NEVRO CORP
Form 10-K
February 21, 2019

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 year ended December 31, 2018

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	56-2568057
(State or other jurisdiction of incorporation or organization)	(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	Name of exchange on which registered
Common Stock, par value $0.001 per share	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of June 29, 2018, 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 $2,310 million based on the closing sale price for the registrant's common stock on The New York Stock Exchange on that date of $79.85 per share.

As of February 14, 2019, there were 30,377,977 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the registrant's 2019 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, 2018.

NEVRO CORP.

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PART I

ITEM 1. BUSINESS

Overview

We are a global medical device company focused on providing innovative products that improve the quality of life of patients suffering from chronic pain. We have developed and commercialized the Senza® spinal cord stimulation (SCS) system, an evidence-based neuromodulation platform for the treatment of chronic pain. Our proprietary paresthesia-free HF10™ therapy, delivered by our Senza system, was demonstrated in our SENZA-RCT study to be superior to traditional SCS therapy with it 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. Comparatively, traditional SCS therapy has limited efficacy in treating back pain and is used primarily for treating leg pain, limiting its market adoption. Our SENZA-RCT study, along with our European studies, represents what we believe is the most robust body of clinical evidence for any SCS therapy. We believe the superiority of HF10 therapy over traditional SCS therapies will allow us to capitalize on and expand the approximately $2.4 billion existing global SCS market by treating both back and leg pain without paresthesia.

We launched Senza commercially in the United States in May 2015, after receiving a label from the U.S. Food and Drug Administration (FDA) which supports the superiority of our HF10 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 new surgical lead, marketed as the Surpass™ surgical lead. In January 2018, we received FDA approval for our next generation Senza II™ SCS system. 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.

	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018
Revenue from:	(in millions)											
U.S. sales	$29.5	$40.6	$47.2	$56.0	$53.1	$63.0	$66.3	$81.1	$70.6	$79.9	$79.6	$91.6
International sales	12.2	14.8	13.7	14.5	15.3	15.0	16.0	16.9	17.0	16.2	16.0	16.3
Total revenue	$41.7	$55.4	$60.9	$70.5	$68.4	$78.0	$82.3	$98.0	$87.6	$96.1	$95.6	$107.9

	2014	2015	2016	2017	2018
	(in millions)				
Total revenue	$32.6	$69.6	$228.5	$326.7	$387.3

With a primary focus on treating leg pain, the global market for SCS therapy was estimated to be approximately $2.4 billion in 2018. We believe the superiority of HF10 therapy over traditional SCS therapies will allow us to capitalize on and potentially help expand that market to approximately $4.0 billion by 2022 by expanding into other pain-related indications, such as upper limb and neck pain, painful diabetic neuropathy and non-surgical back pain, 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 and an increasing number of failed back surgeries, 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 our HF10 therapy will continue to both take share of and expand the SCS therapy market due to HF10 therapy being a paresthesia-free therapy and having 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, sometimes causes a shocking or jolting sensation with changes in posture and is a continuous reminder of the patient's chronic condition. Compared to traditional SCS therapy which typically operates at 50 Hz to 60 Hz, HF10 therapy delivers spinal cord stimulation at a lower amplitude and a higher frequency waveform of 10,000 Hz. In addition, HF10 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 HF10 therapy to deliver pain relief without paresthesia provides a substantial benefit over traditional SCS therapy to patients and physicians.

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 HF10 therapy in both pain reduction and responder rates against the other prospective Level 1 studies conducted.

1. Al-Kaisy 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.

1. Al-Kaisy 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 over 40,000 patients implanted with Senza, extensive intellectual property and a proven management team with substantial neuromodulation experience. With the well-demonstrated superior efficacy of our HF10 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 HF10 therapy by investing in the development of evidence for new indications such as chronic upper limb and neck pain, painful neuropathies (including painful diabetic neuropathy) and non-surgical refractory back pain. On this front, we initiated two randomized controlled trials in 2018, SENZA-PDN and SENZA-NSRBP, which are evaluating HF10 therapy for the treatment of painful diabetic neuropathy and non-surgical refractory back pain.

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 conventional medical management. 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% 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. 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 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. 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 at sub-threshold amplitudes aimed at reducing the reliance on paresthesia. For example, Abbott Laboratories has developed a SCS system that offers an alternate low frequency waveform called BurstDR. Medtronic is promoting a high-density programming approach. Additionally, Boston Scientific is now offering sub-threshold therapy at frequencies below 1.2 kHz.

Our Solution for Chronic Pain

HF10 Therapy

Our HF10 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 HF10 therapy offers superior efficacy for patients and provides significant advantages to physicians and hospitals. We believe the advantages of our proprietary HF10 therapy over traditional SCS include:

- Demonstrated superior efficacy data for both leg and back pain: In our SENZA-RCT pivotal study, HF10 therapy was demonstrated to provide significant and sustained back pain relief in addition to leg pain relief. HF10 therapy was shown in both number of patients that respond and in treatment efficacy to be superior to traditional SCS therapy as it is 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 HF10 therapy among patients, payors and providers and may enable us to gain significant market share in the approximately $2.4 billion existing global SCS market in 2018, which is primarily based on treating leg pain. 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.
- Paresthesia free pain relief for patients: HF10 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.

- Anatomical lead placement for physicians. Since HF10 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 HF10 therapy is a platform technology that we believe can provide treatment benefits for a broader group of chronic pain indications. We are currently investigating the use of HF10 therapy to address additional indications such as chronic upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. Based on analysis from our SENZA-RCT and European studies, we believe HF10 therapy may be an attractive treatment option for some non-surgical refractory back pain patients due to its cost, reversibility and initial trial period. Due to the removal of paresthesia, HF10 may also be an effective therapy for patients with chronic upper limb and neck pain as it will 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.

Our Growth Strategy

Our mission is to be the neuromodulation leader in the treatment of chronic pain by developing innovative, evidence-based solutions. To accomplish this objective we intend to:

- Drive adoption of HF10 therapy through a world-class sales and marketing organization: We will continue to build our worldwide sales organization consisting of direct sales representatives and, in some international markets, a network of distributors and sales agents. In particular, we are continuing to make significant investments in building our U.S. commercial infrastructure and sales force. This is a lengthy process that requires significant investment to recruit and train qualified 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 is required to achieve our expected growth rate. Our sales representatives target physician specialties involved in SCS treatment decisions, including neurosurgeons, physiatrists, interventional pain specialists and orthopedic spine surgeons. Further, we expect that our direct sales force will target the approximately 2,400 hospitals and outpatient surgery centers at which we believe an estimated 90% of SCS procedures in the United States are performed. To complement our sales representatives, we intend for our marketing and reimbursement teams to drive HF10 therapy adoption through creating awareness and demand among additional stakeholders involved in the SCS treatment decision, including third-party payors, hospital administrators, and patients and their families. Internationally, we plan to increase coverage in certain of our existing markets by continuing the expansion of our direct sales force.
- Expand the existing SCS market by treating back pain: We believe we are expanding the existing SCS market by delivering a system that provides meaningful treatment for chronic back pain, which we believe represents a significant opportunity in the global SCS market. With traditional SCS therapy, patients who experience predominant back pain are 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. In contrast to traditional SCS therapy, we believe HF10 therapy is positioned to expand the existing SCS market by effectively treating back pain in addition to leg pain.
- Communicate the clinically demonstrated, superior efficacy of HF10 therapy to patients, physicians and payors globally: Given our robust clinical evidence that demonstrates the superior efficacy of our HF10 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 HF10 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. Product enhancements have recently included a next-generation IPG and enhanced MRI capability, both of which were approved in Europe in 2017, with the next-generation IPG, or Senza II, gaining approval by the FDA in January 2018. We also expect to continue developing enhancements to Senza to further increase performance and introduce new benefits including next generation IPGs 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 HF10 therapy.

- Scale our business to achieve cost and production efficiencies: We plan to improve the efficiency of our third-party 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.

Growth Opportunities in Other Chronic Pain Indications

We plan to use our platform technology to generate evidence on HF10 therapy for use in other chronic pain indications, including chronic upper limb and neck pain, non-surgical back pain, and painful neuropathies. There can be no assurance that we will be successful in generating evidence for HF10 therapy in other indications or in receiving additional regulatory approvals and reimbursement coverage to promote Senza and HF10 therapy for use in other indications. Below are three areas where preliminary results have been promising:

Chronic Upper Limb and Neck Pain

Chronic neck pain with or without upper limb pain is prevalent in 48% of women and 38% of men in the general adult population, with persistent complaints in 22% of women and 16% of men. Multiple treatments currently exist in the market today, such as epidural injections, but there is a lack of clinically efficacious treatments for some patients. In addition, there has been a very small body of evidence published on the application of SCS in chronic neck pain and upper limb pain by placing the leads in the cervical spine. The evidence has suggested limited therapeutic response when traditional SCS therapy is used, where the paresthesia in the cervical spine associated with traditional SCS therapy can create intolerable discomfort, limiting its viability. We believe Senza can overcome this barrier due to its ability to deliver pain relief without paresthesia, combined with its demonstrated superior efficacy relative to the traditional SCS for back and leg pain. The results from our SENZA Upper Limb and Neck study, which were presented at the North America Neuromodulation Society (NANS) conference in January 2019, demonstrated a 76% responder rate for neck pain (n=42) and 83% for upper limb pain (n=24) at three months, the primary endpoint. At twelve months, the responder rate was 89% for neck pain (n=37) and 95% for upper limb pain (n=20). Further, average neck pain scores (as measured on the Visual Analog Scale (VAS)) declined from 7.6 (n=42) at baseline to 2.4 (n=42) at three months and 1.5 (n=37) at twelve months. For upper limb pain, average VAS scores declined from 7.1 (n=19) at baseline to 1.8 (n=24) at three months and 1.0 (n=20) at twelve months.

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. HF10 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 2.5 (12 months, n=11) and 8.1 to 3.4 (24 months, n=14), as well as a decrease in leg pain VAS scores from 7.1 to 2.3 (12 months, n=11) and 5.9 to 2.8 (24 months, n=14). More recent results in patients who were not candidates for major spine surgery and treated with HF10 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 will compare HF10 therapy delivered in conjunction with conventional medical management (CMM) to CMM alone in non-surgical refractory back pain (NSRBP) patients.

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 HF10 therapy could help this patient group. Results of a prospective, multicenter feasibility study treating chronic intractable pain of the limbs from peripheral polyneuropathy using HF10 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 which will compare HF10 therapy combined with conventional medical management (CMM) to CMM alone for patients suffering from painful diabetic neuropathy.

The results we have seen in these chronic pain conditions are consistent with those of our back and leg pain results as seen in the below chart. These initial results led to the initiation of the SENZA-NSRPB and SENZA-PDN RCTs to further build the evidence base for these pain etiologies.

1. Al-Kaisy 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.
2. Kapural L, et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-month Results from a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery. Published 09 2016 [Epub ahead of Print].
3. Al-Kaisy, Adnan, Palmisani, Stefano, Smith, Thomas E. Carganillo, Roy, Houghton, Russell, Pang, David, Burgoyne, William, Lam, Khai, Lucas, Jonathan. Long-Term Improvements in Chronic Axial Low Back Pain Patients Without Previous Spinal Surgery: A Cohort Analysis of 10-kHz High-Frequency Spinal Cord Stimulation over 36 Months. Pain Medicine 2017; 0: 1–8
4. Data file presented at NANS 2019. PPN Feasibility study ongoing, N’s do not reflect total sample size.

Clinical Data

To support development of our proprietary HF10 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 HF10 therapy to traditional SCS therapy on all primary and secondary endpoints through 24 months.
- HF10 therapy was nearly twice as successful in treating back pain as traditional SCS therapy, with 84.3% of patients receiving HF10 therapy reporting 50% or more pain relief at three months, as compared to 43.8% of patients receiving traditional SCS therapy. The superiority of HF10 therapy for treating back pain was maintained through the 24-month follow-up period of the study.
- HF10 therapy was 1.5 times as successful in treating leg pain as traditional SCS therapy, with 83.1% of patients receiving HF10 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 HF10 therapy for treating leg pain was maintained through the 24-month follow-up period of the study.

- HF10 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 HF10 therapy for reducing back pain was maintained through the 24-month follow-up period of the study. HF10 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 HF10 therapy for reducing leg pain was maintained through the 24-month follow-up period of the study. Superiority of HF10 therapy to traditional SCS therapy demonstrated for both back and leg pain at each designated study endpoint throughout 24 months.
- Patients receiving HF10 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 HF10 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 HF10 therapy for achieving remitter status for back pain was maintained through the 24-month follow-up period of the study.
- Two-thirds of HF10 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 HF10 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 HF10 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
Back pain responders								
HF10 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	
Leg pain responders								
HF10 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	
Back pain reduction from Baseline								
HF10 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	
Leg pain reduction from Baseline								
HF10 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 HF10 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 demonstrates the superior efficacy of HF10 therapy over traditional SCS therapy for all primary and secondary endpoints.

The 12-month outcomes for HF10 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 HF10 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 HF10 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 HF10 therapy and 10.3% of traditional SCS therapy subjects) and uncomfortable paresthesia (in 11.3% of traditional SCS therapy subjects and in no HF10 therapy subjects). Lead migration leading to revision occurred in 3.0% of HF10 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 HF10 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.

Our Senza System

The Senza system is approved to create electrical impulses from 2 Hz to 10,000 Hz, including our proprietary HF10 therapy, which allows for pain relief without paresthesia. HF10 therapy delivers proprietary waveforms at 10,000 Hz pulse rate with a statistically driven and clinically verified programming algorithm.

Senza, similar to other commercially available SCS systems, consists of leads, a trial stimulator, an IPG, surgical tools, a clinician laptop programmer, a patient remote control and a mobile charger. These components enable physicians to implant the leads and the IPG, and patients to operate the system.

Implantable Pulse Generator (IPG): The IPG contains a rechargeable battery and electronics that deliver electrical pulses to the lead. It can connect to one or two leads, and up to 16 electrodes. It is a programmable device and can deliver the required customized programs for each patient. The IPG is rechargeable and is placed surgically under the skin, usually above the buttock or the abdomen. The Senza and Senza II SCS systems are CE Marked and FDA-approved with labeling for “at least a 10 year battery life”. The Senza II SCS system received CE Mark clearance in Europe in November of 2017 and FDA approval in January of 2018.

Percutaneous Leads: The percutaneous leads vary in length and are thin, insulated medical wires in a cylindrical, flexible and steerable shape that conduct electrical pulses from the IPG to near the spinal cord. The insertion of the percutaneous leads can also be minimally invasive as they can be inserted in the epidural space through a needle.

Surpass Surgical Leads: The Surpass surgical leads are similar to our percutaneous leads but in a larger paddle-shaped format that provides a larger surface area that broadens exposure of the lead along the vertebrae. Our Surpass surgical leads received initial approval from the FDA in late 2016 with a further approval received in January 2017 and we commenced a controlled commercial launch in early 2017. We believe the availability of Surpass leads gives us access to up to approximately 30% of the U.S. SCS market that we previously did not address without a surgical lead.

Trial Stimulator: The trial stimulator contains electronics that deliver electrical pulses to the lead. It is an external device that is worn around the waist during the evaluation period that typically lasts several days. It is powered by batteries.

Surgical Tools: Surgical tools include percutaneous insertion needles that are 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.

Programmer: The clinician laptop programmer contains proprietary software that allows the customized per patient programming of the IPG. It can non-invasively interrogate the IPG and transmit programming information and download diagnostic information.

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. To charge, the charging coil of the charger is placed over the location of the IPG and then initiated by pushing a button on the charger. The charger is mobile and can be worn around the waist using a belt when charging is needed, so that the patient can perform various tasks while charging. Charging sessions are usually performed daily and are expected to average approximately 45 minutes a day.

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 at a hospital or outpatient surgery center 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 and determined by the relative values of the professional service rendered. 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 addition, CMS and the National Center for Health Statistics (NCHS) are jointly responsible for overseeing changes and modifications to billing codes used by hospitals to report inpatient procedures, known as ICD-10-PCS codes on and after October 1, 2015. In the United States, CMS approved a transitional pass-through payment for High-Frequency Stimulation under the Medicare hospital outpatient prospective payment system effective January 1, 2016 and expired December 31, 2017, assigning a new Healthcare Common Procedure Coding System (HCPCS) Level II billing code to describe High-Frequency Stimulation. This pass-through payment for HF10 therapy was in addition to the established reimbursement for spinal cord stimulation implant procedures and devices. CMS determined that the Senza SCS System delivering HF10 therapy met the criteria for a new transitional pass-through device category based on evidence submitted from our SENZA-RCT study. We believe that SCS procedures using Senza are adequately described by existing CPT, HCPCS II and ICD-10-PCS codes for the implantation of spinal cord stimulators and related leads performed in various sites of care.

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 convince such payors of the advantages of HF10 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, 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.

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 HF10 therapy through enhancements to Senza and the development of new indications. Research and development (R&D) expenses were $33.7 million, $37.6 million and $48.5 million, for the years ended December 31, 2016, 2017 and 2018, 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, 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, second generation clinician programmer software, a second and third generation IPG with improved shape and compatibility for scans of the head and extremities with both 1.5 and 3 Tesla (T) MRI machines, conditional full body MRI approval for our Senza 1000 and 1500 IPG systems in Europe and Australia, and our Surpass surgical lead to complement our percutaneous lead. We also expect to continue developing enhancements to Senza 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 2018, we continued to grow 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 in order to provide ongoing support to physicians and patients for the use of Senza.

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 an additional seven 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

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- 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 launch new products and release additional clinical evidence within the next few years. 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 is performing studies to collect data on existing SCS products for back pain and also testing their high-density programming approach. Additionally, Boston Scientific has commenced a randomized clinical trial of a high-frequency SCS therapy in their Accelerate study and has also presented the results of a sub-threshold therapy through their Whisper study. 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. In November 2015, Nuvectra, a company that was spun-off from Greatbatch, received FDA approval for its SCS system, which is similar to many of the other traditional SCS systems currently on the market.

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, 2018, we owned 170 issued patents globally, of which 105 were issued U.S. utility patents, 2 were issued U.S. design patents, 34 were issued Australian utility patents, one was an Australian design patent, 14 were issued European utility patents, one was a European design patent, 5 were issued German Utility Models, 3 were issued Japanese patents, one was an issued Korean utility patent, one was an issued Korean design patent, two were issued Chinese utility patents and one was an issued Chinese design 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 HF10 therapy. As of December 31, 2018, we held 134 patent applications pending globally, of which 73 were patent applications pending in the United States, and 58 were patent applications pending across Europe, Australia, Canada, Japan, China 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 2038.

