein by reference.

#### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable

## **PART II**

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

#### **Market Information**

Our common stock has been publicly traded on the NYSE under the symbol “NVRO” since the initial public offering (IPO) of our common stock on November 6, 2014. Prior to that time, there was no public market for our common stock.

#### **Holders of Record**

As of February 16, 2022, there were approximately 15 stockholders of record of our common stock, and the closing price per share of our common stock was \$70.98. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

#### **Dividends**

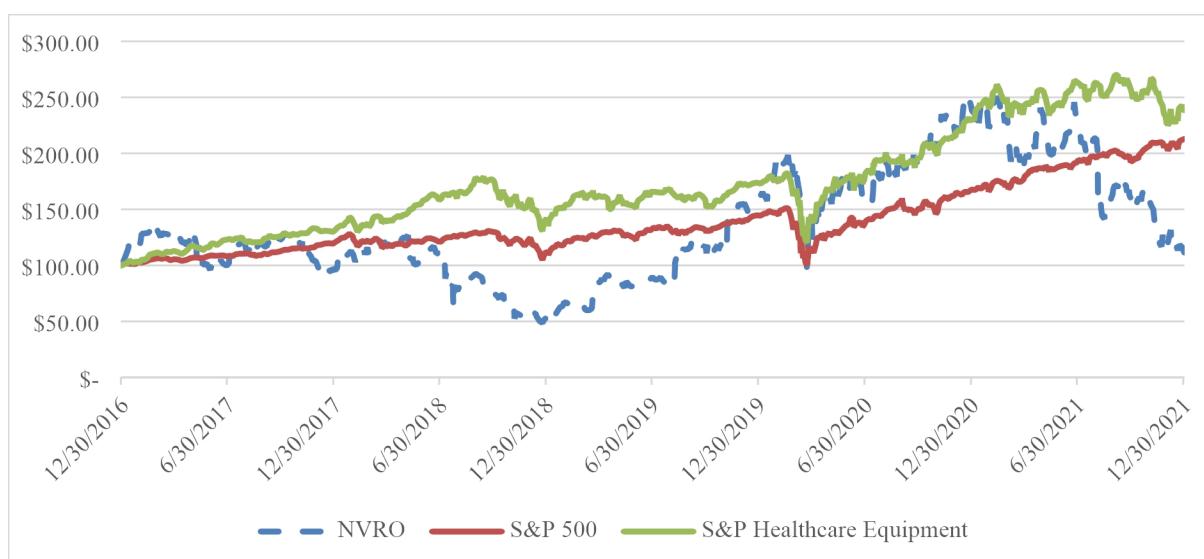
We have never declared or paid cash dividends on our common stock. Because we currently intend to retain all future earnings to finance future growth, we do not anticipate paying any cash dividends in the near future.

#### **Securities Authorized for Issuance under Equity Compensation Plans**

The information required by this Item 5 regarding equity compensation plans is incorporated by reference from the information under the captions “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” that will be contained in the Proxy Statement.

## Stock Performance Graph

The following graph illustrates a comparison of the total cumulative five-year stockholder return on our common stock to two indices: the S&P 500 Composite Index and the S&P Healthcare Equipment Index. An investment of \$100 is assumed to have been made in our common stock and in each of the indices on December 31, 2015 and its relative performance is tracked through December 31, 2021. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



<u>\$100 investment in stock or index</u>	December 31,					
	2016	2017	2018	2019	2020	2021
Nevro Corp. (NVRO)	\$ 100.00	\$ 95.02	\$ 53.52	\$ 161.77	\$ 238.23	\$ 111.57
S&P 500 (GSPC)	\$ 100.00	\$ 119.42	\$ 111.97	\$ 144.31	\$ 167.77	\$ 212.89
S&P Healthcare Equipment (SPSIHE)	\$ 100.00	\$ 129.98	\$ 141.99	\$ 173.80	\$ 230.87	\$ 238.52

## Recent Sales of Unregistered Securities

None.

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

## ITEM 6. [RESERVED]

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

This Annual Report includes “forward-looking statements” within the meaning of the federal securities laws, particularly statements referencing our expectations relating to the productivity of our sales force, revenues, deferred revenues, cost of revenues, operating expenses, stock-based compensation and provision for income taxes; the

growth of our customer base and customer demand for our products; the sufficiency of our cash balances and cash flows; the impact of recent changes in accounting standards; the impact of changes in the tax code as a result of recent federal tax legislation and uncertainty as to how some of those changes may be applied; market risk sensitive instruments; contractual obligations; and assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "intends," "plans," "anticipates," "estimates," "potential," or "continue," or the negative thereof, or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, these expectations or any of the forward-looking statements could prove to be incorrect, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to risks and uncertainties, including but not limited to the factors set forth in this Annual Report under Part I, Item 1A. *Risk Factors*. All forward-looking statements and reasons why results may differ included in this Annual Report are made as of the date of the filing of this Annual Report, and we assume no obligation to update any such forward-looking statements or reasons why actual results may differ.

The following discussion should be read in conjunction with our consolidated financial statements and notes thereto appearing in Part II, Item 8 of this Annual Report.

## Overview

We are a global medical device company focused on delivering comprehensive, life-changing solutions that continue to set the standard for enduring patient outcomes in chronic pain treatment. We have developed and commercialized the Senza® spinal cord stimulation (SCS) system, an evidence-based neuromodulation platform for the treatment of chronic pain, with the Senza® Omnia™ platform being our latest addition to the Senza family of products. Our proprietary, paresthesia-free 10 kHz Therapy, delivered by our Senza system, was demonstrated in our SENZA randomized controlled trial (RCT) to be superior to traditional SCS therapy, with 10 kHz Therapy being nearly twice as successful in treating back pain and 1.5 times as successful in treating leg pain when compared to traditional SCS therapy. In addition to the original approval of our therapy in back and leg pain, we received approval of unilateral or bilateral pain, associated with painful diabetic neuropathy (PDN) in July 2021 and we received expanded labeling in non-surgical refractory back pain (NSRBP) in January 2022. Our SENZA-RCT study, along with our SENZA-PDN clinical study, SENZA-NSRBP clinical study and European studies, represents what we believe is the most robust body of clinical evidence for any SCS therapy. We believe the superiority of 10 kHz Therapy over traditional SCS therapies will allow us to capitalize on and expand the approximately \$2.3 billion global SCS market by treating patients with debilitating chronic pain, including back and leg pain, NSRBP and PDN.

We launched Senza commercially in the United States in May 2015, after receiving a label from the U.S. Food and Drug Administration (FDA) supporting the superiority of our 10 kHz Therapy over traditional SCS. The Senza system has been commercially available in certain European markets since November 2010 and in Australia since August 2011. We have experienced significant revenue growth in the United States since commercial launch. Senza is currently reimbursed by all of the major insurance providers. In early 2017, we commenced a controlled commercial launch of our family of surgical leads, marketed as the Surpass surgical lead, and in April 2020 received FDA approval for our reduced-size Surpass-C surgical lead. In January 2018, we received FDA approval of our next generation Senza II SCS system. In the fourth quarter of 2019, we received FDA approval of our next generation product platform, Senza Omnia, which we launched in the United States in the fourth quarter of 2019. Additionally, we received approval to commercially launch Senza Omnia in Europe during the second quarter of 2020 and in Australia in July 2020. In the first quarter of 2021, we received FDA approval for our first Senza Omnia upgrade, Omnia™ Powered by HFX Connect™, and our next generation trial stimulator. In July 2021, we received FDA approval of our 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN. This approval is specific to our unique 10 kHz stimulation, and the Senza system was the first spinal cord stimulation system approved by the FDA with a specific indication to treat certain forms of pain associated with PDN.

The tables below set forth our revenue from U.S. and international sales the past three years on a quarterly basis and total revenue for each of the past five years.

	<u>Q1 2019</u>	<u>Q2 2019</u>	<u>Q3 2019</u>	<u>Q4 2019</u>	<u>Q1 2020</u>	<u>Q2 2020</u>	<u>Q3 2020</u>	<u>Q4 2020</u>	<u>Q1 2021</u>	<u>Q2 2021</u>	<u>Q3 2021</u>	<u>Q4 2021</u>
<u>Revenue from:</u>	(in millions)											
U.S. sales	\$65.8	\$78.1	\$ 84.2	\$ 97.9	\$75.3	\$51.0	\$ 90.9	\$ 94.6	\$74.7	\$ 85.0	\$78.1	\$ 88.4
International sales	16.3	15.5	16.0	16.5	12.2	5.4	17.5	15.1	13.9	17.3	15.2	14.3
Total revenue	<u>\$82.1</u>	<u>\$93.6</u>	<u>\$100.2</u>	<u>\$114.4</u>	<u>\$87.5</u>	<u>\$56.4</u>	<u>\$108.5</u>	<u>\$109.7</u>	<u>\$88.6</u>	<u>\$102.3</u>	<u>\$93.2</u>	<u>\$102.8</u>

	<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>
<u>Revenue from:</u>	(in millions)				
U.S. sales	\$ 263.5	\$ 321.8	\$ 326.0	\$ 311.9	\$ 326.2
International sales	63.2	65.5	64.3	50.2	60.7
Total revenue	<u>\$ 326.7</u>	<u>\$ 387.3</u>	<u>\$ 390.3</u>	<u>\$ 362.0</u>	<u>\$ 386.9</u>

Since our inception, we have financed our operations primarily through equity and debt financings and borrowings under a debt facility. Our accumulated deficit as of December 31, 2021 was \$624.2 million. A significant amount of our capital resources has been used to support the development of our Senza products and our 10 kHz Therapy, and we have also made a significant investment building our U.S. commercial infrastructure and sales force to support our commercialization efforts in the United States. We intend to continue to make significant investments in our U.S. commercial infrastructure, including a sales organization that targets physician specialties involved in PDN treatment decisions, as well as in research and development (R&D) to develop Senza to treat other chronic pain indications, including conducting clinical trials to support our future regulatory submissions. In order to further enhance our R&D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to raise additional funds, which may include future equity and debt financings.

In April 2020, we issued \$165.0 million aggregate principal amount of 2.75% convertible senior notes due 2025 (the 2025 Notes) in a registered underwritten public offering and an additional \$24.8 million aggregate principal amount of such notes pursuant to the underwriters' exercise in full of their option to purchase additional 2025 Notes. The 2025 Notes' interest rates are fixed at 2.75% per annum, with interest payable semi-annually in arrears on April 1 and October 1 of each year, which commenced on October 1, 2020. The total net proceeds from the 2025 Notes, after deducting initial purchase discounts and debt issuance costs, were approximately \$183.6 million. In connection with the offering of the 2025 Notes, we entered into convertible note hedge transactions in which we have the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of common stock at a price of approximately \$105.00 per share. The total cost of the convertible note hedge transactions was \$52.4 million. In addition, we sold warrants to certain bank counterparties whereby the holders of the warrants have the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of our common stock at a price of \$147.00 per share. We received \$34.9 million in cash proceeds from the sale of these warrants. The net cost incurred in connection with the convertible note hedge and warrant transactions was \$17.5 million. Concurrent with the registered underwritten public offering of the 2025 Notes, we completed an underwritten public offering of common stock and issued 1,868,750 shares of common stock, including 243,750 shares issued pursuant to the exercise in full of the underwriters' option to purchase additional shares. As a result of this public offering of common stock, we received cash proceeds of \$147.1 million, net of underwriting discounts and commissions and offering costs. On June 1, 2021, our outstanding 1.75% convertible senior notes due 2021 (2021 Notes) matured, and we paid \$172.5 million to settle the outstanding principal and issued 682,912 shares of common stock to holders who elected to convert the 2021 Notes. In addition, we exercised our option under the bond hedge and received 682,916 shares of common stock from the bank counterparties. As of December 31, 2021, the 2021 Notes were no longer outstanding.

We rely on third-party suppliers for all of the components of our Senza products, and currently for the assembly of these systems. Several of these suppliers are currently single-source suppliers. We have entered into and/or amended several supply agreements in an effort to reinforce our supply chain. We are also required to maintain high levels of inventory, and, as a result, we are subject to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges. Additionally, as compared to direct manufacturers, our dependence on third-party manufacturers makes us vulnerable to supply shortage problems and exposes us to greater lead times, increasing our risk of inventory obsolescence. In the third quarter of 2020, we made the strategic decision to vertically integrate the assembly of IPG's peripherals and various other manufacturing related activities

to mitigate our reliance on third-party manufacturers and improve our long-term gross margins. We plan on conducting these manufacturing activities in a facility in Costa Rica, for which our lease began in April 2021. The integration process is expected to be completed in mid-2022. Even after this integration process is completed, we expect that we will continue to rely on third-party manufacturers to provide key components to support the assembly process. We may incur significant capital expenditures and implementation costs to initiate the manufacturing operations in Costa Rica.

## **COVID-19 Pandemic**

We are subject to risks related to the public health crises such as the global pandemic associated with COVID-19. The COVID-19 outbreak has negatively impacted, and continues to negatively impact our operations and revenues and overall financial condition as demand for elective procedures remains unpredictable and the number of Senza trials and permanent system implant procedures has not recovered to pre-pandemic levels. The magnitude of the risks and uncertainties related to the pandemic are unpredictable and could be further aggravated by the spread of new variants of the COVID-19 virus such as the Delta and Omicron variants, which may be more contagious and/or virulent. During the initial stages of the pandemic, the number of Senza systems procedures performed, similar to other elective surgical procedures, decreased significantly as health care organizations globally prioritized the treatment of patients with COVID-19. For example, in the United States in the first half of 2020 and more recently in connection with the spread of the Omicron variant, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments, be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. Additionally, overall patient willingness to pursue elective procedures has decreased due to the pandemic. Throughout 2021, the COVID-19 pandemic negatively impacted the global SCS therapy market, which we estimate decreased by approximately 5% to 10%. These challenges may arise again at any time throughout the duration of the pandemic, which is uncertain, and could reduce our revenue while the pandemic continues.

Notably, the predictability of trial and permanent implant procedures continues to be challenging to forecast in light of the ongoing pandemic and recent surges in cases caused by the Delta and then Omicron variants. Even if the severity of the pandemic subsides, we are unable to predict the timing that demand for Senza system procedures may return to historic levels as prospective patients may decide to delay their procedures. As a result of the spread of more contagious and virulent variants, the COVID-19 pandemic could continue to result in a meaningful delay in patients seeking to have a Senza system trial. Further, we anticipate that the substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions will result in patients seeking to have Senza system trials or implant procedures performed having to navigate limited provider capacity, due to, among other reasons, a growing trend of labor shortages with nurses and other healthcare facility staff. We believe these factors may have an adverse effect on the recovery of the global SCS therapy market and, as a result, the amount of time we predict for our sales to recover following the end of the pandemic.

Further, numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Multiple times in 2020, the governor of California, where our headquarters are located, issued a “shelter-in-place” or “stay at home” orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions have resulted in our headquarters closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on our personnel and personnel of partners to travel and access customers for training and case support; delays in approvals or certifications by regulatory authorities and notified bodies; delays in product development efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our Senza systems. For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the Medical Devices Regulation (EU) No 2017/745 (the EU Medical Devices Regulation). While several notified bodies have been designated, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation as a consequence of which review times have lengthened. This situation could impact our ability to grow our business in

the EU and EEA. In addition, even after the lift of “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19, we continue to experience disruptions to our business as a result of patients and customers continuing to be cautious in restarting elective procedures in light of the continued risk posed by the virus.

Global and domestic supply chains and the timely availability of raw materials and products may be materially disrupted by quarantines, factory slowdowns or shutdowns, border closings and travel restrictions resulting from the COVID-19 pandemic. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future activities.

While the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity, including our ability to repay our 2.75% convertible senior convertible notes due 2025 (the 2025 Notes). We expect any further shelter-in-place policies and restrictions on elective surgical procedures worldwide to have a substantial impact on our revenue. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. During the COVID-19 pandemic, our customers, including hospitals, ASCs and physician offices, have experienced financial hardship and some of them may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for bankruptcy or being acquired by larger health systems, leading to reduced procedures and/or additional pricing pressure on our products. The COVID-19 pandemic has also resulted in a significant increase in unemployment in the United States, Europe and Australia, which may continue even after the pandemic. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of Senza systems sold after the pandemic has ended.

### **Important Factors Affecting our Results of Operations**

In addition to the impact of COVID-19, we believe that the following factors have impacted, and we expect will continue to impact, our results of operations.

#### ***Importance of Physician Awareness and Acceptance of Our Products***

We continue to invest in programs to educate physicians who treat chronic back and leg pain about the advantages of Senza. This requires significant commitment by our marketing team and sales organization, and can vary depending upon the physician’s practice specialization, personal preferences and geographic location. Further, we are competing with well-established companies in our industry that have strong existing relationships with many of these physicians. Educating physicians about the advantages of our Senza products, including our latest product, Senza Omnia, and influencing these physicians to use these products to treat chronic pain, is required to grow our revenue.

In July 2021, we received FDA approval of our 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN, and we have initiated a commercial rollout. In order to successfully commercialize our PDN opportunity, we will need to invest in and incur significant costs for this new indication and patient population, including costs to continue to build our sales force, marketing efforts and continuing clinical activities. Our success in the PDN market will be dependent on, among other factors, the perceived efficacy of our therapy for PDN patients, our ability to educate and generate awareness of our therapy for referring physicians, treating physicians and patients, and our ability to obtain sufficient third-party coverage or reimbursement for use of our therapy in PDN patients.

#### ***Reimbursement and Coverage Decisions by Third-Party Payors***

Healthcare providers in the United States generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to cover and reimburse all or part of the cost of our products and the related implant procedure for patients. The revenue we are able to generate from sales of our products depends in large part on the availability of reimbursement from such payors. While we currently have a favorable National

Coverage Determination (NCD) and reimbursement by Medicare for chronic back and leg pain, we have more limited coverage for PDN and NSRBP procedures, and decisions of coverage and reimbursement for Senza and the related implant procedure from private health insurance providers can vary. In general, these decisions require that such payors perform analyses to determine if the procedure is medically necessary and if our technology is covered under their existing coverage policies. These payors may deny reimbursement if they determine that the device or procedure was not medically necessary for the patient and used in accordance with the payor's coverage policy.

A significant component of our commercial efforts includes working with private payors to ensure positive coverage decisions for our products. For our traditional chronic back and leg pain market, we believe that favorable coverage and reimbursement for procedures using our products from Medicare and certain commercial payors, such as Aetna, Cigna, Humana, Blue Cross Blue Shield and Kaiser, have contributed to our increase in revenue to date. Although the largest commercial payors and Medicare cover procedures using Senza, there can be no assurance that all private health insurance plans will cover the therapy. Effective July 1, 2021, Medicare now requires Prior Authorization for certain hospital outpatient procedures, including SCS procedures. In January 2022, we announced that UnitedHealthcare will provide coverage for our 10 kHz Therapy for the treatment of PDN for dates of service on or after March 1, 2022. A significant number of negative coverage and reimbursement decisions by private insurers may impair our ability or delay our ability to grow our revenue.

We are working to expand payor coverage to include the use of our 10 kHz Therapy for the management of PDN and NSRBP. This effort could be costly and could take many years to gain broad acceptance, and there can be no guarantee that it will be successful.

### ***Inventory Buildup and Supply Chain Management***

Our products are composed of a substantial number of individual components and, in order to market and sell them effectively, we must maintain high levels of inventory. In particular, since our commercial launch of Senza in the United States, we have continued to add suppliers to fortify our supply chain and we have maintained increased levels of inventory. As a result, a significant amount of our cash used in operations has been associated with maintaining these levels of inventory. There may also be times in which we determine that our inventory does not meet our product requirements. Further, the manufacturing process for our products requires lengthy lead times, during which components may become obsolete. We may also over- or underestimate the quantities of required components, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. These factors subject us to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges. The sum of the charges for the items listed above were \$2.5 million and \$2.7 million for the years ended December 31, 2021 and 2020, respectively. Additionally, as we release later generations of products that contain advancements or additional features, the earlier generations may become obsolete, as was the case in the years ended December 31, 2021 and 2020, when we recorded a charge of \$1.8 million and \$2.6 million, respectively.

