NEVRO CORP
Form 10-K
March 18, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the year ended December 31, 2014

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.)**

4040 Campbell Avenue

Menlo Park, California 94025

(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 x

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 x

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 x No ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post 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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer x Smaller reporting company ¨

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter, and therefore cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

As of February 28, 2015, there were 24,875,156 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the registrant s 2015 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, 2014.

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PART I

ITEM 1. *BUSINESS*

Overview

We are a medical device company that has developed and commercialized an innovative neuromodulation platform for the treatment of chronic pain. Our Senza system is the only spinal cord stimulation, or SCS, system that delivers our proprietary HF10 therapy. Our SENZA-RCT U.S. pivotal study, a non-inferiority study, met its primary and secondary endpoints, and our post-hoc statistical analysis supports the superiority of HF10 therapy over traditional SCS therapies for treating both leg and back pain. While SCS therapy is indicated and reimbursed for treating back and leg pain, it has limited efficacy in treating back pain and is used primarily for treating leg pain, limiting its market adoption. In our pivotal study, HF10 therapy was demonstrated to provide significant and sustained back pain relief in addition to leg pain relief. Additionally, HF10 therapy was demonstrated to provide pain relief without paresthesia, a constant tingling sensation that is the basis of traditional SCS therapy. HF10 therapy is also designed to reduce variability in the operating procedure, providing meaningful benefits to both patients and physicians. We believe we are positioned to transform and grow the approximately $1.5 billion existing global SCS market under current reimbursement by treating back pain in addition to leg pain and by eliminating paresthesia.

In June 2014, we submitted our premarket approval, or PMA, application to the U.S. Food and Drug Administration, or FDA, for our Senza SCS system, or Senza, and, in January 2015, we received a letter from the FDA informing us of the approvability of our PMA, subject to satisfaction of regulatory inspections and audits of manufacturing facilities, methods and controls for Senza, as well as finalization of the products labeling with the FDA. We are working to satisfy the conditions of approval and anticipate initial commercial availability in the United States by mid-2015, if approved by the FDA. Outside of the United States, Senza is indicated for the treatment of chronic intractable pain of the trunk and limbs, is reimbursed under existing SCS codes, and has been commercially available in certain European markets since November 2010 and in Australia since August 2011. Due to market penetration in Europe and Australia, we expect that our future revenue growth, if any, will be largely from sales in the U.S. market, if we receive FDA approval for Senza.

We completed our SENZA-RCT pivotal study in March 2014, which was the first prospective randomized controlled pivotal study in the history of SCS and the first to directly demonstrate comparative effectiveness between SCS therapies. The SENZA-RCT study was designed as a non-inferiority trial comparing HF10 therapy to traditional commercially available SCS therapy and met its primary and secondary endpoints. Although the statistical analysis plan filed with the FDA did not include a superiority analysis, we performed a post-hoc superiority analysis of the clinical results.

Key highlights of our SENZA-RCT pivotal study are as follows:

- The SENZA-RCT study results demonstrated the non-inferiority of HF10 therapy to traditional SCS therapy on all primary and secondary endpoints. Additionally, our post-hoc statistical analysis supports the superiority of HF10 therapy over traditional SCS therapy in all primary and secondary endpoints.

- HF10 therapy was nearly twice as successful in treating back pain as traditional SCS therapy, with 84.3% of patients receiving HF10 therapy, as compared to 43.8% of patients receiving traditional SCS therapy,

reporting 50% or more pain relief at three months, results that were statistically superior based on our post-hoc analysis.

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 statistically superior based on our post-hoc analysis.

HF10 therapy provided a 69.2% reduction in back pain as measured by the Visual Analog Scale, or VAS, versus 44.2% for traditional SCS therapy, at three months, results that were statistically superior based on our post-hoc analysis.

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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 statistically superior based on our post-hoc analysis.

Our post-hoc statistical analysis supports superior efficacy of HF10 therapy for both back and leg pain at each measurement throughout the 12-month study.

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.

Based on our post-hoc analysis, 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), twice the number of traditional SCS therapy patients, results that were statistically superior.

Based on our post-hoc analysis, three-fourths 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, twice the number of traditional SCS therapy patients, results that were statistically superior.

Safety outcomes were consistent across the control and test groups.

The outcomes for HF10 therapy in our pivotal study 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.

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.

Traditional SCS therapy utilizes low frequency stimulation, typically between 40 Hz and 60 Hz, to generate paresthesia, a constant tingling sensation that 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, HF10 therapy delivers spinal cord stimulation at a lower amplitude and a higher frequency waveform of 10,000 Hz. HF10 therapy relies on consistent anatomical placement of the stimulation leads across patients, thus reducing procedure variability relative to traditional SCS therapy. Comparatively, traditional SCS therapy requires individualized lead placement by the physician during the implant procedure utilizing paresthesia mapping, an often time-consuming portion of the procedure in which the patient is awakened and queried by the physician as to whether they feel the paresthesia over the site of their pain. Paresthesia mapping is an often cumbersome and variable process, which creates variability in the implant procedure and can greatly impact a physician s schedule. In contrast, HF10 therapy is intended to relieve pain without causing paresthesia, while increasing the predictability of the procedure. 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 our proprietary HF10 therapy has distinct advantages over traditional SCS therapy, including:

Compelling efficacy data for both leg and back pain. We believe that the results of our pivotal clinical trial provide compelling efficacy data in back and leg pain that may enable us to gain significant market share in the approximately $1.5 billion existing global SCS market, 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 by meeting demand from back pain patients who are largely untreated by traditional SCS therapies.

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Strong global clinical evidence. We believe the strength of our clinical evidence base supporting HF10 therapy differentiates it from traditional SCS therapies and we expect it to drive adoption among patients, providers and payors through increased referrals and utilization.

Paresthesia free pain relief for patients. HF10 therapy does not induce or require paresthesia to provide pain relief. By delivering pain relief without paresthesia, HF10 therapy removes a major barrier for many patients who would otherwise benefit from SCS.

Anatomical lead placement for physicians. Since HF10 therapy relies on 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. We are currently investigating the use of HF10 therapy to treat pre-spinal surgery patients, chronic intractable neck and upper extremity pain and refractory chronic migraine.

We believe we have built competitive advantages through our proprietary technology, clinical evidence base, strong track record of execution including over 3,000 patients implanted with Senza, and proven management team with a substantial amount of neuromodulation experience. With what we believe are compelling efficacy data for both leg and back pain compared to traditional SCS therapy, we aim to secure U.S. FDA approval, drive adoption 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 Senza for new indications.

Market Overview

Chronic Pain

Chronic pain has been defined by the International Association for the Study of Pain (IASP) as pain that lasts longer than the time required for tissues to heal, which is often defined to be three months. According to a report by the Institute of Medicine, chronic pain is widespread and has seen an increase in prevalence due to aging populations, progress in saving lives after suffering catastrophic injuries, increases in failed surgeries, and greater public understanding of pain. About 1.5 billion people suffer from chronic pain worldwide, including approximately 100 million Americans, which is greater than the sum of patients with heart disease, diabetes and cancer combined. Approximately 10% of chronic pain sufferers have severe disabling pain, which significantly affects their daily activities and quality of life, and is often linked to suicide.

The back is the most common location of chronic pain, with an estimated 84 million patients in the United States experiencing chronic back pain. Among U.S. adults reporting pain, low back pain was the highest reported location at 28%, followed by knee pain at 20% and severe headache/migraine at 16%. In a study conducted by the University of North Carolina at Chapel Hill and published in 2009, the prevalence of low back pain more than doubled from 1992 to 2006. According to data from users of the Department of Veterans Affairs health system, the annualized increase in prevalence of low back pain is larger than increases in the three other conditions studied, which were depression, diabetes and hypertension. In terms of impact, the annual cost of back pain in the United States is estimated to be $34 billion for treatment, with another $100 billion in lost productivity.

Existing Treatments for Chronic Pain and Limitations

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.

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Spine Surgery

Spine surgery is a common invasive surgical procedure for the treatment of pain and typically precedes traditional SCS therapy. Despite the possibility of surgical complications, recent data suggests that over 500,000 spinal procedures are performed in the United States every year. Common surgeries include spinal fusion, which involves joining spinal bones to limit movement, and laminectomy, which entails removing part of the bone or ligaments in the back. These surgical procedures often fail to treat certain difficult types of chronic pain, such as severe neuropathic and intractable back pain. Failed Back Surgery Syndrome, or FBSS, is a common outcome of spine surgery where chronic back and/or leg pain continues to persist and affects an estimated 10% to 40% of patients receiving spine surgery. Given the failure rate for spine surgery, FBSS patients make up a significant portion of the addressable patient population for SCS.

Oral Opioids

Oral opioids are prescription pain medications that suppress the patient s acute perception of pain but lack clinical evidence supporting their long term use to treat chronic pain including back pain. Oral opioids can significantly compromise the patient s quality of life, with patients often reporting being in a fog and commonly experiencing side effects such as nausea, vomiting, constipation and dizziness. Less common side effects can include immunologic dysfunction, hormonal dysfunction and muscle rigidity. Oral opioids are also known to present a high risk of addiction. Abuse and accidental overdoses have led to dramatic increases in deaths over the past two decades.