As of December 31, 2018, our trademark portfolio contained 29 trademark registrations, of which there were 6 U.S. trademark registrations, 7 Australian trademark registrations, 8 European trademark registrations, one U.K. trademark registration, 2 Japanese trademark registrations, one Norwegian trademark registration, 2 Swiss trademark

registration and 2 Turkish trademark registrations. Our trademark portfolio also contained 8 pending applications, of which 3 are pending U.S. trademark applications and 5 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. 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 have not yet identified and qualified second-source replacements 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 may have difficulty maintaining sufficient production of our products at the standards we require. Where practicable, we seek out and validate second-source manufacturers for our single-source components. We believe that existing third-party

facilities will be adequate to meet our current and anticipated manufacturing needs. We do not currently plan to manufacture the Senza SCS system components ourselves.

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. Our supply agreement is scheduled to expire in July 2019, unless terminated earlier. We may terminate the agreement without cause upon six months' prior written notice, and Pro-Tech may terminate without cause upon 18 months' prior written notice. In addition, we and Pro-Tech have the right to terminate the agreement upon 30 days' prior written notice in the event of the other party's material breach that remains uncured at the end of such 30-day period.

Stellar 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 Greatbatch Ltd., as one of our manufacturers of our IPGs. In April 2012, we entered into our original supply agreement with CCC, which we later amended in March 2013, June 2014 and November 2016. On November 15, 2016, we entered into a new multi-year supply agreement with CCC, pursuant to which CCC agreed to a revised arrangement with regard to the manufacture and

supply of our IPGs. The agreement is effective as of November 11, 2016 and, pursuant to its terms, terminated our existing supply agreement with CCC entered into on March 13, 2015.

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.

Vention 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.

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, guidances, 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. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, though certain Class II devices are exempt from this premarket review process. 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.

Submission and FDA approval of a PMA application is required before marketing of a Class III device can proceed.

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. 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.

The timing of FDA review of an initial PMA application can vary substantially and, in some cases, require several years to complete. The FDA can delay, limit, or deny approval of a PMA application for many reasons, including:

- it is not demonstrated that there is reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended or suggested in the proposed labeling;

- the data from preclinical studies and clinical trials may be insufficient; and
- the manufacturing process, methods, controls or facilities used for the manufacture, processing, packing or installation of the device do not meet applicable requirements.

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If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, 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. 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. For example, if we seek approval to expand the label of Senza to include additional pain indications, we anticipate that we will be required to submit and receive approval for a PMA supplement.

Clinical Studies

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. The FDA or the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

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.

In the European Economic Area (EEA), which is comprised of the 28 Member States of the European Union (EU) plus Norway, Liechtenstein and Iceland, we need to comply with the requirements of the EU Active Implantable Medical Devices Directive (AIMDD) and appropriately affix the CE Mark on our products to attest to such compliance. To achieve compliance, our products must meet the "Essential Requirements" laid down in Annex I of the AIMDD relating to safety and performance. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. The assessment of the conformity of Senza has been certified by our Notified Body (the British Standards Institution, or BSI).

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 studies 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 studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming. Additionally, Senza must continue to comply with the requirements of certain EU Directives.

We are subject to continued surveillance by our Notified Body and will be required to report any serious adverse incidents to the appropriate authorities. We also must comply with additional requirements of individual countries in which our products are marketed.

The assessment of the conformity of Senza with the AIMDD and the Radio and Telecommunications Terminal (R&TTE) Directive has been certified by the BSI.

In April 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform,

transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will however only become applicable three years after publication (in May 2020). Once applicable, the new regulations will among other things:

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

Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market.

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 patient 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 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 which is discussed below. 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. Penalties for a federal civil False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties that range, as of August 1, 2016, from approximately $10,781 to $21,563 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.

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 Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the processing of personal data. The new EU-wide General Data Protection Regulation (GDPR) entered into force in May 2016 and became applicable on May 25, 2018, replacing the current data protection laws of each EU member state. The GDPR will implement 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 pseudonymised (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. The GDPR provides that EU 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 could increase, and harm our business and financial condition.

We are also subject to evolving EU laws on data export, as we may transfer personal data from the EU to other jurisdictions. For example, in 2015, the Court of Justice of the European Union invalidated the U.S.-EU Safe Harbor framework regarding the transfer of personal data from the EU to the U.S. EU and U.S. negotiators agreed in February 2016 to a new framework, the Privacy Shield, which would replace the Safe Harbor framework. However, this framework is under review and there is currently litigation challenging other EU mechanisms for adequate data

transfers (e.g. the standard contractual clauses). It is uncertain whether the Privacy Shield framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the U.S., and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

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.

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 20,000,000 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), 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) 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.

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 Affordable Care Act impacted existing government healthcare programs and resulted in the development of new programs. The Affordable Care Act's provisions of importance include, but are not limited to, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, effective January 1, 2013. In December 2015, Former President Obama signed into law the Consolidated Appropriations Act, 2016, which included a two-year moratorium on the medical device excise tax such that medical device sales in 2016 and 2017 are exempt from the medical device excise tax. As part of continuing resolution legislation signed by the U.S. President and passed by Congress in January 2018, the medical device excise tax moratorium was further extended until January 1, 2020.

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 up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 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 scheduled to begin in 2019 that are based on various

performance measures and physicians' participation in alternative payment models such as accountable care organizations.

There have been judicial and congressional challenges to certain aspects of the ACA. In addition, Congress could consider subsequent legislation to repeal or potentially replace certain elements of the ACA. 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 to any person, including non-UK government officials and 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 for bribes given, offered or promised to any person, including non-UK government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability 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

As of December 31, 2018, we had 804 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.

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. 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. 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 and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could 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.

Risks Related to our Business

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. In May 2015, the FDA approved our PMA to market Senza in the United States and we commenced commercial sales in the United States in mid-2015. We expect to continue to incur losses as we build our U.S. commercial sales force and continue to investigate the use of our HF10 therapy to treat other chronic pain conditions. We incurred net losses of $49.2 million, $36.7 million and $31.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, our accumulated deficit was $306.1 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.

We are substantially dependent on continued market acceptance in the United States for our HF10 therapy, and the failure of our HF10 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 HF10 therapy for the treatment of chronic leg and back pain. Prior to mid-2015, our revenue was derived nearly entirely from sales of Senza in Europe and Australia. Although we received approval of our PMA in May 2015, we are still in the relatively early stages of our commercialization efforts in the United States and have a limited history of commercializing our product in the United States. We have incurred, and anticipate we will in the future incur, significant costs, including costs to continue to build our sales force in order to sustain our commercial sales in the United States. If we are unable to continue 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 Senza and our next generation IPG (Senza II) or are unable to market our products as a result of a quality problem, failure to maintain or obtain additional regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to our HF10 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:

- 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;
- the inability to obtain sufficient supply of the components for Senza 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 HF10 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 HF10 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 are currently, and may in the future become, involved in lawsuits to protect or enforce our intellectual property, which could be 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 system 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.

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 the pending lawsuit filed by 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, in November 2016, we filed a complaint against Boston Scientific Corporation in order to enforce certain of our patents, the ruling of which is currently under appeal, and in February 2019, we filed a lawsuit for patent infringement and false advertisement against Stimwave Technologies. 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.”

We must continue to educate physicians and demonstrate to them the merits of our HF10 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 HF10 therapy and Senza, particularly because Senza and high-frequency neuromodulation treatment is relatively new as compared to existing low-frequency traditional SCS systems. As a result, our success depends, in large part, on effectively marketing our HF10 therapy to physicians, including the results of our pivotal SENZA-RCT study. In order for us to sell Senza, we must successfully demonstrate to physicians the merits of our HF10 therapy compared to our competitors’ SCS systems for use in treating patients with chronic leg and back pain. Acceptance of our HF10 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’ SCS systems, and communicating to physicians the proper application of our HF10 therapy. Physicians typically need to perform several procedures to become comfortable using HF10 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 HF10 therapy or educating them on the use of Senza, they may not use Senza 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 HF10 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 current and potential 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 existing global SCS market in 2018 is estimated to be approximately $2.4 billion, with the United States comprising approximately 80% of the market. 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 trials to demonstrate the results of their SCS systems. The results of these trials 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 Senza, 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 HF10 therapy and Senza for the treatment of chronic pain conditions. Any product we develop that achieves regulatory clearance or approval, including Senza, 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 and salesforce experience and relationships. We face significant competition in the United States and internationally, which we believe will continue to intensify as we grow our presence in the U.S. market. 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 system and Abbott Laboratories launched the Proclaim system. Additionally, we believe that Boston Scientific is in the later stages of a randomized clinical trial of high-frequency SCS therapy and they have presented the results of a sub-threshold therapy through their Whisper study. In addition to these major competitors, we also face competition from smaller companies such as Nuvectra and Stimwave, and may face competition from Saluda, Nalu Medical and Neuspera Medical in the future. 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 enjoy several advantages over us, including:

- more experienced sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;
- earlier regulatory approval;
- long established relationships with physicians and hospitals;
- 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 or approval for products and marketing approved 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 clearance or approvals 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 trial sites and enrolling patients in clinical studies. If our competitors are more successful than we are in these matters, our business may be harmed.

Our success depends on physicians' use of our HF10 therapy to treat chronic back pain.

Our success is dependent on physicians' acceptance and use of our HF10 therapy to treat chronic back pain. We believe a significant limitation of current neuromodulation systems is the limited evidence supporting efficacy of traditional SCS for treating chronic back pain. 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. 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 HF10 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 back pain, our potential to expand the existing neuromodulation market will be significantly limited and our revenue potential will be negatively impacted.

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 Senza 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 sales from sales of Senza to hospitals and outpatient surgery centers 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 Senza 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 Senza 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, 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. This pass-through payment (HCPCS C1822) for HF10 therapy was in addition to the established reimbursement for spinal cord stimulation devices; however, this additional pass-through payment ended on December 31, 2017.

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. Favorable reimbursement decisions from federal 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 HF10 therapy. However, there can be no assurance that all private health insurance plans will cover the product. 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. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. For example, the governmental healthcare system in France has not yet approved reimbursement of Senza. 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.

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

As we continue our commercial launch and increase our 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 that 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.

We do not expect our worldwide revenue growth to continue at historic rates.

Our worldwide revenue has increased from $23.5 million for the year ended December 31, 2013 to $387.3 million for the year ended December 31, 2018. Since May 2015 when we commenced the commercial launch of Senza in the U.S., our worldwide revenue growth has been substantially driven by sales of Senza in the United States. In addition, over the past two years, our revenue growth in international markets has slowed significantly. Despite the significant growth in sales in the U.S., we do not expect to continue this historic rate of revenue growth in the U.S. or on a worldwide basis. Further, due to a number of factors, including governmental reimbursement constraints in the European SCS market limiting the number of annual SCS implants, market pressure in Australia and our current penetration in these markets, we expect minimal, if any, growth in our international markets.

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

The FDA requires manufacturers of medical devices to maintain regulatory approval by filing timely reports and complying with numerous regulations. 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

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- 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 system in the United States.

Failing to maintain FDA approval could result in unexpected and significant costs for us and consume management's time and other resources. The FDA 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 prior to making any modification to the device, and the FDA may revoke the approval 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, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited.

We are currently conducting clinical trials for Senza to explore the potential for HF10 therapy to treat other chronic pain indications, including chronic upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. We will likely need to conduct additional clinical studies in the future to support approval for these new indications. Senza may not be approved for these additional indications.

Traditional SCS has been available for over 50 years, while Senza has only been commercially available since 2010 and, as a result, we have a limited track record compared to our competitors.

Traditional SCS has been commercialized since 1967, while we only began commercializing Senza internationally in 2010 and in the United States since May 2015. Because we have a relatively limited commercial track record compared to our competitors and Senza has been implanted in patients for significantly less time than our competitors' products, physicians may be slower to adopt or recommend Senza. Further, while we believe our international commercial experience and relatively recent U.S. commercial experience, and our European two-year study and U.S. pivotal study support the safety and effectiveness of our HF10 therapy, future studies or patient experience over a longer period of time may indicate that treatment with our HF10 therapy does not achieve non-inferiority status as compared to treatment with competitive products or that our HF10 therapy causes unexpected or serious complications or other unforeseen negative effects. Such results would likely slow the adoption of Senza and significantly reduce our sales, which would harm our business and adversely affect our results of operations.

Furthermore, if patients with traditional SCS implantations were to experience unexpected or serious complications or other unforeseen effects, the market for Senza may be adversely affected, even if such effects are not applicable to Senza.

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

In 2010, we began selling Senza in Europe and, in August 2011, we began selling Senza in Australia. As of December 31, 2018, 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, Kuwait and Ireland. 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;
- 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.

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.

Recently enacted legislation has significantly changed U.S. federal income tax laws, the consequences of which could have a material impact on the value of our deferred tax assets and could increase our future U.S. income tax expense. The legislation could be subject to potential amendments and technical corrections, and will be subject to further interpretation and implementing regulations by the Treasury and Internal Revenue Service (IRS), any of which could mitigate or increase certain adverse effects of the legislation. In addition, it remains unclear how some of these U.S. federal income tax changes will affect state and local taxation.

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.

We are 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 rely on a limited number of suppliers who manufacture and assemble certain components of Senza.

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 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 Senza, impacting our ability to maintain our PMA approval, 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 may require product redesign and possibly submission to FDA, European Economic Area (EEA) Notified Bodies or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;
- one or more of our sole- or single-source suppliers may be unwilling or unable to supply components of Senza, 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 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. 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 Senza, 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 Senza 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 Senza 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. We have not entered into manufacturing, supply or quality agreements with some of 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, 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, 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.

We may not be able to establish or strengthen our brand.

We believe that establishing and strengthening the Nevro and Senza brands is critical to achieving widespread acceptance of HF10 therapy, particularly because of the highly competitive nature of the market for SCS products. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product for successful treatment of chronic leg and back pain. Additionally, we believe the quality and reliability of our product is critical to building physician support of this new therapy in the United States and any negative publicity regarding the quality or reliability of Senza could significantly damage our reputation in the market. Further, given the established nature of our competitors, and our relatively recent commercial launch in the United States, it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our HF10 therapy may not be accepted by physicians, which would adversely affect our business, results of operations and financial

condition.

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

Currently, the gross profit generated from the sale of Senza 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. 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 we fail to properly manage our anticipated growth, our business could suffer.

We have been growing rapidly in recent periods and have a relatively short history of operating as a commercial company. As an organization, we have only relatively recently commercially launched our product in the United States and commenced a sales representative training program. A commercial launch and training program of this size is a significant undertaking that requires substantial financial and managerial resources. We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force in the United States requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

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 European Union (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 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 significant 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 HF10 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 or approval in the United States or elsewhere, we will be unable to commercialize Senza for these indications.

We are currently conducting clinical trials for Senza to explore the potential for HF10 therapy to treat other chronic pain indications, including chronic upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. We will likely need to conduct additional clinical studies in the future to support regulatory approval for the use of Senza 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, EU Competent Authorities 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;
- 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 EEA Member State or other foreign regulations governing clinical trials;
- 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 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.

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 or approval and, ultimately, the commercialization of that device or indication for use.

We could also encounter delays if the FDA 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 trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials 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 concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the FDA 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 the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval 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 trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

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 July 2018, we terminated the employment of our Vice President Worldwide Sales. This is an important role for us and, we believe, will take a significant amount of time to identify, recruit and hire the appropriate candidate. This process will require significant management attention diverting from other areas of our business.

In addition, many of our employees have become, or will soon become, vested in a substantial amount of Company 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.

Failure to protect our information technology infrastructure 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, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. 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.

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 FDA regulatory clearance;
- 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 in the ordinary course of business with respect to intellectual property. For more information regarding our ongoing litigation with Boston Scientific, as well as our lawsuit for patent infringement and false advertisement against Stimwave Technologies, 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, and 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 1.75% convertible senior notes due 2021 (the 2021 Notes). 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.

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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. 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.

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.

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, as well as our Chairman of the Board, 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. Even if we are successful in defending against these claims, litigation

could result in substantial costs and could be a distraction to management. If our defense to those 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 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 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

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, investigate the use of our HF10 therapy for the treatment of other chronic pain conditions, continue to otherwise grow our business 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, 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 trials and obtaining regulatory approvals.

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 Senza and our HF10 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 Senza 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;
    - 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 Senza 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 2021 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.

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:

- physician and payor acceptance of Senza and our HF10 therapy;
- the timing, expense and results of our commercialization efforts in the United States and elsewhere, R&D activities, clinical trials and regulatory approvals;
- our success in initiating patient trials for HF10 therapy and converting those trials into permanent implants;
- fluctuations in our expenses associated with inventory buildup or write-downs from analyzing our inventory for obsolescence or conformity with our product requirements;
- difficulties in collecting receivables related to our sales in the United States;
- fluctuations in the expenses related to pursuing and defending our lawsuits with Boston Scientific;
- fluctuations in expenses as a result of expanding our commercial operations and operating as a public company;
- the introduction of new products and technologies by our competitors;
- the productivity of our sales representatives;
- supplier, manufacturing or quality problems with our products;
- the timing of stocking orders from our distributors;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers; and
- changes in coverage amounts or government and third-party payors' reimbursement policies.

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 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 our commercial launch of 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. 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 and we would be required to record an impairment charge. In addition, we have also experienced inventory write-downs as a result of inventory that did not meet our product requirements. 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, primarily due to the 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 are now experiencing these industry trends to a greater degree than in our initial U.S. commercial launch phase. 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 2021 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, 2018, we had federal and state NOLs of $291.6 million and $124.2 million, respectively, available to offset future taxable income, which if not utilized will begin to expire in 2026 for federal purposes and begin to expire in 2020 for state purposes.

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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 EU legislative bodies and the EEA Member State Competent Authorities. The FDA and other U.S., EEA and foreign governmental agencies and authorities 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 trials;
- product safety;
- marketing, sales and distribution;
- pre-market regulatory clearance and approval;
- 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 EEA 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 or approvals, 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 introduce new or improved products.

Our products must comply with regulatory requirements imposed by the FDA in the United States and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency 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);
- European Union CE Mark requirements;

- Medical Device Quality Management System Requirements (ISO 13485:2003);
- 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 may not approve Senza and any of our future products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals 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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation remains unclear. 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, certain policies of the United States presidential administration may impact our business and industry. Namely, the United States presidential administration has taken 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 how these Executive Orders will be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose constraints on FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In April 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States.