### ***Investment in Research and Clinical Trials***

We intend to continue investing in R&D to help our commercialization efforts around and to expand into new indications and chronic pain conditions, as well as develop product enhancements to improve outcomes and enhance the physician and patient experience. For example, we commenced commercial launches of Surpass, our surgical lead product family in early 2017 and Senza II SCS System in late 2017. Most recently, we launched our next generation product platform, Senza Omnia, in the United States in late 2019, in Europe during the second quarter of 2020 and in Australia in July 2020. In the first quarter of 2021, we received FDA approvals for our first Senza Omnia upgrade and a new trial stimulator. In July 2021, we received FDA approval of our 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN. We are continuing to invest in product improvements to Senza, including enhanced MRI capabilities and next generation IPGs. While R&D and clinical testing are time consuming and costly, we believe expanding into new indications, implementing product improvements and continuing to demonstrate the efficacy, safety and cost effectiveness of the 10 kHz Therapy through clinical data are all critical to increasing the adoption of this therapy. We initiated two randomized controlled trials in 2018, SENZA-PDN and SENZA-NSRBP, which evaluate the 10 kHz Therapy for the treatment of PDN and NSRBP, respectively. In January 2020 at NANS 2020, we presented the three-month data from our SENZA-PDN study, which was the largest SCS randomized controlled trial conducted to

date for PDN. In January 2021, we presented the six-month data from our SENZA-PDN study at NANS 2021. In April 2021, the six-month data from the SENZA-PDN study was additionally published in JAMA Neurology, an international peer-reviewed journal. In June 2021, we presented the 12-month follow-up results and the 6-month crossover patient data at the American Diabetes Association 81st Scientific Sessions. With regard to the SENZA-NSRBP study, we presented the three-month primary endpoint results in January 2021 at NANS 2021, representing the first release of data from this randomized controlled trial. In June 2021, we presented the 6-month data from SENZA-NSRBP at the American Society of Interventional Pain Physicians 23rd annual meeting. Both the SENZA-PDN and SENZA-NSRBP studies are ongoing, and further data will be presented and published in leading journals as the data becomes available. In July 2021, we received FDA approval of our 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN.

### ***Significant Investment in U.S. Sales Organization***

In 2021, we established a sales organization to support the launch of our PDN indication in the U.S. This sales organization targets physician specialties involved in PDN treatment decisions, including primary care physicians, endocrinologists, internal medicine and podiatrists, to create awareness of 10 kHz Therapy to treat PDN patients. We are continuing to make investments in building our U.S. commercial infrastructure and recruiting and training our U.S. sales force. This is a lengthy process that requires recruiting appropriate sales representatives, establishing and, on occasion, refining a commercial infrastructure in the United States and training our sales representatives. Following initial training for Senza, our sales representatives typically require lead time in the field to grow their network of accounts and produce sales results. Successfully recruiting and training a sufficient number of productive sales representatives has been required to achieve growth at the rate we expect.

### ***Access to Hospital Facilities***

In the United States, in order for physicians to use our products, the hospital facilities where these physicians treat patients often require us to enter into purchasing contracts directly with the hospital facilities or with the Group Purchasing Organizations of which the hospital facilities are members. This process can be lengthy and time-consuming and requires extensive negotiations and management time. In Europe, we may be required to engage in a contract bidding process in order to sell our products, where the bidding processes are only open at certain periods of time, and we may not be successful in the bidding process.

### ***Critical Accounting Policies, Significant Judgments and Use of Estimates***

Our management's discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in 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. Actual results may differ from these estimates under different assumptions and conditions. We believe that the estimates, judgments and assumptions involved in the accounting for revenue recognition, inventory, stock-based compensation, income taxes and allowance for doubtful accounts have the greatest potential impact on our consolidated financial statements, so we consider these to be our critical accounting policies. We discuss below the critical accounting estimates associated with these policies. Historically, our estimates, judgments, and assumptions relative to our critical accounting policies have not differed materially from actual results. Our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

### ***Revenue***

Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of the Company's goods to its customers. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring the goods. Under ASC 606, *Revenue from Contracts*

*with Customers*, assuming all other revenue recognition criteria have been met, we also recognize revenue for arrangements where we have satisfied the performance obligations but have not issued invoices. These amounts are recorded as unbilled receivables, which are included in accounts receivable on the consolidated balance sheet, as we have an unconditional right to payment at the end of the applicable period.

For a majority of sales, where our sales representative delivers our product at the point of implantation at hospitals or medical facilities, we recognize revenue upon completion of the procedure and authorization, which represents the point in time when control transfers to the customers.

For the remaining sales, which are sent from the Company's distribution centers directly to hospitals and medical facilities, as well as distributor sales, where product is ordered in advance of an implantation, the transfer of control occurs at the time of shipment of the product. These customers are obligated to pay within specified terms regardless of when or if they ever sell or use the products. We do not offer rights of return or price protection. To the extent that we have a post-delivery obligation, such as programming devices that have been delivered as part of a direct-ship order, we defer revenue and the associated cost of goods sold associated with the post-delivery obligation only if the amounts are deemed material.

Sales, value add, and other taxes the Company collects concurrent with revenue-producing activities are excluded from revenue. The expected costs associated with warranty obligations continue to be recognized as expense when the products are sold. The Company periodically provides incentive offers, in the form of rebates, to customers based on their aggregate levels of purchases. Product revenue is recorded net of such incentive offers.

The Company recognizes revenue upon the transfer of control of the product and there are no material future performance obligations beyond such transfer. As a result, the Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed. The Company does not capitalize incremental costs when the amortization period of the asset is less than a year.

### ***Inventory Valuation***

We contract with third parties for the manufacturing and packaging of all of the components of our Senza products. We plan the manufacture of our systems based on estimates of market demand. The nature of our business requires that we maintain sufficient inventory on hand to meet the requirements of our customers. Inventories are stated at the lower of cost or net realizable value. Cost is determined using the standard cost method, which approximates the first-in, first-out basis. Net realizable value is determined as the prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation.

We regularly review inventory quantities compared to forecasted sales to record a provision for excess and obsolete inventory when appropriate. Inventory write-downs are recorded for excess and obsolete inventory. We estimate forecasted sales by considering:

- product acceptance in the marketplace;
- customer demand;
- historical sales;
- product obsolescence; and
- technological innovations.

Any inventory write-downs are recorded in cost of revenue within the statements of operations during the period in which such write-downs are determined necessary by management.

## **Stock-Based Compensation**

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The fair value is recognized on a straight-line basis over the requisite service period of the stock option award, which is generally the vesting term of four years, with the exception of performance based stock option awards, whose fair value is recognized as expenses when it is determined that achieving the performance metrics are probable.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. The assumptions used in our option-pricing model represent management's best estimates. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment, so that they are inherently subjective. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

*Risk-Free Interest Rate.* We base the risk-free interest rate used in the Black-Scholes valuation model on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term of the options for each option group.

*Expected Term.* The expected term represents the period that our stock-based awards are expected to be outstanding. We utilize our historical data for the calculation of expected term.

*Volatility.* We have incorporated our historical stock trading volatility with those of our peer group for the calculation of volatility. Industry peers consist of several public companies in the medical device technology industry with comparable characteristics including enterprise value, risk profiles and position within the industry. We regularly evaluate our peer group to assess changes in circumstances where identified companies may no longer be similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

*Dividend Yield.* The expected dividend assumption is based on our current expectations about our anticipated dividend policy. We currently do not expect to issue any dividends.

In addition to assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation for our awards. We will continue to use judgment in evaluating the assumptions related to our stock-based compensation on a prospective basis. As we continue to accumulate additional data, we may have refinements to our estimates, which could materially impact our future stock-based compensation expense.

In 2015, we began issuing restricted stock units (RSUs). We account for stock-based compensation for the RSUs at their fair value, based on the closing market price of our common stock on the grant date. These costs are recognized on a straight-line basis over the requisite service period, which is generally the vesting term of four years.

In 2016, we granted performance based RSUs to our former CEO that only vest upon the achievement of specific operational performance criteria. The stock-based compensation for these performance based RSUs are recognized as expenses when it is determined that achieving the performance metrics are probable. Upon the former CEO's resignation from the Company in March 2019, the unvested shares subject to this award as of the separation date have been cancelled.

In 2019, we granted performance stock units (PSUs) to our current CEO, which entitle him to receive a number of shares of our common stock based on our stock price performance compared to a specified target composite index over a three-year period. The number of shares to be issued upon vesting ranges from zero to 3.5 times the number of PSUs granted, depending on the relative performance of our common stock compared to the targeted composite index. In 2020 and 2021, the Company granted PSUs to certain members of the management team, subject to continued service to the Company and based on the total shareholder return of the Company's

common stock price compared to the targeted composite index over a three-year period. The number of shares to be issued upon vesting of these PSUs range from 0 to 1.5 times the target number of shares granted, depending on the Company's performance against the targeted composite index. The fair value of these PSUs is determined by using the Monte Carlo simulation model, which is based on a discounted cash flow approach, and requires inputs such as expected volatility of our stock price, expected volatility of the targeted composite index, correlation between the changes in our stock price and the target composite index, risk-free interest rate and expected dividends. The expected volatility of our stock and the target composite index is based on the historical data. Correlation is based on the historical relationship between our stock price and the target composite index. The risk-free interest rate is based upon the treasury yield consistent with the vesting term of the grant. The expected dividend yield is zero. Stock-based compensation for these PSUs is recognized over the specified performance measurement.

We estimate the fair value of the rights to purchase shares by employees under our Employee Stock Purchase Plan using the Black-Scholes option pricing formula. Our Employee Stock Purchase Plan provides for consecutive six-month offering periods and we use our own historical volatility data in the valuation.

#### **Income Tax**

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. We periodically evaluate the positive and negative evidence bearing upon realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and difficulty in accurately forecasting our future results, we maintained a full valuation allowance on our net U.S. federal and state deferred tax assets as of December 31, 2021 and 2020. We intend to maintain a full valuation allowance on the federal and state deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

As of December 31, 2021, we had federal net operating loss carryforwards (NOLs) of \$588.4 million, of which \$329.4 million was generated in fiscal year 2018 and thereafter, which can be carried forward indefinitely under the 2017 Tax Act, as well as state NOLs of \$336.5 million, of which \$54.3 million may be carried forward indefinitely. If not utilized, the remaining federal NOLs will begin to expire in 2026 and the state NOLs will begin to expire in 2022. We have no significant foreign NOL carryforwards. We also have federal research tax credit carryforwards that will begin to expire in 2026 and California research tax credits that do not expire. Realization of these NOL and research tax credit carryforwards depends on future income, and there is a risk that our existing carryforwards could expire unused and be unavailable to reduce future income tax liabilities, which could materially and adversely affect our results of operations.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code) our ability to utilize NOL carryforwards or other tax attributes such as research tax credits, in any taxable year may be limited if we experience, or have experienced, a Section 382 "ownership change." 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 a greater than 50 percentage point change (by value) over a rolling three-year period. Similar rules may apply under state tax laws.

No deferred tax assets have been recognized on our balance sheet related to our federal and state NOLs and tax credits, as they are fully reserved by a valuation allowance. We experienced a Section 382 "ownership change" as a result of our June 2015 underwritten public offering. We currently estimate this "ownership change" will not inhibit our ability to utilize our NOLs. However, we may, in the future, experience one or more additional Section 382 "ownership changes" as a result of subsequent changes in our stock ownership, some of which changes are outside our control. If so, we may not be able to utilize a material portion of our NOLs and tax credits even if we achieve profitability and generate sufficient taxable income. If we are limited in our ability to use our NOLs and tax credits in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits. This could materially and adversely affect our results of operations.

We record unrecognized tax benefits as liabilities and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax

expense in the period in which new information is available. Our policy is to recognize interest and penalties related to income taxes as a component of income tax expense.

### **Allowance for Doubtful Accounts**

We make estimates as to the overall collectability of accounts receivable and provide an allowance for accounts receivable considered uncollectible based on current expected credit losses. We specifically analyze accounts receivable based on historical bad debt experience, customer concentrations, customer credit-worthiness, the age of the receivable, current economic trends, and changes in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. We record the adjustment in general and administrative expense. Our accounts receivable balance was \$70.5 million, net of allowance of \$1.4 million, as of December 31, 2021 and \$77.7 million, net of allowance of \$3.0 million, as of December 31, 2020.

### **Components of Results of Operations**

#### **Revenue**

Our revenue is generated primarily from sales to two types of customers: hospitals and outpatient medical facilities, with each being served primarily through a direct sales force. Sales to these entities are billed to, and paid by, the hospitals and outpatient medical facilities as part of their normal payment processes, with payment received by us in the form of an electronic transfer, check or credit card payment. Product sales to third-party distributors are billed to and paid by the distributors as part of their normal payment processes, with payment received by us in the form of an electronic transfer.

U.S. revenue is generally recognized after our sales representatives deliver our product at the point of implantation and upon the completion and authorization of the implant procedure. In response to competitive practices and pressures, we have offered some volume price discounting for larger orders, where products are ordered in advance of an implantation and revenue is recognized when the transfer of control occurs at the time of shipment.

Revenue from sales of our Senza products fluctuate based on the selling price of the system, as the average sales price of a system varies geographically and by the type of system sold, and based on the mix of sales by geography. Our revenue from international sales can also be significantly impacted by fluctuations in foreign currency exchange rates, as our sales are denominated in the local currency in the countries in which we sell our products.

We expect our revenue to fluctuate from quarter to quarter due to a variety of factors, including seasonality. For example, the industry generally experiences lower revenues in the first and third quarters of the year and higher revenues in the fourth quarter. Our revenue has historically been impacted by these industry trends. Further, the impact of the buying patterns and implant volumes of hospitals and medical facilities, and third-party distributors may vary, and as a result could have an effect on our revenue from quarter to quarter. The normal seasonal fluctuations of our revenue have been disrupted by the COVID-19 pandemic, as we have seen significant fluctuations in our quarterly revenue based on current events directly caused by the pandemic. We have recorded revenue of approximately \$326.0 million, \$311.9 million and \$326.2 million for the years ended December 31, 2019, 2020 and 2021, respectively, for sales in the United States. We anticipate that our total revenue will increase as we continue our commercialization in the United States.

#### **Cost of Revenue**

We utilize contract manufacturers for the production of Senza products. Cost of revenue consists primarily of acquisition costs of the components of Senza, manufacturing overhead, royalty payments, scrap and inventory excess and obsolescence charges, as well as distribution-related expenses, such as logistics and shipping costs, net of costs charged to customers.

We calculate gross margin as revenue less cost of revenue divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, but primarily by our average sales price and the costs to have our

products manufactured. While costs are primarily incurred in U.S. dollars, international revenue may be impacted by the appreciation or depreciation of the U.S. dollar, which may impact our overall gross margin. Our gross margin is also affected by our ability to reduce manufacturing costs as a percentage of revenue.

### ***Operating Expenses***

Our operating expenses consist of R&D expense, and sales, general and administrative (SG&A) expense. Personnel costs are the most significant component of operating expenses and consist primarily of salaries, bonus incentives, benefits, stock-based compensation and sales commissions.

***Research and Development.*** R&D costs are expensed as incurred. R&D expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation expenses for our R&D employees. R&D expense also includes costs associated with product design efforts, development prototypes, testing, clinical trial programs and regulatory activities, contractors and consultants, equipment and software to support our development, facilities and information technology. We expect product development expenses to increase in absolute dollars as we continue to develop product enhancements to Senza. Our R&D expenses may fluctuate from period to period due to the timing and extent of our R&D and clinical trial expenses.

***Sales, General and Administrative.*** SG&A expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation expenses for our sales and marketing personnel, including sales commissions, and for administrative personnel that support our general operations, such as information technology, executive management, financial accounting, customer service and human resources personnel. We expense commissions at the time of the sale. SG&A expense also includes costs attributable to marketing, as well as travel, intellectual property and other legal fees, financial audit fees, insurance, fees for other consulting services, depreciation and facilities.

We significantly increased the size of our sales presence worldwide during 2019, and we have maintained the overall size of our sales organization in 2020. In 2021, we established a sales organization to support the launch of our PDN indication in the U.S. This sales organization targets physician specialties involved in PDN treatment decisions, including primary care physicians, endocrinologists, internal medicine and podiatrists, to create awareness of 10 kHz Therapy to treat PDN patients. In the last three years, we have increased marketing spending in order to generate additional sales opportunities. Additionally, we have made substantial investments in our U.S. commercial infrastructure to support our commercialization efforts in the United States. We expect SG&A expenses to decrease as a percent of revenue as we engage in activities that leverage our existing sales and marketing personnel to support the commercialization of our products in the United States.

During 2019, 2020 and 2021 we had experienced significant legal expenses associated with our intellectual property litigation with Boston Scientific. We anticipate significant continued expenses associated with these legal activities. Additionally, we continue to incur significant expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, including compliance under the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), director and officer insurance premiums and investor relations costs associated with being a public company. Our SG&A expense may fluctuate from period to period due to the seasonality of our revenue, the timing and extent of our SG&A expense, and the direct impact of the COVID-19 pandemic on certain discretionary spend items such as travel and trade shows.

***Certain litigation charges.*** We record a liability for loss contingencies related to legal actions when a loss is known or considered probable and the amount may be reasonably estimated. When determining the estimated loss or range of loss, significant judgment is required. We record litigation charges that we consider to be unusual or infrequent and significant as *Certain litigation charges* in our consolidated statements of operations. All other legal expenses are recorded within SG&A expense.

### ***Interest Income and Interest Expense***

Interest income consists primarily of interest income earned on our investments and interest expense consists of interest paid on our outstanding debt and the amortization of debt discount and debt issuance costs.

### **Other Income (Expense), Net**

Other income (expense), net consists primarily of foreign currency transaction gains and losses and the gains and losses from the remeasurement of foreign-denominated balances to the U.S. dollar.

### **Provision for Income Taxes**

The provision for income taxes consists primarily of income taxes in foreign jurisdictions in which we conduct business as well as states where we have determined we have state nexus. We maintain a full valuation allowance for substantially all of our deferred tax assets including net operating loss (NOL) carryforwards and federal and state tax credits.

### **Recent Accounting Pronouncements**

For recent accounting pronouncements, see Note 2, *Summary of Significant Accounting Policies*, of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

### **Comparison of the Years Ended December 31, 2021 and 2020**

#### **Revenue, Cost of Revenue, Gross Profit and Gross Margin**

(in thousands)	Years Ended December 31,		
	2021	2020	Change
Revenue	\$ 386,905	\$ 362,048	\$ 24,857
Cost of revenue	120,863	112,146	8,717
Gross profit	\$ 266,042	\$ 249,902	\$ 16,140
Gross margin	69%	69%	(0)%

*Revenue.* Revenue increased to \$386.9 million in 2021 from \$362.0 million in 2020, an increase of \$24.9 million, or 7%. Revenue in the United States was \$326.2 million in 2021, a 5% increase from \$311.9 million in the 2020. International revenue was \$60.7 million in 2021, compared to \$50.2 million in 2020. Our revenue in 2020 was negatively impacted by the COVID-19 pandemic, when we experienced worldwide decline in procedure volume in the first half of 2020, as healthcare systems diverted resources to meet the increasing demands of managing COVID-19 and as elective procedures were significantly limited or halted, which was offset by some recovery in revenue in the second half of 2020 due to the rescheduling of implant procedures from the first half of 2020. We experienced some recovery from the pandemic in the first half of 2021, although the Delta and Omicron variants disrupted the pace of this recovery in the second half of 2021. Compared to 2020, our overall unit shipments increased in 2021.

*Cost of Revenue, Gross Profit and Gross Margin.* Cost of revenue increased to \$120.9 million in 2021, compared to \$112.1 million in 2020, an increase of \$8.7 million, or 8%. This increase was primarily due to an increase of \$9.1 million in the costs of manufactured product components and \$4.3 million related to costs associated to initiating the manufacturing facility in Costa Rica, offset by a decrease of \$3.1 million in royalty expenses and \$1.6 million under-absorption of overhead in 2020. Gross profit increased to \$266.0 million in 2021 from \$249.9 million in 2020, an increase of \$16.1 million, or 6%. Gross profit as a percentage of revenue, or gross margin, remained steady at 69% in 2021 and 2020.

## Operating Expenses

(in thousands)	Years Ended December 31,					
	2021		2020		% of Total Revenue	Change Amount
	Amount	%	Amount	%		
Operating expenses:						
Research and development	\$ 47,665	12%	\$ 45,600	13%	\$ 2,065	
Sales, general and administrative	309,311	80%	267,154	74%	42,157	
Certain litigation charges	20,000	5%	—	0%	20,000	
Total operating expenses	<u>\$ 376,976</u>	<u>97%</u>	<u>\$ 312,754</u>	<u>86%</u>	<u>\$ 64,222</u>	

*Research and Development (R&D) Expenses.* R&D expenses increased to \$47.7 million in 2021 from \$45.6 million in 2020, an increase of \$2.1 million, or 5%. The increase was primarily due to an increase in development activities of \$2.5 million and personnel costs of \$1.7 million, which were partially offset by a decrease in clinical and regulatory expenses of \$2.1 million.