Traditional Spinal Cord Stimulation

SCS is a type of neuromodulation technology that utilizes an implantable pacemaker-like device to deliver electrical impulses to the spinal cord. Traditional SCS therapy is a long-established pain treatment designed to induce paresthesia, a tingling sensation that overlaps the distribution 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 compact, 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, 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.

With a primary focus on treating leg pain, the global market for traditional SCS therapy has grown from approximately $300 million in 2001 to approximately $1.4 billion in 2012, a compound annual growth rate of approximately 8%. The global SCS market is estimated to be approximately $1.5 billion in 2014 and is expected to grow to approximately $1.8 billion per year by 2017. The United States represents approximately 80% of this global market due in part to governmental reimbursement restraints in international markets. In addition, the addressable market in the United States for potential SCS candidates is estimated to be 1 million patients. We believe that due to factors such as an aging population, and an increasing number of failed back surgeries, the number of candidates for SCS will continue to grow. Despite the sizeable potential market, only approximately 40,000 SCS systems are implanted each year in the United States, representing less than 10% of the addressable U.S. market at a cost of approximately $25,000 per procedure. According to 2012 IMS data, there are approximately 4,400 facilities in the United States where SCS systems are implanted by a variety of physicians, including neurosurgeons, physiatrists, interventional pain specialists and orthopedic spine surgeons. However, only approximately half of chronic pain patients are considered candidates for traditional SCS therapy. A key reason for this may be the limited evidence supporting efficacy of traditional SCS therapy for back pain. We believe there is an additional opportunity for an SCS therapy that effectively treats back pain that is approximately the size of the existing global SCS market.

Traditional SCS therapy generally consists of two phases, an evaluation period, also called the trial period, which typically lasts several days, and a permanent implant for those patients who experience a successful trial. The trial period involves a percutaneously placed insulated wire, called a lead that a physician implants near the

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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 for the patient. The patient is able to control their stimulation during the trial period by utilizing the patient remote control, which resembles a small television remote control. The remote control allows a patient to turn the therapy on and off, in addition to other functions. If the trial period is successful, a permanent system is implanted in the patient. The success criterion is typically at least 50% reduction in pain during the evaluation period.

A key part of the permanent system is the Implantable Pulse Generator, or IPG, which is a miniaturized version of the external stimulator. The implant procedure involves connecting the leads to the IPG that is implanted under the skin. The IPG should provide the patient with multiple years of use and can be either rechargeable or non-rechargeable. Primary cell IPGs, or non-rechargeable IPGs, are used in cases where the patient requires a lower level of stimulation and such systems have a limited life. Rechargeable IPGs, a more recent innovation, are more expensive but allow for higher levels of stimulation and can last 10 years or more. Due to payor constraints in certain European countries, the transition from primary cell IPGs to rechargeable IPGs has been slow. In the United States and Australia, most IPGs implanted are rechargeable.

Traditional SCS products have required paresthesia to provide pain relief, and have focused on ancillary features with incremental benefits. Paresthesia coverage has been used as a surrogate metric for successful pain relief. 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 or different changes that include smaller IPGs and improved compatibility with magnetic resonance imaging, or MRI. Even with successful paresthesia coverage, patients still may not receive pain relief or often lose pain relief after a period of time.

Limitations of Traditional SCS Therapy

Limited clinical evidence: To date, we believe there are only two published prospective randomized SCS studies that provide long-term (at least 12 months) data, both of which focused on leg pain. Neither of these studies was done to support initial regulatory approval of an SCS system. We believe this limited clinical evidence has inhibited market adoption of traditional SCS therapy.

Lack of evidence supporting efficacy in back pain: We believe predominant back pain is more difficult to treat with traditional SCS therapy than leg pain due to the reduced ability to achieve and maintain pain coverage in the back. We are not aware of a prospective, randomized clinical trial supporting the efficacy of traditional SCS therapy in treating back pain. The Kumar study is a widely cited study on SCS and focused on patients with predominant leg pain. The study demonstrated a reduction in leg pain over the 24 month study period, while reductions in back pain at six, 12, and 24 month follow-up were not significant when compared to baseline. The average back pain reduction was 13% at 24 months. As a result, back pain patients are usually not recommended for treatment with traditional SCS therapy.

Paresthesia: Traditional SCS therapy relies on paresthesia to mask pain with a constant tingling sensation. Paresthesia is often considered unpleasant or uncomfortable, 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 activated. Medtronic, the current leader in neuromodulation, has released a survey showing that 71% of patients find paresthesia uncomfortable at times.

Paresthesia mapping: A crucial part of the traditional SCS procedure is called 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

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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. In the operating room, the surgical procedure is as follows:

1. The patient is sedated and leads are inserted into the epidural space along the spine with the guidance of fluoroscopy;

2. Sedation is reduced and the patient is awakened;

3. The patient is queried by the physician and verbal feedback is gathered on paresthesia distribution over the pain site. This process can complicate anesthesia management as patients need to be sedated enough to tolerate the manipulation of the leads in the epidural space, but kept conscious enough to be able to interact with the physician to respond to questions about their sensations of pain and paresthesia. Patients are often groggy from the anesthesia and can have difficulty accurately confirming the overlap of the paresthesia with their pain.

4. The leads are repositioned or reprogrammed to redirect paresthesia. This is often a cumbersome and variable process as steps 3 and 4 are repeated as required. Multiple iterations are often required, impacting operating room scheduling efficiency.

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, which we refer to as evidence-based. By overcoming many of the limitations of traditional SCS therapy, HF10 therapy offers benefits to patients, physicians and hospitals. We believe the advantages of our proprietary HF10 therapy over traditional SCS include:

Compelling 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 to be nearly twice as successful in treating back pain and 1.5 times as successful in treating leg pain relative to traditional SCS therapy. We believe that the results of our pivotal clinical trial provide compelling efficacy data in leg and back pain that may enable us to gain significant market share in the approximately $1.5 billion existing global SCS market, 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 by meeting demand from back pain patients who are largely untreated by traditional SCS therapies.

Strong global clinical evidence: We believe the strength of our clinical evidence base supporting HF10 therapy differentiates it from traditional SCS therapies and we expect it to drive adoption among patients, providers and payors through increased referrals and utilization. Our SENZA-RCT pivotal study included 198 patients across 11 U.S. clinical trial sites and was the first randomized controlled prospective pivotal study in SCS. We believe the results of the SENZA-RCT study, which met all its primary and secondary endpoints, are consistent with and confirmatory of the results from our European Long Term Clinical Study that included 83 patients.

Paresthesia free pain relief for patients: HF10 therapy does not induce or require paresthesia to provide pain relief. By delivering pain relief without paresthesia, HF10 therapy removes a major barrier for many patients who would otherwise benefit from SCS therapy. HF10 therapy offers the notable benefit to patients of achieving significant and sustained pain relief without requiring them to endure the uncomfortable shocking or jolting sensations commonly associated with paresthesia.

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Anatomical lead placement for physicians. Since HF10 therapy relies on 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 treat pre-spinal surgery patients, chronic intractable neck and upper extremity pain and refractory chronic migraine. Based on analysis from our SENZA-RCT and European studies, we believe HF10 therapy may be an attractive treatment option for some pre-spinal surgery patients without mechanical instability due to its cost, reversibility and initial trial period. Due to the removal of paresthesia, HF10 therapy may overcome the intense discomfort that traditional SCS generates for patients with neck pain when leads are placed in the cervical spine. For chronic migraine patients, HF10 therapy s ability to treat without paresthesia enables cervical lead placement, rather than occipital nerve stimulation which requires lead insertion at the base of the skull under traditional SCS therapy.

Clinical Data

To support development of our proprietary HF10 therapy, the technology was evaluated in preclinical studies and further studied in prospective clinical trials, all of which have now been published or are pending publication in peer-reviewed journals. The results from the clinical studies have been consistent across studies and across outcome measures. Most notably, in 2014 we completed our prospective, comparative, randomized, controlled U.S. pivotal study, called SENZA-RCT, to support approval of our PMA for Senza.

Clinical Program Overview

Clinical Trial	Number of Patients Enrolled	Clinical Trial Sites	Year Completed	Trial Overview	Status
U.S. Pivotal (SENZA-RCT)	241	11 U.S. sites	2014	One year evaluation of Senza in patients with back and leg pain in the United States	Completed (submitted but not yet accepted for publication in peer reviewed journal)
EU Long-term (Prospective Multicenter European Clinical Study)	83	2 European sites	2013	Two year evaluation of Senza primarily in patients with predominant back pain in Europe	Completed (published in peer reviewed journal: Pain Medicine)
U.S. Feasibility	24	5 U.S. sites	2009	One week evaluation of Senza in patients	Completed (published in peer reviewed journal:

	with predominant back pain in the United States	Neuromodulation)

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Key Metrics for Studies

Statistical significance is denoted by p-values in the figures below for both non-inferiority and our post-hoc superiority analysis. The p-value is the probability that the reported result was achieved purely by chance (i.e., a non-inferiority p-value <0.001 in the Primary Endpoint Results chart means that there is a less than a 0.1% chance that the demonstrated non-inferiority of HF10 therapy in relation to traditional SCS therapy was purely due to chance). The superiority p-value is the probability that the results of the test group are statistically superior to those of the control group (i.e., a between group p-value <0.001 in the Primary Endpoint Results chart means that there is a less than a 0.1% chance that the demonstrated superiority of HF10 therapy in relation to traditional SCS therapy was purely due to chance).