The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will, however, only become fully applicable three years after publication (in May 2020). Once applicable, the Medical Devices Regulation will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
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improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;

- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market.

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.

In the EEA, Senza must comply with the Essential Requirements laid down in Annex I to the EU Active Implantable Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE Mark to Senza, without which Senza cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark to Senza, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (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 studies 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 studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

In order to continue to sell Senza in Europe, we must maintain our CE Mark and continue to comply with certain EU Directives. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by the BSI, which could impair our ability to market products in the EEA in the future.

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, CE Marked in the EEA 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 judgment 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 by the applicable regulatory 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 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.

In April 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will however only become applicable three years after publication (in May 2020). Once applicable, the new regulations will among other things:

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

Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market.

In the EEA, 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 EEA Member State legislation governing the advertising and promotion of medical devices. EEA 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.

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

The FDA, EEA Competent Authorities 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 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 or approvals, 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 EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the EU Medical Devices Directive (Directive 93/42/EEC), an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

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, an EEA Competent Authority 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 Competent Authorities of the EEA countries 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 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, 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;
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, 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;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- 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) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
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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.

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, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, effective January 1, 2013. Subsequently, multiple moratoriums were implemented such that medical device sales in 2016 through 2019 are exempt from the medical device excise tax. The tax is currently due to be automatically reinstated for sales of medical devices on or after January 1, 2020, which will result in a significant increase in the tax burden on our industry. If any efforts we undertake to offset the excise tax are unsuccessful as we sell the product in the United States, the increased tax burden could have an adverse effect on our results of operations and cash flows. Other elements of the ACA, including comparative effectiveness research, an independent payment advisory board and payment system reforms, including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

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 up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 unless additional Congressional action is taken. 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 scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Namely, the United States presidential administration has taken several executive actions, including the issuance of a number of Executive Orders that could have a

significant impact on the ACA. Congress also could consider subsequent legislation to replace elements of the ACA that may be repealed, or could appropriate funding for CSR payments. At this time, the full effect that the ACA, the Executive Orders and any subsequent legislation would have on our business remains unclear. 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.

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 or approval 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 Senza may be used and/or develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval 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 or approvals 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 may be volatile and 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 2021 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:

- 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;
- 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;
- 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;
- any intellectual property infringement actions in which we may become involved, including our lawsuits with Boston Scientific;
- 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;
- 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; and
- the loss of any of our key scientific or management personnel.

Because the 2021 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 2021 Notes. Holders who receive shares of our common stock upon conversion of the 2021 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 2021 Notes and the market price quoted for the 2021 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 2021 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 2021 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.

Recent and future regulatory actions and other events may adversely affect the value and liquidity of the 2021 Notes.

We expect that many investors in, and potential purchasers of, the 2021 Notes will employ, or seek to employ, a convertible arbitrage strategy with respect to the 2021 Notes. Investors would typically implement such a strategy by selling short the common stock underlying the 2021 Notes and dynamically adjusting their short position while continuing to hold the 2021 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. 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 (the Dodd-Frank Act). Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, the 2021 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 value and the liquidity of the 2021 Notes.

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. 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.

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 2021 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 2021 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 2021 Notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options (ASC 470-20). Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the 2021 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 2021 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 2021 Notes. As a result, we are 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 2021 Notes to their face amount over the term of the 2021 Notes. We will report lower net income 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 value of the 2021 Notes.

In addition, under certain circumstances, convertible debt instruments (such as the 2021 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 2021 Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the 2021 Notes exceeds their principal amount. 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. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the

2021 Notes, then our diluted earnings per share would be adversely affected.

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 2021 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 2021 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 2021 Notes to fall.

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 2021 Notes could decline. As of December 31, 2018, we had outstanding a total of approximately 30.3 million shares of common stock, and approximately 7.5 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 2021 Notes could decline.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting

to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. The repurchase right under the 2021 Notes in connection with a fundamental change and any increase in the conversion rate in connection with a make-whole fundamental change could also discourage a potential acquirer.

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.

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 office space in Switzerland and a small amount of warehouse space in San Carlos, California.

For additional information, see Note 6. Commitments and Contingencies of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

ITEM 3. LEGAL PROCEEDINGS

On November 28, 2016, we filed a lawsuit for patent infringement against Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, “Boston Scientific”). The lawsuit, filed in the United States District Court for the Northern District of California (the “Court”), asserts that Boston Scientific is infringing our patents covering inventions relating to our Senza system and HF10 therapy. The lawsuit seeks preliminary and permanent injunctive relief against further infringement as well as damages and attorney’s fees. On July 24, 2018, the Court issued an order on claim construction and summary judgment. In the order, the Court ruled that six asserted method claims in three of the Company’s asserted patents were patent eligible and not invalid as indefinite. Specifically, the claims upheld in the ruling were claims 11, 21 and 23 of U.S. Patent No. 8,359,102; claim 18 of U.S. Patent No. 8,792,988; and claims 1 and 5 of U.S. Patent No. 8,768,472. Collectively, these six claims cover methods for delivering SCS therapy at frequencies between 1.5 kHz and 100 kHz.

The Court, however, found that Boston Scientific is not currently infringing the six upheld method claims. Specifically, the Court found that Boston Scientific's sale of the Spectra WaveWriter systems for commercial use in the United States does not infringe the upheld method claims because the Spectra WaveWriter systems cannot be programmed to generate signals above 1.2 kHz. With regard to the use of the Spectra WaveWriter and the Precision with MultiWave systems in patients that have completed the ACCELERATE clinical trial, the Court found such use to fall within the safe harbor provision of 35 U.S.C. § 271(e). The Court further held that 35 U.S.C. § 271(f) does not apply to method claims, and therefore the sale of the Precision with MultiWave systems in Europe does not infringe the upheld method claims. The Court also found that the asserted system claims in four of the Company's asserted patents were invalid as indefinite. Specifically, the Court invalidated claims 18, 34, and 55 of U.S. Patent No. 9,327,125; claims 5 and 34 of U.S. Patent No. 9,333,357; claims 7, 12, 35, 37, and 58 of U.S. Patent No. 8,712,533; and claims 1 and 22 of U.S. Patent No. 9,480,842.

On July 27, 2018, the parties submitted a joint statement to the Court wherein Boston Scientific asserted to the Court that, with respect to whether any U.S. launch of a high-rate product (such as the Precision with Multiwave and Spectra WaveWriter models used in the ACCELERATE study or any other system that is programmable at any frequency in the range 1.5 to 100 kHz) is imminent, Boston Scientific, as of now, has not decided whether to launch such a product; has not established a timeline for when such a decision might be made, if ever; and has not determined what frequencies would be enabled if it were to decide to launch such a product in the future. Boston Scientific further confirmed its public statements that the ACCELERATE study has been extended into 2019, with an estimated study completion date between April 2019 and November 2019. On the basis of the foregoing, the parties agreed to

dismissal on ripeness grounds of Nevro's declaratory judgment claims without prejudice, each side to bear its own fees and costs as to these claims, and jointly requested that the Court enter such a dismissal. The dismissal was thereafter entered as a court order on July 31, 2018. On that same day, the Company filed a Notice of Appeal with the intent of appealing portions of the Court's July 24th ruling.

On December 9, 2016, Boston Scientific filed a first lawsuit alleging our manufacture, use and sale of the Senza system infringes certain of Boston Scientific's patents covering SCS technology related to stimulation leads,

rechargeable batteries and telemetry. The lawsuit, filed in the United States District Court for the District of Delaware, seeks unspecified damages and attorney's fees, as well as preliminary and permanent injunctive relief against further infringement. This patent infringement lawsuit has been stayed since June 2018, pending completion of inter partes proceedings at the USPTO.

On April 27, 2018, Boston Scientific filed a second lawsuit alleging patent infringement, theft of trade secrets, and tortious interference with contract. The lawsuit, filed in the United States District Court for the District of Delaware, seeks unspecified damages and attorney's fees, as well as preliminary and permanent injunctive relief against further infringement.

On August 23, 2018, the Oklahoma Police Pension and Retirement System filed a putative securities class action complaint against us and certain individual officers alleging violations of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 of the Exchange Act. The lawsuit, filed in the United States District Court for the Northern District of California, seeks unspecified damages and attorneys' fees based on alleged misleading statements or omissions by us and the individual officers regarding our rights in technology underlying the Senza SCS systems and the termination of our former Vice President of Worldwide Sales. On November 3, 2018, a related shareholder derivative lawsuit was filed in the United States District Court for the Northern District of California seeking unspecified damages, injunctive relief and attorneys' fees based on alleged violations of Section 14(a) of the Securities and Exchange Act of 1934, breach of fiduciary duties, unjust enrichment and waste of corporate assets.

In February 2019, we filed a lawsuit for patent infringement against Stimwave Technologies, Inc. ("Stimwave") asserting that Stimwave is infringing our patents covering inventions related to our HF10 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). The lawsuit seeks preliminary and permanent injunctive relief against further infringement as well as damages and attorney fees.

We are and may from time to time continue to be involved in various legal proceedings of a character normally incident to the ordinary course of our business, including several pending European patent oppositions at the European Patent Office initiated by our competitors Medtronic and Boston Scientific, and an entitlement action filed by Boston Scientific in Germany, which we do not deem to be material to our business and consolidated financial statements at this stage.

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 14, 2018, there were approximately 20 stockholders of record of our common stock, and the closing price per share of our common stock was $48.95. 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 stockholder return on our common stock since November 6, 2014, which is the date our common stock first began trading on the NYSE, to two indices: the S&P 500 Composite Index and the S&P Healthcare Equipment Index. 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.

$100 investment in stock or index	November 6, 2014	December 31, 2015	December 31, 2016	December 31, 2017	December 31, 2018
Nevro Corp. (NVRO)	$ 100.00	$ 268.00	$ 288.45	$ 274.08	$ 154.39
S&P 500 (GSPC)	$ 100.00	$ 100.63	$ 110.22	$ 131.63	$ 123.42
S&P Healthcare Equipment (SPSIHE)	$ 100.00	$ 116.37	$ 130.81	$ 170.02	$ 185.74

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data is qualified in its entirety by, and should be read in conjunction with the consolidated financial statements and the notes thereto included in Part II, Item 8 and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II, Item 7 of this Annual Report. The selected consolidated statements of operations data for each of the five years in the period ended December 31, 2018, and the consolidated balance sheet data as of December 31, 2018, 2017, 2016, 2015 and 2014 have been derived from our audited consolidated financial statements.

	Years Ended December 31,				
	2018	2017	2016	2015	2014
(in thousands, except per share data)					
Selected Consolidated Statements of Operations Data:					
Revenue	$387,289	$326,674	$228,504	$69,606	$32,573
Cost of revenue	113,965	98,981	75,433	28,120	11,278
Gross profit	273,324	227,693	153,071	41,486	21,295
Operating expenses:					
Research and development	48,459	37,560	33,729	21,382	19,824
Sales, general and administrative	266,608	219,712	142,423	82,471	29,777
Total operating expenses	315,067	257,272	176,152	103,853	49,601
Loss from operations	(41,743)	(29,579)	(23,081)	(62,367)	(28,306)
Interest and other income (expense), net	(6,694)	(5,671)	(5,806)	(3,898)	(1,896)
Loss on extinguishment of debt	—	—	(1,268)	—	—
Loss before income taxes	(48,437)	(35,250)	(30,155)	(66,265)	(30,202)
Provision for income taxes	768	1,408	1,623	1,166	478
Net loss	$(49,205)	$(36,658)	$(31,778)	$(67,431)	$(30,680)
Net loss per share attributable to common stockholders, basic and diluted	$(1.64)	$(1.25)	$(1.12)	$(2.54)	$(6.94)
Shares used in computing basic and diluted net loss per common share	30,051,961	29,424,054	28,485,003	26,581,890	4,440,663

	Years Ended December 31,				
	2018	2017	2016	2015	2014
(in thousands, except per share data)					
Selected Consolidated Balance Sheet Data:					
Cash and cash equivalents	$51,266	$42,845	$41,406	$87,036	$25,287
Short-term investments	$213,281	$226,467	$234,951	$106,634	$151,521
Working capital	$381,445	$383,177	$378,093	$246,242	$190,327
Total assets	$463,116	$454,056	$430,583	$291,183	$202,496
Long-term debt	$152,394	$145,019	$138,140	$19,740	$19,511
Total stockholders' equity	$245,483	$249,172	$249,034	$234,592	$172,070

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," "po 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 providing innovative products that improve the quality of life of patients suffering from chronic pain. We have developed and commercialized the Senza spinal cord stimulation (SCS) system, an evidence-based neuromodulation platform for the treatment of chronic pain. Our proprietary paresthesia-free HF10 therapy, delivered by our Senza system, was demonstrated in our SENZA-RCT study to be superior to traditional SCS therapy, with Senza 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. Comparatively, traditional SCS therapy has limited efficacy in treating back pain and is used primarily for treating leg pain, limiting its market adoption. Our SENZA-RCT study, along with our European studies, represents what we believe is the most robust body of clinical evidence for any SCS therapy. We believe the superiority of HF10 therapy over traditional SCS therapies will allow us to capitalize on and expand the approximately $2.4 billion existing global SCS market by treating both back and leg pain without paresthesia.

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 HF10 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 surgical lead, marketed as the Surpass surgical lead. In January 2018, we received FDA approval of our next generation Senza II SCS system. 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.

	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018
Revenue from:	(in millions)											
U.S. sales	$29.5	$40.6	$47.2	$56.0	$53.1	$63.0	$66.3	$81.1	$70.6	$79.9	$79.6	$91.6
International sales	12.2	14.8	13.7	14.5	15.3	15.0	16.0	16.9	17.0	16.2	16.0	16.3
Total revenue	$41.7	$55.4	$60.9	$70.5	$68.4	$78.0	$82.3	$98.0	$87.6	$96.1	$95.6	$107.9

	2014	2015	2016	2017	2018
	(in millions)				
Total revenue	$32.6	$69.6	$228.5	$326.7	$387.3

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, 2018 was $306.1 million. A significant amount of

our capital resources has been used to support the development of Senza and our HF10 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, 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.

We rely on third-party suppliers for all of the components of Senza and for the assembly of the system. 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. In particular, we have substantially increased our levels of inventory in order to meet our estimated demand in the United States and, as a result, incur significant expenditures associated with such increases in our inventory. Additionally, as compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times, increasing our risk of inventory obsolescence.

Important Factors Affecting our Results of Operations

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 Senza

We continue to invest in programs to educate physicians who treat chronic 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 Senza, and influencing these physicians to use Senza to treat chronic pain, is required to grow our revenue.

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 Senza and the related implant procedure for patients. The revenue we are able to generate from sales of Senza depends in large part on the availability of reimbursement from such payors. While we currently have a favorable reimbursement decision from federal Medicare, 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 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 and reimbursement decisions for Senza. Favorable reimbursement decisions from federal 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 federal Medicare cover Senza, there can be no assurance that all private health insurance plans will cover the product. A significant number of negative coverage and reimbursement decisions by private insurers may impair our ability or delay our ability to grow our revenue.

Inventory Buildup and Supply Chain Management

Our Senza product consists of a substantial number of individual components and, in order to market and sell Senza 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 substantially increased our levels of inventory. As a result, a significant amount of our cash used in operations has been associated with the increases in our inventory, as demand for Senza in the United States is developing. There may also be times in which we determine that our inventory does not meet our product requirements, as was the case for the years ended December 31, 2018 and 2017, wherein we recorded a write down of inventory of $1.4 million and $3.6 million,

respectively. Further, the manufacturing process for Senza 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.

Investment in Research and Clinical Trials

We intend to continue investing in R&D to expand into new indications and chronic pain conditions for Senza, as well as develop product enhancements to improve outcomes and enhance the physician and patient experience. For example, in early 2017, we commenced controlled commercial launches of Surpass, our surgical lead product, in early 2017 and the next generation Senza II SCS System in late 2017. We are continuing to invest in product improvements to Senza, including enhanced MRI capabilities and a next generation IPG. While R&D and clinical testing are time consuming and costly, we believe expanding into new indications, implementing product improvements and continuing to demonstrate HF10 efficacy, safety and cost effectiveness through clinical data are all critical to increasing the adoption of HF10 therapy.

Significant Investment in U.S. Sales Organization

We are continuing to make significant 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 a commercial infrastructure in the United States and training our sales representatives, and will continue to require significant investment. 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 is required to achieve growth at the rate we expect.

Access to Hospital Facilities

In the United States, in order for physicians to use Senza, the hospital facilities where these physicians treat patients often require us to enter into purchasing contracts. 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 Senza, where the bidding processes are only open at certain periods of time, and we may not be successful in the bidding process.

We Do Not Expect Our Worldwide Revenue Growth Rate to Continue at Historic Rates

Our worldwide revenue has increased from $18.2 million for the year ended December 31, 2012 to $387.3 million for the year ended December 31, 2018. Since May 2015 when we commenced the commercial launch of Senza in the U.S., our worldwide revenue growth has been substantially driven by sales of Senza in the United States. In addition, over the past two years, our revenue growth in international markets has slowed significantly. Despite the significant growth in sales in the U.S., we do not expect to continue this historic rate of revenue growth in the U.S. or on a worldwide basis. Further, due to a number of factors, including governmental reimbursement constraints in the European SCS market limiting the number of annual SCS implants, market pressure in Australia and our current penetration in these markets, we expect minimal, if any, growth in our international markets.

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

On January 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers, using the modified retrospective method applied to contracts which were not completed as of that date. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 605, Revenue Recognition. Under ASC 606, assuming all other revenue recognition criteria have been met, the Company will recognize revenue earlier for arrangements where the Company has satisfied its performance obligations but has not issued invoices. These amounts are recorded as unbilled receivables, which are included in accounts receivable on the consolidated balance sheet, as the Company has an unconditional right to payment at the end of the applicable period.

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.

For further discussion on revenue recognition see Note 3, Revenue, of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

Warranty Obligations

We provide a limited one- to five-year warranty to most customers and we warrant that our products will operate substantially in conformity with product specifications. We record an estimate for the provision for warranty claims in cost of revenue when the related revenues are recognized. This estimate is based on historical and anticipated rates of warranty claims, the cost per claim and the number of units sold. We regularly assess the adequacy of our recorded warranty liabilities and adjusts the amounts as necessary.