*Sales, General and Administrative (SG&A) Expenses.* SG&A expenses increased to \$309.3 million in 2021 from \$267.2 million in 2020, an increase of \$42.2 million, or 23%. This increase was primarily driven by increased legal expenses of \$13.9 million related to ongoing intellectual property litigation efforts, marketing and PDN related initiative expenses of \$12.8 million, consulting and contract labor expenses of \$5.7 million, personnel expenses of \$6.3 million, and travel and meeting expenses of \$3.5 million.

*Certain litigation charges.* Certain litigation charges in 2021 relates to the jury award of \$20.0 million to Boston Scientific in connection with our patent infringement proceedings. We plan to appeal the decision, which may take approximately 18 to 24 months to resolve.

## Interest Income, Interest Expense, Other Income (Expense), Net, Loss on Extinguishment of Debt and Provision for Income Taxes

(in thousands)	Years Ended December 31,		
	2021	2020	Change
Interest income	\$ 671	\$ 2,956	\$ (2,285)
Interest expense	(19,749)	(21,806)	2,057
Other income (expense), net	(814)	(495)	(319)
Provision for income taxes	534	868	(334)

*Interest Income.* Interest income decreased to \$0.7 million in 2021 from \$3.0 million in 2020, primarily as a result of a decrease in our investment yield rate, as well as a decreased cash balance from the settlement of our 2021 Notes.

*Interest Expense.* Interest expense decreased to \$19.7 million in 2021 from \$21.8 million in 2020. There was a \$6.5 million decrease in expenses for the interest and amortization of debt discount and debt issuance costs related to the 2021 Notes, which were settled in June 2021. This decrease was offset by an increase of \$4.4 million for similar expenses related to the 2025 Notes, which was outstanding for the full year in 2021 compared to nine months in 2020.

*Other Income (Expense), Net.* Other income (expense), net was primarily comprised of foreign currency transaction gains and losses, and the gains and losses from the remeasurement of foreign-denominated balances. We recorded a net loss of \$0.7 million in 2021 and a net gain of \$41,000 in 2020 relation to the two items previously mentioned. Our remeasurement gains and losses are affected by changes in the foreign currency translation rates of

the countries in which we conduct business. Additionally, in 2020, we recorded a net expense of \$0.4 million for the impairment charge related to the value of the right to acquire a privately-held company.

*Income Tax Expense.* Income tax expense was \$0.5 million in 2021 and \$0.9 million in 2020. Our income tax expense is associated primarily with foreign and state income taxes. We continue to generate tax losses for U.S. federal and state tax purposes and have NOL carryforwards creating a deferred tax asset. We have a full valuation allowance on the majority of our deferred tax assets. The change in income tax expense was primarily due to changes in foreign income taxes on profits realized by our foreign subsidiaries.

## **Liquidity, Capital Resources and Plan of Operations**

Since our inception, we have financed our operations through private placements of preferred stock, the issuance of common stock in our IPO in November 2014 and our underwritten public offering in June 2015, borrowings under our credit facility, which we have subsequently repaid, and the June 2016 issuance of convertible senior notes due 2021. In April 2020, we completed a concurrent underwritten public offering of common stock and convertible senior notes due 2025. Our total net proceeds from the April 2020 offerings, after giving effect to the note hedge transactions and warrant transactions and associated offering expense was \$313.3 million. On June 1, 2021, our outstanding 2021 Notes matured and we paid \$172.5 million to settle the outstanding principal and issued 682,912 shares of common stock to holders who elected to convert the 2021 Notes. At December 31, 2021, we had cash, cash equivalents and short-term investments of \$362.0 million. Based on our current operating plan, we expect that our cash and cash equivalents on hand, together with the anticipated funds from the collection of our receivables, will be sufficient to fund our operations through at least the next 12 months.

We expect to incur continued expenditures in the future in support of our commercial infrastructure and sales force. In addition, we intend to continue to make investments in the further development of our Senza product platform and 10 kHz Therapy for the treatment of other chronic pain conditions, including ongoing R&D programs and conducting clinical trials. Further, we expect to expend significant cash resources pursuing and defending our ongoing intellectual property lawsuits. In order to further enhance our R&D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to raise additional funds.

We may continue to seek funds through equity or debt financings, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies. Should we choose to raise additional capital, the requirements will depend on many factors, including:

- the impact and duration of the ongoing COVID-19 pandemic and any recession or other market correction resulting from the pandemic;
- the costs related to the continued commercialization of our products in the United States and elsewhere, including product sales, marketing, manufacturing and distribution;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including, in particular, the costs of enforcing our patent rights in the action we filed against Boston Scientific and in defending against Boston Scientific's action against us;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- 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 market acceptance of our products in the United States and elsewhere;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- costs related to the development of our internal manufacturing capabilities;
- 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.

Our success depends, in part, upon our ability to establish a competitive position in the neuromodulation market by securing broad market acceptance of our 10 kHz Therapy and our Senza product platform for the treatment of chronic pain conditions. Any product we develop that achieves regulatory clearance or approval will have to compete for market acceptance and market share. We face significant competition in the United States and internationally, which we believe will intensify as we continue to commercialize in the United States. For example, our major competitors, Medtronic, Boston Scientific and Abbott Laboratories, each have approved neuromodulation systems in at least the United States, Europe and Australia and have been established for several years. In addition to these major competitors, we may also face competition from other emerging competitors and smaller companies with active neuromodulation system development programs that may emerge in the future.

If we are unable to raise, or have access, to sufficient funds when needed, we may be required to delay, reduce, or terminate some or all of our commercial development plans.

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

	Years Ended December 31,		
	2021	2020	2019
<b>(in thousands)</b>			
Net cash provided by (used in)			
Operating activities	\$ (41,881)	\$ 1,191	\$ (50,225)
Investing activities	201,715	(369,868)	32,330
Financing activities	(169,381)	346,905	32,093
Effect of exchange rate on cash flows	(340)	646	259
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (9,887)</u>	<u>\$ (21,126)</u>	<u>\$ 14,457</u>

*Cash Provided by (Used in) Operating Activities.* Net cash used in operating activities was \$41.9 million for the year ended December 31, 2021, primarily due to the net losses during the period of \$131.4 million. The cash used in operating activities for the year ended December 31, 2021 was also affected by an increase in inventories of \$17.2 million. These changes were offset by a net increase in accounts payable and accrued liabilities of \$12.2 million, an increase in other long-term liabilities of \$14.2 million and a decrease in accounts receivable of \$8.2 million, as well as non-cash stock based compensation expense of \$44.4 million, non-cash interest expense of \$13.3 million, depreciation and amortization of \$4.9 million, write-down of inventories of \$4.3 million and amortization of operating lease assets of \$3.8 million. Net cash provided by operating activities was \$1.2 million for the year ended December 31, 2020. The cash provided by operating activities for the year ended December 31, 2020 was affected by a decrease in prepaids and other assets of \$7.5 million, a decrease in accounts receivable of \$3.4 million, and a decrease in inventory of \$2.5 million, as well as non-cash stock based compensation expense of \$42.7 million, non-cash interest expense of \$14.9 million, inventory write-down of \$5.4 million, depreciation and amortization of \$4.8 million, amortization of operating lease assets of \$3.4 million and provision of doubtful accounts of \$2.2 million. These changes were offset by a net loss of \$83.1 million for the year and a decrease in long term liabilities of \$2.4 million. Net cash used in operating activities was \$50.2 million for the year ended December 31, 2019, primarily due to the net losses during the period of \$103.7 million. The cash used in operating activities for the year ended December 31, 2019 was affected by an increase in accounts receivable of \$2.2 million and an increase in prepaids and other assets of \$3.2 million. These changes were offset by a net increase in accounts payable and accrued liabilities of \$5.7 million and write-down of inventories of \$1.5 million, as well as non-cash stock based compensation expense of \$41.7 million, non-cash interest expense of \$7.9 million, depreciation and amortization of \$4.6 million and amortization of operating lease assets of \$3.2 million.

*Cash Used in Investing Activities.* Investing activities consisted primarily of changes in investment balances, including purchases and maturities of short-term investments, and purchases of property and equipment. For the year ended December 31, 2021, we had net proceeds from the sales and maturity of investments of \$214.1 million and purchases in property and equipment of \$12.3 million. For the year ended December 31, 2020, we had net purchases of investments of \$371.3 million and purchases in property and equipment of \$6.0 million, offset by the receipt of

\$7.5 million for the repayment of secured convertible notes from a private company. For the year ended December 31, 2019, we had net proceeds from the sales and maturity of investments of \$43.3 million, offset by purchases in property and equipment of \$3.5 million. Additionally, we purchased secured convertible notes totaling \$7.5 million in the year ended December 31, 2019.

*Cash Provided by Financing Activities.* Cash used in financing activities was \$169.4 million for the year ended December 31, 2021. We paid \$172.5 million to settle the principal for our 2021 Notes. Additionally, we had tax withholdings of \$8.1 million, offset by proceeds from issuance of common stock of \$11.2 million. Cash provided by financing activities was \$346.9 million for the year ended December 31, 2020. The majority of this cash was from the proceeds of \$183.6 million, net of issuance costs, from the 2025 Notes and the proceeds of \$147.1 million, net of issuance costs, from the concurrent public common stock offering. The cash received from these activities was offset by a net \$17.5 million cost of convertible note hedge and warrant transactions, which included the \$52.4 million purchase of convertible note hedges and proceeds of \$34.9 million related to the sale of warrants. Additionally, we received cash of \$33.6 million from the issuance of common stock to employees pursuant to the exercise of employee stock options and our employee stock purchase plan, net of tax withholdings. Cash provided by financing activities was \$32.1 million for the year ended December 31, 2019, primarily due to the cash received from the issuance of common stock to employees of \$35.2 million pursuant to the exercise of employee stock options and our employee stock purchase plan, offset by \$3.1 million for tax withholdings paid on behalf of employees for net share settlement.

### **Contractual Obligations and Commitments**

We have lease obligations primarily consisting of operating leases for our principal offices, which expire as set forth below, and for our warehouse space that expires in 2022. In 2020, we also entered into an operating lease for a manufacturing facility with a planned commencement date of April 2021 and a planned expiration date of June 2031.

In March 2015, we entered into a lease agreement for approximately 50,740 square feet of office space located in Redwood City, California for a period beginning in June 2015 and ending in May 2022, with initial annual payments of approximately \$2.0 million, increasing to \$2.4 million annually in the final year of the lease term. In December 2016, we entered into a first amendment to the lease for an additional approximately 49,980 square feet of office space adjacent to the premises under the original lease (the Expansion Premises) with initial annual payments of \$1.2 million, increasing to \$2.9 million in the final year of the amended lease term. The lease for the Expansion Premises commenced on June 1, 2018. The first amendment also extends the lease term for the original premises to terminate on the same date as the amended lease, which is May 31, 2025. In April 2017, we entered into a second amendment to the lease for a temporary space of approximately 8,171 square feet for a period beginning in May 2017, and which ended on June 1, 2018, the Commencement Date of the Expansion Premises. See Note 7, *Commitments and Contingencies*, of Notes to Consolidated Financial Statements for additional information.

In February 2017, we entered into a separate non-cancellable facility lease for warehouse space beginning March 1, 2017 through February 28, 2022, under which we are obligated to pay approximately \$0.4 million in lease payments over the term of the lease. In October 2021, we extended our warehouse lease through May 2025, under which we are obligated to pay approximately \$0.4 million over the extended term.

In August 2020, we entered into a lease for approximately 35,411 square feet of manufacturing space to begin in April 2021 and to last through June 2031 at a facility in Costa Rica, under which we are obligated to pay approximately \$3.9 million in lease payments over the term of the lease. We plan to use this facility to build-out certain manufacturing capabilities so that we can vertically integrate the assembly of IPG's peripherals and various other manufacturing related activities.

We have also entered into a service agreement for which we are committed to pay \$2.5 million in each of the next three years over the term of the service agreement, as well as a license agreement for which we are committed to pay \$0.2 million over the remaining term of license agreement.

As of December 31, 2021, our contractual obligations related to the 2025 Notes are payments of interest of \$5.2 million due each year from 2022 through 2024, and payments of interest and principal totaling \$192.4 million due in 2025.

The following table summarizes our contractual obligations as of December 31, 2021 (in thousands):

	Payment date by period				
	Total	Less than 1 year	1 to 3 years (in thousands)	4 to 5 years	More than 5 years
Notes payable, including contractual interest	\$ 208,013	\$ 5,218	\$ 10,436	\$ 192,359	\$ —
Lease obligations	23,173	5,720	12,220	3,254	1,979
Purchase obligations	8,520	3,506	5,014	—	—
Total	<u>\$ 239,706</u>	<u>\$ 14,444</u>	<u>\$ 27,670</u>	<u>\$ 195,613</u>	<u>\$ 1,979</u>

## Off-Balance Sheet Arrangements

Through December 31, 2021, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. For information regarding indemnification obligations, refer to Note 7, *Commitments and Contingencies*, of Notes to the Consolidated Financial Statements within Part II, Item 8 of this Annual Report.

## Segment Information

We have one primary business activity and operate as one reportable segment.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### Interest Rate Risk

We are exposed to limited market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve our capital to fund our operations.

We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of December 31, 2021, we had cash and cash equivalents of \$34.7 million, consisting of cash, corporate notes and money market funds, and short-term investments of \$327.3 million, consisting of agency bonds, commercial paper, corporate notes and treasury bonds. We maintained investments in money market funds that were not federally insured during the year ended December 31, 2021 and held cash in foreign banks of approximately \$8.6 million at December 31, 2021 that was not federally insured. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 1% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

### Foreign Currency Exchange Risk

To date, a portion of our revenue and operating expenses are incurred outside the United States and are denominated in foreign currencies and are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Australian dollar, the Euro and the United Kingdom pound sterling. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. As a component of other income (expense), we recognized net foreign currency transaction

losses of \$0.7 for the year ended December 31, 2021, gains of \$41,000 for the year ended December 31, 2020 and losses of \$0.6 million for each of the years ended December 31, 2019. A hypothetical 10% favorable or unfavorable change in the weighted average foreign exchange rates for the year ended December 31, 2021 would have affected the Company's net loss by approximately 2%. To date, we have not engaged in any foreign currency hedging transactions. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates.

We do not believe that inflation and change in prices had a significant impact on our results of operations for any periods presented in our consolidated financial statements.

See Note 2, *Summary of Significant Accounting Policies*, of Notes to Consolidated Financial Statements for further information on foreign currency translation.

#### **Market Risk and Market Interest Risk**

In June 2016, we issued \$172.5 million aggregate principal amount of 1.75% convertible senior notes due 2021. On June 1, 2021, these 2021 Notes matured and we settled the 2021 Notes by paying \$172.5 million to settle the outstanding principal and issuing 682,912 shares of common stock to holders who elected to convert the 2021 Notes. In addition, we exercised our option under the bond hedge and received 682,916 shares of common stock from the bank counterparties. None of the holders of the warrants associated with the 2021 Notes exercised the option to purchase shares. As of December 31, 2021, the 2021 Notes were no longer outstanding. In April 2020, we issued \$189.8 million aggregate principal amount of 2.75% convertible senior notes due 2025. The fair value of these convertible senior notes is subject to interest rate risk, market risk and other factors due to the convertible feature. The fair value of the convertible senior notes will generally increase as our common stock price increases and will generally decrease as our common stock price declines in value. The interest and market value changes affect the fair value of our convertible senior notes but do not impact our financial position, cash flows or results of operations due to the fixed nature of the debt obligation. Additionally, we carry the convertible senior notes at face value less unamortized discount on our balance sheet, and we present the fair value for required disclosure purposes only.

See Note 8, *Long-term Debt*, of Notes to Consolidated Financial Statements for further information.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The following consolidated financial statements, and the related notes thereto, of Nevro Corp. and the Report of the Company's Independent Registered Public Accounting Firm are filed as a part of this Annual Report.

## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Nevro Corp.

### ***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheets of Nevro Corp. and its subsidiaries (the “Company”) as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of stockholders’ equity and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

### ***Basis for Opinions***

The Company’s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company’s internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

### ***Definition and Limitations of Internal Control over Financial Reporting***

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made

only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

#### **Critical Audit Matters**

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

#### *Inventory Valuation - Excess and Obsolete Inventory*

As described in Notes 2 and 6 to the consolidated financial statements, inventories are stated at the lower of cost or net realizable value. Management regularly reviews inventory quantities compared to forecasted sales to record a provision for excess and obsolete inventory when appropriate. Inventory write downs are recorded for excess and obsolete inventory. Management estimates forecasted sales considering product acceptance in the marketplace, customer demand, historical sales, product obsolescence, and technological innovations. As of December 31, 2021, total inventories were \$93.5 million.

The principal considerations for our determination that performing procedures relating to inventory valuation - excess and obsolete inventory is a critical audit matter are the significant judgment by management to estimate the excess and obsolete inventory provision, related to an analysis of forecasted sales. This in turn led to significant auditor judgment, subjectivity, and effort in performing procedures to test management's estimates about forecasted sales and in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to inventory valuation and the excess and obsolete inventory provision, including controls over development of the forecasted sales. These procedures also included, among others, testing management's process for estimating the excess and obsolete inventory provision, including evaluating the appropriateness of the analysis of forecasted sales and testing the completeness, accuracy and relevance of underlying data used in the analysis.

Evaluating management's analysis of forecasted sales involved evaluating whether the assumptions used by management were reasonable considering management's forecasting accuracy and whether these assumptions were consistent with evidence obtained in other areas of the audit.

/s/ PricewaterhouseCoopers LLP  
San Jose, California  
February 23, 2022

We have served as the Company's auditor since 2008.