The performance of SCS therapy is evaluated using a number of commonly used metrics, including the following:

Visual analog score (VAS): VAS measures a patient s pain intensity on a 0 to 10 scale, with 0 representing no pain and 10 representing the worst pain imaginable. The VAS score is used to calculate changes in patient pain.

Oswestry Disability Index (ODI): The questionnaire measures the levels of a patient s disability.

U.S. Pivotal Clinical Study (SENZA-RCT)

Our 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. The study completed enrollment in seven months and study visits took place at one, three, six, nine, and 12 months. Each screened patient was required to have a leg and back pain VAS score of at least 5 to be randomized between the test and control arms. 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. The subjects in our pivotal study were evaluated over a 12-month period, which we believe is considered sufficient by clinicians treating patients with chronic pain with SCS therapies to provide long-term efficacy information regarding the therapy. Although the statistical analysis plan filed with the FDA did not include a superiority analysis, we also performed a post-hoc superiority analysis of the clinical results. We believe our post-hoc statistical analysis supports the superior efficacy of HF10 therapy over traditional SCS therapy.

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The following is a graphical representation of the study design:

Patient analysis population

The three analysis populations were:

Intention to Treat (ITT; n=198) All subjects who met enrollment criteria and received a randomization assignment. Subjects who did not complete a trial or who failed a trial were considered non-responders in this analysis population.

Per Protocol (PP; n=179) All randomized subjects who completed a primary endpoint assessment. Subjects who had an unsuccessful SCS trial were considered non-responders in this analysis population.

Permanent Implant Subsets (PS; n=171) All randomized subjects who had a successful SCS trial and received a permanent implant.

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Primary Endpoint

The primary endpoint of the study is the percentage of subjects who respond to SCS therapy for back pain in both the test and control groups and do not have a stimulation-related neurological deficit at three months. A non-inferiority analysis was performed to assess the primary endpoint and response was defined as 50% or more back pain relief at three months. Subjects who did not have a successful trial or who experienced a stimulation-related neurological deficit were considered non-responders towards the primary endpoint.

Primary Endpoint Results

The chart below shows a comparison of the response rate for each analysis population at the primary endpoint, as measured by the percent of patients who achieved 50% or more back pain reduction according to their VAS score. The results demonstrate that HF10 therapy was nearly twice as successful in each of the three analysis populations in treating back pain at three months when compared to traditional SCS therapy. These results demonstrated non-inferiority, and, additionally, we believe our post-hoc statistical analysis supports the statistical superiority of HF10 therapy over traditional SCS therapy. Finally, the relatively consistent success across all three analysis populations speaks to the robustness of both the study design and results.

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The following figure demonstrates the difference in response rate between the two treatment groups for all three analysis populations. The center point of each confidence interval is the result of subtracting the test arm response rate from the control arm demonstrating the difference between treatment groups. The results are negative because the test response rate is greater than the control response rate. Since the right hash of the confidence interval for all three analysis populations is to the left of the 10% non-inferiority margin, the results for all three analysis populations are considered statistically to be non-inferior. Furthermore since the right hash of the confidence interval for all three analysis populations is to the left of the 0% line, the results for all three analysis populations are considered statistically superior.

Secondary Endpoints

We used a hierarchical statistical process to assess certain of the secondary endpoints. The study defined seven secondary endpoints to be successively evaluated until non-inferiority was not demonstrated (Per Protocol Population). These secondary endpoints were chosen to complement the primary endpoint responder rate by showing the percent decrease in back and leg pain at three, six and 12 months, as well as disability level at three months. All secondary endpoint analysis on these endpoints demonstrated non-inferiority and our post-hoc statistical analysis supported the superiority of HF10 therapy for all of these endpoints.

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The following figure sets forth the hierarchy of this secondary endpoint analysis:

In addition to the seven hierarchical secondary endpoints, we evaluated other secondary endpoints, including Back Pain Responder Rate at three and 12 months, paresthesia sensation and safety results.

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Secondary Endpoints Results

Back Pain Permanent Implant Subset

The longitudinal back pain VAS scores for each of the three, six and 12 month measurements are presented in the chart appearing on the left below. The percentage change in back pain results, as calculated by change in VAS score from baseline, at the three, six and 12 month measurements is presented in the chart appearing on the right below. We demonstrated non-inferiority based on percentage change from baseline in back pain at the three, six and 12 month measurement points, which were secondary endpoints. Additionally, our post-hoc statistical analysis supports the superiority of HF10 therapy over traditional SCS therapy at the three, six and 12 month follow-up for both the longitudinal VAS score and percent change in back pain measurements. In particular, at 12 months, mean back pain VAS decreased 66% (or 4.3 points) with HF10 therapy compared to a decrease of 45% (or 2.5 points) for traditional SCS therapy.

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Leg Pain Permanent Implant Subset

The longitudinal leg pain VAS scores for each of the three, six and 12 month measurements are presented in the chart appearing on the left below. The percentage change in leg pain results, as calculated by change in VAS score from baseline, at the three, six and 12 month measurements are presented in the chart appearing on the right below. We demonstrated non-inferiority based on percentage change from baseline in leg pain at the three, six and 12 month measurement points, which were secondary endpoints. Additionally, our post-hoc statistical analysis supports the superiority of HF10 therapy over traditional SCS therapy at the three, six and 12 month follow-up for both the longitudinal VAS score and percentage change in leg pain measurements. In particular, at 12 months, mean leg pain VAS decreased 70% (or 3.9 points) with HF10 therapy compared to a decrease of 48% (or 2.1 points) for traditional SCS therapy.

Change in Disability (ODI) at Three Months

As part of the hierarchical secondary endpoint analysis, we evaluated change in disability, as measured by percentage change in ODI score from baseline to three months. The mean ODI score decreased by 31.5% for subjects receiving HF10 therapy, compared to 24% for subjects receiving traditional SCS therapy (10% non-inferiority p-value: <0.001, post-hoc superiority p-value: 0.042).

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Back Pain Responder Rate

The chart below presents the secondary endpoint of the back pain responder rate at three and 12 months. The response rate is defined as the percent of patients who achieve 50% or more pain reduction from baseline as measured by VAS score. The following results demonstrate non-inferiority at each of the measurement points for the secondary endpoint and, based on our post-hoc statistical analysis, support the statistical superiority of the response rate of HF10 therapy for treating back pain at each of the three, six and 12 month measurement points over traditional SCS therapy.

Paresthesia Results

At the three and 12 month time points, subjects were asked to report whether they perceived paresthesia and if so if they general found the stimulation to be uncomfortable. 0% of subjects in the test group reported feeling paresthesia at both three and 12 months, compared to 46.5% and 44.4% of subjects in the control group who reported feeling uncomfortable stimulation at three and 12 months, respectively. No subjects in the test group reported uncomfortable stimulation. The secondary endpoint only considered the response at three months.

Additional Analysis

In addition to the secondary endpoint analysis in our statistical analysis plan filed with the FDA, we also performed two additional analyses of our pivotal trial results a leg pain responder rate analysis and a remitter status analysis.

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Leg Pain Responder Rate

The chart below presents the secondary endpoint of the leg pain responder rate at three and 12 months. The response rate is defined as the percent of patients who achieve 50% or more pain reduction from baseline as measured by VAS score. The following results demonstrate non-inferiority at each of the measurement points for the secondary endpoint and, based on our post-hoc statistical analysis, support the statistical superiority of the response rate of HF10 therapy for treating leg pain at each of the three, six and 12 month measurement points over traditional SCS therapy.

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Remitter Status Back Pain and Leg Pain

In the practice of pain management, a VAS score above 4 is generally considered to be the threshold for pharmaceutical intervention such as oral opioids. In analyzing the results of the SENZA-RCT pivotal study, we utilized a more conservative threshold of a VAS score less than or equal to 2.5 to assess the ability of both therapies to provide a level of pain relief that would not impact quality of life and activities of daily living. Patients meeting this criteria were considered to be remitters. Based on this definition, nearly twice the number of patients receiving HF10 therapy achieved remitter status for both back and leg pain compared to patients receiving traditional SCS therapy, a result that was statistically superior.

Safety Results

Safety results were consistent between the test and control groups. Study-related serious adverse events, or 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 participants). 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.

Tertiary Endpoint Analysis

Per our protocol, we collected data on a number of tertiary endpoints regarding functional outcomes and patient satisfaction. The analysis of these tertiary endpoints support the results from the primary and secondary endpoints, with several demonstrating statistical superiority between HF10 therapy and traditional SCS therapy based on our post-hoc analysis.

Consistency of Results

We also performed a comparison of the trial results from SENZA-RCT with our European long-term clinical study. This comparison demonstrates consistency of results across these two studies.

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The chart below compares longitudinal back pain, as measured by change in VAS score from baseline of HF10 therapy in SENZA-RCT to our European long-term clinical study at each of the three, six and 12 month measurement points, demonstrating consistency across the results of these two studies.

The figure below compares the trial-to-implant ratio in SENZA-RCT to that of our European long-term clinical study based on achieving a 50% pain reduction from baseline, as measured by change in VAS score, demonstrating consistency across the results of these two studies.

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In addition, the figure below compares change in disability from baseline to 12 months, as measured by percentage change in ODI score, in SENZA-RCT to that of our European long-term clinical study, demonstrating consistency across the results of these two studies.