Inventory Valuation

We contract with third parties for the manufacturing and packaging of all of the components of Senza. 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 market value. Cost is determined using actual cost on a first-in, first-out basis. Market value is determined as the lower of replacement cost or net realizable value.

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We regularly review inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. Inventory write downs are recorded for excess and obsolete inventory. We periodically assess the recoverability of all inventories to determine whether write downs for impairment are required. We evaluate projected future demand as compared to remaining shelf life and other obsolescence and excess criteria in assessing the recoverability of our inventory. In determining the adequacy of reserves, we analyze the following, among other things:

- Current inventory quantities on hand;
- Product acceptance in the marketplace;
- Customer demand;
- Historical sales;
- Forecast sales;
- Product obsolescence;
- Technological innovations; and
- Character of the inventory as a distributed item, finished manufactured item or system components.

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 have historically used the Staff Accounting Bulletin (SAB) 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period for the period. Starting in late 2016, we have started to utilize our historical data for the calculation of expected term.

Volatility. We have historically determined the price volatility factor based on the historical volatilities of our peer group as we did not have a sufficient trading history for our common stock. Starting in late 2016, we have started to incorporate 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, with the exception of performance based RSUs, which are recognized as expenses when it is determined that achieving the performance metrics are probable.

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 the majority of our net deferred tax assets as of December 31, 2018 and all of the net deferred tax assets as of December 31, 2017. 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, 2018, we had federal and state net operating loss (NOL) carryforwards of $291.6 million and $124.2 million, respectively, due to prior period losses, available to offset future taxable income, which if not utilized will begin to expire in 2026 for federal purposes and will begin to expire in 2020 for state purposes. We have no foreign NOL carryforwards. We also have federal research tax credit carryforwards that will begin to expire in 2026. 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 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. No interest or penalties related to income taxes have been recognized in the statements of operations and comprehensive loss in 2018, 2017 and 2016.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act) was enacted into law. The SEC staff previously issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allowed us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As of December 31, 2018, the SAB 118 measurement period has ended and we have completed our accounting for the income tax effects of the 2017 Tax Act with immaterial adjustments to provisional estimates recorded in previous periods. The recorded impact for the effects of the 2017 Tax Act is based on our current knowledge, assumptions and interpretations of available guidance. We elected to account for Global Intangible Low-Taxed Income (GILTI) as a current period expense when incurred. We will continue to monitor the issuance of additional regulatory or accounting guidance and record any necessary adjustments in the period for which additional guidance is issued.

Allowance for Doubtful Accounts

We must make estimates of the collectability of accounts receivable. In doing so, we analyze historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for doubtful accounts. Our accounts receivable balance was $80.7 million, net of allowance of $0.8 million, as of December 31, 2018 and $67.3 million, net of allowance of $1.3 million, as of December 31, 2017.

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.

Revenue from sales of Senza fluctuate based on the selling price of the system, as the average sales price of a system varies geographically, 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. As we grow, we expect our revenue to be 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. In addition, in the second quarter of 2015, we commenced commercial sales of Senza in the United States. Since then, we have recorded

revenue of approximately $24.4 million, $173.3 million, $263.5 million and $321.8 million for the years ended December 31, 2015, 2016, 2017 and 2018, 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. Cost of revenue consists primarily of acquisition costs of the components of Senza, manufacturing overhead, royalty payments, scrap and inventory obsolescence, 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. We expect our gross margin to be positively affected over time to the extent we are successful in reducing manufacturing costs as our sales volume increases. However, our gross margin may fluctuate from period to period.

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. We expect operating expenses to increase in absolute dollars, as we continue to invest in growing our business.

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 R&D expense to increase in absolute dollars as we continue to develop product enhancements to Senza and develop our HF10 therapy to treat other chronic pain indications, including conducting additional clinical studies for other indications such as chronic upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. 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.

In the last three years, we significantly increased the size of our sales presence worldwide and 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 continue to increase in absolute dollars as we build up our sales and marketing personnel to support commercialization of Senza in the United States, continue to increase the size of our sales and marketing organizations and increase our international presence and develop and assist our channel partners.

During 2017 and 2018, we had a significant increase in SG&A headcount and experienced a significant increase in legal expenses associated with our intellectual property litigation with Boston Scientific. We anticipate significant continued expenses associated with these legal activities. We also expect our administrative expenses to continue to increase as we increase our headcount and expand information technology to support our growing operations. 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 and the timing and extent of our 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.

Allowance for Doubtful Accounts

We make estimates as to the overall collectability of accounts receivable and provide an allowance for accounts receivable considered uncollectible. 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.

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, 2018 and 2017

Revenue, Cost of Revenue, Gross Profit and Gross Margin

	Years Ended December 31,		
	2018	2017	Change
(in thousands)			
Revenue	$387,289	$326,674	$60,615
Cost of revenue	113,965	98,981	14,984
Gross profit	$273,324	$227,693	$45,631
Gross margin	71%	70%	1%

Revenue. Revenue increased to $387.3 million in 2018 from $326.7 million in 2017, an increase of $60.6 million, or 19%, due to increased sales of the Senza system in the United States and continued adoption of the Senza system in international markets where it had historically been sold. The increase in sales of the Senza system was further driven

in part by our expanded sales force in the United States in 2018.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased to $114.0 million in 2018 from $99.0 million in 2017, an increase of $15.0 million, or 15%. This increase was primarily due to a $14.4 million increase in the costs of manufactured product components as sales volumes increased. Gross profit increased to $273.3 million in 2018 from $227.7 million in 2017, an increase of $45.6 million, or 20%. Gross profit as a percentage of revenue, or gross margin, increased to 71% in 2018 compared to 70% in 2017. The increase in gross margin was partly due to lower inventory write downs, but was partly offset by the negative impact on international revenue as a result of the appreciation of the U.S. dollar during 2018.

Operating Expenses

	Years Ended December 31,				
	2018		2017		
	Amount	% of Total Revenue	Amount	% of Total Revenue	Change Amount
(in thousands)					
Operating expenses:					
Research and development	$48,459	13%	$37,560	11%	$10,899
Sales, general and administrative	266,608	69%	219,712	67%	46,896
Total operating expenses	$315,067	81%	$257,272	79%	$57,795

Research and Development (R&D) Expenses. R&D expenses increased to $48.5 million in 2018 from $37.6 million in 2017, an increase of $10.9 million, or 29%. The increase was primarily due to an increase in clinical and development expenses of $4.0 million, headcount and related personnel and consulting costs of $4.8 million and facilities-related and depreciation expenses of $1.2 million.

Sales, General and Administrative (SG&A) Expenses. SG&A expenses increased to $266.6 million in 2018 from $219.7 million in 2017, an increase of $46.9 million, or 21%. This increase was primarily due to an increase in personnel costs of $31.8 million in relation to an increase in headcount for SG&A personnel in support of our continued U.S. commercial launch, increased legal and other professional services costs of $8.0 million, partially associated with legal expenses incurred in connection with the Boston Scientific litigations, increased travel, training and additional hardware expense of $4.5 million, increased other healthcare professional related expenses of $1.6 million and increased depreciation expenses of $0.9 million.

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

	Years Ended December 31,		
	2018	2017	Change
(in thousands)			
Interest income	$4,871	$3,164	$1,707
Interest expense	(10,401)	(9,902)	(499)
Other income (expense), net	(1,164)	1,067	(2,231)
Provision for income taxes	768	1,408	(640)

Interest Income. Interest income increased to $4.9 million in 2018 from $3.2 million in 2017, primarily as a result of an increase in our investment yield rate.

Interest Expense. Interest expense increased to $10.4 million in 2018 from $9.9 million in 2017, primarily as a result of an increase in the amortization of debt discount and debt issuance costs related to the issuance of the 2021 Notes.

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 $0.9 million in 2018 and a net gain of $1.3 million in 2017 in 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.

Income Tax Expense. Income tax expense was $0.8 million in 2018 and $1.4 million in 2017. 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.

Comparison of the Years Ended December 31, 2017 and 2016

Revenue, Cost of Revenue, Gross Profit and Gross Margin

	Years Ended December 31,		
	2017	2016	Change
(in thousands)			
Revenue	$326,674	$228,504	$98,170
Cost of revenue	98,981	75,433	23,548
Gross profit	$227,693	$153,071	$74,622
Gross margin	70%	67%	3%

Revenue. Revenue increased to $326.7 million in 2017 from $228.5 million in 2016, an increase of $98.2 million, or 43%, due to increased sales of the Senza system in the United States and continued adoption of the Senza system in international markets where it had historically been sold. The increase in sales of the Senza system was further driven in part by our expanded sales force in the United States in 2017.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased to $99.0 million in 2017 from $75.4 million in 2016, an increase of $23.5 million, or 31%. This increase was primarily due to a $20.6 million increase in the costs of manufactured product components as sales volumes increased, as well as a $1.4 million increase related to product accessories used as part of ramping our operational infrastructure in the U.S. Gross profit increased to $227.7 million in 2017 from $153.1 million in 2016, an increase of $74.6 million, or 49%. Gross profit as a percentage of revenue, or gross margin, increased to 70% in 2017 compared to 67% in 2016. The increase in gross margin was partly due to lower manufacturing costs as a percentage of sales, but was partly offset by the negative impact on international revenue as a result of the appreciation of the U.S. dollar during 2017.

Operating Expenses

	Years Ended December 31,				
	2017		2016		
	Amount	% of Total Revenue	Amount	% of Total Revenue	Change Amount
(in thousands)					
Operating expenses:					
Research and development	$37,560	11%	$33,729	15%	$3,831
Sales, general and administrative	219,712	67%	142,423	62%	77,289
Total operating expenses	$257,272	79%	$176,152	77%	$81,120

Research and Development (R&D) Expenses. R&D expenses increased to $37.6 million in 2017 from $33.7 million in 2016, an increase of $3.8 million, or 11%. The increase was primarily due to an increase in headcount and related personnel and consulting costs of $6.0 million, which was offset by decreases in other healthcare professional related expenses of $1.3 million and clinical and development expenses of $1.1 million.

Sales, General and Administrative (SG&A) Expenses. SG&A expenses increased to $219.7 million in 2017 from $142.4 million in 2016, an increase of $77.3 million, or 54%. This increase was primarily due to an increase in personnel costs of $47.7 million in relation to an increase in headcount for SG&A personnel in support of our continued U.S. commercial launch, increased legal and other professional services costs primarily associated with legal expenses of $17.8 million incurred in 2017 in connection with the Boston Scientific litigations, increased other healthcare professional related expenses of $5.6 million, increased travel, training and associated supply costs of $4.2 million and additional facilities-related costs of $1.8 million.

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

	Years Ended December 31,		
	2017	2016	Change
(in thousands)			
Interest income	$3,164	$1,685	$1,479
Interest expense	(9,902)	(6,394)	(3,508)
Other income (expense), net	1,067	(1,097)	2,164
Loss on extinguishment of debt	—	(1,268)	1,268
Provision for income taxes	1,408	1,623	(215)

Interest Income. Interest income increased to $3.2 million in 2017 from $1.7 million in 2016, primarily as a result of the increase in average investment balances and an increase in our investment yield rate.

Interest Expense. Interest expense increased to $9.9 million in 2017 from $6.4 million in 2016, primarily as a result of recording a full year of expenses for the amortization of debt discount and debt issuance costs related to the issuance of the 2021 Notes.

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 gain of $1.3 million in 2017 and a net loss of $0.9 million in 2016 in 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.

Loss on Extinguishment of Debt. We paid in full the outstanding obligation under our credit facility in June 2016. The difference between the total payment to the lenders under the credit facility and the net carrying amount of the obligation recorded on our balance sheet was recorded as a loss on extinguishment of debt, which was incurred in 2016.

Income Tax Expense. Income tax expense was $1.4 million in 2017 and $1.6 million in 2016. 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 for 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. At December 31, 2018, we had cash, cash equivalents and short-term investments of $264.5 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.

In June 2016, we paid the outstanding principal and repayment fees under our credit facility with Capital Royalty Partners and certain of its affiliates and terminated the credit facility. As of December 31, 2018, we do not have a credit facility in place.

We expect to incur continued expenditures in the future in connection with the expansion of our U.S. commercial infrastructure and sales force in connection with commercializing Senza in the United States. In addition, we intend to continue to make investments in the development of Senza and HF10 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 with Boston Scientific. 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 costs of commercialization activities related to commercializing Senza 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 Senza 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.

Our success depends, in part, upon our ability to establish a competitive position in the neuromodulation market by securing broad market acceptance of our HF10 therapy and Senza 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,		
	2018	2017	2016
(in thousands)			
Net cash provided by (used in)			
Operating activities	$(5,708)	$(14,273)	$(58,503)
Investing activities	6,433	4,069	(131,787)
Financing activities	7,754	11,199	145,164
Effect of exchange rate on cash flows	(258)	444	(604)
Net increase (decrease) in cash, cash equivalents and restricted cash	$8,221	$1,439	$(45,730)

Cash Used in Operating Activities. Net cash used in operating activities was $5.7 million, $14.3 million and $58.5 million for the years ended December 31, 2018, 2017 and 2016, respectively, primarily due to the net losses during the periods of $49.2 million, $36.7 million and $31.8 million, respectively. The cash used in operating activities for the year ended December 31, 2018 was affected by a net increase in accounts payable and accrued liabilities of $4.9 million and a decrease in inventory of $3.8 million, as well as non-cash stock based compensation expense of $36.6 million, non-cash interest expense of $7.4 million, depreciation and amortization of $3.9 million

and a write down of inventory of $2.0 million. These changes were offset by an increase in accounts receivable of $12.2 million and an increase in other assets of $2.6 million. The cash used in operating activities for the year ended December 31, 2017 was affected by a net increase of $14.4 million in accounts payable and accrued liabilities, as well as non-cash stock based compensation expense of $26.1 million, non-cash interest expense of $6.9 million and a write down of inventories of $4.0 million. These changes were offset by increases in our inventory balances of $16.3 million and accounts receivable of $13.9 million. The cash used in operating activities for the year ended December 31, 2016 was affected by a net increase of $6.6 million in accounts payable and accrued liabilities, as well as non-cash stock based compensation expense of $15.8 million, a write down of inventories of $4.1 million and non-cash interest expense of $3.7 million. These changes were offset by increases in our accounts receivable of $32.2 million and inventory balances of $27.0 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, 2018, we had net proceeds from the sales and maturity of investments of $14.7 million, which was offset by purchases in property and equipment of $8.2 million. For the year ended December 31, 2017, we had net proceeds from the sales and maturity of investments of $8.4 million, which was offset by purchases in property and equipment of $4.3 million. For the year ended December 31, 2016, we had net purchases of investments of $128.4 million and purchases in property and equipment of $3.4 million.

Cash Provided by Financing Activities. Cash provided by financing activities was $7.8 million for the year ended December 31, 2018, primarily due to the cash received from the issuance of common stock to employees of $9.5 million pursuant to the exercise of employee stock options and our employee stock purchase plan. Cash provided by financing activities was $11.2 million for the year ended December 31, 2017, primarily due to the cash received from the issuance of common stock to employees of $12.2 million pursuant to the exercise of employee stock options and our employee stock purchase plan. Cash provided by financing activities was $145.2 million for the year ended December 31, 2016. The majority of this cash was provided by the issuance of $172.5 million in aggregate principal amount of the 2021 Notes. Additionally, in 2016, we received proceeds of $10.3 million from the issuance of common stock to employees pursuant to the exercise of employee stock options and our employee stock purchase plan. The cash received from these activities was partially offset by a net expense of $12.0 million incurred in connection with the purchase of convertible note hedge and warrant transactions, which included the $45.1 million purchase of convertible note hedges and proceeds of $33.1 million related to the sale of warrants. The increase in cash provided by financing activities was partially offset by $6.2 million of issuance costs incurred in connection with the 2021 Notes and $19.5 million used in relation to the repayment of the credit facility.

Contractual Obligations and Commitments

We have lease obligations consisting of operating leases for our principal offices, which expire as set forth below, and for our warehouse space that expires in 2022, as well as for office space in Switzerland that expires in 2019.

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 6, Commitments and

Contingencies, of Notes to Consolidated Financial Statements for additional information.

In August 2014, we entered into a facility lease for warehouse space beginning on August 21, 2014 through May 31, 2015. In March 2015, we extended our warehouse lease through February 2017, at which time the lease terminated.

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.

We have entered into supply agreements with certain of our suppliers that required certain minimum annual purchase agreements. As of December 31, 2018, we had minimum annual purchase commitments of $6.2 million due in 2019 and $6.0 million due in 2020.

We have also entered into a service agreement for which we are committed to pay $2.4 million over the remaining term of the service agreement, as well as a license agreement for which we are committed to pay $0.4 million over the remaining term of license agreement.

As of December 31, 2018, our contractual obligations related to the 2021 Notes are payments of $3.0 million due each year in 2019 and 2020, as well as payments in interest and principal totaling $174.0 million due in 2021.

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

	Payment date by period				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
	(in thousands)				
Notes payable, including contractual interest	$180,047	$ 3,019	$177,028	$—	$ —
Lease obligations	32,852	3,989	9,997	10,780	8,086
Purchase obligations	14,997	7,500	7,397	100	—
Total	$227,896	$ 14,508	$194,422	$10,880	$ 8,086

Off-Balance Sheet Arrangements

Through December 31, 2018, 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 6, 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, 2018, we had cash and cash equivalents of $51.3 million, consisting of cash, money market funds, commercial paper and corporate notes, and short-term investments of $213.3 million, consisting of commercial paper and corporate notes. We maintained investments in money market funds that were not federally insured during the year ended December 31, 2018 and held cash in foreign banks of approximately $4.1 million at December 31, 2018 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 $0.9 million for the year ended December 31, 2018 and gains of $1.3 million for the year ended December 31, 2017 and losses of $0.9 million for the years ended December 31, 2016, respectively. A hypothetical 10% favorable or unfavorable change in the weighted average foreign exchange rates for the year ended December 31, 2018 would have affected the Company’s net loss by approximately 8%. 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. The fair value of our 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 7, 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, 2018 and December 31, 2017, and the related consolidated statements of operations and comprehensive loss, stockholder’ equity and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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, 2018 and December 31, 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018, 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 consoldiated 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.