**Nevro Corp.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 34,710	\$ 44,597
Short-term investments	327,317	543,373
Accounts receivable, net of allowance for doubtful accounts of \$1,385 and \$3,000 at December 31, 2021 and 2020, respectively	70,475	77,667
Inventories	93,517	83,296
Prepaid expenses and other current assets	5,185	4,173
Total current assets	531,204	753,106
Property and equipment, net	20,664	13,531
Operating lease assets	17,577	18,142
Other assets	4,493	4,043
Restricted cash	606	606
Total assets	<u>\$ 574,544</u>	<u>\$ 789,428</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	\$ 31,999	\$ 23,109
Accrued liabilities	45,517	43,305
Short-term debt	—	168,776
Other current liabilities	4,687	3,975
Total current liabilities	82,203	239,165
Long-term debt	151,310	141,771
Long-term operating lease liabilities	15,402	16,689
Other long-term liabilities	22,013	3,343
Total liabilities	<u>270,928</u>	<u>400,968</u>
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at December 31, 2021 and 2020, respectively; zero shares issued and outstanding at December 31, 2021 and 2020, respectively	—	—
Common stock, \$0.001 par value, 290,000,000 shares authorized at December 31, 2021 and 2020, respectively; 35,709,570 shares issued and 35,026,654 shares outstanding at December 31, 2021; 34,583,064 shares issued and outstanding at December 31, 2020	35	35
Additional paid-in capital	928,138	880,660
Accumulated other comprehensive income / (loss)	(364)	598
Accumulated deficit	(624,193)	(492,833)
Total stockholders' equity	<u>303,616</u>	<u>388,460</u>
Total liabilities and stockholders' equity	<u><u>\$ 574,544</u></u>	<u><u>\$ 789,428</u></u>

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

**Nevro Corp.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share data)

	Years Ended December 31,		
	2021	2020	2019
Revenue	\$ 386,905	\$ 362,048	\$ 390,255
Cost of revenue	120,863	112,146	121,905
Gross profit	266,042	249,902	268,350
Operating expenses			
Research and development	47,665	45,600	59,017
Sales, general and administrative	309,311	267,154	305,812
Certain litigation charges	20,000	—	—
Total operating expenses	376,976	312,754	364,829
Loss from operations	(110,934)	(62,852)	(96,479)
Interest income	671	2,956	6,020
Interest expense	(19,749)	(21,806)	(10,931)
Other income (expense), net	(814)	(495)	(697)
Loss before income taxes	(130,826)	(82,197)	(102,087)
Provision for income taxes	534	868	1,599
Net loss	(131,360)	(83,065)	(103,686)
Other comprehensive loss:			
Changes in foreign currency translation adjustment	(469)	991	449
Changes in unrealized gains (losses) on short-term investments, net	(493)	(80)	315
Net change in other comprehensive loss	(962)	911	764
Comprehensive loss	\$ (132,322)	\$ (82,154)	\$ (102,922)
Net loss per share, basic and diluted	\$ (3.77)	\$ (2.47)	\$ (3.37)
Weighted average number of common shares used to compute basic and diluted net loss per share	<u>34,823,258</u>	<u>33,677,641</u>	<u>30,803,872</u>

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

**Nevro Corp.**  
**Consolidated Statements of Stockholders' Equity**  
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2018</b>	30,263,536	30	552,612	(306,082)	(1,077)	245,483
Exercise of common stock options	828,722	1	28,606	—	—	28,607
Issuance of common stock upon release of restricted stock units	325,839	—	—	—	—	—
Shares withheld for tax obligations	(38,696)	—	(3,057)	—	—	(3,057)
Issuance of common stock under employee stock purchase plan	164,960	1	6,544	—	—	6,545
Stock based compensation	—	—	41,696	—	—	41,696
Net loss	—	—	—	(103,686)	—	(103,686)
Other comprehensive loss	—	—	—	—	764	764
<b>Balances at December 31, 2019</b>	<b>31,544,361</b>	<b>32</b>	<b>626,401</b>	<b>(409,768)</b>	<b>(313)</b>	<b>216,352</b>
Issuance of common stock upon underwritten public offering, net of issuance costs	1,868,750	2	147,142	—	—	147,144
Conversion feature of convertible senior notes due 2025, net of allocated costs	—	—	48,340	—	—	48,340
Purchase of bond hedges	—	—	(52,390)	—	—	(52,390)
Sales of warrants	—	—	34,933	—	—	34,933
Exercise of common stock options	756,797	1	34,624	—	—	34,625
Issuance of common stock upon release of restricted stock units	395,971	—	—	—	—	—
Shares withheld for tax obligations	(62,782)	—	(8,564)	—	—	(8,564)
Issuance of common stock under employee stock purchase plan	79,967	—	7,513	—	—	7,513
Stock based compensation	—	—	42,661	—	—	42,661
Net loss	—	—	—	(83,065)	—	(83,065)
Other comprehensive loss	—	—	—	—	911	911
<b>Balances at December 31, 2020</b>	<b>34,583,064</b>	<b>35</b>	<b>880,660</b>	<b>(492,833)</b>	<b>598</b>	<b>388,460</b>
Exercise of common stock options	90,582	—	4,331	—	—	4,331
Issuance of common stock upon release of restricted stock units	346,602	—	—	—	—	—
Shares withheld for tax obligations	(58,787)	—	(8,062)	—	—	(8,062)
Issuance of common stock under employee stock purchase plan	65,197	—	6,849	—	—	6,849
Issuance of common stock from conversion of convertible senior notes due 2021	682,912	1	(1)	—	—	—
Exercise of bond hedge for convertible senior notes due 2021	(682,916)	(1)	1	—	—	—
Stock based compensation	—	—	44,360	—	—	44,360
Net loss	—	—	—	(131,360)	—	(131,360)
Other comprehensive loss	—	—	—	—	(962)	(962)
<b>Balances at December 31, 2021</b>	<b>35,026,654</b>	<b>\$ 35</b>	<b>\$ 928,138</b>	<b>\$ (624,193)</b>	<b>\$ (364)</b>	<b>\$ 303,616</b>

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

**Nevro Corp.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Years Ended December 31,		
	2021	2020	2019
<b>Cash flows from operating activities</b>			
Net loss	\$ (131,360)	\$ (83,065)	\$ (103,686)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	4,882	4,794	4,563
Amortization of operating lease assets	3,796	3,392	3,237
Stock-based compensation expense	44,367	42,655	41,697
Amortization of premium (accretion of discount) on short-term investments	1,510	320	(2,037)
Provision for (recovery of) doubtful accounts	(1,528)	2,165	(27)
Write-down of inventory	4,257	5,366	1,456
Loss on disposal of equipment	—	12	—
Amortization of debt discount and issuance costs	13,263	14,946	7,912
Unrealized gains (losses) on foreign currency transactions	3,083	(184)	(450)
Changes in operating assets and liabilities			
Accounts receivable	8,205	3,369	(2,153)
Inventories	(17,225)	2,523	(938)
Prepaid expenses and other current assets	(1,027)	5,666	(3,222)
Other assets	(451)	1,802	514
Accounts payable	9,006	7,678	(7,472)
Accrued liabilities	3,185	(7,897)	13,205
Other long-term liabilities	14,156	(2,351)	(2,824)
Net cash provided by / (used in) operating activities	(41,881)	1,191	(50,225)
<b>Cash flows from investing activities</b>			
Purchases of short-term investments	(446,916)	(668,371)	(211,006)
Proceeds from maturity of short-term investments	660,971	297,028	254,308
Repayment from (investment in) private company	—	7,500	(7,500)
Purchases of property and equipment	(12,340)	(6,025)	(3,472)
Net cash provided by / (used in) investing activities	201,715	(369,868)	32,330
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock in public offering, net	—	147,144	—
Proceeds from issuance of convertible notes	—	189,750	—
Convertible notes debt issuance costs	—	(6,105)	—
Proceeds from issuance of warrants	—	34,933	—
Purchase of convertible note hedges	—	(52,390)	—
Repayment of convertible notes	(172,500)	—	—
Minimum tax withholding paid on behalf of employees for net share settlement	(8,062)	(8,564)	(3,057)
Proceeds from issuance of common stock to employees	11,181	42,137	35,150
Net cash provided by financing activities	(169,381)	346,905	32,093
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(340)	646	259
Net increase in cash, cash equivalents and restricted cash	(9,887)	(21,126)	14,457
<b>Cash, cash equivalents and restricted cash</b>			
Cash, cash equivalents and restricted cash at beginning of year	45,203	66,329	51,872
Cash, cash equivalents and restricted cash at end of year	\$ 35,316	\$ 45,203	\$ 66,329
<b>Supplemental disclosures of cash flow information</b>			
Cash paid for income taxes	\$ 1,283	\$ 1,307	\$ 1,338
Cash paid for interest	\$ 6,728	\$ 5,555	\$ 3,019
<b>Significant non-cash transactions</b>			
Purchases of property and equipment in accounts payable	\$ 526	\$ 850	\$ 285

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

**Nevro Corp.**  
**Notes to Consolidated Financial Statements**

## **1. Formation and Business of the Company**

The Company was incorporated in Minnesota on March 10, 2006 to manufacture and market innovative active implantable medical devices for the treatment of neurological disorders initially focusing on the treatment of chronic pain. Subsequently, the Company was reincorporated in Delaware on October 4, 2006 and relocated to California.

Since inception, the Company has incurred net losses. During the year ended December 31, 2021, the Company incurred a net loss of \$131.4 million and had \$41.9 million of cash used in operations. At December 31, 2021, the Company had an accumulated deficit of \$624.2 million. The Company has financed operations to date primarily through private placements of equity securities, borrowings under a debt agreement, the issuance of common stock in its November 2014 initial public offering, its June 2015 underwritten public offering and its June 2016 underwritten public offering of convertible senior notes due in 2021 (2021 Notes). Additionally, in April 2020, the Company issued a total of \$189.8 million aggregate principal amount of convertible senior notes due 2025 (2025 Notes). The total net proceeds from this debt offering, after deducting initial purchase discounts and debt issuance costs, were approximately \$183.6 million. Concurrent with this debt offering, the Company also completed an underwritten public offering for 1,868,750 shares of its common stock, from which the Company received cash proceeds of \$147.1 million, net of underwriting discounts and commissions and offering costs. The Company's ability to continue to meet its obligations and to achieve its business objectives for the foreseeable future is dependent upon, amongst other things, generating sufficient revenues and its ability to continue to control expenses to meet its obligations as they become due. Failure to increase sales of its products, manage discretionary expenditures or raise additional financing, if required, may adversely impact the Company's ability to achieve its intended business objectives.

### **Public Offerings**

In June 2016, the Company issued \$150.0 million aggregate principal amount of 1.75% convertible senior notes due 2021 in a registered underwritten public offering and an additional \$22.5 million aggregate principal amount of such notes pursuant to the exercise in full of the over-allotment options of the underwriters (the 2021 Notes). The interest rates are fixed at 1.75% per annum and are payable semi-annually in arrears on June 1 and December 1 of each year, commencing on December 1, 2016. The total net proceeds from the debt offering, after deducting transaction costs, were approximately \$166.2 million.

In April 2020, the Company issued \$165.0 million aggregate principal amount of 2.75% convertible senior notes due 2025 in a registered underwritten public offering and an additional \$24.8 million aggregate principal amount of such notes pursuant to the exercise in full of the over-allotment options of the underwriters (the 2025 Notes). The interest rates are fixed at 2.75% per annum and are payable semi-annually in arrears on April 1 and October 1 of each year, commencing on October 1, 2020. The total net proceeds from the debt offering, after deducting transaction costs, were approximately \$183.6 million.

Concurrent with the 2025 Notes, the Company completed an underwritten public offering of its common stock and issued 1,868,750 shares of common stock, including 243,750 shares issued pursuant to the exercise in full by the underwriters of their option to purchase additional shares. The Company received cash proceeds of approximately \$147.1 million, net of underwriting discounts and commissions and offering costs paid by the Company.

## **2. Summary of Significant Accounting Policies**

### **Basis of Presentation**

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP). The consolidated financial statements include the Company's accounts and those of its five operational wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated.

## **Other Risks and Uncertainties**

The Company is subject to risks related to the public health crises such as the global pandemic associated with COVID-19, which has spread to most countries and all 50 states within the United States. The COVID-19 outbreak has negatively impacted, and continues to negatively impact, our operations, revenues and overall financial condition and demand for elective procedures remains unpredictable. Additionally, overall patient willingness to pursue elective procedures has decreased due to the pandemic. Although some restrictions on elective procedures have eased, the effect of the pandemic and recent surges in cases continue to affect patient willingness for interventional therapy for chronic pain and the number of elective procedures being performed. These challenges will likely continue for the duration of the pandemic, which is uncertain, and will affect our revenue while the pandemic continues.

In addition, the Company is also subject to risks common to medical device companies, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, manufacturing quality and scaling, continued reimbursement from third-party payors, uncertainty of market acceptance of products and the need to obtain additional financing. The Company is currently dependent on third-party suppliers, which, in some cases, are sole- or single-source suppliers. Although the Company is in the process of initiating the development of internal manufacturing capabilities, it will remain dependent on third-party manufacturers until such internal manufacturing capabilities are fully operational.

There can be no assurance that the Company's products or services will continue to be accepted in its existing marketplaces, nor can there be any assurance that any future products or services can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products or services will be successfully marketed, if at all.

The Company may choose to raise additional funds to further enhance its research and development efforts, for product expansion opportunities or to acquire a new business or products that are complementary to its business. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

## **Segments**

The chief operating decision maker for the Company is the Chief Executive Officer. The Chief Executive Officer reviews financial information presented on a consolidated basis, accompanied only by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level, other than revenue. Accordingly, the Company has determined that it has a single reportable and operating segment structure. The Company and its Chief Executive Officer evaluate performance based primarily on revenue in the geographic locations in which the Company operates.

Until 2015, the Company had derived most of its revenue from sales to customers in Australia and Europe. In May 2015, the U.S. Food and Drug Administration (FDA) approved the Company's premarket approval (PMA) application to market Senza in the United States and the Company launched sales in the United States in 2015. Revenue by geography is based on the billing address of the customer.

Long-lived assets and operating income outside the United States are not material; therefore, disclosures have been limited to revenue.

## **Foreign Currency Translation**

The Company's consolidated financial statements are prepared in U.S. dollars (USD). Its foreign subsidiaries in Europe and Australia use their local currency as their functional currency and maintain their records in the local currency. Accordingly, the assets and liabilities of these subsidiaries are translated into USD using the current exchange rates in effect at the balance sheet date and equity accounts are translated into USD using historical rates. Revenues and expenses are translated using the monthly average exchange rates during the period when the

transaction occurs. The resulting foreign currency translation adjustments from this process are recorded in accumulated other comprehensive income (loss) in the consolidated balance sheets. Unrealized foreign exchange gains and losses from the remeasurement of assets and liabilities denominated in currencies other than the functional currency of the reporting entity are recorded in other income (expense), net. The Company recorded net unrealized foreign currency transaction losses of \$3.3 million during the year ended December 31, 2021, gains of \$0.3 million during the year ended December 31, 2020 and gains of \$1.0 million during the year ended December 31, 2019. Additionally, realized gains and losses resulting from transactions denominated in currencies other than the local currency are recorded in other income (expense), net. The Company recorded realized foreign currency transaction gains of \$2.6 million during the year ended December 31, 2021, losses of \$0.2 million during the year ended December 31, 2020 and losses of \$1.6 million during the year ended December 31, 2019.

To the extent that the Company's international operations grow, the effect of fluctuations in currency rates will become greater, and the Company will continue to reassess its approach to managing this risk. In addition, currency fluctuations or a weakening U.S. dollar can increase the costs of the Company's international expansion. To date, the Company has not entered into any foreign currency hedging contracts. Based on its current international structure, the Company does not plan on engaging in hedging activities in the near future.

## **Use of Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant accounting estimates and management judgments reflected in the consolidated financial statements include items such as allowances for doubtful accounts; warranty obligations; stock-based compensation; depreciation and amortization lives; inventory valuation; valuation of investments; loss contingencies; and accounting for income taxes. Estimates are based on historical experience, where applicable, and other assumptions believed to be reasonable by management. Actual results may differ from those estimates under different assumptions or conditions.

## **Concentration of Credit Risk and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The majority of the Company's cash is held by one financial institution in the United States in excess of federally insured limits. The Company maintained investments in money market funds that were not federally insured during the years ended December 31, 2021 and 2020, and held cash in foreign banks of approximately \$8.6 million and \$17.6 million at December 31, 2021 and 2020, respectively, that was not federally insured. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's convertible note hedge transactions, entered into in connection with the 2025 Notes, subject the Company to credit risk such that the counterparties may be unable to fulfill the terms of the transactions. The associated risk is mitigated by limiting the counterparties to major financial institutions.

In the international markets in which the Company participates, the Company uses both a direct sales force and distributors to sell its products, while in the United States the Company generally utilizes a direct sales force. The Company performs ongoing credit evaluations of some of its direct customers and distributors, does not require collateral, and maintains allowances for potential credit losses on customer accounts when deemed necessary.

## **Credit Losses**

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which replaces existing incurred loss impairment guidance and establishes a single allowance framework for financial assets carried at amortized cost. The Company adopted Topic 326 on January 1, 2020, using a modified retrospective transition method, which requires a cumulative-effect adjustment, if any, to the opening balance of retained earnings to be recognized on the date of adoption with prior periods not restated. The Company did not have any cumulative-effect adjustments.

## **Fair Value of Financial Instruments**

Carrying amounts of certain of the Company's financial instruments, including cash equivalents, short term investments, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

## **Cash and Cash Equivalents**

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents.

## **Investment Securities**

The Company classifies its investment securities as available-for-sale. The Company classifies these investment securities as short-term or long-term based on the nature of the investment, its maturity date and its availability for use in current operations. Those investments with original maturities greater than three months at the date of purchase and remaining maturities of less than 12 months are considered short-term investments. Those investments with remaining maturities greater than 12 months are also classified as short-term investments as management considers them to be available for current operations if needed. The Company's investment securities are recorded at fair value based on the fair value hierarchy. Money market funds and treasury bonds are classified within Level 1 of the fair value hierarchy, and agency bonds, commercial paper and corporate notes are classified within Level 2 of the fair value hierarchy. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss).

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums (discounts) are amortized (accrued) over the life of the related security as an adjustment to yield using the straight-line interest method. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold.

## **Inventories**

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the standard cost method which approximates the first-in, first-out basis. Net realizable value is determined as the prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company regularly reviews inventory quantities compared to forecasted sales to record a provision for excess and obsolete inventory when appropriate. The Company estimates forecasted sales by considering product acceptance in the marketplace, customer demand, historical sales, product obsolescence and technological innovations.

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 inaccurate based on actual sales, the Company may increase the write-down for excess inventory for that component and record a charge to inventory impairment in the accompanying consolidated statements of operations and comprehensive loss. The Company's estimation of the future demand for a particular component of the Company's products may vary and may result in changes in estimates in any particular period.

## **Shipping and Handling Costs**

Shipping and handling costs are expensed as incurred and are included in cost of revenue.

## **Revenue Recognition**

The Company has revenue arrangements that generally consist of a single performance obligation, although, in some instances, revenue arrangements may consist of two performance obligations. The Company recognizes

revenue at the point in time when it transfers control of promised goods to its customers. Revenue is measured as the amount of consideration it expects to receive in exchange for transferring goods.

Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of the Company's goods to its customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring the goods.

For a majority of sales, where the Company's sales representative delivers its product at the point of implantation at hospitals or medical facilities, the Company recognizes revenue upon completion of the procedure and authorization, which represents the point in time when control transfers to the customers.

For the remaining sales, which are sent from the Company's distribution centers directly to hospitals and medical facilities, as well as distributor sales, where product is ordered in advance of an implantation, the transfer of control occurs at the time of shipment of the product. These customers are obligated to pay within specified terms regardless of when or if they ever sell or use the products. The Company does not offer rights of return or price protection. To the extent the Company has a post-delivery obligation, such as programming devices that have been delivered as part of a direct-ship order, the Company defers revenue and the associated cost of goods sold associated with the post-delivery obligation only if the amounts are deemed material.

Sales, value add, and other taxes the Company collects concurrent with revenue-producing activities are excluded from revenue. The expected costs associated with warranty obligations continue to be recognized as expense when the products are sold (see Note 7). The Company periodically provides incentive offers, in the form of rebates, to customers based on their aggregate levels of purchases. Product revenue is recorded net of such incentive offers.

*Practical Expedients and Exemptions* - The Company recognizes revenue upon the transfer of control of the product and there are no material future performance obligations beyond such transfer. As a result, the Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed. The Company does not capitalize incremental costs when the amortization period of the asset is less than a year.

### **Allowance for Doubtful Accounts**

The Company makes estimates of the collectability of accounts receivable and provide an allowance for accounts receivable considered uncollectible based on current expected credit losses. In doing so, the Company analyzes historical bad debt trends, customer concentrations, customer credit worthiness, the age of the receivable, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for doubtful accounts. For the years ended December 31, 2021, 2020 and 2019, the Company recognized bad debt expenses of \$0.1 million, \$2.8 million and \$1.3 million, respectively.

### **Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment, other than leasehold improvements, is computed using the straight-line method over the assets' estimated useful lives of three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the life of the lease. Upon retirement or sale, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

### **Impairment of Long-Lived Assets**

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group might not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net

cash flows to the related asset group's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. There were no impairment charges, or changes in estimated useful lives, recorded through December 31, 2021.

### **Lease Accounting**

The Company has operating leases for office space, warehouse, research and development facilities, manufacturing facilities and equipment. Leases with terms of 12 months or less are not recorded on the balance sheet, as the related lease expenses are recognized on a straight-line basis over the lease term. The Company accounts for lease components (such as fixed payments) separately from nonlease components (such as common area expenses). Operating lease assets and operating lease liabilities are recognized based on the present value of minimum lease payments over the remaining lease term. The Company uses its incremental borrowing rate based on information available when determining the lease liabilities. Lease cost is recognized on a straight-line basis over the expected lease term.

### **Income Taxes**

The Company records income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or income tax returns. In estimating future tax consequences, expected future events other than enactments or changes in the tax law or rates are considered. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company operates in various tax jurisdictions and is subject to audit by various tax authorities. To date, taxes paid have been predominantly due to income taxes in foreign and state jurisdictions in which we conduct business. The Company provides for tax contingencies whenever it is deemed probable that a tax asset has been impaired or a tax liability has been incurred for events such as tax claims or changes in tax laws. Tax contingencies are based upon their technical merits, relative tax law, and the specific facts and circumstances as of each reporting period. Changes in facts and circumstances could result in material changes to the amounts recorded for such tax contingencies.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) a determination is made as to whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold the Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to income taxes as a component of income tax expense.