Results of Published Prospective Studies

The following chart sets forth the evidence base for HF10 therapy in light of the history of published prospective studies of SCS therapy for leg and back pain. Traditional SCS therapy performed better in our recent Senza-RCT pivotal study relative to the Kumar Process study, a widely cited study on SCS. This is possibly due to factors such as improvements in technology and patient selection.

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Comparatively the evidence base for HF10 therapy as demonstrated in SENZA-RCT and Van Buyten/Al Kaisy studies stands out along several lines. First, both HF10 therapy studies will have 24-month data which matches the total number of 24-month studies in SCS history (Kumar and North). Second, both HF10 therapy studies are uniquely the first to study and show efficacy in treating back pain as can be seen from the back pain portion of the table below. Third, the efficacy demonstrated in treating leg pain exceeds both the control arm in SENZA-RCT and historical data for treating leg pain per this chart. Finally, the table demonstrates the strength of the overall evidence base for HF10 therapy in both quality and quantity of evidence relative to traditional SCS therapy. This can be seen in terms of number of patients treated, relative efficacy in both back and leg pain and comprehensiveness of results reported.

					Leg				Back			
Study	**System**	**Patient**	**Trail Success**		**Base**	**6m**	**12m**	**24m**	**Base**	**6m**	**12m**	**24m**
SENZA-RCT	Nevro Senza	Back & Leg Pain	81/92	VAS Response[5]	7.1	2.3	2.1	TBD	7.5	2.7	2.5	TBD
						81%	79%	TBD		76%	79%	TBD
2014			88%[4]	N	90	90	90	TBD	90	90	90	TBD
AL-Kaisy & Van Buyten [6]	Nevro Senza	Predom	72/82	VAS Response[5]	5.4	1.5	2	2.3	8.4	2.7	2.8	3.3
						86%	65%	71%		74%	70%	60%
2013		Back Pain	88%[4]	N	72	72	67	65	72	72	67	65
SENZA-RCT	Boston Precision	Back & Leg Pain	71/87	VAS Response[5]	7.6	3.6	3.8	TBD	7.8	4.2	4.3	TBD
						54%	51%	TBD		51%	51%	TBD
2014			82%[4]	N	81	81	81	TBD	81	81	81	TBD
Oakley[7] 2007	Boston Precision	Predom	49/65	VAS Response[5]	8	3.9	2.2	NR	NR	NR	NR	NR
						55%	75%	NR	NR	NR	NR	NR
		Leg Pain	75%[4]	N	49	33	12	NR	NR	NR	NR	NR
Schultz[8] 2012	Medtronic Restore Sensor	Predom	NA[1]	VAS Response[5]	5.9	4.3[2]	NR	NR	NR	NR	NR	NR
						NR	NR	NR	NR	NR	NR	NR
		Leg Pain		N	76	71[2]	NR	NR	NR	NR	NR	NR
North[9] 2005	Medtronic Itrel	Predom	17/27	VAS Response[5]	NR	NR	NR	NR	NR	NR	NR	NR
						NR	NR	47%[3]	NR	NR	NR	NR
		Leg Pain	71%[4]	N	24	24	NR	19	NR	NR	NR	NR
Kumar[10,11] 2008	Medtronic Synergy	Predom	43/52	VAS Response[5]	7.6	4	4.4	4.4	5.5	4.1	4.5	4.8
						48%	38%	40%		NR	NR	NR
		Leg Pain	83%[4]	N	52	50	42	42	52	50	42	42

NR: Not reported

Studies with minimum six month follow up.

(1) NA: Not applicable, subjects already implanted

(2) At follow-up of 16 weeks post implantation

(3) At follow-up of 2.9±1.1 years

(4) Trial Success rates are based on the % of patients who had at least 50% reduction in VAS score from baseline at the end of the trial phase

(5) Response rate defined as % of patients who had at least 50% reduction in VAS score from baseline

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(6) Al-Kaisy, A., Van Buyten, J., Smet, I., Palmisani, S., Pang, D., Smith, T. (2014). 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 Medicine 2014; 15: 347-354

(7) Oakley, J., Krames, E., et al. A New Spinal Cord Stimulation System Effectively Relieves Chronic, Intractable Pain: A Multicenter Prospective Clinical Study. Neuromodulation 2007; Volume 10, Number 3

(8) Schultz, D., Webster, L., et al. Sensor-Driven Position-Adaptive Spinal Cord Stimulation for Chronic Pain. Pain Physician 2012; 15:1-12

(9) North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal Cord Stimulation Versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial. Neurosurgery 2005;56:98-106.

(10) Kumar K, Taylor RS, Jacques L, et al. The Effects of Spinal Cord Stimulation in Neuropathic Pain are Sustained:A 24-Month Follow-Up of the Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation. Neurosurgery 2008;63:762-70.

(11) Kumar K, Taylor RS, Jacques L, 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 (200&), doi:10.1016/j.pain2007.07.028

European Long-Term Clinical Study

The two-year follow up of the European long-term clinical study was completed in 2013. The open label, prospective study was conducted at two sites in Belgium and the United Kingdom. 82 chronic pain patients completed the therapy evaluation phase, or trial phase, for HF10 therapy and 72 were permanently implanted as a result of successful evaluation phase. 65 of these patients were followed to two years.

Among the patients who went through the evaluation phase, 87% enrolled had predominant back pain, 17% had failed traditional SCS therapy previously, and 19% of the patients did not have prior back surgery. These are difficult-to-treat patients that have been excluded from traditional SCS therapy studies in the past.

Key safety results:

- No evidence of neurologic deficit or dysfunction attributable to prolonged delivery of HF10 therapy was observed.

- Investigators reported that adverse events were similar in nature and frequency to those seen with traditional SCS therapy. The most common adverse events were implant site pain, infection and lead migration.

Key efficacy results:

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.

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 ODI improved by an average of 15 points at 24 months, a clinically and statistically significant improvement.

Opioid intake decreased, with 86% of patients taking some form of opioid at baseline, and to 57% at 24 months. The mean dosage of oral morphine equivalents per patient decreased from 84 milligrams per day, or mg/day, at baseline to 27 mg/day at 24 months.

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Other results:

- HF10 therapy did not produce paresthesia.

Pilot Study

Senza and HF10 therapy offers a favorable safety profile. In an initial caprine histological study of HF10 therapy no stimulation-related damage to any evaluated structures was shown, including dorsal nerve rootlets, connective tissue and spinal cord. These results allowed us to move on to an initial pilot study in humans.

In the initial pilot study, twenty-four patients with back pain greater than leg pain who were candidates for spinal cord stimulation were trialed at five centers in the United States in a prospective, open label trial. Results showed there was significant improvement from baseline in overall pain scores (8.68 to 2.03, $p < 0.001$) and back pain scores (8.12 to 1.88, $p < 0.001$) with Senza. Senza was preferred to the commercially available systems in 21 of 24 patients (88%).

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:

- **Secure FDA approval for Senza in the United States:** We completed our SENZA-RCT U.S. pivotal study in March 2014. The study met its primary endpoint and we believe it supports the safety and effectiveness of Senza and HF10 therapy. The FDA accepted for filing our June 2014 PMA for Senza. We are working to satisfy the conditions of approval and anticipate initial commercial availability in the U.S. by mid-2015, but there can be no assurance we will receive FDA approval within this timeframe or at all.

- **Communicate what we believe is the compelling clinical efficacy of HF10 therapy to patients, physicians and payors globally:** Given our clinical evidence, we believe we will be able to position our therapy with patients, providers and payors in a differentiated way. The statistical analysis from our U.S. pivotal study support the clinical superiority of HF10 therapy to traditional SCS therapy for treating both leg and back pain. To date, we believe there have been only two other randomized, controlled SCS clinical studies comparing pain treatments. However, these studies only focused on leg pain. Given our pivotal study focused on both back and leg pain in a head-to-head comparison with traditional SCS, if approved, we anticipate being able to differentiate HF10 therapy by communicating its clinical benefits and advantages to patients, physicians and payors.

- **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 a network of distributors and sales agents. In anticipation of FDA regulatory approval in the United States, we expect to initially recruit, hire and train approximately 30 to 40 experienced sales representatives in advance of initial commercial availability in the U.S., which we anticipate to occur by mid-2015, with additional hires over the following 24 months, who will target physician specialties involved in SCS treatment decisions, including neurosurgeons, physiatrists, interventional pain specialists and orthopedic spine surgeons. 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. Our marketing and reimbursement teams intend to drive HF10 therapy adoption through creating awareness and demand among additional stakeholders involved in the SCS treatment decision, including third-party payors, hospitals administrators and patients and their families. We do not believe that any changes will be required to existing patient referral flows or existing coverage and reimbursement policies in order to facilitate adoption in the approximately $1.2 billion existing U.S. SCS market. Internationally, we plan to increase coverage of our target markets through an expansion of our existing direct sales force or our network of distributors and sales agents.

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Expand the existing SCS market by treating back pain: We believe we can significantly expand the existing SCS market by delivering a system that can provide meaningful treatment to the chronic back pain patient population. We believe there is an additional opportunity for an SCS therapy that effectively treats back pain that is approximately the size of the existing global SCS market. With traditional SCS therapy, patients who experience predominant back pain are associated with lower levels of treatment success. Consequently, predominant back pain patients are typically not recommended for treatment with traditional SCS therapy due to the difficulty of achieving and maintaining pain coverage. We believe HF10 therapy is positioned to expand the existing SCS market by effectively treating back pain in addition to leg pain.