/s/ PricewaterhouseCoopers LLP

San Jose, California

February 21, 2019

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, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 51,266	$ 42,845
Short-term investments	213,281	226,467
Accounts receivable, net of allowance for doubtful accounts of $824 and $1,333 at December 31, 2018 and 2017, respectively	80,656	67,287
Inventories	92,035	98,119
Prepaid expenses and other current assets	6,621	6,463
Total current assets	443,859	441,181
Property and equipment, net	12,801	8,819
Other assets	5,850	3,250
Restricted cash	606	806
Total assets	$ 463,116	$ 454,056
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 23,505	$ 18,492
Accrued liabilities	38,790	39,390
Other current liabilities	119	122
Total current liabilities	62,414	58,004
Long-term debt	152,394	145,019
Other long-term liabilities	2,825	1,861
Total liabilities	217,633	204,884
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2018 and 2017, respectively; zero shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Common stock, $0.001 par value, 290,000,000 shares authorized at December 31, 2018 and 2017, respectively; 30,263,536 and 29,737,561 shares issued and outstanding at December 31, 2018 and 2017, respectively	30	30
Additional paid-in capital	552,612	508,228
Accumulated other comprehensive loss	(1,077)	(1,242)

Accumulated deficit	(306,082)	(257,844)
Total stockholders' equity	245,483	249,172
Total liabilities and stockholders' equity	$ 463,116	$ 454,056

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,		
	2018	2017	2016
Revenue	$387,289	$326,674	$228,504
Cost of revenue	113,965	98,981	75,433
Gross profit	273,324	227,693	153,071
Operating expenses			
Research and development	48,459	37,560	33,729
Sales, general and administrative	266,608	219,712	142,423
Total operating expenses	315,067	257,272	176,152
Loss from operations	(41,743)	(29,579)	(23,081)
Interest income	4,871	3,164	1,685
Interest expense	(10,401)	(9,902)	(6,394)
Other income (expense), net	(1,164)	1,067	(1,097)
Loss on extinguishment of debt	—	—	(1,268)
Loss before income taxes	(48,437)	(35,250)	(30,155)
Provision for income taxes	768	1,408	1,623
Net loss	(49,205)	(36,658)	(31,778)
Other comprehensive loss:			
Changes in foreign currency translation adjustment	(37)	(360)	(163)
Changes in unrealized gains (losses) on short-term investments, net	202	(204)	(340)
Net change in other comprehensive loss	165	(564)	(503)
Comprehensive loss	$(49,040)	$(37,222)	$(32,281)
Net loss per share, basic and diluted	$(1.64)	$(1.25)	$(1.12)
Weighted average number of common shares used to compute basic and diluted net loss per share	30,051,961	29,424,054	28,485,003

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 Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balances at December 31, 2015	28,143,573	$ 28	$ 424,147	$ (189,408)	$ (175)	$ 234,592
Conversion feature of convertible senior notes due 2021, net of allocated costs	—	—	31,767	—	—	31,767
Purchase of bond hedges	—	—	(45,092)	—	—	(45,092)
Sales of warrants	—	—	33,120	—	—	33,120
Exercise of common stock options	669,337	1	6,807	—	—	6,808
Issuance of common stock upon release of restricted stock units	1,384	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	72,568	—	3,499	—	—	3,499
Vesting of early exercised stock options	—	—	47	—	—	47
Stock based compensation	—	—	15,760	—	—	15,760
Tax benefit from stock option deductions	—	—	814	—	—	814
Net loss	—	—	—	(31,778)	—	(31,778)
Other comprehensive loss	—	—	—	—	(503)	(503)
Balances at December 31, 2016	28,886,862	29	470,869	(221,186)	(678)	249,034
Exercise of common stock options	707,410	1	7,492	—	—	7,493
Issuance of common stock upon release of restricted stock units	83,121	—	—	—	—	—
Shares withheld for tax obligations	(13,094)	—	(991)	—	—	(991)
Issuance of common stock under employee stock purchase plan	73,262	—	4,697	—	—	4,697
Vesting of early exercised stock options	—	—	7	—	—	7
Stock based compensation	—	—	26,154	—	—	26,154
Net loss	—	—	—	(36,658)	—	(36,658)
Other comprehensive loss	—	—	—	—	(564)	(564)
Balances at December 31, 2017	29,737,561	30	508,228	(257,844)	(1,242)	249,172
Adoption of accounting standard (Note 3)	—	—	—	967	—	967
Exercise of common stock options	247,768	—	3,976	—	—	3,976
Issuance of common stock upon release of restricted stock units	196,274	—	—	—	—	—
Shares withheld for tax obligations	(28,107)	—	(1,742)	—	—	(1,742)
	110,040	—	5,520	—	—	5,520

Issuance of common stock under employee stock purchase plan						
Stock based compensation	—	—	36,630	—	—	36,630
Net loss	—	—	—	(49,205)	—	(49,205)
Other comprehensive loss	—	—	—	—	165	165
Balances at December 31, 2018	30,263,536	$ 30	$ 552,612	$ (306,082)	$ (1,077)	$ 245,483

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,		
	2018	2017	2016
Cash flows from operating activities			
Net loss	$(49,205)	$(36,658)	$(31,778)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	3,887	2,507	1,717
Stock-based compensation expense	36,637	26,143	15,760
Accretion of discount on short-term investments	(1,257)	(116)	(231)
Non-cash loss on extinguishment of debt	—	—	1,156
Payment of original issue discount	—	—	(1,500)
Provision for (recovery of) doubtful accounts	(501)	293	909
Write-down of inventory	2,005	3,984	4,056
Loss on disposal of equipment	—	—	287
Non-cash interest expense	7,382	6,884	3,681
Unrealized gains (losses) on foreign currency transactions	1,188	(799)	1,854
Changes in operating assets and liabilities			
Accounts receivable	(12,214)	(13,899)	(32,181)
Inventories	3,846	(16,297)	(27,031)
Prepaid expenses and other current assets	(767)	(501)	(1,997)
Other assets	(2,601)	(892)	(505)
Accounts payable	5,170	2,162	(5,586)
Accrued liabilities	(242)	12,269	12,136
Other long-term liabilities	964	647	750
Net cash used in operating activities	(5,708)	(14,273)	(58,503)
Cash flows from investing activities			
Purchases of short-term investments	(213,723)	(287,938)	(372,309)
Proceeds from sales of short-term investments	—	5,993	—
Proceeds from maturity of short-term investments	228,373	290,341	243,890
Purchases of property and equipment	(8,217)	(4,327)	(3,368)
Net cash provided by (used in) investing activities	6,433	4,069	(131,787)
Cash flows from financing activities			
Proceeds from issuance of convertible notes	—	—	172,500
Convertible notes initial issuance discount and debt issuance costs	—	—	(6,171)
Proceeds from issuance of warrants	—	—	33,120
Purchase of convertible note hedges	—	—	(45,092)
Repayment of debt	—	—	(19,500)
Minimum tax withholding paid on behalf of employees for net share settlement	(1,742)	(991)	—
Proceeds from issuance of common stock to employees	9,496	12,190	10,307
Net cash provided by financing activities	7,754	11,199	145,164
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(258)	444	(604)
Net increase (decrease) in cash, cash equivalents and restricted cash	8,221	1,439	(45,730)

Cash, cash equivalents and restricted cash			
Cash, cash equivalents and restricted cash at beginning of year	43,651	42,212	87,942
Cash, cash equivalents and restricted cash at end of year	$51,872	$43,651	$42,212
Supplemental disclosures of cash flow information			
Cash paid for income taxes	$1,847	$687	$492
Cash paid for interest	$3,019	$3,019	$2,469
Significant non-cash transactions			
Purchases of property and equipment in accounts payable	$245	$592	$725
Vesting of early-exercised stock options	$—	$7	$47

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 and negative cash flows from operations. During the year ended December 31, 2018, the Company incurred a net loss of $49.2 million and used $5.7 million of cash in operations. At December 31, 2018, the Company had an accumulated deficit of $306.1 million and does not expect to experience positive cash flows in the immediate future. 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 and its June 2015 underwritten public offering, as well as its June 2016 underwritten public offering of convertible senior notes due in 2021. 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 November 2014, the Company completed its initial public offering (IPO) of shares of its common stock and as a result, the following transactions were recorded in the Company's consolidated financial statements during the fourth quarter of 2014:

- the sale of 8,050,000 shares of common stock, including 1,050,000 from the exercise by the underwriters of their overallotment option, at an offering price of $18.00 per share, for net proceeds of $131.6 million, after deducting the underwriters' discounts, commissions and offering costs paid by us; and
- immediately prior to the completion of the IPO, all the outstanding shares of the Company's redeemable convertible preferred stock and convertible preferred stock were converted into 15,208,048 shares of common stock.

In June 2015, the Company completed an underwritten public offering of its common stock, which included shares of its common stock held by certain of its stockholders, and issued 2,470,587 shares of common stock, including 705,882 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 $118.4 million, net of underwriting discounts and commissions and offering costs paid by the Company.

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.

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 four wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated.

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

	Years Ended December 31,		
	2018	2017	2016
United States	83%	81%	76%

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 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 $0.6 million during the year ended December 31, 2018, gains of $0.8 million during the year ended December 31, 2017 and losses of $1.6 million during the year ended December 31, 2016. 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 losses of $0.4 million during the year ended December 31, 2018, gains of $0.5 million during the year ended December 31, 2017 and gains of $0.7 million during the year ended December 31, 2016.

As 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 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, 2018 and 2017, and held cash in foreign banks of approximately $4.1 million and $4.5 million at December 31, 2018 and 2017, 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 2021 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 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.

There were no customers that accounted for 10% or more of the Company's revenue for each of the years ended December 31, 2018, 2017 and 2016. Additionally, there were no customers that accounted for 10% or more of the Company's accounts receivable balance as of December 31, 2018 and 2017.

The Company is 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, uncertainty of market acceptance of products and the need to obtain additional financing. The Company is dependent on third party manufacturers and suppliers, in some cases sole- or single-source suppliers.

There can be no assurance that the Company's products or services will continue to be accepted in the marketplace, 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 expects to incur operating losses in the near term and may need to obtain additional financing. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

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. Cash and cash equivalents include money market funds in the amount of $15.6 million and $30.3 million as of December 31, 2018 and 2017, respectively. At December 31, 2018 and 2017, the Company's cash equivalents were held in institutions in the United States and include deposits in a money market fund which were unrestricted as to withdrawal or use.

Restricted Cash

Restricted cash as of December 31, 2018 and 2017 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. Restricted cash as of December 31, 2017 additionally includes certificates of deposit of $0.2 million collateralizing payment of charges related to the Company's credit cards.

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 are classified within Level 1 of the fair value hierarchy, and 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 (accreted) 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 to purchase or manufacture the inventory or the net realizable value of such inventory. Cost is determined using the standard cost method which approximates the first-in, first-out basis. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life to record a provision for excess and obsolete inventory when appropriate.

The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily dependent on the Company's estimates of future demand for a particular product. If the estimate of future demand is 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 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 years ended December 31, 2018, 2017 and 2016, the Company recognized total write downs of $2.0 million, $4.0 million and $4.1 million for its inventories. 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.

See Note 3 for further discussion on Revenue Recognition.

Allowance for Doubtful Accounts

The Company makes estimates of the collectability of accounts receivable. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for doubtful accounts.

Warranty Obligations

The Company provides a limited one- to five-year warranty and warrants that its products will operate substantially in conformity with product specifications. The Company records an estimate for the provision for warranty claims in cost of revenue when the related revenues are recognized. This estimate is based on historical and anticipated rates of warranty claims, the cost per claim and the number of units sold. The Company regularly assesses the adequacy of its recorded warranty obligations and adjusts the amounts as necessary.

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, 2018.

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. No interest or penalties related to income taxes have been recognized in the statements of operations and comprehensive loss in 2018, 2017 and 2016.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act) was enacted into law. The Securities and Exchange Commission (SEC) staff previously issued Staff Accounting Bulletin No. 118 (SAB 118), Income Tax Accounting Implications of the Tax Cuts and Jobs Act, which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As of December 31, 2018, the SAB 118 measurement period has ended, and the Company has completed its accounting for the income tax effects of the 2017 Tax Act with immaterial adjustments to provisional estimates recorded in previous periods. The recorded impact for the effects of the 2017 Tax Act is based on the Company's current knowledge, assumptions and interpretations of available guidance. The Company elected to account for Global Intangible Low-Tax Income (GILTI) as a current period expense when incurred. The Company will continue to monitor the issuance of additional regulatory or accounting guidance and record any necessary adjustments in the period for which additional guidance is issued.

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. The adoption did not result in a cumulative-effect adjustment to accumulated deficit as of January 1, 2017 using the modified retrospective method. 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 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 highly complex and subjective variables. These variables include, but are not limited to, the expected term that options will remain outstanding, the expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends.

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 completion of performance goals. 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.

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 and common stock options 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

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases, which provides clarification to ASU 2016-02, and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which provides another transition method in addition to

the existing transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption (the optional transition method). These ASU's (collectively, the new lease standard) require an entity to recognize assets and liabilities for leases with lease terms of more than 12 months on the balance sheet. The Company plans to adopt the new standard on January 1, 2019 and elect the optional transition method. The

Company will also elect the package of transitional practical expedients such that the Company will not need to reassess whether contracts are leases and will retain lease classification and initial direct costs for leases existing prior to the adoption of the new lease standard. The Company will also elect the hindsight practical expedient. The Company expects that the adoption of the new lease standard will have a material impact on its consolidated balance sheets, primarily related to the recognition of right-of-use assets of approximately $24.3 million to $25.3 million and the recognition of lease liabilities of approximately $25.7 million to $26.7 million. The Company does not expect the adoption of the new lease standard to have a material impact on its consolidated statements of operations

In March 2017, the FASB issued ASU No. 2017-08, Receivables – Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities. This update shortens the premium amortization period for certain purchased callable debt securities held at a premium. ASU 2017-08 is effective for public entities for annual periods beginning after December 15, 2018. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220). This update provides companies with the option to reclassify stranded tax effects caused by the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act) from accumulated other comprehensive income to retained earnings. ASU 2018-02 is effective for public entities for annual periods beginning after December 15, 2018, with early adoption permitted. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-based Payments. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees and aligns the accounting for share-based payments for employees and nonemployees. ASU 2018-07 is effective for public entities for annual periods beginning after December 15, 2018, with early adoption permitted. The guidance should be applied to new awards granted after the date of adoption. The Company is currently evaluating the effect ASU 2018-07 will have on the consolidated financial statements.

3. Revenue

Adoption of ASC 606

On January 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers, using the modified retrospective method applied to contracts which were not completed as of that date. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 605, Revenue Recognition. Under ASC 606, assuming all other revenue recognition criteria have been met, the Company will recognize revenue earlier for arrangements where the Company has satisfied its performance obligations but has not issued invoices. These amounts are recorded as unbilled receivables, which are included in accounts receivable on the consolidated balance sheet, as the Company has an unconditional right to payment at the end of the applicable period.

The Company recognized the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of accumulated deficit. The cumulative effect of the changes made to the consolidated balance sheet as of January 1, 2018 for the adoption of ASC 606 were as follows (in thousands):

	Balance at December 31, 2017	Adjustments Due to ASC 606	Balance at January 1, 2018
Balance Sheet:			
Accounts receivable, net	$67,287	$ 1,447	$68,734
Prepaid expenses and other current assets	6,463	(476)	5,987
Accumulated other comprehensive loss	(1,242)	4	(1,238)
Accumulated deficit	(257,844)	967	(256,877)

In accordance with ASC 606, the disclosure of the impact of adoption on the Consolidated Balance Sheet was as follows (in thousands):

	December 31, 2018		
	Balance As Reported	Balance Without ASC 606 Adoption	Effect of Change
Balance Sheet:			
Accounts receivable, net	$80,656	$ 78,142	$ 2,514
Inventories	92,035	92,126	(91)
Prepaid expenses and other current assets	6,621	7,514	(893)

In accordance with ASC 606, the disclosure of the impact of adoption on the Consolidated Statements of Operations was as follows (in thousands):

	Year Ended December 31, 2018		
	Balance As Reported	Balance Without ASC 606 Adoption	Effect of Change
Statement of Operations:			
Revenue	$387,289	$386,212	$ 1,077
Cost of revenue	113,965	113,441	524

Revenue Recognition

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

	Year Ended December 31, 2018	
	2018	2017
United States	$321,781	$263,462
International	65,508	63,212
Total revenue	$387,289	$326,674

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.

4. 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 includes investments in money market funds that 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. The Company’s cash equivalents and short-term investments also includes commercial paper and corporate notes, which have been classified within 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):

Balance as of December 31, 2018	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (i)	$15,572	$—	$ —	$15,572
Commercial paper (ii)	—	119,602	—	119,602
Corporate notes (ii)	—	111,532	—	111,532
Total assets	$15,572	$231,134	$ —	$246,706

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Balance as of December 31, 2017	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (i)	$30,278	$—	$ —	$30,278
Commercial paper (iii)	—	61,086	—	61,086
Corporate notes (iii)	—	165,381	—	165,381
Total assets	$30,278	$226,467	$ —	$256,745

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

Convertible Senior Notes

As of December 31, 2018, the fair value of the 1.75% convertible senior notes due 2021 was $160.5 million. 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.

5. 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, 2018			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investment Securities				
Commercial paper	$119,692	$ —	$ (90)	$119,602
Corporate notes	111,652	—	(120)	111,532
Total securities	$231,344	$ —	$ (210)	$231,134

	December 31, 2017			
	Amortized Cost	Gross Unrealized	Gross Unrealized	Aggregate Fair Value

		Holding Gains	Holding Losses	
Investment Securities				
Commercial paper	$61,167	$ —	$ (81)	$61,086
Corporate notes	165,712	1	(332)	165,381
Total securities	$226,879	$ 1	$ (413)	$226,467

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, 2018 were as follows (in thousands):

	Amortized Cost	Fair Value
Amounts maturing within one year	$231,344	$231,134
Amounts after one year through five years	—	—
Total investment securities	$231,344	$231,134

Inventories (in thousands)

	December 31,	
	2018	2017
Raw materials	$37,453	$51,602
Finished goods	54,582	46,517
Total inventories	$92,035	$98,119

Property and Equipment, Net (in thousands)

	December 31,	
	2018	2017
Laboratory equipment	$2,874	$2,416
Computer equipment and software	8,751	5,076
Furniture and fixtures	3,903	2,241
Leasehold improvements	4,218	1,221
Construction in process	1,811	2,734
Total	21,557	13,688
Less: Accumulated depreciation and amortization	(8,756)	(4,869)
Property and equipment, net	$12,801	$8,819

Depreciation and amortization expense for the years ended December 31, 2018, 2017 and 2016 was $3.9 million, $2.5 million and $1.7 million, respectively.