### **Other Comprehensive Income (Loss)**

Other comprehensive income (loss) represents all changes in stockholders' equity except those resulting from distributions to stockholders. The Company's unrealized gains on short-term available-for-sale investment securities and foreign currency translation adjustments represent the components of other comprehensive income (loss) that are excluded from the reported net loss and are presented in the consolidated statements of operations and comprehensive loss.

### **Research and Development**

Research and development expenses, including new product development, regulatory compliance, and clinical research, are charged to operations as incurred in the consolidated statements of operations and comprehensive loss. Such costs include personnel-related costs, including stock-based compensation, supplies, services, depreciation, allocated facilities and information services, clinical trial and related clinical manufacturing expenses, fees paid to investigative sites, and other indirect costs.

## **Stock-Based Compensation**

The Company accounts for stock-based compensation arrangements with employees in accordance with Accounting Standards Codification (ASC) 718, *Compensation—Stock Compensation*. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all share-based payments including stock options.

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-09, *Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting*, which the Company adopted on January 1, 2017. Under ASU 2016-09, entities are permitted to make an accounting policy election to either estimate forfeitures on share-based payment awards, as previously required, or to recognize forfeitures as they occur. The Company has elected to continue to estimate forfeitures expected to occur to determine the amount of compensation cost recognized in each period. ASU 2016-09 also requires that entities recognize, on a prospective basis, all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement as discrete items in the reporting period in which they occur. Additionally, under ASU 2016-09, excess tax benefits are classified as an operating activity in the statement of cash flows. The Company has elected the presentation of excess tax benefits in the statement of cash flows using the prospective transition method.

The Company's determination of the fair value of stock options, other than performance-based awards, on the date of grant utilizes the Black-Scholes option-pricing model, and is impacted by its common stock price as well as changes in assumptions regarding a number of subjective variables. The expected term that the award will remain outstanding is based on the Company's own historical data. The expected volatility over the term of the awards is based on the Company's own common stock volatility and those of its peer group. The risk-free interest rate is based on the U.S. Treasury yield for zero-coupon U.S. Treasury notes with maturities. The expected dividend is zero, as the Company has never paid dividends and has no current plans to do so.

The fair value of stock options is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period), on a straight-line basis. Stock-based compensation expense recognized at fair value includes the impact of estimated forfeitures. The Company estimates future forfeitures at the date of grant and revises the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company estimates the fair value of the rights to purchase shares by employees under the Employee Stock Purchase Plan using the Black-Scholes option pricing formula. The Employee Stock Purchase Plan provides for consecutive six-month offering periods and the Company uses its own historical volatility data in the valuation.

Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustments as the underlying equity instruments vest. The fair value of options granted to consultants is expensed when vested. The non-employee stock-based compensation expense was not material for all periods presented.

The Company accounts for stock-based compensation for the restricted stock units at their fair value, based on the closing market price of the Company's common stock on the grant date. These costs are recognized on a straight-line basis over the requisite service period, which is generally the vesting term of four years.

The Company also issues stock options and restricted stock units with vesting based upon achievement of specific operational performance criteria. The fair value for these performance-based awards is recognized over the period during which the goals are to be achieved. Stock-based compensation expense recognized at fair value includes the impact of estimated probability that the goals would be achieved, which is assessed prior to the requisite service period for the specific goals.

The Company additionally grants performance stock units with vesting based on its stock price performance compared to a specified target composite index over a certain period. The fair value of these grants is determined by using the Monte Carlo simulation model, which is based on a discounted cash flow approach, and requires inputs such as expected volatility of our stock price, expected volatility of the targeted composite index, correlation

between the changes in our stock price and the target composite index, risk-free interest rate and expected dividends. The expected volatility of our stock and the target composite index is based on the historical data. Correlation is based on the historical relationship between our stock price and the target composite index. The risk-free interest rate is based upon the treasury yield consistent with the vesting term of the grant. The expected dividend yield is zero. Stock-based compensation for these performance stock units is recognized over the specified performance measurement period.

Upon adoption of ASU 2016-09 as described above, excess tax benefits or deficiencies from share-based award activity are reflected in the consolidated statements of operations as a component of the provision for income taxes, whereas they were previously recognized as additional paid-in capital.

### **Net Loss per Share of Common Stock**

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, restricted stock units, common stock options and the conversion spread for the Company's outstanding convertible senior notes are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

### **Recent Accounting Pronouncements**

#### *Accounting Pronouncements Recently Adopted*

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This ASU eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences related to changes in ownership of equity method investments and foreign subsidiaries. The Company adopted ASU 2019-12 on January 1, 2021. The adoption of ASU 2019-12 did not have a material effect on the consolidated financial statements.

#### *Accounting Pronouncements Not Yet Effective*

In August 2020, the FASB issued ASU No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)*. This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity. The ASU also modifies the impact on the diluted EPS calculations from particular convertible instruments and certain contracts that may be settled in cash or shares. The ASU is effective for public entities for annual reporting period beginning after December 15, 2021, with early adoption permitted for annual periods beginning after December 15, 2020. The Company does not expect to early adopt this guidance and has not determined the potential effects of the guidance on its consolidated financial statements.

### **3. Revenue**

The following table presents revenue by geography, based on the billing address of the customer (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2021</b>	<b>2020</b>	<b>2019</b>
United States	\$ 326,216	\$ 311,873	\$ 326,012
International	60,689	50,175	64,243
<b>Total revenue</b>	<b>\$ 386,905</b>	<b>\$ 362,048</b>	<b>\$ 390,255</b>

The United States is the only country that accounts for 10% or more of the revenue during the periods presented:

	Years Ended December 31,		
	2021	2020	2019
United States	84%	86%	84%

There were no customers that accounted for 10% or more of the Company's revenue for each of the years ended December 31, 2021, 2020 and 2019. Additionally, there were no customers that accounted for 10% or more of the Company's accounts receivable balance as of December 31, 2021 and 2020.

In July 2021, the Company received FDA approval of its proprietary 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with painful diabetic neuropathy (PDN). For the year ended December 31, 2021, worldwide revenue includes approximately \$5.7 million of revenue for PDN indication since the July 2021 FDA approval.

#### 4. Leases

As of December 31, 2021, the Company has leases with remaining terms of 3 year to 10 years, some of which may include options to extend the lease term for up to 5 years.

The weighted average lease terms and discounts rates are as follows:

	December 31,	
	2021	2020
<b>Operating Lease Term and Discount Rate</b>		
Weighted-average remaining lease term	4.20 years	4.32 years
Weighted-average discount rate	7.0%	7.0%

As of December 31, 2021, the maturity of lease liabilities are as follows (in thousands):

	<b>Operating Leases</b>
2022	\$ 5,720
2023	6,019
2024	6,201
2025	2,849
2026	405
Thereafter	1,979
Total lease payments	23,173
Less: Interest	(3,183)
Present value of lease liabilities	<u><u>\$ 19,990</u></u>

Supplemental lease cost information are as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Operating lease cost	\$ 5,243	\$ 4,936

Supplemental balance sheet information are as follows (in thousands):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating Leases:</b>		
Operating lease assets	\$ 17,577	\$ 18,142
Other current liabilities	\$ 4,588	\$ 3,876
Long term operating lease liabilities	15,402	16,689
<b>Total operating lease liabilities</b>	<b>\$ 19,990</b>	<b>\$ 20,565</b>

Supplemental cash flow information are as follows (in thousands):

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash paid for amounts included in the measurement of lease liabilities:</b>		
Operating cash flow from operating leases	\$ 5,253	\$ 4,923

See Note 7 for further details of the Company's lease commitments.

## 5. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level 1 — Observable inputs, such as 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.

## Cash Equivalents and Short Term Investments

The Company's cash equivalents include investments in money market funds that which are unrestricted as to withdrawal or use and are classified as Level 1 of the fair value hierarchy. To value its money market funds, the Company values the funds at \$1 stable net asset value, which is the quoted price in active markets for identical assets that the Company has the ability to access. At December 31, 2021 and 2020, the Company's cash equivalents were held in institutions in the United States. The Company's cash equivalents and short-term investments also includes agency bonds, commercial paper, corporate notes and treasury bonds, which have been classified within Level 1 or Level 2 of the fair value hierarchy because of the sufficient observable inputs for revaluation. The Company's Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of any broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs. The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis, by level, within the fair value hierarchy (in thousands):

<b>Balance as of December 31, 2021</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Money market funds (i)	\$ 9,562	\$ —	\$ —	\$ 9,562
Agency bonds (ii)	—	42,538	—	42,538
Commercial paper (ii)	—	61,884	—	61,884
Corporate notes (iii)	—	30,351	—	30,351
Treasury bonds (ii)	197,552	—	—	197,552
<b>Total assets</b>	<b>\$ 207,114</b>	<b>\$ 134,773</b>	<b>\$ —</b>	<b>\$ 341,887</b>

<b>Balance as of December 31, 2020</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Money market funds (i)	\$ 16,273	\$ —	\$ —	\$ 16,273
Agency bonds (ii)	—	210,302	—	210,302
Commercial paper (ii)	—	277,602	—	277,602
Corporate notes (ii)	—	25,395	—	25,395
Treasury bonds (ii)	30,074	—	—	30,074
<b>Total assets</b>	<b>\$ 46,347</b>	<b>\$ 513,299</b>	<b>\$ —</b>	<b>\$ 559,646</b>

- (i) Included in cash and cash equivalents on the consolidated balance sheets.
- (ii) Included in short-term investments on the consolidated balance sheets.
- (iii) Included in either cash and cash equivalents or short-term investments on the consolidated balance sheets.

## Convertible Senior Notes

On June 1, 2021, the Company settled the 2021 Notes at maturity, and as of December 31, 2021, the 2021 Notes were no longer outstanding. As of December 31, 2020, the fair value of the 1.75% convertible senior notes due 2021 was \$312.8 million. As of December 31, 2021 and 2020, the fair value of the 2.75% convertible senior notes due 2025 was \$212.0 million and \$348.1 million, respectively. The fair value was determined on the basis of market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy.

## 6. Balance Sheet Components

### Investments

The fair value of the Company's cash equivalents and short-term investments approximates their respective carrying amounts due to their short-term maturity. The following is a summary of the gross unrealized gains and unrealized losses on the Company's investment securities (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
<b>Investment Securities</b>				
Agency bonds	\$ 42,546	\$ —	\$ (8)	\$ 42,538
Commercial paper	61,886	2	(4)	61,884
Corporate notes	30,371	—	(20)	30,351
Treasury bonds	197,889	2	(339)	197,552
<b>Total securities</b>	<b>\$ 332,692</b>	<b>\$ 4</b>	<b>\$ (371)</b>	<b>\$ 332,325</b>

	December 31, 2020			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
<b>Investment Securities</b>				
Agency bonds	\$ 210,225	\$ 79	\$ (2)	\$ 210,302
Commercial paper	277,593	23	(14)	277,602
Corporate notes	25,364	40	(9)	25,395
Treasury bonds	30,064	10	—	30,074
<b>Total securities</b>	<b>\$ 543,246</b>	<b>\$ 152</b>	<b>\$ (25)</b>	<b>\$ 543,373</b>

Realized gains or losses from the sale of investments and other-than-temporary impairments, if any, on available-for-sale securities are reported in other income (expense), net as incurred. The cost of securities sold was determined based on the specific identification method. The amount of realized gains and realized losses on investments for the periods presented have not been material.

The amortized costs and estimated fair values of the Company's available-for-sale securities by contractual maturities as of December 31, 2021 were as follows (in thousands):

	Amortized Cost	Fair Value
Amounts maturing within one year	\$ 305,844	\$ 305,535
Amounts after one year through five years	26,848	26,790
<b>Total investment securities</b>	<b>\$ 332,692</b>	<b>\$ 332,325</b>

### Inventories (in thousands)

	December 31,	
	2021	2020
Raw materials	\$ 50,160	\$ 34,405
Finished goods	43,357	48,891
<b>Total inventories</b>	<b>\$ 93,517</b>	<b>\$ 83,296</b>

The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or net realizable value approach as that has been used to value the inventory.

The Company also periodically evaluates inventory quantities in consideration of actual loss experience. As a result of these evaluations, for the year ended December 31, 2021, the Company recognized total write-downs of \$4.3 million for its inventories. For the years ended December 31, 2020 and 2019, the Company recognized total write-downs of \$5.4 million and \$1.6 million, respectively, for its inventories.

### **Property and Equipment, Net (in thousands)**

	December 31,	
	2021	2020
Laboratory equipment	\$ 8,722	\$ 7,072
Computer equipment and software	16,349	12,671
Furniture and fixtures	4,215	3,918
Leasehold improvements	10,316	4,289
Construction in process	3,717	3,354
Total	43,319	31,304
Less: Accumulated depreciation and amortization	(22,655)	(17,773)
Property and equipment, net	<u>\$ 20,664</u>	<u>\$ 13,531</u>

Depreciation and amortization expense for the years ended December 31, 2021, 2020 and 2019 was \$4.9 million, \$4.8 million and \$4.6 million, respectively.

### **Restricted Cash**

Restricted cash as of December 31, 2021 and 2020 includes certificates of deposit of \$0.6 million representing collateral for the Company's Redwood City, CA building lease pursuant to an agreement dated March 5, 2015.

### **Accrued Liabilities (in thousands)**

	December 31,	
	2021	2020
Accrued payroll and related expenses	\$ 30,957	\$ 30,971
Accrued professional fees	6,547	2,101
Accrued taxes	1,074	1,191
Accrued clinical and research expenses	305	668
Accrued interest	1,305	1,548
Accrued warranty	664	699
Accrued other	4,665	6,127
Total accrued liabilities	<u>\$ 45,517</u>	<u>\$ 43,305</u>

## **7. Commitments and Contingencies**

### **Operating Leases**

In March 2015, the Company entered into a lease agreement for approximately 50,740 square feet of office space located in Redwood City, California for a period beginning in June 2015 through May 2022 with initial annual payments of approximately \$2.0 million, increasing to \$2.4 million annually during the final year of the lease term. In December 2016, the Company entered into an amendment for an additional approximately 49,980 square feet of office space adjacent to the premises under the original lease (the Expansion Premises), with initial annual payments of \$1.2 million, increasing to \$2.9 million in the final year of the amended lease term. The lease for the Expansion Premises commenced on June 1, 2018. The amendment also extends the lease term for the original premises to terminate on the same date as the amended lease, which is May 31, 2025.

In February 2017, the Company entered into a separate non-cancellable facility lease for warehouse space beginning March 1, 2017 through February 28, 2022, under which the Company is obligated to pay approximately \$0.4 million in lease payments over the term of the lease. In October 2021, the Company entered into an amendment to extend the lease term to May 31, 2025.

In August 2020, the Company entered into a lease for approximately 35,411 square feet of space for a manufacturing facility in Costa Rica for a period of April 2021 through June 2031, under which it is obligated to pay approximately \$3.9 million in lease payments over the term of the lease.

See Note 4 for further discussion on Leases.

### **Warranty Obligations**

The Company warrants that its products will operate substantially in conformity with product specifications and provides a limited one- to five-year warranty. Activities related to warranty obligations were as follows (in thousands):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Beginning Balance	\$ 699	\$ 1,178
Provision for warranty	2,846	2,150
Utilization	(2,881)	(2,629)
Ending Balance	<u><u>\$ 664</u></u>	<u><u>\$ 699</u></u>

### **Supply Agreements**

The Company has entered into supply agreements with certain of the Company's suppliers that required certain minimum annual purchase agreements. As of December 31, 2021, the Company had \$0.9 million of annual purchase commitments. As of December 31, 2020, the Company had no annual purchase commitments. For the year ended December 31, 2019, the Company recorded a charge of \$3.6 million related to the cancellation of firm purchase commitments for inventory related items.

The Company also entered into a service agreement in January 2020 for which it is committed to pay \$2.5 million annually in each of the next four years.

### **License Agreements**

In March 2006, the Company entered into an amended and restated license agreement with the Mayo Foundation for Medical Education and Research (Mayo) and Venturi Group LLC (VGL), which provides the Company access to the certain know how and licensed patents owned by Mayo and VGL for treatment of central, autonomic and peripheral nervous system disorders, including pain, using devices to modulate nerve signaling. The licenses granted are exclusive and the Company has the right to sub-license. The agreement will terminate upon the last to expire patent application, unless terminated earlier. The agreement can be terminated any time after three years from March 2006 by Mayo or VGL.

Per terms of the license, the Company is required to pay royalties based on the greater of earned royalty or minimum royalty. The earned royalty will be based on a percentage of net sales of licensed products either by the Company or the sub-licensee. The minimum royalty payment will be based on royalty periods as defined in the agreement.

In March 2011, the Company entered into a Phase II License Agreement with Mayo which provides the Company access to the certain know how and licensed patents owned by Mayo. The licenses granted are exclusive and the Company has the right to sub-license. The agreement will terminate upon the last to expire patent application, unless terminated earlier.

Per terms of the license, the Company is required to:

- Pay a retainer fee of \$40,000 per annum starting March 2011 and ending February 2013;
- Pay royalties based on the greater of earned royalty or minimum royalty. The earned royalty is based on a percentage of net sales of licensed products either by the Company or the sub-licensee. The minimum annual royalty payment is \$200,000.

The Mayo License terminates upon the expiration of (1) the last to expire of the licensed patents or (2) our obligation to pay royalties, whichever is later. Such obligations may be subject to change if: (1) additional relevant patents issue that are subject to the Mayo License; or (2) we launch an SCS product, which is subject to the Mayo License, in another country. As of Jan. 1, 2021, the Company does not have an existing obligation to pay royalties under the Mayo License. Therefore, there were no royalties expenses during the year ended December 31, 2021. Royalties expenses during the years ended December 31, 2020 and 2019 were \$3.1 million and \$3.2 million, respectively.

In November 2014, the Company issued Mayo 20,833 shares of common stock owed in connection with the IPO pursuant to the terms of the license, and recorded noncash research and development expense of \$0.5 million for the fair value of the shares on the date of issuance.

In July 2017, the Company entered into a license agreement for which it is committed to pay \$0.1 million over the remaining term of this license agreement, which ends in 2022.

### **Contingent Consideration**

In February 2019, the Company entered into an agreement with a privately-held company to, among other things, provide the privately-held company financing in the form of a secured convertible note. Through March 31, 2020, the Company has provided financing totaling \$8.5 million in the form of two secured convertible notes. The agreement additionally provides the Company with the exclusive right, but not the obligation, to acquire the privately-held company. As of December 31, 2019, the value of the secured convertible notes, measured at amortized cost, was \$7.9 million, while the value of certain rights in relation to the agreement, measured at cost and monitored for impairment on an ongoing basis, was \$1.0 million. These amounts are reported in Other Assets on the Condensed Consolidated Balance Sheet. The accretion of amortized cost is recorded in Interest Income, while any changes in value from impairment assessment are recorded in Other Income (Expense) in the Consolidated Statements of Operations and Comprehensive Income. The Company concluded that the privately-held company is a variable interest entity; however, the Company is not the primary beneficiary as it does not retain power to direct the activities that most significantly impact its economic performance.

In April 2020, the Company elected not to exercise its option to make a further investment in the privately-held company pursuant to the agreement. In connection with this decision, the Company no longer has the exclusive right to acquire the privately-held company. In June 2020, the privately-held company paid off the outstanding principal and accrued interest of its secured convertible notes in full. As a result of these two events, the Company recorded a net expense of \$0.4 million in Other Income (Expense) in the Consolidated Statements of Operations and Comprehensive Income in the year ended December 31, 2020.

### **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. There have been no contingent liabilities requiring accrual at December 31, 2021 and 2020.

### **Indemnification**

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties

for losses suffered or incurred by the indemnified party, including, among other circumstances, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has director and officer insurance coverage that reduces the Company's exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. No liability associated with such indemnifications has been recorded to date.

## **Legal Matters**

### Boston Scientific Litigations

#### *California Litigation Related to High Frequency*

On November 28, 2016, the Company filed a lawsuit for patent infringement against Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, Boston Scientific). The lawsuit, filed in the U.S. District Court for the Northern District of California (the California Court), asserted that Boston Scientific was infringing, or would soon begin infringing, seven of the Company's patents covering inventions relating to the Senza system and 10 kHz Therapy. Shortly after the Company filed this lawsuit in 2016, Boston Scientific cancelled its original launch plan and modified its SCS system to avoid infringing the asserted patents. On July 24, 2018, the California Court issued an order on claim construction and summary judgment. In the order, the California Court ruled that the Company's asserted method claims were patent eligible and not invalid as indefinite. Collectively, the asserted method claims cover methods for delivering SCS therapy at frequencies between 1.5 kHz and 100 kHz.