Develop HF10 therapy for use in other chronic pain indications: We plan to use our platform technology to develop HF10 therapy for use in other chronic pain indications with significant unmet medical need, including chronic intractable neck and upper extremity pain, refractory chronic migraine and pre-spinal surgery patients. There can be no assurance that we will be successful in developing HF10 therapy for use in other chronic pain indications or in receiving required regulatory approvals to market Senza and HF10 therapy for use in other chronic pain indications.

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 in development include a next-generation IPG, full body MRI compatibility and paddle leads. We believe these innovative enhancements 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 process, which we believe will lower our per unit manufacturing cost. We expect to scale our manufacturing operations as we commercialize Senza in the United States following FDA regulatory approval.

Our Senza System

Senza is designed to create electrical impulses from 2 Hz to 10 kHz, including our proprietary HF10 therapy, which allows for pain relief without paresthesia. HF10 therapy delivers proprietary waveforms at 10 kHz 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 implantable pulse generator, or 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.

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Leads: The leads are thin, insulated medical wires that conduct electrical pulses from the IPG to near the spinal cord. Senza uses percutaneous leads, which can be inserted to the epidural space minimally invasively through a needle. The leads are cylindrical, flexible and steerable, and are offered in different lengths.

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.

Implantable Pulse Generator (IPG): The IPG contains a rechargeable battery and electronics that deliver electrical pulses to the lead. It has 16 output channels and can connect to one or two leads. It is a programmable device and can deliver 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 SCS system is CE Marked and has at least 10 year battery life as indicated in its CE label.

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 customized 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.

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.

Growth Opportunities

Senza is a platform technology. We believe that our platform will have applications in other pain indications, and we are actively investigating some of these opportunities.

Pre-Spinal Surgery

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%. With the increasing number of spinal surgeries in the United States, FBSS is also increasing. While there is a clear need for spinal surgery in many patients, given the high rate of FBSS there is a potential for SCS to move up the treatment progression ahead of spinal surgery for some patients without mechanical instability. HF10 therapy could provide an attractive treatment option for these patients due to its cost, reversibility and initial trial period. In subset analysis of pre-spinal surgery patients from our SENZA-RCT and European studies, we 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), respectively, 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) respectively. We have an ongoing feasibility study in this indication.

Chronic Intractable Neck and Upper Extremity Pain

Chronic neck pain with or without upper extremity 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

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currently exist in the market today, such as epidural injections, but there is a lack of clinically efficacious treatments. In addition, there has been a very small body of evidence published on the application of SCS in chronic neck pain and upper extremity pain by placing the leads in the cervical spine. The evidence has suggested promising therapeutic response when traditional SCS therapy is used, but 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. We have an ongoing feasibility study in this indication.

Refractory Chronic Migraine

Chronic migraine is a widespread and debilitating disorder affecting 2% of the general population. Chronic migraine patients have greater than 15 headache-days per four week period lasting more than 3 months. Conventional treatments often include non-steroidal anti-inflammatory drugs, triptans, ergots, acetaminophens, opioids and botox as well as other therapies. Despite all of these pharmacologics, many patients do not respond to these therapies. Recognizing the opportunity and the potential for HF10 therapy to address this unmet need, we have begun to investigate this indication through feasibility studies. The benefit of HF10 therapy in this indication as opposed to traditional SCS therapy in chronic migraine is the treatment of patients without paresthesia through cervical lead placement, rather than occipital nerve stimulation which requires lead insertion at the base of the skull.

Third-Party Coverage and Reimbursement

In the United States, the primary purchasers of Senza are hospitals and outpatient surgery centers. 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. We believe that SCS procedures using Senza, if approved, would be adequately described by existing CPT, HCPCS II, and ICD-9-CM 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 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 tend to vary, the Medicare program is increasingly 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. 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 recognizing 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

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 expenses were $15.7 million, $20.3 million and $19.8 million, for the years ended December 31, 2012, 2013 and 2014, respectively.

Since the launch of the initial Senza system, we have introduced a number of new 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, second generation active anchor with smaller volume, lead adaptors that allow use of competitor leads already implanted in patients, second generation clinician programmer software, second generation IPG with improved shape and compatibility for scans of the head and extremities with both 1.5 and 3 Tesla (T) MRI machines.

We also expect to continue developing enhancements to Senza to further increase performance and introduce new benefits including next generation IPGs and leads and improved MRI compatibility.

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Sales and Marketing

United States

We are in the process of hiring and training a direct sales organization in the United States. In anticipation of FDA regulatory approval we expect to recruit, hire and train a direct sales force in the United States, who will target physician specialties involved in SCS treatment decisions, including neurosurgeons, physiatrists, interventional pain specialists and orthopedic spine surgeons. We plan to target approximately 2,400 hospitals and outpatient surgery centers at which we believe an estimated 90% of SCS procedures are performed in the United States. In addition, our commercial team plans to create awareness and 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 also intend to develop a product support team in order to provide ongoing support to physicians 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 2010 and to date have expanded our direct sales operations to Austria, Australia, Belgium, Germany, Luxembourg, 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-surgeries. Currently, our major competitors are Medtronic, Boston Scientific and St. Jude Medical, who have obtained regulatory approval for SCS systems. We believe that the primary competitive factors in the market are:

- Sales force experience and access
- Company brand recognition
- Product support and service
- Effective marketing and education
- Technological innovation, product enhancements and speed of innovation
- Pricing and reimbursement
- Published clinical efficacy data

Product reliability, safety and durability

Ease of use

Clinical research leadership

Many of our competitors have greater capital resources, more established operations, longer commercial histories and more extensive relationships with physicians. They also have a 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, St. Jude Medical is currently working on a U.S. pivotal study, SUNBurst, to gain approval for its burst stimulation technology, intended for chronic pain relief with minimal paresthesia. Medtronic is performing randomized clinical studies to collect data on existing SCS products for back pain. Additionally, Boston Scientific has commenced recruiting patients for a randomized clinical trial of a high-frequency SCS therapy. Boston Scientific is also expected to introduce incremental product enhancements such

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as a reduction in the size of the IPG, new accessories and improved MRI compatibility labeling. Additionally, there are a number of emerging competitors that we believe are in the process of or have recently received FDA approval.

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 January 31, 2015, we owned 64 issued patents globally, of which 46 were issued U.S. patents, 11 were issued Australian patents, 4 were issued European patents, two were German Utility Models, and one was an issued Chinese design patent. In particular, one of our patent claims covers a SCS systems that are configured to generate a non-parasthesia producing therapy signals at frequencies between 1,500 Hz to 100,000 Hz. As of January 31, 2015, we held 110 patent applications pending globally, of which 55 were patent applications pending in the United States, and 55 were patent applications pending across Europe, Australia, Canada, Japan, China, and Korea. We also have an exclusive license from the Mayo Foundation to one U.S. issued patent and two U.S. pending patent applications. All of our current issued patents are projected to expire between 2028 and 2032.

As of January 31, 2015, our trademark portfolio contained 15 trademark registrations, 4 of which were U.S. trademark registrations, as well as 16 pending U.S. trademark applications and 5 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 patent application in the applicable country. We cannot assure you 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.

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The Mayo License

In October 2006, we entered into a license agreement, or the Mayo License, with the Venturi Group, LLC, or VGL, and the Mayo Foundation for Medical Education and Research, or 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. We were also granted an exclusive worldwide license under certain patents and patent applications, including any patent applications or issued patents claiming inventions that arose out of the device development and testing activities conducted on our behalf by the Mayo Foundation or VGL pursuant to the agreement, to develop, make, use, sell, offer for sale, and import products covered by the licensed patents or patent applications. As of August 5, 2014, two issued patents were covered by the Mayo License. These two patents expire in 2027 and 2028, respectively.

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. Our obligation to pay royalties commences upon the first commercial sale of a licensed product in a particular country and expires, on a country-by-country and product-by-product basis, in the case of products covered by a licensed patent or patent application upon the expiration of the last valid claim covering such product in such country, and in the case of any other licensed product, upon the fifth anniversary of the first commercial sale of such product in such country. We are obligated to pay Mayo a double-digit percentage of any sublicensing revenue we receive from any sublicensees during the term of the Mayo License. In addition, in connection with the consummation of our IPO in November 2014, we issued the Mayo Foundation 20,833 shares of our common stock pursuant to the terms of the Mayo License. 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 (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. In the event of termination as a result of our material breach, all licenses to the licensed patents will terminate, and our licenses to the know-how provided to us by the Mayo Foundation or VGL in the course of the development and testing activities will become non-exclusive. We do not believe a termination of the Mayo License would have a material adverse impact on our ability to develop, market and sell Senza. In the event that we terminate the Mayo License for breach by either the Mayo Foundation or VGL, all licenses to licensed patents continue, our license to the licensed know-how shall become non-exclusive and our obligation to pay royalties on net sales of licensed products shall be reduced by half. The Mayo Foundation or VGL may also terminate in the event of our insolvency.

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 many 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 are currently seeking, or intending to seek, 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.

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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. In the United States, we are required to manufacture any products that we sell in compliance with the FDA s Quality System Regulation, or 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.