Accrued Liabilities (in thousands)

	December 31,	
	2018	2017
Accrued payroll and related expenses	$26,792	$26,108

Accrued professional fees	1,595	4,734
Accrued taxes	2,506	2,827
Accrued clinical and research expenses	1,105	1,279
Accrued interest	243	243
Accrued warranty	1,236	708
Accrued other	5,313	3,491
Total accrued liabilities	$38,790	$39,390

6. 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 April 2017, the Company entered into a second amendment to the lease for a temporary space of 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.

In August 2014, the Company entered into a new facility lease for warehouse space beginning on August 21, 2014 through May 31, 2015, under which it was obligated to pay approximately $100,000 in lease payments over the term of the lease. In March 2015, the Company extended the warehouse lease through February 2017 under which it was obligated to pay approximately $0.3 million in lease payments over the remaining term of the lease.

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.

Rent expense for the years ended December 31, 2018, 2017 and 2016 was $4.0 million, $2.5 million and $2.4 million, respectively.

Future minimum lease payments under operating leases as of December 31, 2018 are as follows (in thousands):

	Leases
Year ending December 31,	
2019	$3,989
2020	4,924
2021	5,073
2022	5,258
2023	5,522
Thereafter	8,086
Total	$32,852

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):

	December 31,	
	2018	2017
Beginning Balance	$708	$645
Provision for warranty	2,334	1,468
Utilization	(1,806)	(1,405)

Ending Balance	$1,236	$708

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, 2018, the Company had minimum annual purchase commitments of $6.2 million due in 2019 and $6.0 million due in 2020.

The Company also entered into a service agreement for which it is committed to pay $2.4 million over the remaining term of the service agreement.

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.

Royalties paid during the years ended December 31, 2018, 2017 and 2016 were $3.1 million, $2.5 million and $1.9 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 $0.4 million over the remaining term of this license agreement, which ends in 2022.

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, 2018 and 2017.

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

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 United States District Court for the Northern District of California (the Court), asserts that Boston Scientific is infringing seven of the Company's patents covering inventions relating to the Senza system and HF10 therapy. The lawsuit seeks preliminary and permanent injunctive relief against further infringement as well as damages and attorney's fees. On July 24, 2018, the Court issued an order on claim construction and summary judgment. In the order, the Court ruled that six asserted method claims in three of the Company's asserted patents were patent eligible and not invalid as indefinite. Specifically, the claims upheld in the ruling were claims 11, 21 and 23 of U.S. Patent No. 8,359,102; claim 18 of U.S. Patent No. 8,792,988; and claims 1 and 5 of U.S. Patent No. 8,768,472. Collectively, these six claims cover methods for delivering SCS therapy at frequencies between 1.5 kHz and 100 kHz.

The Court, however, found that Boston Scientific is not currently infringing the six upheld method claims. Specifically, the Court found that Boston Scientific's sale of the Spectra WaveWriter systems for commercial use in the United States does not infringe the upheld method claims because the Spectra WaveWriter systems cannot be programmed to generate signals above 1.2 kHz. With regard to the use of the Spectra WaveWriter and the Precision with MultiWave systems in patients that have completed the ACCELERATE clinical trial, the Court found such use to fall within the safe harbor provision of 35 U.S.C. § 271(e). The Court further held that 35 U.S.C. § 271(f) does not apply to method claims, and therefore the sale of the Precision with MultiWave systems in Europe does not infringe the upheld method claims. The Court also found that the asserted system claims in four of the Company's asserted patents were invalid as indefinite. Specifically, the Court invalidated claims 18, 34, and 55 of U.S. Patent No. 9,327,125; claims 5 and 34 of U.S. Patent No. 9,333,357; claims 7, 12, 35, 37, and 58 of U.S. Patent No. 8,712,533; and claims 1 and 22 of U.S. Patent No. 9,480,842.

On July 27, 2018, the parties submitted a joint statement to the Court wherein Boston Scientific asserted to the Court that, with respect to whether any U.S. launch of a high-rate product (such as the Precision with Multiwave and Spectra WaveWriter models used in the ACCELERATE study or any other system that is programmable at any frequency in the range 1.5 to 100 kHz) is imminent, Boston Scientific, as of now, has not decided whether to launch such a product; has not established a timeline for when such a decision might be made, if ever; and has not determined what frequencies would be enabled if it were to decide to launch such a product in the future. Boston Scientific further confirmed its public statements that the ACCELERATE study has been extended into 2019, with an estimated study completion date between April 2019 and November 2019. On the basis of the foregoing, the parties agreed to dismissal on ripeness grounds of Nevro's declaratory judgment claims without prejudice, each side to bear its own fees and costs as to these claims, and jointly requested that the Court enter such a dismissal. The dismissal was thereafter

entered as a court order on July 31, 2018. On that same day, the Company filed a Notice of Appeal with the intent of appealing portions of the Court's July 24th ruling.

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 lawsuit, filed in the United States District Court for the District of Delaware, seeks unspecified damages and attorney's fees, as well as preliminary and permanent injunctive relief against further infringement. During this litigation, Boston Scientific unilaterally dismissed their assertions with regard to two of the ten patents. In relation to this lawsuit, the Company filed petitions for inter partes review at the U.S. Patent and Trademark Office (USPTO) against all the eight remaining patents asserted by Boston Scientific. As a result of those petitions, in February 2019, all of the asserted claims of Boston Scientific's U.S. Patent Nos. 6,895,280 and 7,587,241 were found invalid by the Patent Trial and Appeal Board (PTAB) at the USPTO. This patent infringement lawsuit has been stayed pending completion of the inter partes proceedings since June 2018. As of this time, the Company is unable to determine an outcome or potential range of loss.

On April 27, 2018, Boston Scientific filed a second patent lawsuit alleging patent infringement, theft of trade secrets and tortious interference with contract. The lawsuit, filed in the United States District Court for the District of Delaware, seeks unspecified damages and attorney's fees, as well as preliminary and permanent injunctive relief against further infringement. As of this time, the Company is unable to determine an outcome or potential range of loss.

On August 23, 2018, the Oklahoma Police Pension and Retirement System filed a putative securities class action complaint against the Company and certain individual officers alleging violations of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 of the Exchange Act. The lawsuit, filed in the United States District Court for the Northern District of California, seeks unspecified damages and attorneys' fees based on alleged misleading statements or omissions by the Company and the individual officers regarding the Company's rights in technology underlying the Senza SCS systems and the termination of the Company's former Vice President of Worldwide Sales. On November 3, 2018, a related shareholder derivative lawsuit was filed in the United States District Court for the Northern District of California seeking unspecified damages, injunctive relief and attorneys' fees based on alleged violations of Section 14(a) of the Securities and Exchange Act of 1934, breach of fiduciary duties, unjust enrichment and waste of corporate assets.

In February 2019, the Company filed a lawsuit for patent infringement against Stimwave Technologies, Inc. ("Stimwave") asserting that Stimwave is infringing the Company's patents covering inventions related to its HF10 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). The lawsuit seeks preliminary and permanent injunctive relief against further infringement as well as damages and attorney fees.

As of December 31, 2018, the Company did not record a liability, as an outcome or potential loss range cannot be reasonably determined.

The Company is and may from time to time continue to be involved in various legal proceedings of a character normally incident to the ordinary course of its business, including several pending European patent oppositions at the European Patent Office (EPO) initiated by the Company's competitors Medtronic and Boston Scientific, and an entitlement action filed by Boston Scientific in Germany, which the Company does not deem to be material to its business and consolidated financial statements at this stage.

7. Long-term Debt

1.75% Convertible Senior 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 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. It is the Company's current intent and policy to settle conversions through combination settlement with a specified dollar amount per $1,000 principal amount of notes of $1,000. During the three months ended December 31, 2018, the conditions allowing holders of the 2021 Notes to convert have not been met. The 2021 Notes are therefore not convertible during the three months ended March 31, 2019 and are classified as long-term debt. Should the sale price condition be met in a future quarter, the 2021 Notes will be convertible at the holders' option during the immediately following quarter. As of December 31, 2018, the if-converted value of the 2021 Notes did not exceed the principal value of those notes.

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.

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

	December 31,	
	2018	2017
Principal	$172,500	$172,500

Unamortized discount	(17,305)	(23,737)
Unamortized issuance cost	(2,801)	(3,744)
Net carrying amount	$152,394	$145,019

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

	December 31,	
	2018	2017
Debt discount related to value of conversion option	$32,945	$32,945
Debt issuance cost	(1,179)	(1,179)
Net carrying amount	$31,766	$31,766

The following table sets forth the interest expense recognized related to the 2021 Notes (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Contractual interest expense	$3,019	$3,019	$1,652
Amortization of debt discount	6,432	6,046	3,162
Amortization of debt issuance costs	943	833	416
Total interest expense related to the 2021 Notes	$10,394	$9,898	$5,230

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.

Capital Royalty Term Loan

On October 24, 2014, the Company entered into a credit facility (the "credit facility") with Capital Royalty Partners and certain of its affiliates (the "lenders") under which, subject to certain conditions, the Company could enter into three term loan agreements totaling $50.0 million with the lenders on or before September 30, 2015. In June 2016, the Company paid the outstanding principal and repayment fees totaling $21.0 million to the lenders, and the credit facility terminated and is now no longer in effect. The difference between the total payment to the lenders and the net carrying amount of the obligation recorded on the balance sheet was recorded as a loss on extinguishment of debt.

8. 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.

9. Stock-Based Compensation

Common stock reserved for future issuance as of December 31, 2018 was as follows:

	December 31, 2018
Outstanding stock options and restricted stock units	3,539,863
Reserved for grants of future stock options and restricted stock units	2,980,762
Reserved for employee stock purchase plan	1,023,970
Total common stock reserved for future issuance	7,544,595

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 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 CEO in March 2016. This performance based stock option award is subject to the 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 award agreements, the shares subject to vesting under the vesting tranche for that performance metric will be cancelled.

A summary of shares available for grant under the Stock Plans is as follows:

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	Shares Available for Grant
Balance at December 31, 2015	1,856,709
Additional shares reserved	1,125,742
Options and restricted stock granted	(856,043)
Options and restricted stock cancelled	75,831
Balance at December 31, 2016	2,202,239
Additional shares reserved	1,155,474
Shares forfeited for tax	13,094
Options and restricted stock granted	(1,002,063)
Options and restricted stock cancelled	97,502
Balance at December 31, 2017	2,466,246
Additional shares reserved	1,189,502
Shares forfeited for tax	28,107
Options and restricted stock granted	(805,653)
Options and restricted stock cancelled	102,560
Balance at December 31, 2018	2,980,762

A summary of stock option activity under the Stock Plans is as follows:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	3,050,288	$ 19.74	7.8	$ 145,721
Options granted	498,564	$ 66.74		
Options exercised	(667,494)	$ 10.19		$ 46,529
Options cancelled	(60,131)	$ 40.89		
Outstanding at December 31, 2016	2,821,227	$ 29.85	7.4	$ 123,425
Options granted	503,690	$ 74.71		
Options exercised	(707,410)	$ 10.59		$ 50,971
Options cancelled	(57,535)	$ 46.83		
Outstanding at December 31, 2017	2,559,972	$ 43.62	7.3	$ 71,120
Options granted	236,900	$ 47.96		
Options exercised	(247,768)	$ 16.05		$ 15,468
Options cancelled	(19,364)	$ 44.70		
Outstanding at December 31, 2018	2,529,740	$ 46.72	6.7	$ 21,866
Options exercisable as of December 31, 2018	2,478,361	$ 46.40	6.7	$ 21,866
Options vested, exercisable or expected to vest as of December 31, 2018	1,700,383	$ 38.33	5.8	$ 21,866

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 years ended December 31, 2018, 2017 and 2016 was $23.27, $32.35 and $32.11 per share, respectively. The total fair value of options vested during the years ended December 31, 2018, 2017 and 2016 was approximately $14.0 million, $13.3 million and $10.7 million, respectively, based on the grant date fair value.

The options outstanding and vested under the Stock Plans by exercise price, at December 31, 2018, were as follows:

	Options Outstanding			Options Vested	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.44 — $18.00	717,786	4.29	$ 8.62	717,786	$ 8.62
$32.51 — $53.70	517,192	7.32	$ 43.87	315,285	$ 44.40
$54.50 — $63.23	543,534	6.96	$ 58.63	362,733	$ 59.17
$63.39 — $76.81	591,830	8.59	$ 73.13	221,697	$ 72.83
$86.90 — $97.52	159,398	7.89	$ 88.84	82,882	$ 89.05
$1.44 — $97.52	2,529,740	6.72	$ 46.72	1,700,383	$ 38.33

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.

Pursuant to the 2014 Plan, the Company granted performance based RSUs to the CEO in March 2016. The performance based RSUs are subject to the 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.

A summary of RSUs activity under the Stock Plans was as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	5,160	$ 56.09	$ 348
Restricted stock granted	357,479	$ 70.31	
Restricted stock released	(1,384)	$ 56.65	$ 115
Restricted stock cancelled	(15,700)	$ 65.15	
Outstanding at December 31, 2016	345,555	$ 70.39	$ 25,108
Restricted stock granted	498,373	$ 82.60	
Restricted stock released	(83,121)	$ 69.90	$ 1,175
Restricted stock cancelled	(39,967)	$ 81.57	
Outstanding at December 31, 2017	720,840	$ 78.26	$ 49,767
Restricted stock granted	568,753	$ 68.09	
Restricted stock released	(196,274)	$ 77.43	$ 968
Restricted stock cancelled	(83,196)	$ 81.73	
Outstanding at December 31, 2018	1,010,123	$ 72.41	$ 39,284
Restricted stock expected to vest as of	930,205		$ 36,176

December 31, 2018

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.

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,		
	2018	2017	2016
Additional shares reserved	297,375	288,868	281,435
Shares issued	110,040	73,262	72,568
Shares available for future issuance	1,023,970	836,635	621,029
Employee contributions for shares issued (in thousands)	$5,521	$4,697	$3,499

Early Exercises

Stock options previously granted under the 2007 Plan allowed the Board of Directors to grant awards to provide employee option holders the right to elect to exercise unvested options in exchange for restricted common stock. Unvested shares, which amounted to 0 at December 31, 2018, 0 at December 31, 2017 and 1,836 at December 31, 2016, were subject to a repurchase right held by the Company at the original issue price in the event the optionees' employment was terminated either voluntarily or involuntarily. For exercises of employee options, this right lapses according to the vesting schedule designated on the associated option grant. The repurchase terms are considered to be a forfeiture provision. The shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be issued or outstanding for accounting purposes until those shares vest, though they are legally issued and outstanding. In addition, cash received from employees for exercise of unvested options is treated as a refundable deposit shown as a liability on the consolidated balance sheets. As of December 31, 2018 and 2017, there was no cash received related to unvested shares, respectively. Amounts recorded are transferred into common stock and additional paid-in-capital as the shares vest.

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 when performance metrics are achieved. The following assumptions were used in estimating the fair value:

	Years Ended December 31,		
	2018	2017	2016
Stock Options:			
Expected term (in years)	5.5	5.5	5.3 — 6.1
Expected volatility	44%	44% — 51%	46% — 47% — 49%
Risk-free interest rate	2.3%	1.8% — 2.9%	2.2% — 1.3% — 1.9%
Dividend Yield	0%	0%	0%

ESPP:			
Expected term (in years)	0.5	0.5	0.5
Expected volatility	44%	36% — 57%	37% — 46% — 53%
Risk-free interest rate	2.1%	1.0% — 2.5%	0.4% — 0.4% — 0.6%
Dividend Yield	0%	0%	0%

Expected Term. The expected term of stock-based awards represents the weighted-average period that the stock-based awards are expected to remain outstanding. The Company has historically opted to use the “simplified method” for estimating the expected term of the awards, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the awards. Starting in late 2016, the Company started to utilize its own historical data for the calculation of expected term.

Expected Volatility. The Company has historically determined the share price volatility for stock-based awards based on an analysis of the historical volatilities of a peer group of publicly traded medical device companies. Starting in late 2016, the Company has started to incorporate its own stock trading volatility with those of its peer group for the calculation of volatility. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the stock-based awards.

Dividend Rate. The expected dividend was assumed to be zero as the Company has never paid dividends and has no current plans to do so.

Expected Forfeiture Rate. The Company is required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period that the estimates are revised.

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, with the exception of performance based awards whose fair value is recorded as an expense when performance metrics are achieved.

A summary of pre-tax stock-based compensation expense by line items in the consolidated statements of operations was as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Cost of revenue	$2,656	$1,878	$1,094
Research and development	5,871	4,601	3,182
Sales, general and administrative	28,110	19,664	11,484
Total stock-based compensation expense	$36,637	$26,143	$15,760

A summary of pre-tax stock-based compensation expense by category was as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Stock options	$13,765	$13,412	$10,832
Restricted stock units	21,006	11,197	3,548
Employee stock purchase plan	1,866	1,534	1,380
Total stock-based compensation expense	$36,637	$26,143	$15,760

As of December 31, 2018, total stock-based compensation expense not yet recognized, net of estimated forfeitures, were as follows:

	Unrecognized Compensation (in thousands)	Weighted-Average Amortization Period (in years)
Stock options	$ 19,545	2.5
Restricted stock units	57,310	2.8
Employee stock purchase plan	1,107	0.4

10. Income Taxes

The components of the Company's loss before income taxes were as follows:

	Years Ended December 31,		
	2018	2017	2016
	(in thousands)		
Domestic	$(52,755)	$(39,370)	$(34,258)
Foreign	4,318	4,120	4,103
Total loss before income taxes	$(48,437)	$(35,250)	$(30,155)

The components of the provision for income taxes are as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Current:			
Federal	$—	$—	$—
State	220	170	181
Foreign	1,477	1,238	1,442
Total current	1,697	1,408	1,623
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	(929)	—	—
Total deferred	(929)	—	—
Total provision for income taxes	$768	$1,408	$1,623

Income tax expense differs from the amount computed by applying the statutory federal income tax rate as follows:

	Years Ended December 31,		
	2018	2017	2016
Tax at statutory federal rate	21.0 %	34.0 %	34.0 %
State tax, net of federal benefit	(0.4)%	(0.4)%	(0.4)%
Other	(4.9)%	(4.4)%	(3.7)%
Foreign rate differential	(1.0)%	0.5 %	(0.2)%
Tax credits	2.8 %	4.5 %	3.2 %
Excess tax benefits related to stock-based compensation	2.0 %	21.5 %	— %
Effect of Tax Cuts and Jobs Act of 2017	— %	(121.1)%	— %

Change in valuation allowance	(21.2)%	61.4 %	(38.4)%
Total	(1.7)%	(4.0)%	(5.5)%

The tax effects of temporary differences and carryforwards that give rise to significant portions of deferred tax assets are as follows:

	December 31,	
	2018	2017
	(in thousands)	
Net operating loss carryforwards	$68,552	$60,999
Tax credits	12,451	10,198
Depreciation	339	133
Stock-based compensation	10,770	6,983
Accruals and reserves	7,507	7,280
Other	2,057	2,525
Deferred tax assets	101,676	88,118
Other	—	—
Deferred tax liabilities	—	—
Valuation allowance	(100,747)	(88,118)
Net deferred tax assets	$929	$—

The 2017 Tax Act reduces the U.S. statutory corporate tax rate to 21% for the Company's tax years beginning in 2018, which resulted in the re-measurement of the Company's federal deferred tax assets as of December 31, 2017 from 34% to the new 21% tax rate. The Company has established a full valuation allowance against its federal and state deferred tax assets due to the uncertainty surrounding realization of these assets.