The California Court, however, found that Boston Scientific was not currently infringing the six upheld method claims because Boston Scientific cancelled its original launch plans and ultimately never practiced the asserted method claims in the United States. Specifically, the California Court found that Boston Scientific's sale of the Spectra WaveWriter systems for commercial use in the United States did not infringe the upheld method claims because Boston Scientific modified the Spectra WaveWriter systems to prevent them from being programmed to generate signals above 1.2 kHz. The California Court also found that the Company's asserted system claims were invalid as indefinite. As discussed below, the California Court's finding of invalidity was overturned by the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit).

On July 31, 2018, the parties entered into an agreement to dismiss the Company's declaratory judgment claims, without prejudice, so that the Company and Boston Scientific could each appeal portions of the California Court's July 24th ruling to the Federal Circuit. On April 9, 2020, the Federal Circuit returned its ruling, which vacated and remanded the California Court's judgment of invalidity. As a result of the Federal Circuit's ruling, the system claims invalidated by the California Court were reinstated, and thus all of the Company's asserted claims remain valid and enforceable. On December 14, 2020, the parties agreed to the final dismissal of all remaining claims before the California Court based on Boston Scientific's assertion to the court that it did not have any current plans to commercially launch a high frequency SCS system in the United States. The California Court entered the agreed upon dismissal on December 16, 2020.

#### *Delaware Litigations Unrelated to High Frequency*

On December 9, 2016, Boston Scientific filed a patent infringement lawsuit alleging the Company's manufacture, use and sale of the Senza system infringes ten of Boston Scientific's patents covering spinal cord stimulation technology related to stimulation leads, rechargeable batteries and telemetry (the *Delaware I* litigation). On April 27, 2018, Boston Scientific filed a second lawsuit alleging patent infringement of nine patents, trade secret misappropriation and tortious interference with contract (the *Delaware II* litigation). Both lawsuits were filed in the U.S. District Court for the District of Delaware.

In relation to the *Delaware I* litigation, the Company filed petitions for *inter partes* review at the U.S. Patent and Trademark Office (USPTO), which resulted in the invalidation of all of the asserted claims of Boston Scientific's U.S. Patent Nos. 7,587,241 and 6,895,280, in February 2019. The invalidity rulings by the Patent Trial and Appeal Board (PTAB) at the USPTO were later affirmed by the Federal Circuit on May 18, 2020 and May 29, 2020, respectively. In relation to the *Delaware II* litigation, the Company filed seven petitions for *inter partes* review at the PTAB against seven of the nine patents asserted by Boston Scientific. As a result of those petitions, in January 2021, the PTAB invalidated all but two of the challenged Boston Scientific claims across the seven *inter partes* reviews.

Through various orders from the court, portions of Boston Scientific's *Delaware I* case were dismissed, and portions of Boston Scientific's *Delaware II* case have been stayed for future litigation.

In relation to the *Delaware I* case, of the ten patents originally asserted on December 9, 2016, Boston Scientific proceeded to trial with four patents directed to SCS leads and lead manufacturing techniques. On November 1, 2021, a Delaware jury found that the Company infringed Boston Scientific's patents U.S. 7,891,085 ("the '085 patent") and U.S. 8,019,439, and that the Company did not infringe Boston Scientific's patents U.S. 8,646,172 and U.S. 8,650,747. With regard to the '085 patent, the jury found that the infringement was willful, though the infringement of the '085 patent was only directed to a limited number of SCS leads that the Company sold internationally between 2012 and 2014. Boston Scientific does not assert that the Company continues to infringe the '085 patent. The Delaware jury awarded Boston Scientific \$20.0 million. The Company disagrees with this decision and plans to appeal, which could take approximately 18-24 months to resolve. The jury award will not be paid until after the conclusion of the appeal process. The Company recorded a liability of \$20.0 million in relation to the aforementioned *Delaware I* case.

In relation to the *Delaware II* litigation, the Company also filed counterclaims against Boston Scientific, alleging patent infringement of five Nevro patents. In March 2021, on the basis of Boston Scientific's petition, the PTAB initiated *inter partes* reviews of two of Nevro's five counterclaim patents. The Delaware court later stayed Nevro's five counterclaim patents for future litigation.

On February 23, 2021, the Company filed a patent infringement lawsuit against Boston Scientific alleging that its January 2021 launch of the WaveWriter Alpha™ SCS System infringes five of the Company's patents covering spinal cord stimulation technology related to delivering paresthesia-free therapy at frequencies below 1,200 Hz. The lawsuit, filed in the U.S. District Court for the District of Delaware (*the Delaware III* litigation), seeks unspecified damages and attorney's fees, as well as preliminary and/or permanent injunctive relief against further infringement.

As of December 31, 2021, the Company recorded a liability of \$20.0 million in relation to the aforementioned *Delaware I* case.

#### Stimwave Litigation

On February 14, 2019, the Company filed a lawsuit for patent infringement against Stimwave Technologies, Inc. (Stimwave) in the Delaware Court asserting that Stimwave was infringing the Company's patents covering inventions related to its 10 kHz Therapy and the Senza system, as well as a claim for false advertising under the Lanham Action Section 43(a), 15 U.S.C. § 1125(a). In relation to this lawsuit, on July 24, 2019, the Delaware Court granted the Company's motion for preliminary injunction, and issued an order barring Stimwave, and all affiliated persons and entities, from infringing patent claims covering frequencies between 3 kHz and 10 kHz. On February 27, 2020, the Company and Stimwave entered into a Settlement Agreement, in which Stimwave agreed to cease commercialization of all high frequency spinal cord stimulation systems worldwide. Stimwave also agreed to entry of a permanent injunction in the Delaware Court, under which Stimwave's products will not deliver spinal cord

stimulation therapy that includes pulse frequencies between 1,500 Hz and 100,000 Hz. The permanent injunction was filed with the Delaware Court and entered on March 2, 2020. After the Delaware Court entered the permanent injunction, the case (including Stimwave's appeal of the preliminary injunction order) were dismissed. As part of the permanent injunction filing, Stimwave acknowledged the validity of the patents Nevro asserted in the litigation. Per the Company's request, the permanent injunction order does not enjoin Stimwave from providing follow-up care and programming for any patients who were already programmed with high frequency therapy in the United States prior to March 6, 2020, and in the rest of the world prior to April 30, 2020.

#### Nalu Litigation

On February 28, 2020, the Company filed a lawsuit in the Delaware Court for patent infringement against Nalu Medical, Inc. (Nalu) asserting that Nalu is infringing the Company's patents covering inventions related to its 10 kHz Therapy and the Senza system. The Company's patent infringement assertions were based, in part, on Nalu imbedding a high frequency SCS therapy in a version of its "PSP" waveform. During the litigation, Nalu modified its PSP waveform so that it no longer included an imbedded high frequency signal. As a result, on December 21, 2021, the Company announced that it had reached a favorable settlement agreement with Nalu to terminate the litigation.

The Company is and may from time to time continue to be involved in various legal proceedings to defend its intellectual property, including several pending European patent oppositions at the European Patent Office (EPO) initiated by the Company's competitors Medtronic and Boston Scientific, an entitlement action filed by Boston Scientific in Germany, and an invalidity proceeding in China. In addition, the Company is and may from time to time also be involved in various legal proceedings of a character normally incident to the ordinary course of business, such as employment matters, product liability matters, and professional liability matters, which the Company does not deem to be material to its business and condensed consolidated financial statements at this stage.

## **8. Long-term Debt**

### **2021 Notes and Convertible Note Hedge and Warrant Transactions**

In June 2016, the Company issued \$150.0 million aggregate principal amount of 1.75% convertible senior notes due in June 2021 in a registered underwritten public offering and an additional \$22.5 million aggregate principal amount of such notes pursuant to the exercise in full of the over-allotment options of the underwriters (the 2021 Notes). The interest rates are fixed at 1.75% per annum and are payable semi-annually in arrears on June 1 and December 1 of each year, commencing on December 1, 2016. The total net proceeds from the debt offering, after deducting initial purchase discounts and debt issuance costs, were approximately \$166.2 million.

Each \$1,000 principal amount of the 2021 Notes will initially be convertible into 10.3770 shares of the Company's common stock, which is equivalent to an initial conversion price of approximately \$96.37 per share, subject to adjustment upon the occurrence of specified events. The 2021 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding December 1, 2020, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on September 30, 2016 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period (the measurement period) in which the trading price (as defined in the indenture to the 2021 Notes) per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events. On or after December 1, 2020 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2021 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. If the Company undergoes a fundamental change prior to the maturity date, holders of the notes may require the Company to repurchase for cash all or any portion of their notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In

addition, if specific corporate events occur prior to the applicable maturity date, the Company will increase the conversion rate for a holder who elects to convert their notes in connection with such a corporate event in certain circumstances.

In connection with the offering of the 2021 Notes, the Company entered into convertible note hedge transactions with certain bank counterparties in which the Company has the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of the Company's common stock at a price of approximately \$96.37 per share. The total cost of the convertible note hedge transactions was \$45.1 million. In addition, the Company sold warrants to certain bank counterparties whereby the holders of the warrants have the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of the Company's common stock at a price of \$127.28 per share. The Company received \$33.1 million in cash proceeds from the sale of these warrants. Taken together, the purchase of the convertible note hedges and the sale of warrants are intended to offset any actual dilution from the conversion of these notes and to effectively increase the overall conversion price from \$96.37 to \$127.28 per share. As these transactions meet certain accounting criteria, the convertible note hedges and warrants are recorded in stockholders' equity and are not accounted for as derivatives. The net cost of \$12.0 million incurred in connection with the convertible note hedge and warrant transactions was recorded as a reduction to additional paid-in capital on the consolidated balance sheet.

In accounting for the issuance of the convertible senior notes, the Company separated the 2021 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar debt instrument that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was \$32.9 million and was determined by deducting the fair value of the liability component from the par value of the 2021 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The excess of the principal amount of the liability component over its carrying amount (debt discount) is amortized to interest expense over the term of the 2021 Notes expense at an effective interest rate of 6.29% over the contractual terms of the notes.

In accounting for the debt issuance costs of \$6.2 million related to the 2021 Notes, the Company allocated the total amount incurred to the liability and equity components of the 2021 Notes based on their relative values. Issuance costs attributable to the liability component were \$5.0 million and will be amortized to interest expense using the effective interest method over the contractual terms of the 2021 Notes. Issuance costs attributable to the equity component were netted with the equity component in stockholders' equity.

On June 1, 2021, the 2021 Notes matured and the Company settled the 2021 Notes. The Company paid \$172.5 million to settle the outstanding principal and issued 682,912 shares of common stock to holders who elected to convert the 2021 Notes. In addition, the Company exercised its option under the bond hedge and received 682,916 shares of common stock from the bank counterparties. None of the holders of the warrants associated with the 2021 Notes exercised the option to purchase shares. As of December 31, 2021, the 2021 Notes were no longer outstanding.

The net carrying amount of the liability component of the 2021 Notes was as follows (in thousands):

	December 31, 2020
Principal	\$ 172,500
Unamortized discount	(3,182)
Unamortized issuance cost	(542)
Net carrying amount	<u><u>\$ 168,776</u></u>

The net carrying amount of the equity component of the 2021 Notes was as follows (in thousands):

	<u>December 31,</u>
	2020
Debt discount related to value of conversion option	\$ 32,945
Debt issuance cost	(1,179)
<b>Net carrying amount</b>	<b>\$ 31,766</b>

## 2025 Notes and Convertible Note Hedge and Warrant Transactions

In April 2020, the Company issued \$165.0 million aggregate principal amount of 2.75% convertible senior notes due 2025 in a registered underwritten public offering and an additional \$24.8 million aggregate principal amount of such notes pursuant to underwriters' exercise in full of their option to purchase additional 2025 Notes. The interest rates are fixed at 2.75% per annum and are payable semi-annually in arrears on April 1 and October 1 of each year, commencing on October 1, 2020. The total net proceeds from the debt offering, after deducting initial purchase discounts and debt issuance costs, were approximately \$183.6 million.

Each \$1,000 principal amount of the 2025 Notes will initially be convertible into 9.5238 shares of the Company's common stock, which is equivalent to an initial conversion price of approximately \$105.00 per share, subject to adjustment upon the occurrence of specified events. The 2025 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding October 1, 2024, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2020 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period (the measurement period) in which the trading price (as defined in the indenture to the 2025 Notes) per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events. On or after October 1, 2024 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2025 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. If the Company undergoes a fundamental change prior to the maturity date, holders of the notes may require the Company to repurchase for cash all or any portion of their notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if specific corporate events occur prior to the applicable maturity date, the Company will increase the conversion rate for a holder who elects to convert their notes in connection with such a corporate event in certain circumstances. During the three months ended December 31, 2021 the conditions allowing holders of the 2025 Notes to convert have not been met. Therefore, the 2025 Notes may not be converted during the three months ended March 31, 2022. As of December 31, 2021, the if-converted value of the 2025 Notes did not exceed the principal value of those notes.

In connection with the offering of the 2025 Notes, the Company entered into convertible note hedge transactions with certain bank counterparties in which the Company has the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of the Company's common stock at a price of approximately \$105.00 per share. The total cost of the convertible note hedge transactions was \$52.4 million. In addition, the Company sold warrants to certain bank counterparties whereby the holders of the warrants have the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of the Company's common stock at a price of \$147.00 per share. The Company received \$34.9 million in cash proceeds from the sale of these warrants. Taken together, the purchase of the convertible note hedges and the sale of warrants are intended to offset any actual dilution from the conversion of these notes and to effectively increase the overall conversion price from \$105.00 to \$147.00 per share. As these transactions meet certain accounting criteria, the convertible note hedges and warrants are recorded in stockholders' equity and will not be subsequently remeasured as long as they continue to meet the conditions for equity classification. The net

cost of \$17.5 million incurred in connection with the convertible note hedge and warrant transactions was recorded as a reduction to additional paid-in capital on the consolidated balance sheet.

In accounting for the issuance of the convertible senior notes, the Company separated the 2025 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar debt instrument that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was \$49.9 million and was determined by deducting the fair value of the liability component from the par value of the 2025 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The excess of the principal amount of the liability component over its carrying amount (debt discount) is amortized to interest expense over the term of the 2025 Notes expense at an effective interest rate of 10.2% over the contractual terms of the notes.

In accounting for the debt issuance costs of \$6.1 million related to the 2025 Notes, the Company allocated the total amount incurred to the liability and equity components of the 2025 Notes based on the same proportion as the accounting for the proceeds from the issuance of the 2025 Notes. Issuance costs attributable to the liability component were \$4.5 million and will be amortized to interest expense using the effective interest method over the contractual terms of the 2025 Notes. Issuance costs attributable to the equity component were netted with the equity component in stockholders' equity.

The net carrying amount of the liability component of the 2025 Notes was as follows (in thousands):

	December 31,	
	2021	2020
Principal	\$ 189,750	\$ 189,750
Unamortized discount	(35,079)	(43,919)
Unamortized issuance cost	(3,361)	(4,060)
Net carrying amount	\$ 151,310	\$ 141,771

The net carrying amount of the equity component of the 2025 Notes was as follows (in thousands):

	December 31,	
	2021	2020
Debt discount related to value of conversion option	\$ 49,947	\$ 49,947
Debt issuance cost	(1,607)	(1,607)
Net carrying amount	\$ 48,340	\$ 48,340

The following table sets forth the interest expense recognized related to the 2021 Notes and 2025 Notes (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Contractual interest expense	\$ 6,484	\$ 6,860	\$ 3,019
Amortization of debt discount	12,023	13,308	6,843
Amortization of debt issuance costs	1,240	1,634	1,063
Total interest expense	\$ 19,747	\$ 21,802	\$ 10,925

## 9. Convertible Preferred Stock

Prior to its initial public offering, the Company had outstanding 15,208,048 shares of convertible preferred stock. Each share of preferred stock was convertible to one share of common stock. Upon the closing of the Company's initial public offering on November 11, 2014, all shares of outstanding redeemable convertible preferred stock were automatically converted to 15,208,048 shares of the Company's common stock.

## **10. Stock-Based Compensation**

Common stock reserved for future issuance as of December 31, 2021 was as follows:

	<b>Shares</b>
Outstanding stock options and awards	1,713,145
Reserved for grants of future stock options and awards	6,078,869
Reserved for employee stock purchase plan	1,567,514
Total common stock reserved for future issuance	9,359,528

### **Stock Plans**

The Company's Board of Directors (Board) and stockholders previously approved the 2007 Stock Option Plan (the 2007 Plan). In October 2014, the Board adopted the 2014 Equity Incentive Award Plan (the 2014 Plan and, together with the 2007 Plan, the Stock Plans). As of the effective date of the 2014 Plan, the Company suspended the 2007 Plan and no additional awards may be granted under the 2007 Plan. Any shares of common stock covered by awards granted under the 2007 Plan that terminate after the effective date of the 2014 Plan by expiration, forfeiture, cancellation or other means without the issuance of such shares, will be added to the 2014 Plan reserve.

Under the 2014 Plan, 1,854,166 shares of common stock were initially reserved for issuance, plus the number of shares remaining available for future awards under the 2007 Plan, as of the pricing of the IPO. The number of shares initially reserved for issuance under the 2014 Plan is subject to increase by (i) the number of shares represented by awards outstanding under the 2007 Plan that are forfeited or lapse unexercised and which following the pricing date are not issued under the 2007 Plan, and (ii) an annual increase on January 1 of each year.

Under the 2014 Plan, the Company may grant awards such as incentive stock options, nonstatutory stock options, restricted stock units, performance stock units and stock appreciation rights. Incentive stock options (ISO) may be granted only to Company employees (including directors who are also employees). Nonqualified stock options (NSO) may be granted to Company employees, directors and consultants.

### **Stock Options**

Options under the 2014 Plan may be granted for periods of up to ten years and at prices no less than 100% of the estimated fair market value of the shares on the date of grant as determined by the Board, provided, however, that the exercise price of an ISO or an NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair market value of the shares on the date of grant. Upon the exercise of options, the Company issues new common stock from its authorized shares. The vesting provisions of individual options vary but are generally over four years, with the exception of performance based stock options.

Pursuant to the 2014 Plan, the Company granted performance based stock options to the Company's former CEO in March 2016. This performance based stock option award was subject to the CEO's continued service to the Company through each applicable vesting date. Upon the former CEO's resignation from the Company in March 2019, the unvested shares subject to this award as of the separation date have been cancelled.

A summary of shares available for grant under the Stock Plans is as follows:

	Shares Available for Grant
<b>Balance at December 31, 2018</b>	2,980,762
Additional shares reserved	1,210,541
Allowance for PSU for overperformance	(277,778)
Shares forfeited for tax	38,696
Options, RSUs and PSUs granted	(1,077,178)
Options, RSUs and PSUs cancelled	<u>527,963</u>
<b>Balance at December 31, 2019</b>	3,403,006
Additional shares reserved	1,261,774
Allowance for PSU for overperformance	(43,966)
Shares forfeited for tax	62,782
Options, RSUs and PSUs granted	(341,901)
Options, RSUs and PSUs cancelled	<u>258,486</u>
<b>Balance at December 31, 2020</b>	4,600,181
Additional shares reserved	1,383,322
Allowance for PSU for overperformance	(24,830)
Shares forfeited for tax	58,787
Options, RSUs and PSUs granted	(425,266)
Options, RSUs and PSUs cancelled	<u>140,101</u>
<b>Balance at December 31, 2021</b>	<u>5,732,295</u>

A summary of stock option activity under the Stock Plans is as follows:

	Options Outstanding	Weighted Average Remaining Contractual Term (in years)		Aggregate Intrinsic Value (in thousands)
	Number of Options	Weighted Average Exercise Price		
<b>Outstanding at December 31, 2018</b>	2,529,740	\$ 46.72	6.7	\$ 21,866
Options granted	244,075	\$ 56.71		
Options exercised	(828,722)	\$ 34.52		\$ 42,695
Options cancelled	(298,908)	\$ 66.22		
<b>Outstanding at December 31, 2019</b>	1,646,185	\$ 50.80	6.3	\$ 109,870
Options exercised	(756,797)	\$ 45.75		\$ 62,367
Options cancelled	(76,238)	\$ 59.38		
<b>Outstanding at December 31, 2020</b>	813,150	\$ 54.69	5.9	\$ 96,286
Options exercised	(90,582)	\$ 47.82		\$ 6,948
Options cancelled	(21,914)	\$ 43.52		
<b>Outstanding at December 31, 2021</b>	<u>700,654</u>	\$ 55.93	4.8	\$ 18,287
Options exercisable as of December 31, 2021	599,295	\$ 56.06	4.4	\$ 15,656
Options vested, exercisable or expected to vest as of December 31, 2021	696,003	\$ 55.92	4.8	\$ 18,173

The aggregate intrinsic value of options exercised is the difference between the estimated fair market value of the Company's common stock at the date of exercise and the exercise price for in-the-money options. The aggregate intrinsic value of outstanding options is the difference between the closing price as of the date outstanding and the exercise price of the underlying stock options. The weighted-average grant-date fair value of options granted during the year ended December 31, 2019 was \$27.91 per share. No options were granted during the years ended December 31, 2021 and 2020. The total fair value of options vested during the years ended December 31, 2021, 2020 and 2019 was approximately \$3.1 million, \$6.6 million and \$8.3 million, respectively, based on the grant date fair value.