We believe that our most significant supply contracts are as follows:

Pro-Tech Design and Manufacturing

In July 2014, we entered into a new supply agreement with Pro-Tech Design and Manufacturing, Inc., or 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., or Stellar, our single-source supplier of our percutaneous leads and percutaneous lead extenders 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. We refer to the manufacturing agreement as amended by the first amendment as the Stellar Agreement.

Either we or Stellar may terminate the Stellar Agreement at will upon one years 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., or CCC, a subsidiary of Greatbatch Ltd., as our single-source manufacturer of our implantable pulse generator (IPG). In April 2012, we entered into our original supply agreement with CCC,

which we later amended in March 2013 and June 2014. In connection with entry into our new supply agreement, our existing supply agreement with CCC (described below), which was to expire by its terms on March 31, 2015, was terminated.

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On March 13, 2015, we entered into a new multi-year supply agreement with CCC, pursuant to which CCC has agreed to manufacture and supply IPGs, chargers, trial simulators and programmer wands (collectively, the Products). We are obligated to purchase from CCC specified minimum purchase quantities of IPGs during the first two years of the supply agreement and thereafter specified increasing percentages of IPGs, unless CCC is unable to manufacture such IPGs, at similar quantities to those contemplated in the agreement. In addition, if we seek to have a third-party manufacture any products, components and materials not currently produced by CCC as of the effective date of this supply agreement, we are obligated to provide CCC with the opportunity to bid for the supply of such products, components and materials.

The supply agreement continues for ten years unless terminated earlier. The term of the supply 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 applicable renewal period. In the event of a change in control, the supply agreement may be terminated by us or the applicable acquirer, subject to payment of a termination fee of between $50.0 million and $75.0 million and other conditions, upon no earlier than six years after the effective date of the supply agreement. The supply agreement may also be terminated by us, subject to payment of a termination fee of $50.0 million, upon six months prior written notice if we determine that we will discontinue the sale of the IPG; provided, that the effective date of any such termination may not occur prior to the date that is 5 years after the effective date of the supply agreement. In addition, the supply 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.

EaglePicher Medical Power Supply Agreement

In April 2009, we entered into a product supply and development agreement with EaglePicher Medical Power LLC, or 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 has 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 commits us to specified minimum purchase amounts over the course of the term of the agreement 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 provides notice of its intent not to renew prior to the commencement of such renewal term. We have also agreed, subject to certain conditions, to purchase minimum quantities of product. 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.

Other Key Suppliers

We also have other key 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

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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 U.S. Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act, or 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 FDA s Quality System Regulation, or 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. 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.

A Class III product is a product which 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 or special controls. These devices almost always require formal clinical studies to demonstrate safety and effectiveness.

Submission and FDA approval of a premarket approval, or PMA, application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless subject to an exemption, PMA submissions are

subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and

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controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, once the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will formally accept the application for review. The FDA, by statute and by regulation, has 180-days to review an accepted PMA application, although the review of an application more often occurs over a significantly longer period of time, and can take up to several years. In approving a PMA application or clearing a 510(k) application, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

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.

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. 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.

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.

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.

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Clinical Studies

When FDA approval of a Class I, Class II or Class III device requires human clinical trials, and if the device presents a significant risk to human health, the device sponsor is required to file an investigational device exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. If the device is considered a non-significant risk, IDE submission to FDA is not required. Instead, only approval from the Institutional Review Board, or IRB, overseeing the investigation at each clinical trial site is required. 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 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 FDC Act; and the Medical Device Reporting, or MDR, 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, or EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland), we need to comply with the requirements of the EU Active Implantable Medical Devices Directive or 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

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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 R&TTE (Radio and Telecommunications Terminal) Directive has been certified by our Notified Body (the British Standards Institution or BSI).

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the Medical Devices Directive and the Active Implantable Medical Devices Directive with a new regulation (the Medical Devices Regulation). Unlike the Directives that must be implemented into national laws, the Regulation would be directly applicable in all EEA Member States and so is intended to eliminate current national differences in regulation of medical devices.

In October 2013, the European Parliament approved a package of reforms to the European Commission s proposals. Under the revised proposals, only designated special notified bodies would be entitled to conduct conformity assessments of high-risk devices, such as active implantable devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high-risk device. The European Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group, or MDCG, (a new, yet to be created, body chaired by the European Commission, and representatives of Member States) for an opinion. These new procedures may result in the re-assessment of our existing medical devices, or a longer or more burdensome assessment of our new products.

If adopted, the Medical Devices Regulation is expected to enter into force in 2015 and become applicable three years thereafter. In its current form it would, among other things, also impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a qualified person

responsible for regulatory compliance, and provide for more strict clinical evidence requirements.

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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 of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs and criminal liability. The majority of states also have statutes or regulations similar to the federal Anti-Kickback and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Health Insurance Portability and Accountability Act of 1996: The federal Health Insurance Portability and Accountability Act, or 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

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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, or HITECH 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. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA and HITECH.

EU Data Protection Directive: 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. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration and, if adopted, could lead to additional and stricter requirements and penalties in the event of non-compliance.

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 the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members. Certain states also require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, require pharmaceutical companies to comply with the industry s voluntary compliance guidelines and the applicable compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources.

Healthcare Reform: In March 2010 the Affordable Care Act 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.

The full impact of the ACA, as well as other laws and reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

The Foreign Corrupt Practices Act: The Foreign Corrupt Practices Act, or 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

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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, 2014, we had 132 employees globally. We believe the success of our business will depend, 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 under the symbol NVRO. We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, and therefore we are subject to reduced public company reporting requirements. Our principal executive offices are located at 4040 Campbell Avenue, Menlo Park, California 94025. 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 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 (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. Copies of this information may be obtained at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. 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 on Form 10-K or any other filings we make with the SEC.

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ITEM 1A. *RISK FACTORS*

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Annual Report on Form 10-K, including our 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 we expect to continue to incur losses for the foreseeable future. We expect to continue to incur losses as we seek U.S. regulatory approval of Senza, build our U.S. commercial sales force and initiate our commercial launch in the United States, as well as continue to investigate the use of our HF10 therapy to treat other chronic pain conditions. We incurred net losses of $30.7 million and $26.0 million for the years ended December 31, 2014 and 2013, respectively, and as of December 31, 2014, our accumulated deficit was $122.0 million. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders deficit 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. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

If we fail to obtain or maintain U.S. Food and Drug Administration approval to market and sell Senza, or if such approval is delayed, we will be unable to commercially distribute and market Senza in the United States

The process of seeking regulatory approval to market a medical device is expensive and time consuming. There can be no assurance that approval will be granted. Although the Senza SCS system is CE marked for sale in the European Economic Area, or EEA, and approved for sale in Australia, we have not received regulatory approval to commercialize Senza in the United States. If we are not successful in obtaining timely approval of Senza from the U.S. Food and Drug Administration, or FDA, we may never be able to generate significant revenue and may be forced to cease operations. We are currently seeking FDA premarket approval, or PMA, of Senza for the treatment of chronic intractable pain of the trunk and/or limbs, including but not limited to unilateral or bilateral pain associated with failed back surgery syndrome and intractable low back pain and leg pain. The PMA process requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The FDA can delay, limit or deny approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA s satisfaction that our product is safe and effective for its intended use;

the FDA may disagree that our clinical data supports the label that we are seeking;

the FDA may disagree that the data from our preclinical studies and clinical trials is sufficient to support approval; and

the manufacturing process and facilities we use may not meet applicable requirements.

Obtaining approval from the FDA could result in unexpected and significant costs for us and consume management s time and other resources. The FDA could ask us to supplement our submissions, collect additional non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our application. In addition, if approved, 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

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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. Additionally, even if approved, Senza may not be approved for the indications that are necessary or desirable for successful commercialization or profitability.

We are substantially dependent on the FDA s approval of Senza, as well as market acceptance in the United States for our HF10 therapy, and our failure to receive FDA approval of Senza or the failure of our HF10 therapy to gain such 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. From inception through December 31, 2014, our total revenue was $81.9 million and was derived entirely from sales of Senza in Europe and Australia. We have not yet received approval from the FDA to market and sell Senza in the United States. However, we have incurred and will in the future incur significant costs, including costs to build our sales force, in anticipation of PMA approval. If we are unable to obtain approval from the FDA to market and sell Senza in the United States and then to achieve significant market acceptance in the United States, our results of operations will be adversely affected as the United States is expected to be the principal market for this product. Further, because we have incurred costs prospectively in advance of PMA approval, we would be unable to recoup these costs if Senza is not approved by the FDA. Because we do not have any other products currently in development, if we are unsuccessful in commercializing Senza or are unable to market Senza as a result of a quality problem, failure to maintain or obtain 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 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 commercialize our existing or future products. 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 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 sufficiently broadly to prevent others from marketing products and services similar to ours

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or designing 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 U.S. Patent and Trademark Office, or 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, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. 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 need to initiate infringement claims or litigation. Adverse proceedings such as litigation 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 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 could place one or more of our patents at risk of being invalidated or interpreted narrowly. 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

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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 demonstrate to physicians 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, as a result, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing our HF10 therapy to physicians. 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. If we are not successful in convincing physicians 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 support of our products by 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.

Our competitors are large, well-established companies with substantially greater resources than us 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 do. The existing global SCS market is estimated to be approximately $1.5 billion in 2014, 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 prepare to initiate our commercial launch and launch in the United States our competitors will take aggressive action to protect their current market position. For example, in 2012, one of our principal competitors, Boston Scientific Corporation, made a number of allegations regarding the SENZA-RCT U.S. pivotal study, including that we had introduced bias into the study. 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.