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 $12.6 million, $2.4 million and $18.7 million for the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, the Company had net operating loss carryforwards (NOLs) for federal and state income tax purposes of approximately $291.6 million and $124.2 million, respectively. These NOLs are available to reduce future taxable income, if any. The federal NOLs begin expiring in 2026, and the state NOLs begin expiring in 2020.

As of December 31, 2018, the Company had research and development credit carryforwards of approximately $9.6 million and $6.8 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 $5.2 million as of December 31, 2018. The deferred tax assets associated with these UTBs are fully offset by a valuation allowance. The following table summarizes the activity related to UTBs (in thousands):

Balance at December 31, 2015	$3,844
Increases related to current year tax provisions	1,059
Decreases related to prior year tax provisions	(1,519)
Balance at December 31, 2016	3,384
Increases related to current year tax provisions	790
Increases related to prior year tax provisions	193
Decreases related to prior year tax provisions	(134)
Balance at December 31, 2017	4,233
Increases related to current year tax provisions	893
Increases related to prior year tax provisions	80
Decreases related to prior year tax provisions	(6)
Balance at December 31, 2018	$5,200

All of these UTBs, if recognized, would affect the effective tax rate before consideration of the valuation allowance.

In accordance with ASC 740, Income Taxes, the Company is classifying interest and penalties as a component of tax expense. There were no interest or penalties accrued at December 31, 2018, December 31, 2017, and December 31, 2016.

The Company files U.S. federal and state income tax and foreign income tax returns with varying statues of limitations. The Company’s tax years from inception in 2006 will remain open to examination due to the carryover of the unused NOLs and tax credits. The Company does not have any tax audits or other proceedings pending.

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.

11. 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,		
	2018	2017	2016
Net loss	$(49,205)	$(36,658)	$(31,778)
Weighted average shares outstanding	30,051,961	29,424,360	28,492,091
Less: weighted average shares subject to repurchase	—	(306)	(7,088)
Weighted average shares used to compute basic and diluted net loss per share	30,051,961	29,424,054	28,485,003

Net loss per share, basic and diluted	$(1.64)	$(1.25)	$(1.12)

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. 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,		
	2018	2017	2016
Unreleased restricted stock	1,010,123	720,840	345,555
Options to purchase common stock	2,529,740	2,559,972	2,821,227
Convertible senior notes	1,790,033	1,790,033	1,790,033
Warrants related to the issuance of convertible senior notes	1,790,033	1,790,033	1,790,033
Total	7,119,929	6,860,878	6,746,848

Additionally, since the Company expects to settle the principal amount of its outstanding convertible senior notes in cash, the Company uses the treasury stock method for calculating any potential dilutive effect of the conversion spread on diluted net income per share, if applicable. The conversion spread 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 $96.37 per share for the 2021 Notes, which has not occurred as of December 31, 2018. In connection with the issuance of the 2021 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, 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.

12. 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, 2018, 2017 and 2016, the Company recorded expenses of $2.5 million, $2.2 million and $1.3 million for matching contributions, respectively.

13. Selected Quarterly Financial Information (Unaudited)

	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
	(in thousands, except per share data)			
Total revenue	$107,944	$95,630	$96,080	$87,635
Gross profit	$76,154	$67,248	$67,921	$62,001
Loss from operations	$(8,603)	$(9,237)	$(8,201)	$(15,702)
Net loss	$(9,607)	$(11,265)	$(10,620)	$(17,713)
Net loss per share, basic and diluted	$(0.32)	$(0.37)	$(0.35)	$(0.59)
Shares used in computing net loss per common share, basic and diluted	30,214,454	30,123,188	30,028,985	29,836,277

	Three Months Ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
	(in thousands, except per share data)			
Total revenue	$97,963	$82,256	$78,016	$68,439
Gross profit	$69,512	$57,940	$53,873	$46,368
Loss from operations	$(2,172)	$(4,418)	$(9,938)	$(13,051)
Net loss	$(4,311)	$(6,230)	$(11,610)	$(14,507)
Net loss per share, basic and diluted	$(0.15)	$(0.21)	$(0.40)	$(0.50)
Shares used in computing net loss per common share, basic and diluted	29,664,926	29,513,842	29,351,414	29,159,509

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, 2018, 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, 2018, the end 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, 2018, 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, 2018 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.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Significant Employee and Non-Employee Directors of the Registrant

The following table sets forth information regarding our executive officers, significant employees and directors, as of February 1, 2019:

Name	Age	Position(s)
Executive Officers		
Rami Elghandour	40	President and Chief Executive Officer
Andrew H. Galligan	62	Chief Financial Officer
Doug Alleavitch	58	Vice President, Quality
Christofer Christoforou	49	Vice President, Research and Development
Kashif Rashid	45	General Counsel
Patrick Schmitz	59	Vice President, Operations
Significant Employees		
David Caraway, M.D., Ph.D.	62	Chief Medical Officer
Richard B. Carter	48	Vice President of Finance, Corporate Controller
Divya Ghatak	48	Vice President, Human Resources
Bradford E. Gliner	53	Vice President, Clinical & Regulatory Affairs
Katherine H. Neuenfeldt	40	Vice President, Market Access
Neeraj Teotia	44	Vice President, Marketing
Non-Employee Directors		
Michael DeMane	62	Chairman of the Board
Ali Behbahani, M.D.[2][3]	42	Director
Lisa D. Earnhardt[1][3]	49	Director
Frank Fischer[3]	77	Director
Wilfred E. Jaeger, M.D.[1][2]	63	Director
Shawn T McCormick[1]	54	Director
Brad Vale, Ph.D., D.V.M.[2]	66	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Rami Elghandour joined us in October 2012, and has served as our Chief Business Officer and currently serves as our President and Chief Executive Officer. From September 2008 to October 2012, Mr. Elghandour managed investments for Johnson & Johnson Development Corporation, or JJDC, where he led several investments and served on the board of directors of a number of private companies, including our board of directors. Additionally, he led strategic initiatives in the development and management of JJDC's portfolio. From 2001 to 2006, Mr. Elghandour worked for Advanced Neuromodulation Systems, Inc. (acquired by St. Jude Medical), a medical device company, where he led

firmware design and development on several implantable neurostimulators. Mr. Elghandour received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. in Electrical and Computer Engineering from Rutgers University School of Engineering. We believe that Mr. Elghandour is qualified to serve on our Board due to his investment and engineering experience, strategic track record, and his service as our President and Chief Executive Officer.

Andrew H. Galligan has served as our Chief Financial Officer since May 2010. From February 2009 to July 2010, Mr. Galligan served as Vice President of Finance and Chief Financial Officer at Ooma, a consumer electronics manufacturer and VOIP service provider. From 2007 to 2008, Mr. Galligan served as Vice President of Finance and CFO of Reliant Technologies, Inc. (later acquired by Solta Medical, Inc.), a medical device company. Mr. Galligan has also held the top financial executive position at several other medical device companies and began

his career in various financial positions at KPMG and Raychem Corp. Mr. Galligan has served on the board of directors at OOMA, a publicly held consumer telecommunications company, since December 2014. Mr. Galligan also served on the board of directors of DiaDexus, Inc., a public medical diagnostics company, until January 2015. Mr. Galligan received a degree in Business Studies from Trinity College in Dublin, Ireland and is also a Fellow of the Institute of Chartered Accountants in Ireland.

Doug Alleavitch has served as our Vice President, Quality since April 2015. From October 2009 to April 2015, Mr. Alleavitch served as Vice President, Operations and Quality Assurance at AEGEA Medical, Inc., a medical device company, where he oversaw manufacturing and quality assurance procedures. From August 2007 to September 2009, Mr. Alleavitch served first as Senior Director, Manufacturing and later as Vice President, Operations at AngioScore, Inc., a medical device company, where he oversaw AngioScore's production, supply chain management and manufacturing engineering. From February 2002 to July 2007, Mr. Alleavitch served first as Director, Quality Assurance and later as Director, Operations at Boston Scientific, a medical device company. Mr. Alleavitch received a BS in Chemical Engineering from Cornell University, an M.S. in Industrial Engineering, and an M.B.A. from the University of Illinois, and an M.S. in Chemical Engineering from the Illinois Institute of Technology.

Christofer Christoforou has served as our Vice President, Research and Development since July 2016. From December 2014 to July 2016, Mr. Christoforou served as Vice President, Quality Engineering at Thoratec Corporation, a medical device company where he oversaw the operational, design and supplier quality engineering functions. From October 1999 to December 2014, Mr. Christoforou served in several leadership positions of increasing levels of responsibility at Thoratec Corporation. From August 1993 to February 1999, Mr. Christoforou served as a Manager of Engineering and various Engineering positions for United States Surgical Corporation, a producer of tools for use in surgery. Mr. Christoforou received a B.S. in Biomedical Engineering from Boston University and a M.S. in Biomedical Engineering from The Johns Hopkins University in Maryland.

Kashif Rashid has served as our General Counsel, Corporate Secretary and Chief Compliance Officer since December 2017. From March 2017 to December 2017, Mr. Rashid served as Vice President, Legal at Atara Biotherapeutics, Inc., a biotechnology company focused on T-cell immunotherapy. From June 2008 to February 2017, Mr. Rashid served first as Associate General Counsel and later as Deputy General Counsel at St. Jude Medical, Inc., a medical device company. From September 1998 to June 2008, Mr. Rashid served in roles of increasing responsibility at General Electric Company's Healthcare business, Loews Corporation and Kaye Scholer, LLP, a global law firm. Mr. Rashid received a B.S. in Business Administration from the George Washington University and a J.D. from Georgetown University Law Center.

Patrick Schmitz has served as our Vice President, Operations since March 2016. From 2005 to October 2015, Mr. Schmitz served as Vice President, Operations at Thoratec Corporation, a medical device company, where he oversaw all domestic and international operations. From 2003 to 2005, Mr. Schmitz served as Vice President, North American Operations at GN ReSound, a medical device company. Mr. Schmitz also held several leadership positions in increasing levels of responsibility at St. Jude from 1993 to 2003. Mr. Schmitz holds a B.S. in Industrial Technology from the University of Wisconsin – Stout.

Significant Employees

David Caraway, M.D., Ph.D. has served as our Chief Medical Officer since April 2014. Before joining Nevro, from 2001 to May 2014, Dr. Caraway was the CEO of The Center for Pain Relief, Tri-State, L.L.C., in partnership with St. Mary's Regional Medical Center in Huntington, West Virginia. Dr. Caraway has maintained an active medical practice for over 20 years and has held leadership positions in the North American Neuromodulation and the American Society of Interventional Pain Physicians. As a nationally recognized expert in the treatment of chronic pain, he has lectured regionally, nationally and internationally in the field of Interventional Pain Medicine and

authored numerous publications in this field. Dr. Caraway received a B.S. in chemical engineering from the University of Virginia School of Engineering, an M.D. from the University of Virginia School of Medicine and a Ph.D. in biophysics from the University of Virginia Graduate School of Arts and Sciences. He also received post-graduate training in anesthesiology and pain management from the University of Virginia. Dr. Caraway is board certified by the American Board of Anesthesiology.

Richard B. Carter has served as our Vice President of Finance, Corporate Controller since November 2015, having held roles of increasing responsibility in finance and accounting since joining Nevro as Corporate Controller in September 2014. From October 2013 to October 2014, Mr. Carter served as Corporate Controller at ClearEdge Power, Inc., a privately held fuel cell manufacturing company. From December 2011 to October 2013, Mr. Carter served as the Vice President of Finance and Corporate Controller at Kovio, Inc., a privately held electronic device manufacturing company. From March 2007 to December 2011, Mr. Carter served as Vice President of Finance and Corporate Controller at MiaSolé, a thin-film solar panel manufacturer. Previously, Mr. Carter served as the Corporate Controller at PortalPlayer, Inc. and Transmeta Corporation, both publicly traded fabless semiconductor companies. Mr. Carter received a B.S. in Business Administration from California State University, Chico. Mr. Carter is a Certified Public Accountant (inactive license) and began his career as an auditor at Ernst & Young, LLP.

Divya Ghatak has served as our Vice President, Human Resources since April 2017. From January 2014 to April 2017, Ms. Ghatak served as Chief People Officer at GoodData, a data products and business intelligence company. From June 2007 to September 2013, Ms. Ghatak held various leadership roles at Cisco Systems. From October 2004 to June 2007, Ms. Ghatak held several leadership roles at Tavant Technologies. From January 1999 to September 2004, Ms. Ghatak founded and ran her own executive search firm. Ms. Ghatak received a B.A. in Economics from Delhi University and an M.A. in Human Resources from Tata Institute of Social Sciences in Mumbai, India.

Bradford E. Gliner has served as our Vice President, Clinical and Regulatory Affairs since May 2011. From 2008 to May 2011, Mr. Gliner was President and CEO at MitoGuard Neuroscience, Inc., a photobiomodulation medical device company. From 1999 to 2008, Mr. Gliner was Vice President of Research at Northstar Neuroscience, Inc., a medical device company, where he led research on numerous neuromodulation applications. From 1992 to 1999, Mr. Gliner was also a co-founder of Heartstream, Inc. (acquired by Koninklijke Philips Electronics NV), a medical device company that manufactures and markets automatic external defibrillators. Mr. Gliner received a B.S. in Electrical Engineering from the University of Illinois and a M.S. in Biomedical Engineering from Johns Hopkins University in Maryland.

Katherine H. Neuenfeldt has served as our Vice President, Market Access since June 2017, having held roles of increasing responsibility since joining Nevro as a Senior Director, Marketing in October 2013. Ms. Neuenfeldt joined the product marketing team at Medtronic in October 2008 and held increasing roles of responsibility and served as the Director of Professional Education and the Director of Marketing at Medtronic Vascular until July 2013. From August 2002 to September 2008, Ms. Neuenfeldt held roles in commercial marketing at Centocor, a Johnson & Johnson company; HealthTech, a think-tank forecasting the impact of future technology on healthcare delivery; and Triage, a healthcare consulting firm focused on hospital reimbursement and process improvement. Ms. Neuenfeldt received a M.B.A. from the Darden School of Business at the University of Virginia, a M.S. in Epidemiology from the Stanford School of Medicine, and holds a B.A. in Human Biology from Stanford University.

Neeraj Teotia has served as our Vice President, Marketing since May 2016, having held roles of increasing responsibility in marketing since joining Nevro as Director, Marketing in April 2014. From July 2012 to April 2014 Mr. Teotia served as a Director, New Business Development in the Global Surgery Group at Johnson & Johnson where he was responsible for assessing various licensing and acquisition opportunities. Prior to his role in New Business Development, Mr. Teotia worked in various marketing, licensing & acquisitions and research & development roles within the medical device group at Johnson & Johnson. Mr. Teotia received a M.B.A. from the Kellogg School of Management at Northwestern University and holds a B.S. in Electrical Engineering from the University of Illinois at Urbana-Champaign.

Non-Employee Directors

Michael DeMane joined us in March 2011 and has served as our Chief Executive Officer and as Executive Chairman. Effective January 1, 2017, Mr. DeMane transitioned to non-executive Chairman of the Board. Mr. DeMane has served on the board of directors of several private companies since 2009, as well as on the board of directors of eResearch Technology, Inc., a public company specializing in contract research clinical services, from July 2008 to April 2012. From March 2009 to June 2010, Mr. DeMane served as a Senior Advisor to Thomas, McNerney & Partners, a healthcare venture firm. Mr. DeMane served as the Chief Operating Officer of Medtronic, Inc. from August 2007 to April 2008. Prior to his COO role, Mr. DeMane served at Medtronic Inc. as

Senior Vice President from May 2007 to August 2007, Senior Vice President and President: Europe, Canada, Latin America and Emerging Markets from August 2005 to May 2007, Senior Vice President and President: Spinal, ENT and Navigation from February 2002 to August 2005, and President, Spinal from January 2000 to February 2002. Prior to that, he was President at Interbody Technologies, a division of Medtronic Sofamor Danek, Inc., from June 1998 to December 1999. From April 1996 to June 1998, Mr. DeMane served at Smith & Nephew Pty. Ltd. as Managing Director, Australia and New Zealand, after a series of research and development and general management positions with Smith & Nephew Inc. Mr. DeMane earned a B.S. in Chemistry from St. Lawrence University and an M.S. in Bioengineering from Clemson University. We believe that Mr. DeMane is qualified to serve on our Board due to his investment experience, strategic leadership track record, service on other boards of directors of companies in the healthcare industry and his previous service as our Chief Executive Officer.

Ali Behbahani, M.D. has served on our Board since September 2014. Dr. Behbahani joined New Enterprise Associates, Inc., or NEA, in 2007 and is a General Partner on the healthcare team. Prior to joining NEA, Dr. Behbahani worked as a consultant in business development at The Medicines Company, a specialty pharmaceutical company developing acute care cardiovascular products. Dr. Behbahani previously held positions as a venture associate at Morgan Stanley Venture Partners and as a healthcare investment banking analyst at Lehman Brothers. He conducted basic science research in the fields of viral fusion inhibition and structural proteomics at the National Institutes of Health and at Duke University. Dr. Behbahani currently serves on the board of directors of several private companies. Dr. Behbahani has also been a director of Adaptimmune Therapeutics plc, a public biopharmaceutical company, since September 2014, and serves on the nominating and governance committee. Dr. Behbahani has been a director of CRISPR Therapeutics AG, a public company, since March 2015. Dr. Behbahani has been a director of Genocea Biosciences, Inc., a public biopharmaceutical company, since February 2018 and serves on the audit committee. Dr. Behbahani holds an M.D. from The University of Pennsylvania School of Medicine, an M.B.A. from The University of Pennsylvania Wharton School and a B.A. in Biomedical Engineering, Electrical Engineering and Chemistry from Duke University. We believe that Dr. Behbahani is qualified to serve on our Board due to his experience in the life science industry and his investment experience.