The options outstanding and vested under the Stock Plans by exercise price, at December 31, 2021, were as follows:

Exercise Price	Options Outstanding			Options Vested	
	Number Outstanding	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$3.60 — \$36.55	116,179	3.15	\$ 19.18	111,929	\$ 18.52
\$38.79 — \$45.04	114,032	5.52	\$ 47.12	94,094	\$ 42.08
\$45.07 — \$63.23	156,883	4.48	\$ 57.56	129,344	\$ 59.12
\$63.39 — \$64.95	141,004	6.94	\$ 64.28	91,835	\$ 64.21
\$65.51 — \$87.62	152,556	3.95	\$ 79.37	152,093	\$ 79.36
\$97.52	20,000	4.62	\$ 97.52	20,000	\$ 97.52
\$3.60 — \$97.52	<u>700,654</u>	<u>4.81</u>	<u>\$ 55.93</u>	<u>599,295</u>	<u>\$ 56.06</u>

### Restricted Stock Units

In 2015, the Company began granting restricted stock units (RSUs) under the 2014 Plan. Holders of RSUs do not have stockholder rights. Upon the release of RSUs, the Company issues new common stock from its authorized shares. RSUs generally vest four years from the date of grant.

A summary of RSU activity under the Stock Plans was as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
<b>Outstanding at December 31, 2018</b>	1,002,161	\$ 72.55	\$ 38,974
Restricted stock granted	721,992	\$ 58.37	
Restricted stock released	(321,858)	\$ 70.89	\$ 4,064
Restricted stock cancelled	<u>(225,074)</u>	<u>\$ 70.51</u>	
<b>Outstanding at December 31, 2019</b>	1,177,221	\$ 64.70	\$ 138,371
Restricted stock granted	252,703	\$ 123.31	
Restricted stock released	(395,971)	\$ 66.42	\$ 23,789
Restricted stock cancelled	<u>(180,976)</u>	<u>\$ 71.26</u>	
<b>Outstanding at December 31, 2020</b>	852,977	\$ 79.87	\$ 147,650
Restricted stock granted	368,230	\$ 146.64	
Restricted stock released	(346,602)	\$ 76.26	\$ 22,902
Restricted stock cancelled	<u>(110,799)</u>	<u>\$ 98.76</u>	
<b>Outstanding at December 31, 2021</b>	<u>763,806</u>	<u>\$ 110.96</u>	<u>\$ 61,922</u>
Restricted stock expected to vest as of December 31, 2021	696,348	\$ 109.78	\$ 56,453

The aggregate intrinsic value of RSUs released is calculated using the fair market value of the Company's common stock at the date of release. The aggregate intrinsic value of outstanding RSUs is calculated based on the closing price of the Company's common stock as of the date outstanding.

### Performance Stock Units

Pursuant to the 2014 Plan, the Company granted performance based RSUs to the former CEO in March 2016. The performance based RSUs are subject to the former CEO's continued service to the Company through each applicable vesting date. If a performance metric is not met within the time limits specified in the RSU agreement, the shares subject to vesting under the vesting tranche for that performance metric will be cancelled. Upon the former CEO's resignation from the Company in March 2019, the unvested shares subject to this award as of the separation date have been cancelled.

In March 2019, the Company granted performance stock units (PSUs) to the current CEO, subject to his continued service to the Company and based on the total shareholder return (the TSR) of the Company's common stock price compared to the S&P Healthcare Equipment Select Industry Index (the Index) over a three-year period. The number of shares to be issued upon vesting of these PSUs range from 0 to 3.5 times the target number of shares granted, depending on the Company's performance against the targeted composite index.

In March 2020, the Company granted PSUs to certain members of the management team. The number of shares to be issued upon vesting was based on the total shareholder return of the Company's common stock compared to the Index, as well as certain performance criteria related to a specific financial target over a two-year performance period. For the three months ended March 31, 2020, the Company determined that the achievement status for these PSUs was not possible, and therefore did not record stock-based compensation expenses related to these grants. During the three months ended June 30, 2020, the Company modified the performance criteria for these PSUs to reflect the changed market conditions as a result of the COVID-19 pandemic, such that the remaining performance criteria is based on total shareholder return compared to the Index. The Company also granted PSUs that incorporated the same modified performance criteria to the Company's Chief Executive Officer PSUs. Additional similar PSUs were issued to new members of management in the year ended December 31, 2020.

In 2021, the Company granted PSUs to certain member of the management team, subject to continued service to the Company and based on the TSR of the Company's common stock price compared to the Index over a three-year period. The number of shares to be issued upon vesting of these PSUs range from 0 to 1.5 times the target number of shares granted, depending on the Company's performance against the targeted composite index.

A summary of PSU activity under the Stock Plans was as follows:

	<b>Number of Restricted Stock Units</b>	<b>Weighted Average Grant Date Fair Value</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
<b>Outstanding at December 31, 2018</b>	7,962	\$ 54.50	\$ 310
PSU granted	111,111	\$ 67.29	
PSU released	(3,981)	\$ 54.50	\$ —
PSU cancelled	(3,981)	\$ 54.50	
<b>Outstanding at December 31, 2019</b>	111,111	\$ 67.29	\$ 13,060
PSU granted	89,198	\$ 128.71	
PSU cancelled	(1,272)	\$ 125.27	
<b>Outstanding at December 31, 2020</b>	199,037	\$ 94.20	\$ 34,453
PSU granted	57,036	\$ 183.20	
PSU cancelled	(7,388)	\$ 136.77	
<b>Outstanding at December 31, 2021</b>	248,685	\$ 113.35	\$ 20,161
PSU expected to vest as of December 31, 2021	247,815	\$ 113.22	\$ 20,090

The aggregate intrinsic value of outstanding PSUs is calculated based on the closing price of the Company's common stock as of the date outstanding.

#### **2014 Employee Stock Purchase Plan**

In October 2014, the Board adopted the 2014 Employee Stock Purchase Plan (the ESPP). A total of 196,666 shares of common stock were initially available for future issuance under the 2014 Employee Stock Purchase Plan, subject to an annual increase on January 1 of each year. The ESPP provides eligible employees with an opportunity to purchase shares of the Company's common stock through payroll deductions of up to 15% of their eligible compensation, subject to plan limitations. Under the ESPP, the purchase price of the Company stock is equal to 85% of the lower of its fair market value at the start and end of a six-month purchase period.

A summary of ESPP activity was as follows:

	December 31,		
	2021	2020	2019
Additional shares reserved	235,590	315,443	302,635
Shares issued	65,197	79,967	164,960
Shares available for future issuance	1,567,514	1,397,121	1,161,645
Employee contributions for shares issued (in thousands)	\$ 6,849	\$ 7,513	\$ 6,544

### Employee Stock-Based Compensation

The Company estimated the fair value of stock options granted to employees and shares purchased by employees under the ESPP using the Black-Scholes option valuation model. The fair value is amortized on a straight-line basis over the requisite service period of the awards, with the exception of performance based stock options whose fair value is recorded as expenses based on the probability that the performance metrics will be achieved. The following assumptions were used in estimating the fair value:

	Years Ended December 31,		
	2021	2020	2019
<b>Stock Options:</b>			
Expected term (in years)	N/A	N/A	5.7
Expected volatility	N/A	N/A	51% — 52%
Risk-free interest rate	N/A	N/A	1.4% — 2.6%
Dividend Yield	N/A	N/A	0%
<b>ESPP:</b>			
Expected term (in years)	0.5	0.5	0.5
Expected volatility	36% — 49%	39% — 68%	48% — 61%
Risk-free interest rate	0.1%	0.1% — 0.2%	1.6% — 2.4%
Dividend Yield	0%	0%	0%

The Company accounts for RSUs at their fair value, based on the closing market price of the Company's common stock on the grant date. The fair value is amortized on a straight-line basis over the requisite service period of the awards, which is generally the vesting term of four years.

In 2016, the Company granted performance based RSUs to its former CEO that only vest upon the achievement of specific operational performance criteria. The stock-based compensation for these performance based RSUs are recognized as expenses when it is determined that achieving the performance metrics are probable. Upon the former CEO's resignation from the Company in March 2019, the unvested shares subject to this award as of the separation date have been cancelled.

In connection with the former CEO's resignation in March 2019, the Company amended the terms of his then vested nonqualified stock options such that they remain exercisable through the second anniversary of his separation date. This modification resulted in a charge of \$1.6 million in stock-based compensation.

In 2019, the Company granted PSUs to its current CEO that only vest based on the total shareholder return (TSR) of the Company common stock price relative to that of the Index.

In 2020 and 2021, the Company granted PSUs to the CEO and other members of its management team that vest based on the total shareholder return of the Company common stock price relative to that of the Index.

The company estimates the grant-date fair value of these PSUs based on the Monte Carlo simulation model and records the related stock-based compensation over the period for which the TSR is measured against the Index, which is generally two to three years. The use of the Monte Carlo simulation model requires the input the following assumptions:

	Years Ended December 31,		
	2021	2020	2019
Index volatility	51% — 53%	44% — 51%	36%
Company volatility	49% — 54%	57% — 59%	45%
Risk-free interest rate	0.1% — 0.3%	0.1% — 0.2%	2.4%
Correlation with index	0.32 — 0.35	0.38 — 0.41	0.28
Dividend Yield	0%	0%	0%

A summary of stock-based compensation expense by line items in the consolidated statements of operations is as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Cost of revenue	\$ 1,637	\$ 2,433	\$ 3,061
Research and development	6,455	6,141	6,323
Sales, general and administrative	36,273	34,081	32,313
Total stock-based compensation expense	<u>\$ 44,365</u>	<u>\$ 42,655</u>	<u>\$ 41,697</u>

A summary of pre-tax stock-based compensation expense by category was as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Stock options	\$ 2,997	\$ 6,289	\$ 10,312
Restricted stock units	29,234	27,977	26,854
Performance stock units	10,017	5,694	1,991
Employee stock purchase plan	2,117	2,695	2,540
Total stock-based compensation expense	<u>\$ 44,365</u>	<u>\$ 42,655</u>	<u>\$ 41,697</u>

As of December 31, 2021, total stock-based compensation expense not yet recognized, net of estimated forfeitures, are as follows:

	Unrecognized Compensation (in thousands)	Weighted-Average Amortization Period (in years)
Stock options	\$ 2,597	1.2
Restricted stock units	61,107	2.1
Performance stock units	10,389	0.7
Employee stock purchase plan	1,219	0.4

## 11. Income Taxes

The components of the Company's income / (loss) before income taxes were as follows:

	Years Ended December 31,		
	2021	2020 (in thousands)	2019
Domestic	\$ (129,135)	\$ (83,893)	\$ (106,010)
Foreign	(1,691)	1,696	3,923
Total loss before income taxes	<u>\$ (130,826)</u>	<u>\$ (82,197)</u>	<u>\$ (102,087)</u>

The components of the expense / (benefit) for income taxes are as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
<b>Current:</b>			
Federal	\$ —	\$ —	\$ (103)
State	244	188	187
Foreign	585	656	1,644
<b>Total current income tax expense / (benefit)</b>	<b>829</b>	<b>844</b>	<b>1,728</b>
<b>Deferred:</b>			
Federal	—	—	—
State	—	—	—
Foreign	(295)	24	(129)
<b>Total deferred income tax expense / (benefit)</b>	<b>(295)</b>	<b>24</b>	<b>(129)</b>
<b>Total income tax expense / (benefit)</b>	<b>\$ 534</b>	<b>\$ 868</b>	<b>\$ 1,599</b>

Income tax expense differs from the amount computed by applying the statutory federal income tax rate as follows:

	Years Ended December 31,		
	2021	2020	2019
Tax at statutory federal rate	21.0%	21.0%	21.0%
State tax, net of federal benefit	(0.2)%	(0.2)%	(0.1)%
Foreign rate differential	(0.5)%	(0.4)%	(0.7)%
Tax credits	3.0%	1.4%	3.0%
Stock-based compensation	(0.2)%	9.8%	3.8%
Change in valuation allowance	(23.3)%	(33.6)%	(26.4)%
Other	(0.2)%	0.9%	(2.2)%
<b>Total</b>	<b>(0.4)%</b>	<b>(1.1)%</b>	<b>(1.6)%</b>

The tax effects of temporary differences and carryforwards that give rise to significant portions of deferred tax assets and liabilities are as follows:

	December 31,	
	2021 (in thousands)	2020
Net operating loss carryforwards	\$ 154,614	\$ 127,347
Tax credits	25,087	18,919
Depreciation	650	662
Stock-based compensation	6,969	7,390
Accruals and reserves	13,404	9,531
Right of use asset	4,225	5,055
Other	1,130	869
Gross deferred tax assets	206,079	169,773
Valuation allowance	(201,088)	(164,278)
Deferred tax assets	4,991	5,495
Lease liabilities	(3,660)	(4,459)
Deferred tax liabilities	(3,660)	(4,459)
<b>Net deferred tax assets</b>	<b>\$ 1,331</b>	<b>\$ 1,036</b>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, substantially all of the net deferred tax assets have been offset by a valuation allowance. The valuation allowance increased by \$36.8 million and \$32.5 million for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, the Company had federal net operating loss carryforwards (NOLs) of approximately \$588.4 million, of which \$329.4 million was generated in fiscal year 2018 and thereafter, which can be carried forward indefinitely under the 2017 Tax Act, as well as state NOLs of approximately \$336.5 million, of which \$54.3 million may be carried forward indefinitely. If not utilized, the remaining federal NOLs will begin to expire in 2026, and the remaining state NOLs will begin to expire in 2022.

As of December 31, 2021, the Company had research and development credit carryforwards of approximately \$20.5 million and \$13.9 million for federal and California state income tax purposes, respectively. The federal credit carryforward begins expiring in 2026, and the state credits carry forward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, the Company's ability to utilize NOLs or other tax attributes such as research tax credits, in any taxable year may be limited if the Company experiences, or has experienced, a Section 382 "ownership change." A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders, who own at least 5% of the Company's stock, increase their ownership by a greater than 50 percentage point change (by value) over a rolling three-year period. Similar rules may apply under state tax laws. As a result of the Company's June 2015 underwritten public offering, the Company experienced a Section 382 "ownership change." The Company currently estimates that this "ownership change" will not inhibit its ability to utilize its NOLs. However, the Company may, in the future, experience one or more additional Section 382 "ownership changes" as a result of subsequent changes in its stock ownership, some of which changes are outside the Company's control. If so, the Company may not be able to utilize a material portion of its NOLs and tax credits, even if the Company achieves profitability.

The Company had unrecognized tax benefits (UTBs) of approximately \$10.4 million as of December 31, 2021. The following table summarizes the activity related to UTBs (in thousands):

Balance at December 31, 2018	\$ 5,200
Increases related to current year tax provisions	1,611
Increases related to prior year tax provisions	572
Decreases related to prior year tax provisions	—
Balance at December 31, 2019	7,383
Increases related to current year tax provisions	891
Increases related to prior year tax provisions	—
Decreases related to prior year tax provisions	(54)
Balance at December 31, 2020	8,220
Increases related to current year tax provisions	1,412
Increases related to prior year tax provisions	860
Decreases related to prior year tax provisions	(62)
Balance at December 31, 2021	<u>\$ 10,430</u>

If these UTBs were recognized, approximately \$10.4 million would affect the effective tax rate before consideration of the valuation allowance. The Company files U.S. federal and state income tax and foreign income tax returns with varying statutes of limitations. The Company's U.S. federal and the majority of state tax years from inception in 2006 onward will remain open to examination due to the carryover of the unused NOLs and tax credits. The Company does not have any material active tax audits or other proceedings pending, and believes it has provided adequate reserves for all tax deficiencies or reductions in tax benefits that could result from federal, state and foreign tax audits. The Company does not expect any material changes to the estimated amount of liability associated with its uncertain tax positions within the next twelve months.

In accordance with ASC 740, *Income Taxes*, the Company is classifying interest and penalties as a component of tax expense. There was \$0.2 million, \$0.1 million and \$0.1 million of interest and penalties accrued at each of December 31, 2021, 2020 and 2019, respectively.

## 12. Net Loss Per Share

The following table summarizes the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Years Ended December 31,		
	2021	2020	2019
Net loss	\$ (131,360)	\$ (83,065)	\$ (103,686)
Weighted average shares used to compute basic and diluted net loss per share	34,823,258	33,677,641	30,803,872
Net loss per share, basic and diluted	\$ (3.77)	\$ (2.47)	\$ (3.37)

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period, determined using the treasury-stock method, if inclusion of these is dilutive. The conversion spread for the Company's outstanding convertible senior notes will have a dilutive impact on diluted net income per share of common stock when the average market price of the Company's common stock for a given period exceeds the conversion price of \$105.00 for the 2025 Notes. This condition was not met in the three months ended December 31, 2021.

In connection with the issuance of the 2021 Notes and 2025 Notes, the Company entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding for the periods presented, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments the Company is required to make upon conversion of the 2021 Notes and 2025 Notes. When the 2021 Notes matured on June 1, 2021, the Company exercised its option under the bond hedge. As of December 31, 2021, the bond hedges related to the 2021 Notes are no longer outstanding. 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.

The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computation of diluted shares outstanding:

	December 31,		
	2021	2020	2019
Unreleased restricted and performance stock units	1,012,491	1,052,014	1,288,332
Options to purchase common stock	700,654	813,150	1,646,185
Convertible senior notes	1,807,141	3,597,174	1,790,033
Warrants related to the issuance of convertible senior notes	1,807,141	3,597,174	1,790,033
Total	5,327,427	9,059,512	6,514,583

## 13. Employee Benefit Plan.

In 2007, the Company adopted a 401(K) plan for its employees whereby eligible employees may contribute up to the maximum amount permitted by the Internal Revenue Code of 1986, as amended. In June 2016, the Company adopted a policy to match a portion of employee contributions for all qualified employees participating in the 401(k) plan. For the years ended December 31, 2021, 2020 and 2019, the Company recorded expenses of \$2.9 million, \$2.6 million and \$3.1 million for matching contributions, respectively.

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES****Evaluation of Disclosure Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) refers to controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021, the end of the period covered by this Annual Report. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

**Management’s Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Our management assessed our internal control over financial reporting as of December 31, 2021, the end of the period covered by this Annual Report. Management based its assessment on criteria established in “Internal Control—Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on management’s assessment of our internal control over financial reporting, management concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or

improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears in Part II, Item 8 of this Annual Report.

#### **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the most recent fiscal quarter covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION**

None.

#### **ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

#### **Executive Officers, Significant Employee and Non-Employee Directors of the Registrant**

The information required by this Item 10 is hereby incorporated by reference from the information under the captions “Executive Officers,” “Election of Directors”, “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” that will be contained in the Proxy Statement for our 2022 Annual Meeting of Stockholders (or the Proxy Statement).

We have adopted a written code of conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons serving similar functions. The text of our code of business conduct and ethics has been posted on our website at <http://www.nevro.com>. We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Conduct by posting such information on our website at the website address specified above.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 is incorporated by reference from the information under the captions “Director Compensation,” “Executive Compensation” and “Corporate Governance” that will be contained in the Proxy Statement.

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

The information required by this Item 12 is incorporated by reference from the information under the captions “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” that will be contained in the Proxy Statement.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item 13 is incorporated by reference from the information under the captions “Certain Relationships and Related Transactions” and “Corporate Governance” that will be contained in the Proxy Statement.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item 14 is incorporated by reference from the information under the caption “Ratification of Appointment of Independent Registered Public Accounting Firm” that will be contained in the Proxy Statement.