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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 we are unable to educate physicians on the safe and effective use of our HF10 therapy and Senza, we may be unable to achieve our expected growth.

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. In addition, we will need to spend substantial time educating physicians using traditional SCS systems on the value of our HF10 therapy as demonstrated by our pivotal U.S. clinical data. 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. It is critical to the success of our commercialization efforts to educate physicians on the proper use of Senza, and to provide them with adequate product support during clinical procedures. It is 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.

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 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 intensify if we enter the U.S. market. For example, our major competitors, Medtronic, Inc., Boston Scientific Corporation and St. Jude Medical, Inc., each has approved neuromodulation systems in at least the United States, Europe, and Australia and have been established for several years. In addition, we understand that St. Jude Medical is working on a U.S. pivotal study for its burst stimulation technology, intended for chronic pain relief with minimal paresthesia, and that Boston Scientific has made public its commencement of recruiting patients for a randomized clinical trial of a high-frequency SCS therapy. 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. 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;

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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 research and development, 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 us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than us 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 us in these matters, our business may be harmed.

We only recently began commercializing Senza in the EEA and Australia and we may never achieve market acceptance.

Senza has been CE marked since 2010, enabling us to commercialize it throughout the EEA, which is comprised of the 28 Member States of the European Union, or EU, plus Norway, Liechtenstein and Iceland. It was also approved by the Australia Therapeutic Goods Administration, or TGA, in 2011. Senza has not yet been approved by the FDA. As a result, we have a limited history of commercializing our product and no history of selling Senza in the United States. We have limited experience engaging in commercial activities and limited established relationships with physicians and hospitals as well as third-party suppliers on whom we depend for the manufacture of our product. We may be unable to gain broader market acceptance in the countries in which we have already begun to commercialize Senza, or, if approved by the FDA, successfully commercialize it in the United States 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

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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 and Senza, do not achieve significantly greater market acceptance of our product, do not gain momentum in our sales activities, 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.

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

In order to commercialize Senza in the United States, if approved by the FDA, we must build a substantial direct sales force. As we initiate our commercial launch and increase our marketing efforts, we will need to retain, grow and develop our direct sales personnel. We intend to make a significant investment in recruiting and training sales representatives in advance of PMA approval. 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, and 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. Also, to the extent we hire personnel from our competitors, 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, and we have been in the past, and may be subject to future allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business.

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.

Traditional SCS has been available for over 40 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. Because we have a limited commercial track record compared to our competitors and Senza has been implanted in patients for less than five years, physicians may be slower to adopt or recommend Senza. Further, while we believe our international 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.

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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 past results in the international markets in which we commercialize Senza should not be relied upon as an indication of our future performance in those markets or, if approved for sale, in the United States

Our revenue has increased from $18.2 million for the year ended December 31, 2012 to $23.5 million for the year ended December 31, 2013 to $32.6 million for the year ended December 31, 2014 on the basis of our sales of Senza in Europe and Australia; however, we do not expect to continue this rate of revenue growth in these international markets. Due to our current penetration in these markets, we expect to grow less rapidly in the future than we have in the past in these markets.

In addition, the characteristics of these markets differ significantly from the U.S. market, including as a result of differences in payor systems and patient treatment regimens. As a result of the differences in these markets, you should not compare our financial results in the international market to any potential future results in the U.S. market nor should you rely on our past results as an indication of our future performance.

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

Sales of Senza outside the United States represented all of our revenue from Senza sales in the years ended December 31, 2013 and 2014. In 2010, we began selling Senza in the EEA through distributors and, in August 2011, we began selling Senza in Australia through our own sales force and distributors. As of December 31, 2014, we sell Senza directly in Austria, Switzerland, United Kingdom, Sweden, Australia, Belgium, Luxembourg and Germany and through distributors and agents located in the Netherlands, 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 U.S. 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;

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;

competitive disadvantage to competition with established business and customer relationships;

foreign currency exchange rate fluctuations;

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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 trade;

the imposition of restrictions on the activities of foreign agents, representatives and distributors;

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

laws and business practices favoring local companies;

longer payment cycles;

difficulties in maintaining consistency with our internal guidelines;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

the imposition of costly and lengthy new export licensing requirements;

the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and

the imposition of new trade restrictions.

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

We are 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:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;
- 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 an adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of Senza or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers may require product redesign and possibly submission to FDA, EEA Notified Bodies, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;

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- one or more of our sole- or single-source suppliers may be unwilling or unable to supply components of Senza;
- 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.

If Senza is approved for sale in the United States, we may not be able to quickly establish additional or alternative suppliers if necessary, in part because we may need to undertake additional activities to establish 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 our IPGs, leads and lead extenders, neurostimulator components, telemetry modules, batteries, and packaging services. Our ability to supply Senza commercially depends, in part, on our ability to obtain a supply of these components that has 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 all 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. 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 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.

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.

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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 need to, among other things, 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, improve manufacturing efficiency or increase 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.

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. Given the established nature of our competitors, and our lack of commercialization 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.

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 selling of our products in certain territories in Europe and Australia. 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.

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.

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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.

Because there is generally no separate reimbursement for medical devices and other supplies used in such procedures, including Senza and our HF10 therapy, and because we believe that SCS procedures using Senza, if approved, would be adequately described by existing CPT, HCPCS II and ICD-9-CM codes for the implantation of spinal cord stimulators and related leads performed in various sites of care, some of our target customers may be unwilling to adopt Senza over more established or lower cost therapeutic alternatives already available or 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. 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 receive access to hospital facilities, our sales may decrease.

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

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. We intend to continue to grow and may experience periods of rapid growth and expansion,

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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 our 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 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 our products 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 pre-spinal surgery patients, chronic intractable neck and upper extremity pain and refractory chronic migraine. We will likely need to conduct additional clinical studies in the future to support approval for these new indications. Clinical testing takes 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, or 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;

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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 stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of our PMA by the FDA. 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.

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

Manufacturing and marketing of 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, the U.S. Supreme Court recently declined to hear an appeal where the U.S. Court of Appeals for the Ninth Circuit ruled that the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act 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 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

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employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business.

In addition, many of our employees have become or will soon become vested in a substantial amount of stock or 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 employees in the neuromodulation and medical device industry are subject to strict non-compete or confidentiality agreements with their employers, including our main competitors Medtronic, Inc., Boston Scientific Corp., and St. Jude Medical, Inc. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us. Boston Scientific Corp., for example, has initiated a lawsuit against one of our employees alleging that the employee cannot work for us without inevitably disclosing Boston Scientific s proprietary information. Although we are not a party to this lawsuit, it has impeded our ability to utilize this employee. It is likely that we will experience similar aggressive tactics by our competitors as they seek to protect their market position, particularly as we prepare to enter the U.S. market.

Our credit facility contains restrictions that limit our flexibility in operating our business.

In October 2014, we entered into a term loan agreement with Capital Royalty Partners and certain of its affiliates, which we refer to as our credit facility. Subject to certain conditions, we have access to borrow up to $50.0 million principal amount of senior secured term loan financing in up to three draws on or before September 30, 2015 under the credit facility. In December 2014, we drew down $20.0 million under this facility. Our credit facility also contains various covenants that limit our ability to engage in specified types of transactions. Subject to limited exceptions, these covenants limit our ability to, among other things:

- sell, lease, transfer, exclusively license or dispose of our assets;
- create, incur, assume or permit to exist additional indebtedness or liens;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our capital stock;
- make specified investments (including loans and advances);

merge, consolidate or liquidate; and

enter into certain transactions with our affiliates.

In addition, our credit facility contains certain financial covenants, including certain minimum pre-specified liquidity and revenue requirements. In particular, we are required to maintain a minimum of $5.0 million of cash and certain cash equivalents, and we must achieve minimum revenue of $25.0 million in 2015, $30.0 million in 2016, $40.0 million in 2017, $50.0 million in 2018 and $70.0 million in 2019. The covenants in our credit facility may limit our ability to take certain actions and, in the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate the commitment to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness, which includes our intellectual property. In addition, if we fail to meet the required covenants, we will not have access to the additional tranches under the credit facility.

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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 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. 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, Inc., Boston Scientific Corp., and St. Jude Medical, Inc., 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 noninfringement 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.

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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. 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. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

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

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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. 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. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. 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. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. 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.

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

Recent 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, or 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, may affect patent litigation, and 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

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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 the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

If we fail to comply with our obligations under our existing intellectual property license with the Mayo Foundation or under future license agreements, we could lose license rights that are important to our business.

We are currently a party to a license agreement, or the Mayo License, with the Mayo Foundation for Medical Education and Research, or the Mayo Foundation. Our Mayo License imposes, and we expect that future license agreements will impose, various diligence, royalty, insurance and other obligations on us. For example, the Mayo License requires that we continue to use commercially reasonable efforts to commercialize products incorporating the technology we license and to satisfy other specified obligations, including the payment of royalties on the sales of such products. If we fail to comply with our obligations under the Mayo License or future license agreements, the counterparty to the license may have the right to terminate such license. We do not believe a termination of the Mayo License would have an adverse impact on our ability to commercialize Senza due, in part, to our proprietary patent rights; however, if the Mayo Foundation terminates the license, we may be subject to disputes with them that could be costly and time-consuming. Further, if any future licenses we enter into are terminated, we may need to negotiate new or reinstated licenses with less favorable terms, and we could lose access to critical technology related to our existing or future products.