Lisa D. Earnhardt has served on our Board since June 2015. She has served as President and Chief Executive Officer of Intersect ENT and as a member of its board of directors since March 2008. Prior to joining Intersect ENT, Ms. Earnhardt served as President of Boston Scientific's Cardiac Surgery division (formerly known as Guidant Corporation, or Guidant) from June 2006 to January 2008 until its sale to Getinge Group. From August 1996 to April 2006, Ms. Earnhardt worked at Guidant in a variety of sales and marketing leadership positions. Ms. Earnhardt served on the board of directors of Kensey Nash, a publicly traded company from 2011 until it was acquired by Royal DSM NA in 2012, where she served on the board's nominating and governance and audit committees. Ms. Earnhardt holds an M.B.A. from Northwestern's Kellogg School of Management and a B.S. in Industrial Engineering from Stanford University. We believe that Ms. Earnhardt is qualified to serve on our Board due to her operational and management experience in the medical device industry.

Frank Fischer has served on our Board since October 2012. Mr. Fischer joined NeuroPace, Inc., a privately held developer of treatment devices for neurological disorders, in 2000 and currently serves as its President and Chief Executive Officer. From May 1998 to September 1999, Mr. Fischer was President, Chief Executive Officer and a director of Heartport, Inc., a formerly publicly traded cardiac surgery company (later acquired by Johnson & Johnson in 2001). From 1987 to 1997, Mr. Fischer served as President and Chief Executive Officer of Ventritex, Inc., a publicly traded designer, developer, manufacturer and marketer of implantable defibrillators and related products for the treatment of ventricular tachycardia and ventricular fibrillation, which was acquired by St. Jude Medical in 1997. Mr. Fischer currently serves on the board of directors of several privately held companies. Mr. Fischer received a B.S. in Mechanical Engineering and a M.S. in Management from Rensselaer Polytechnic Institute. We believe that Mr. Fischer is qualified to serve on our Board due to his extensive operational and management experience in the life science and medical device industries.

Wilfred E. Jaeger, M.D. has served on our Board since January 2012. Dr. Jaeger cofounded Three Arch Partners in 1993 and has served as a Partner and Managing Member since that time. Prior to co-founding Three Arch Partners, Dr. Jaeger was a general partner at Schroder Ventures. Dr. Jaeger currently serves on the board of directors of Concert Pharmaceuticals, Inc., a public clinical stage biopharmaceutical company, as well as numerous private companies. Dr. Jaeger received a B.S. in Biology from the University of British Columbia, an M.D. from the University of British Columbia School of Medicine and an M.B.A from the Stanford Graduate School of Business.

We believe that Dr. Jaeger is qualified to serve on our Board due to his investment experience, strategic leadership track record and service on other boards of directors of life sciences companies.

Shawn T McCormick has served on our Board since September 2014. Mr. McCormick served as Chief Financial Officer of Tornier N.V., a public medical device company, from September 2012 to October 2015 when Tornier merged with Wright Medical Group. From April 2011 to February 2012, Mr. McCormick was Chief Operating Officer of Lutonix, Inc., a medical device company acquired by C. R. Bard, Inc. in December 2011. From January 2009 to July 2010, Mr. McCormick served as Senior Vice President and Chief Financial Officer of ev3 Inc., a public endovascular device company acquired by Covidien plc in July 2010. From May 2008 to January 2009, Mr. McCormick served as Vice President, Corporate Development at Medtronic, Inc., a public medical device company, where he was responsible for leading Medtronic's worldwide business development activities. From 2007 to 2008, Mr. McCormick served as Vice President, Corporate Technology and New Ventures of Medtronic. From 2002 to 2007, Mr. McCormick was Vice President, Finance for Medtronic's Spinal, Biologics and Navigation business. Prior to that, Mr. McCormick held various other positions with Medtronic, including Corporate Development Director, Principal Corporate Development Associate, Manager, Financial Analysis, Senior Financial Analyst and Senior Auditor. Prior to joining Medtronic, he spent four years with the public accounting firm KPMG Peat Marwick. He was a director of Entellus Medical, Inc., a public medical device company, and served as the chairman of the audit committee and as a member of the nominating and corporate governance committee from November 2014 to February 2018 when Entellus was sold to Stryker. Mr. McCormick has been a director of SurModics, Inc., a public medical device and in vitro diagnostic technologies company, since December 2015 and serves on the audit committee and corporate governance and nominating committee. Mr. McCormick earned his M.B.A. from the University of Minnesota's Carlson School of Management and his B.S. in Accounting from Arizona State University. He is a Certified Public Accountant (inactive license) and a National Association of Corporate Directors (NACD) Fellow. We believe that Mr. McCormick is qualified to serve on our Board due to his financial expertise and extensive operational experience in the medical device industry.

Brad Vale, Ph.D., D.V.M., has served on our Board since March 2015. Dr. Vale was Head of Johnson & Johnson Development Company, or JJDC, from January 2012 to March 2015. Dr. Vale joined JJDC in March 1992, and in April 2008, was appointed to the position of Vice President, Head of Venture Investments. From September 1989 to March 1992, Dr. Vale supported Johnson & Johnson's medical device businesses at the Corporate Office of Science and Technology as an Executive Director. From 1982 to 1989, he was at Ethicon, Inc., a Johnson & Johnson subsidiary, working on preclinical studies, new business development, and a coronary artery bypass graft internal venture. Dr. Vale currently serves or has served on the board of directors of several private companies. Dr. Vale holds a Ph.D. from Iowa State University, a D.V.M. from Washington State University and a B.S. in Chemistry and Biology from Beloit College. We believe that Dr. Vale is qualified to serve on our Board due to his investment experience and strategic leadership in the life sciences industry.

The remaining information required by this Item 10 is hereby incorporated by reference from the information under the captions "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" that will be contained in the Proxy Statement for our 2017 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.

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.

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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

		Incorporated by Reference			
Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Nevro Corp.	8-K	11/12/2014	3.1	
3.2	Amended and Restated Bylaws of Nevro Corp.	8-K	11/12/2014	3.1	
4.1	Reference is made to exhibits 3.1 and 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	10/27/2014	4.2	
4.3	Indenture, dated as of June 13, 2016, by and between the Company and Wilmington Trust, National Association.	8-K	6/13/2016	4.1	
4.4	First Supplemental Indenture, dated as of June 13, 2016, by and between the Company and Wilmington Trust, National Association.	8-K	6/13/2016	4.2	
4.5	Form of 1.75% Convertible Senior Note Due 2021.	8-K	6/13/2016	4.3	
10.1†	Amended and Restated License Agreement, dated October 2, 2006, by and among the Company and Mayo Foundation for Medical Education and Research, Venturi	S-1/A	10/15/2014	10.1	

	Group, LLC.			
10.2(a)†	Stellar Manufacturing Agreement, dated as of July 1, 2009, by and between the Company and Stellar Technologies, Inc.	S-1/A	10/15/2014	10.2(a)
10.2(b)†	First Amendment to Stellar Manufacturing Agreement, dated as of July 1, 2014, by and between the Company and Stellar Technologies, Inc.	S-1/A	10/15/2014	10.2(b)
10.2(c)†	Second Amendment to Stellar Manufacturing Agreement, dated as of January 28, 2016, by and between the Company and Stellar Technologies, Inc.	10-K	2/29/2016	10.2(c)

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.3†	Supply Agreement, dated as of July 23, 2014 by and between the Company and Pro-Tech Design and Manufacturing, Inc.	S-1/A	10/15/2014	10.3	
10.4(a)†	Supply Agreement, dated April 1, 2012, by and between the Company and CCC del Uruguay S.A.	S-1/A	10/15/2014	10.4(a)	
10.4(b)†	Amendment to Supply Agreement, dated as of March 20, 2013, by and between the Company and CCC del Uruguay S.A.	S-1/A	10/15/2014	10.4(b)	
10.5(a)†	Product Supply and Development Agreement, dated as of April 15, 2009, by and between the Company and EaglePicher Medical Power LLC.	S-1/A	10/15/2014	10.5	
10.5(b)†	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.	10-K	3/18/2015	10.5(b)	
10.5(c)†	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.	10-K	2/29/2016	10.5(c)	
10.5(d)	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.	10-Q	11/6/2017	10.1	
10.6(a)	Amended and Restated Registration Rights Agreement, dated February 8, 2013, by and among the Company and the investors listed therein.	S-1	10/03/2014	10.6(a)	
10.6(b)	Amendment to Amended and Restated Registration Rights Agreement, dated March 5, 2013, by and among the Company and the investors listed therein.	S-1	10/03/2014	10.6(b)	
10.6(c)	Second Amendment to Amended and Restated Registration Rights Agreement, dated October 24, 2014, by and among the Company and the investors listed	S-1/A	11/04/14	10.6(c)	

	therein.			
10.7(a)	Multi-Tenant Space Lease, dated as of March 15, 2010, by and between Deerfield Campbell LLC and the Company.	S-1	10/03/2014	10.7(a)
10.7(b)	First Amendment to Lease, dated as of October 18, 2012, by and between Deerfield Campbell LLC and the Company.	S-1	10/03/2014	10.7(b)
10.7(c)	Second Amendment to Lease, dated as of February 18, 2015, by and between Deerfield Campbell LLC and the Company.	10-K	3/18/2015	10.7(c)

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.8(a)#	Nevro Corp. 2007 Stock Incentive Plan, as amended as of March 5, 2013.	S-1	10/03/2014	10.8(a)	
10.8(b)#	Form of Incentive Stock Option Agreement (ISO) under the 2007 Stock Incentive Plan, as amended.	S-1	10/03/2014	10.8(b)	
10.8(c)#	Form of Non-Incentive Stock Option Agreement (NSO) under the 2007 Stock Incentive Plan, as amended.	S-1	10/03/2014	10.8(c)	
10.8(d)#	Form of Stock Purchase Right Grant Notice and Restricted Stock Purchase Agreement under the 2007 Stock Incentive Plan, as amended.	S-1	10/03/2014	10.8(d)	
10.9(a)#	Nevro Corp. 2014 Equity Incentive Award Plan.	S-8	11/12/2014	99.2(a)	
10.9(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan.	S-1/A	10/10/2014	10.9(b)	
10.9(c)#	Form of Restricted Stock Award Agreement and Restricted Stock Award Grant Notice under the 2014 Equity Incentive Award Plan.	S-1/A	10/10/2014	10.9(c)	
10.9(d)#	Form of Restricted Stock Unit Award Agreement and Restricted Stock Unit Award Grant Notice under the 2014 Equity Incentive Award Plan.	S-1/A	10/10/2014	10.9(d)	
10.10#	Nevro Corp. 2014 Employee Stock Purchase Plan.	S-8	11/12/2014	99.3	
10.11#	Form of Indemnification Agreement for directors and officers.	S-1/A	10/10/2014	10.11	
10.12#	Amended and Restated Company Bonus Plan.	10-Q	5/7/2018	10.1	
10.13#	Nevro Corp. Non-Employee Director Compensation Program, as amended.				X
10.14#	Offer Letter, dated as of October 9, 2012, by and between Rami Elghandour and the Company.	S-1	10/03/2014	10.13	
10.14(b)#		10-Q	5/9/2016	10.3	

	Employment Agreement, effective as of June 1, 2016, by and between Rami Elghandour and the Company.			
10.15#	Offer Letter, dated as of May 12, 2010, by and between Andrew H. Galligan and the Company.	S-1	10/03/2014	10.14
10.16(a)	Amended and Restated Stockholders' Agreement, dated February 8, 2013, by and among the Company and the stockholders listed therein.	S-1	10/03/2014	10.15(a)
10.16(b)	Amendment to Amended and Restated Stockholders' Agreement, dated March 5, 2013, by and among the Company and the stockholders listed therein.	S-1	10/03/2014	10.15(b)

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.16(c)	Second Amendment to Amended and Restated Stockholders' Agreement, dated October 24, 2014, by and among the Company and the investors listed therein.	S-1/A	11/04/14	10.18(c)	
10.17(a)#	Form of Amended and Restated Change in Control Severance Agreement for certain executive officers.	10-Q	5/9/2016	10.4	
10.17(b)#	Amended and Restated Change in Control Severance Agreement, dated as of May 5, 2016, by and between Andrew Galligan and the Company.	10-Q	8/8/2016	10.14	
10.17(c)#	Amended and Restated Change in Control Severance Agreement, dated as of May 5, 2016, by and between Doug Alleavitch and the Company.	10-Q	8/8/2016	10.15	
10.17(d)#	Amended and Restated Change in Control Severance Agreement, dated as of August 3, 2016, by and between Patrick Schmitz and the Company.	10-K	2/22/2018	10.18(d)	
10.17(e)#	Amended and Restated Change in Control Severance Agreement, dated as of August 3, 2016, by and between Christofer Christoforou and the Company.	10-K	2/22/2018	10.18(e)	
10.17(f)#	Amended and Restated Change in Control Severance Agreement, dated as of December 18, 2017, by and between Kashif Rashid and the Company.	10-K	2/22/2018	10.18(g)	
10.18(a)†	Supply Agreement, dated March 13, 2015, by and between the Company and Centro de Construccion de Cardioestimuladores del Uruguay S.A.	10-K/A	5/29/2015	10.22	
10.18(b)†	Supply Agreement, effective as of November 11, 2016, by and between the Company and Centro de Construccion de Cardioestimuladores del Uruguay S.A.	10-K	2/23/2017	10.22(b)	
10.19(a)	Lease Agreement, dated as of March 5, 2015, by and between the Company and Westport Office Park, LLC.	10-K	3/18/2015	10.23	
10.19(b)	First Amendment to Lease, effective as of December 9, 2016, by and between the Company and Westport Office Park, LLC.	10-K	2/23/2017	10.23(b)	

10.19(c)	Second Amendment to Lease, effective as of April 13, 2017, by and between the Company and Westport Office Park, LLC.	10-Q	8/7/2017	10.1
10.19(d)	Third Amendment to Lease, effective as of December 6, 2017, by and between the Company and Westport Office Park, LLC.	10-K	2/22/2018	10.21(d)
10.20#	Offer Letter, dated as of March 30, 2015, by and between the Company and Doug Alleavitch.	8-K	4/9/2015	10.1

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.21(a)†	Manufacturing and Supply Agreement, dated as of December 18, 2015, by and between the Company and Vention Medical Design and Development, Inc.	10-K	2/29/2016	10.25	
10.21(b)†	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.	10-Q	11/6/2017	10.2	
10.21(c)†	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.	10-Q	8/2/2018	10.2	
10.22	Letter Agreement, dated June 7, 2016, between Morgan Stanley & Co. International plc and the Company, regarding the Base Warrants.	8-K	6/13/2016	10.1	
10.23	Letter Agreement, dated June 7, 2016, between Bank of America, N.A. and the Company, regarding the Base Warrants.	8-K	6/13/2016	10.2	
10.24	Letter Agreement, dated June 7, 2016, between Goldman, Sachs & Co. and the Company, regarding the Base Warrants.	8-K	6/13/2016	10.3	
10.25	Letter Agreement, dated June 7, 2016, between Morgan Stanley & Co. International plc and the Company, regarding the Base Call Option Transaction.	8-K	6/13/2016	10.4	
10.26	Letter Agreement, dated June 7, 2016, between Bank of America, N.A. and the Company, regarding the Base Call Option Transaction.	8-K	6/13/2016	10.5	
10.27	Letter Agreement, dated June 7, 2016, between Goldman, Sachs & Co. and the Company, regarding the Base Call Option Transaction.	8-K	6/13/2016	10.6	
10.28	Letter Agreement, dated June 8, 2016, between Morgan Stanley & Co. International plc and the Company, regarding the Additional Warrants.	8-K	6/13/2016	10.7	

10.29	Letter Agreement, dated June 8, 2016, between Bank of America, N.A. and the Company, regarding the Additional Warrants.	8-K	6/13/2016	10.8
10.30	Letter Agreement, dated June 8, 2016, between Goldman, Sachs & Co. and the Company, regarding the Additional Warrants.	8-K	6/13/2016	10.9
10.31	Letter Agreement, dated June 8, 2016, between Morgan Stanley & Co. International plc and the Company, regarding the Additional Call Option Transaction.	8-K	6/13/2016	10.10

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.32	Letter Agreement, dated June 8, 2016, between Bank of America, N.A. and the Company, regarding the Additional Call Option Transaction.	8-K	6/13/2016	10.11	
10.33	Letter Agreement, dated June 8, 2016, between Goldman, Sachs & Co. and the Company, regarding the Additional Call Option Transaction.	8-K	6/13/2016	10.12	
21.1	List of Subsidiaries.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K).				X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1**	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.				X
101.INS	XBRL Instance.				X
101.SCH	XBRL Taxonomy Extension Schema.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase.				X

† 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 21, 2019:

NEVRO CORP.

By: /s/ Rami Elghandour
Rami Elghandour

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 Rami Elghandour and Andrew H. Galligan 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
/s/ RAMI ELGHANDOUR Rami Elghandour	Chief Executive Officer (Principal Executive Officer)	February 21, 2019
/s/ ANDREW H. GALLIGAN Andrew H. Galligan	Chief Financial Officer (Principal Financial and Accounting Officer)	February 21, 2019
/s/ MICHAEL DEMANE Michael DeMane	Chairman of the Board	February 21, 2019

/s/ ALI BEHBAHANI Ali Behbahani, M.D.	Director	February 21, 2019
/s/ LISA EARNHARDT Lisa Earnhardt	Director	February 21, 2019
/s/ FRANK FISCHER Frank Fischer	Director	February 21, 2019
/s/ WILFRED E. JAEGER Wilfred E. Jaeger, M.D.	Director	February 21, 2019
/s/ SHAWN T MCCORMICK Shawn T McCormick	Director	February 21, 2019
/s/ BRAD H. VALE Brad H. Vale, Ph.D., D.V.M	Director	February 21, 2019