## PART IV

### ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES

(a)The following documents are filed as part of this Annual Report:

#### 1. Consolidated Financial Statements:

Reference is made to the Index to consolidated financial statements of Nevro Corp. under Item 8 of Part II hereof.

#### 2. Financial Statement Schedule:

All schedules are omitted because they are not applicable or the amounts are immaterial or the required information is presented in the consolidated financial statements and notes thereto in Part II, Item 8 above.

#### 3. Exhibits

See Exhibit Index below.

**Exhibit Index**

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation of Nevro Corp.</u></a>	8-K	11/12/2014	3.1	
3.1(b)	<a href="#"><u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Nevro Corp.</u></a>	8-K	5/24/2019	3.1	
3.2	<a href="#"><u>Amended and Restated Bylaws of Nevro Corp.</u></a>	8-K	11/12/2014	3.1	
3.2(b)	<a href="#"><u>Amendment to Amended and Restated Bylaws of Nevro Corp.</u></a>	8-K	5/24/2019	3.2	
4.1	<a href="#"><u>Reference is made to exhibits 3.1 and 3.2.</u></a>				
4.2	<a href="#"><u>Form of Common Stock Certificate.</u></a>	S-1/A	10/27/2014	4.2	
4.3	<a href="#"><u>Indenture, dated as of June 13, 2016, by and between the Company and Wilmington Trust, National Association.</u></a>	8-K	6/13/2016	4.1	
4.4	<a href="#"><u>First Supplemental Indenture, dated as of June 13, 2016, by and between the Company and Wilmington Trust, National Association.</u></a>	8-K	6/13/2016	4.2	
4.5	<a href="#"><u>Form of 1.75% Convertible Senior Note Due 2021.</u></a>	8-K	6/13/2016	4.3	
4.6	<a href="#"><u>Second Supplemental Indenture, dated as of April 6, 2020, by and between the Company and Wilmington Trust, National Association, as Trustee.</u></a>	8-K	4/7/2020	4.2	
4.7	<a href="#"><u>Form of 2.75% Convertible Senior Note Due 2025 (included in Exhibit 4.6).</u></a>	8-K	4/7/2020	4.3	
4.8	<a href="#"><u>Description of Nevro Corp.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.</u></a>	10-K	2/25/2020	4.6	

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference Form</b>	<b>Date</b>	<b>Number</b>	<b>Filed Herewith</b>
10.1†	<a href="#"><u>Amended and Restated License Agreement, dated October 2, 2006, by and among the Company and Mayo Foundation for Medical Education and Research, Venturi Group, LLC.</u></a>	S-1/A	10/15/2014	10.1	
10.2(a)†	<a href="#"><u>Stellar Manufacturing Agreement, dated as of July 1, 2009, by and between the Company and Stellar Technologies, Inc.</u></a>	S-1/A	10/15/2014	10.2(a)	
10.2(b)†	<a href="#"><u>First Amendment to Stellar Manufacturing Agreement, dated as of July 1, 2014, by and between the Company and Stellar Technologies, Inc.</u></a>	S-1/A	10/15/2014	10.2(b)	
10.2(c)†	<a href="#"><u>Second Amendment to Stellar Manufacturing Agreement, dated as of January 28, 2016, by and between the Company and Stellar Technologies, Inc.</u></a>	10-K	2/29/2016	10.2(c)	
10.3(a)†	<a href="#"><u>Supply Agreement, dated as of July 23, 2014 by and between the Company and Pro-Tech Design and Manufacturing, Inc.</u></a>	S-1/A	10/15/2014	10.3	
10.3(b)†	<a href="#"><u>Amendment to Supply Agreement, effective as of July 23, 2019, by and between the Company and Pro-Tech Design and Manufacturing, Inc.</u></a>	10-Q	8/5/2020	10.4	
10.4(a)†	<a href="#"><u>Supply Agreement, dated April 1, 2012, by and between the Company and CCC del Uruguay S.A.</u></a>	S-1/A	10/15/2014	10.4(a)	
10.4(b)†	<a href="#"><u>Amendment to Supply Agreement, dated as of March 20, 2013, by and between the Company and CCC del Uruguay S.A.</u></a>	S-1/A	10/15/2014	10.4(b)	
10.4(c)†	<a href="#"><u>Assignment, Assumption and Amendment to Supply Agreement, effective as of December 31, 2019, by and between the Company, Greatbatch Ltd. and Centro de Construccion de Cardioestimuladores del Uruguay S.A.</u></a>	10-Q	5/5/2020	10.10	
10.5(a)†	<a href="#"><u>Product Supply and Development Agreement, dated as of April 15, 2009, by and between the Company and EaglePicher Medical Power LLC.</u></a>	S-1/A	10/15/2014	10.5	
10.5(b)†	<a href="#"><u>First Amendment to the Product Supply and Development Agreement, dated as of March 4, 2015, by and between the Company and EaglePicher Medical Power LLC.</u></a>	10-K	3/18/2015	10.5(b)	
10.5(c)†	<a href="#"><u>Second Amendment to the Product Supply and Development Agreement, dated as of October 23, 2015, by and between the Company and EaglePicher Medical Power LLC.</u></a>	10-K	2/29/2016	10.5(c)	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.5(d)	<a href="#">Third Amendment to the Product Supply and Development Agreement, dated as of September 15, 2017, by and between the Company and EaglePicher Medical Power LLC.</a>	10-Q	11/6/2017	10.1	
10.6(a)	<a href="#">Amended and Restated Registration Rights Agreement, dated February 8, 2013, by and among the Company and the investors listed therein.</a>	S-1	10/03/2014	10.6(a)	
10.6(b)	<a href="#">Amendment to Amended and Restated Registration Rights Agreement, dated March 5, 2013, by and among the Company and the investors listed therein.</a>	S-1	10/03/2014	10.6(b)	
10.6(c)	<a href="#">Second Amendment to Amended and Restated Registration Rights Agreement, dated October 24, 2014, by and among the Company and the investors listed therein.</a>	S-1/A	11/04/14	10.6(c)	
10.7(a)	<a href="#">Multi-Tenant Space Lease, dated as of March 15, 2010, by and between Deerfield Campbell LLC and the Company.</a>	S-1	10/03/2014	10.7(a)	
10.7(b)	<a href="#">First Amendment to Lease, dated as of October 18, 2012, by and between Deerfield Campbell LLC and the Company.</a>	S-1	10/03/2014	10.7(b)	
10.7(c)	<a href="#">Second Amendment to Lease, dated as of February 18, 2015, by and between Deerfield Campbell LLC and the Company.</a>	10-K	3/18/2015	10.7(c)	
10.8(a) #	<a href="#">Nevro Corp. 2007 Stock Incentive Plan, as amended as of March 5, 2013.</a>	S-1	10/03/2014	10.8(a)	
10.8(b) #	<a href="#">Form of Incentive Stock Option Agreement (ISO) under the 2007 Stock Incentive Plan, as amended.</a>	S-1	10/03/2014	10.8(b)	
10.8(c) #	<a href="#">Form of Non-Incentive Stock Option Agreement (NSO) under the 2007 Stock Incentive Plan, as amended.</a>	S-1	10/03/2014	10.8(c)	
10.8(d) #	<a href="#">Form of Stock Purchase Right Grant Notice and Restricted Stock Purchase Agreement under the 2007 Stock Incentive Plan, as amended.</a>	S-1	10/03/2014	10.8(d)	
10.9(a) #	<a href="#">Nevro Corp. 2014 Equity Incentive Award Plan.</a>	S-8	11/12/2014	99.2(a)	
10.9(b) #	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan.</a>	S-1/A	10/10/2014	10.9(b)	
10.9(c) #	<a href="#">Form of Restricted Stock Award Agreement and Restricted Stock Award Grant Notice under the 2014 Equity Incentive Award Plan.</a>	S-1/A	10/10/2014	10.9(c)	
10.9(d) #	<a href="#">Form of Restricted Stock Unit Award Agreement and Restricted Stock Unit Award Grant Notice under the 2014 Equity Incentive Award Plan.</a>	S-1/A	10/10/2014	10.9(d)	

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference Form</b>	<b>Date</b>	<b>Number</b>	<b>Filed Herewith</b>
10.9(e)#[ <a href="#">Form of Performance Stock Award Agreement and Performance Stock Award Grant Notice under the 2014 Equity Incentive Award Plan.</a> ]		10-Q	5/5/2020	10.1	
10.10#[ <a href="#">Nevro Corp. 2014 Employee Stock Purchase Plan.</a> ]	S-8	11/12/2014	99.3		
10.11#[ <a href="#">Form of Indemnification Agreement for directors and officers.</a> ]	S-1/A	10/10/2014	10.11		
10.12#[ <a href="#">Amended and Restated Company Bonus Plan.</a> ]	10-Q	5/7/2018	10.1		
10.12(b)#[ <a href="#">Second Amended and Restated Company Bonus Plan.</a> ]	10-Q	8/5/2020	10.1		
10.13#[ <a href="#">Nevro Corp. Non-Employee Director Compensation Program, as amended.</a> ]					X
10.14#[ <a href="#">Employment Agreement by and between D. Keith Grossman and the Company, effective as of March 19, 2019.</a> ]	10-Q	5/9/2019	10.1		
10.15#[ <a href="#">Offer Letter, dated as of May 5, 2020, by and between Roderick H. MacLeod and the Company.</a> ]	10-Q	8/5/2020	10.2		
10.16(a)[ <a href="#">Amended and Restated Stockholders' Agreement, dated February 8, 2013, by and among the Company and the stockholders listed therein.</a> ]	S-1	10/03/2014	10.15(a)		
10.16(b)[ <a href="#">Amendment to Amended and Restated Stockholders' Agreement, dated March 5, 2013, by and among the Company and the stockholders listed therein.</a> ]	S-1	10/03/2014	10.15(b)		
10.16(c)[ <a href="#">Second Amendment to Amended and Restated Stockholders' Agreement, dated October 24, 2014, by and among the Company and the investors listed therein.</a> ]	S-1/A	11/04/14	10.18(c)		
10.17(a)#[ <a href="#">Form of Amended and Restated Change in Control Severance Agreement for certain executive officers.</a> ]	10-Q	5/9/2016	10.4		
10.17(b)#[ <a href="#">Amended and Restated Change in Control Severance Agreement, dated as of July 22, 2019, by and between Patrick Schmitz and the Company.</a> ]	10-Q	11/6/2019	10.3		
10.17(c)#[ <a href="#">Amended and Restated Change in Control Severance Agreement, dated as of August 3, 2016, by and between Christofer Christoforou and the Company.</a> ]	10-K	2/22/2018	10.18(e)		
10.17(d)#[ <a href="#">Amended and Restated Change in Control Severance Agreement, dated as of July 22, 2019, by and between Kashif Rashid and the Company.</a> ]	10-Q	11/6/2019	10.2		
10.17(e)#[ <a href="#">Change in Control Severance Agreement, dated as of September 16, 2019, by and between Niamh Pellegrini and the Company.</a> ]	10-K	2/25/2020	10.18(g)		
10.17(f)#[ <a href="#">Change in Control Severance Agreement, dated as of June 15, 2020, by and between Roderick H. MacLeod and the Company.</a> ]	10-Q	8/5/2020	10.3		

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.18(a)†	<a href="#">Supply Agreement, dated March 13, 2015, by and between the Company and Centro de Construcion de Cardioestimuladores del Uruguay S.A.</a>	10-K/A	5/29/2015	10.22	
10.18(b)†	<a href="#">Supply Agreement, effective as of November 11, 2016, by and between the Company and Centro de Construcion de Cardioestimuladores del Uruguay S.A.</a>	10-K	2/23/2017	10.22(b)	
10.18(c)†	<a href="#">First Amendment to Supply Agreement, effective as of April 30, 2019, by and between the Company and Centro de Construcion de Cardioestimuladores del Uruguay S.A.</a>	10-Q	8/8/2019	10.3	
10.19(a)	<a href="#">Lease Agreement, dated as of March 5, 2015, by and between the Company and Westport Office Park, LLC.</a>	10-K	3/18/2015	10.23	
10.19(b)	<a href="#">First Amendment to Lease, effective as of December 9, 2016, by and between the Company and Westport Office Park, LLC.</a>	10-K	2/23/2017	10.23(b)	
10.19(c)	<a href="#">Second Amendment to Lease, effective as of April 13, 2017, by and between the Company and Westport Office Park, LLC.</a>	10-Q	8/7/2017	10.1	
10.19(d)	<a href="#">Third Amendment to Lease, effective as of December 6, 2017, by and between the Company and Westport Office Park, LLC.</a>	10-K	2/22/2018	10.21(d)	
10.20#	<a href="#">Transition and Separation Agreement, dated as of January 7, 2020, by and between the Company and Doug Alleavitch.</a>	10-K	2/25/2020	10.21(b)	
10.21(a)†	<a href="#">Manufacturing and Supply Agreement, dated as of December 18, 2015, by and between the Company and Vention Medical Design and Development, Inc.</a>	10-K	2/29/2016	10.25	
10.21(b)†	<a href="#">First Amendment to the Manufacturing and Supply Agreement, dated as of September 30, 2017, by and between the Company and Vention Medical Design and Development, Inc.</a>	10-Q	11/6/2017	10.2	
10.21(c)†	<a href="#">Second Amendment to the Manufacturing and Supply Agreement, dated April 2018, by and between the Company and Nordson MEDICAL Design and Development, Inc., fka Vention Medical Design and Development, Inc.</a>	10-Q	8/2/2018	10.2	
10.22	<a href="#">Settlement Agreement, dated March 19, 2019, by and among Broadfin Capital, LLC and certain of its affiliates named therein and the Company.</a>	8-K	3/20/2019	10.1	

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference Form</b>	<b>Date</b>	<b>Number</b>	<b>Filed Herewith</b>
10.23	<u><a href="#">Letter Agreement, dated June 7, 2016, between Morgan Stanley &amp; Co. International plc and the Company, regarding the Base Warrants.</a></u>	8-K	6/13/2016	10.1	
10.24	<u><a href="#">Letter Agreement, dated June 7, 2016, between Bank of America, N.A. and the Company, regarding the Base Warrants.</a></u>	8-K	6/13/2016	10.2	
10.25	<u><a href="#">Letter Agreement, dated June 7, 2016, between Goldman, Sachs &amp; Co. and the Company, regarding the Base Warrants.</a></u>	8-K	6/13/2016	10.3	
10.26	<u><a href="#">Letter Agreement, dated June 7, 2016, between Morgan Stanley &amp; Co. International plc and the Company, regarding the Base Call Option Transaction.</a></u>	8-K	6/13/2016	10.4	
10.27	<u><a href="#">Letter Agreement, dated June 7, 2016, between Bank of America, N.A. and the Company, regarding the Base Call Option Transaction.</a></u>	8-K	6/13/2016	10.5	
10.28	<u><a href="#">Letter Agreement, dated June 7, 2016, between Goldman, Sachs &amp; Co. and the Company, regarding the Base Call Option Transaction.</a></u>	8-K	6/13/2016	10.6	
10.29	<u><a href="#">Letter Agreement, dated June 8, 2016, between Morgan Stanley &amp; Co. International plc and the Company, regarding the Additional Warrants.</a></u>	8-K	6/13/2016	10.7	
10.30	<u><a href="#">Letter Agreement, dated June 8, 2016, between Bank of America, N.A. and the Company, regarding the Additional Warrants.</a></u>	8-K	6/13/2016	10.8	
10.31	<u><a href="#">Letter Agreement, dated June 8, 2016, between Goldman, Sachs &amp; Co. and the Company, regarding the Additional Warrants.</a></u>	8-K	6/13/2016	10.9	
10.32	<u><a href="#">Letter Agreement, dated June 8, 2016, between Morgan Stanley &amp; Co. International plc and the Company, regarding the Additional Call Option Transaction.</a></u>	8-K	6/13/2016	10.10	
10.33	<u><a href="#">Letter Agreement, dated June 8, 2016, between Bank of America, N.A. and the Company, regarding the Additional Call Option Transaction.</a></u>	8-K	6/13/2016	10.11	
10.34	<u><a href="#">Letter Agreement, dated June 8, 2016, between Goldman, Sachs &amp; Co. and the Company, regarding the Additional Call Option Transaction.</a></u>	8-K	6/13/2016	10.12	
10.35	<u><a href="#">Letter Agreement, dated April 1, 2020, between Goldman Sachs &amp; Co. LLC and Nevro Corp., regarding the Base Warrants.</a></u>	8-K	4/7/2020	10.1	
10.36	<u><a href="#">Letter Agreement, dated April 1, 2020, between Goldman Sachs &amp; Co. LLC and Nevro Corp., regarding the Base Call Option Transaction.</a></u>	8-K	4/7/2020	10.2	

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference Form</u>	<u>Date</u>	<u>Number</u>	<u>Filed Herewith</u>
10.37	<u><a href="#">Letter Agreement, dated April 1, 2020, between Morgan Stanley &amp; Co. International plc and Nevro Corp., regarding the Base Warrants.</a></u>	8-K	4/7/2020	10.3	
10.38	<u><a href="#">Letter Agreement, dated April 1, 2020, between Morgan Stanley &amp; Co. International plc and Nevro Corp., regarding the Base Call Option Transaction.</a></u>	8-K	4/7/2020	10.4	
10.39	<u><a href="#">Letter Agreement, dated April 2, 2020, between Goldman Sachs &amp; Co. LLC and Nevro Corp., regarding the Additional Call Option Transaction.</a></u>	8-K	4/7/2020	10.5	
10.40	<u><a href="#">Letter Agreement, dated April 2, 2020, between Goldman Sachs &amp; Co. LLC and Nevro Corp., regarding the Additional Warrants.</a></u>	8-K	4/7/2020	10.6	
10.41	<u><a href="#">Letter Agreement, dated April 2, 2020, between Morgan Stanley &amp; Co. International plc and Nevro Corp., regarding the Additional Call Option Transaction.</a></u>	8-K	4/7/2020	10.7	
10.42	<u><a href="#">Letter Agreement, dated April 2, 2020, between Morgan Stanley &amp; Co. International plc and Nevro Corp., regarding the Additional Warrants.</a></u>	8-K	4/7/2020	10.8	
21.1	<u><a href="#">List of Subsidiaries.</a></u>				X
23.1	<u><a href="#">Consent of Independent Registered Public Accounting Firm.</a></u>				X
24.1	<u><a href="#">Power of Attorney (included on signature page to this Annual Report on Form 10-K).</a></u>				X
31.1	<u><a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a></u>				X
31.2	<u><a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a></u>				X
32.1**	<u><a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a></u>				X
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference Form</u>	<u>Date</u>	<u>Number</u>	<u>Filed Herewith</u>
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

- † Confidential treatment has been granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.
- # Indicates management contract or compensatory plan.
- \*\* The certification attached as Exhibit 32.1 that accompanies this Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Nevro Corp. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

#### **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, as amended the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

February 23, 2022:

### NEVRO CORP.

By: /s/ D. Keith Grossman  
D. Keith Grossman  
President and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of D. Keith Grossman and Roderick H. MacLeod his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments 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 attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his/her name.

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

Signature	Title	Date
<u>/s/ D. KEITH GROSSMAN</u> D. Keith Grossman	Chief Executive Officer (Principal Executive Officer)	February 23, 2022
<u>/s/ RODERICK H. MACLEOD</u> Roderick H. MacLeod	Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2022
<u>/s/ MICHAEL DEMANE</u> Michael DeMane	Lead Director	February 23, 2022
<u>/s/ FRANK FISCHER</u> Frank Fischer	Director	February 23, 2022
<u>/s/ SRI KOSARAJU</u> Sri Kosaraju	Director	February 23, 2022
<u>/s/ SHAWN T MCCORMICK</u> Shawn T McCormick	Director	February 23, 2022
<u>/s/ KEVIN O'BOYLE</u> Kevin O'Boyle	Director	February 23, 2022
<u>/s/ KAREN PRANGE</u> Karen Prange	Director	February 23, 2022

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ SUSAN E. SIEGEL</u> Susan E. Siegel	Director	February 23, 2022
<u>/s/ BRAD H. VALE</u> Brad H. Vale, Ph.D., D.V.M.	Director	February 23, 2022
<u>/s/ ELIZABETH WEATHERMAN</u> Elizabeth Weatherman	Director	February 23, 2022