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, six of

our nine executive officers and key employees, including our Chief Executive Officer, have worked for our major competitors (or companies acquired by these competitors), which include Boston Scientific

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Corporation, Medtronic, Inc. and St. Jude Medical, Inc. 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,

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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 will be required 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 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 grow our business and transition to operating as a public company. We believe that our growth will depend, in part, on our ability to fund our commercialization efforts and our efforts to develop Senza and our HF10 therapy for the treatment of chronic pain and technology complementary to our current products. Our existing resources may not allow us to conduct all of the activities that we believe would be beneficial for our future growth. As a result, we may need to seek funds in the future. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the year ended December 31, 2014, our net cash used in operating activities was $31.1 million as compared to $21.1 million for the year ended December 31, 2013, and, as of December 31, 2014, our working capital was $190.3 million. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the outcome, timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities, including the potential for the FDA and other regulatory authorities to require that we perform more studies or product tests than we currently expect;
- the scope and timing of our investment in our U.S. commercial infrastructure and sales force;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- the costs of commercialization activities including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of Senza;

changes or fluctuations in our inventory supply needs and forecasts of our supply needs;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the amount and timing of any draws we make under our credit facility;

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.

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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 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 research and development activities, clinical trials and regulatory approvals;
- fluctuations in our expenses associated with increasing our inventory, 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 prepare for our commercial launch of Senza in the U.S., we intend to substantially increase our levels of inventory in order to meet our estimated demand and, as a result, incur significant expenditures associated with such increases in our inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or under-estimate 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 obsolesce 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. For example, during the year ended December 31, 2014 and 2013,

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we recorded charges of $0.8 million and $1.0 million, respectively, for the write down of excess and obsolete inventory. If our estimates of required inventory are too high, we may be exposed to further inventory obsolesce 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, in certain years we have historically experienced lower sales in the summer months and around the holidays, primarily due to the buying patterns and implant volumes of our distributors, hospitals and clinics. 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. In addition, we believe our limited history commercializing our products has, in part, made our seasonal patterns more difficult to discern, making it more difficult to predict future seasonal patterns.

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

All of our current 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 and Australian Dollars. In 2014 and 2013, nearly all of our total revenue was denominated in foreign currencies. 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 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, or the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating loss, or NOL, carryforwards and other tax attributes, such as research and development tax credits to offset future taxable income and taxes.

We may in the future experience one or more Section 382 ownership changes. If so, or if we do not generate sufficient taxable income, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability. 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. As of December 31, 2014, we had federal and state net operating loss

carryforwards, or NOLs, of $108.2 million and $31.7 million, respectively, available to offset future taxable income, due to prior period losses, which if not utilized will begin to expire in 2026 and 2016 for federal and state purposes, respectively.

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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.

Senza is also 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 they 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

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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 our Notified Body (the British Standards Institution, or BSI), which could impair our ability to market products in the EEA in the future.

Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to bring Senza to market in the United States and 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:

the Federal Food, Drug, and Cosmetic Act 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. The FDA and other 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.

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

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development 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.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the Medical Devices Directive and the Active Implantable Medical Devices Directive with a new regulation (the Medical Devices Regulation). Unlike the Directives that must be implemented into national laws, the Regulation would be directly applicable in all EEA Member States and so is intended to eliminate current national differences in regulation of medical devices.

In October 2013, the European Parliament approved a package of reforms to the European Commission s proposals. Under the revised proposals, only designated special notified bodies would be entitled to conduct conformity assessments of high-risk devices, such as active implantable devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high-risk device. The European Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group, or MDCG, (a new, yet to be created, body chaired by the European Commission, and representatives of Member States) for an opinion. These new procedures may result in the re-assessment of our existing medical devices, or a longer or more burdensome assessment of our new products.

If adopted, the Medical Devices Regulation is expected to enter into force in 2015 and become applicable three years thereafter. In its current form it would, among other things, also impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a qualified person responsible for regulatory compliance, and provide for more strict clinical evidence requirements. While we believe that the Medical Device Regulation, if adopted in its current form, would likely require reassessment of Senza, the actual impact on Senza remains uncertain unless and until the adoption of a final Medical Device Regulation.

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 CE Marked in the EEA and approved by the TGA in Australia for specific treatments and anatomies and, if Senza is approved by the FDA, it will be approved for specific treatments and anatomies in the United States. 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 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

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sizable damage awards against us that may not be covered by insurance. In addition, if our products are approved for sale in the United States and the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials 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. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Further, the advertising and promotion of our products is subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices, or the EU Medical Devices Directive, 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 to the general public 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 IFU, 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 FDA s Quality System Regulation, or 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, or MDR, 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

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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.

Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid or other third-party payors for our products, 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

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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;

the federal Health Insurance Portability and Accountability Act of 1996, or 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, or HITECH, 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, or 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. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year;

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 recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management s attention from the business. 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.

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

In March 2010, the ACA was signed into law, which includes, 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. This excise tax is resulting in a significant increase in the tax burden on our industry, and if any efforts we undertake to offset the excise tax are unsuccessful as we begin to 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 PPACA, 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. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals.

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 product candidates or additional pricing pressures.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, 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 develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for 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.

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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 Common Stock

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 Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and the New York Stock Exchange, 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, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the JOBS Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company 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. We also expect that operating as a public company will make it more difficult and expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers

Our stock price may be volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.

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 document and others such as:

- announcements related to our PMA submission with the FDA for Senza, and related announcements related to regulatory approval to market Senza in the United States;

- results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and planned U.S. clinical trials for Senza;

announcements of new products by us or our competitors;

adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;

our operating results;

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;

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any intellectual property infringement actions in which we may become involved;

announcements concerning our competitors or the medical device industry in general;

achievement of expected product sales and profitability;

manufacture, supply or distribution shortages;

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;

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.

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. 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.

An active, liquid and orderly market for our common stock may not develop.

Prior to our IPO in November 2014, there had been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained. An active trading market may not develop following the consummation of our IPO or, if it is developed, may not be sustained. Further, certain of our existing institutional investors, including investors affiliated with certain of our directors, purchased an aggregate of 365,000 shares of our common stock in that offering and consequently fewer shares may be actively traded in the public market because these stockholders are restricted from selling the shares by restrictions under applicable securities laws and the

lock-up agreements entered into in connection with our IPO, which would reduce the liquidity of the market for our common stock. The lack of an active market may impair our stockholders ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies or in-license new product candidates using our shares as consideration.

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.

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We are an emerging growth company and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO in November 2014, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

If we are unable to implement and 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 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, beginning with our second annual report following our IPO, which will be for our fiscal year ending December 31, 2015, provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an emerging growth company, as defined by the JOBS Act. We do not expect to have our independent registered public accounting firm attest to our internal control over financial reporting for so long as we are an emerging growth company.

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. We are in the process of designing and implementing the internal control over financial reporting required to comply with this obligation, which process will be 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, when required in the future, 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 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.

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

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we

may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred

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stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale in connection with our IPO lapse, the trading price of our common stock could decline. As of December 31, 2014, we had outstanding a total of approximately 24.9 million shares of common stock. Of these shares, 8,050,000 shares of our common stock are freely tradable, without restriction (except as otherwise applicable), in the public market. However, J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, the lead underwriters of our IPO, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to our IPO will expire on May 4, 2015, following which at least approximately 17.2 million shares of common stock will be eligible for sale in the public market, approximately 15.2 million of which shares are held by current directors, executive officers and other affiliates and may be subject to Rule 144 under the Securities Act.

In addition, as of December 31, 2014, approximately 3.0 million shares of common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements 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 could decline.

The holders of approximately 18.1 million shares of our outstanding common stock as of December 31, 2014, including shares issuable upon exercise of outstanding options, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

As of December 31, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 61.3% of our outstanding voting stock. These stockholders will have the ability to influence us through this ownership position, and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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;

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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 acquiror;

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 acquiror from conducting a solicitation of proxies to elect the acquiror 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.

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;

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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. Additionally, the terms of our credit facility prohibit us from paying cash dividends on our capital stock. 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 research and development facilities are located in Menlo Park, California, where we lease and occupy approximately 20,900 square feet of office and laboratory space. In March 2015 we extended this lease such that it expires in September 30, 2015. We also lease office space in Switzerland and a small warehouse space in Menlo Park, California.

Subsequent to December 31, 2014, we entered into a lease agreement for approximately 50,000 square feet of office space located in Redwood Shores, California for a period beginning June 2015 through May 2022 with initial annual payments of approximately $2.0 million, increasing to annual payments of $2.4 million in the final year of the lease term.

For additional information, see Note 5. *Commitments and Contingencies* of Notes to Consolidated Financial Statements in Part II, Item 8 of this Report.

ITEM 3. ***LEGAL PROCEEDINGS***

We may from time to time be involved in various legal proceedings of a character normally incident to the ordinary course of our business. We are not currently subject to any material legal proceedings.

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

Not applicable

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PART II

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

Price Range of Common Stock

Our common stock has been publicly traded on the New York Stock Exchange, or the NYSE, under the symbol NVRO since the initial public offering, or IPO, of our common stock on November 6, 2014. Prior to that time, there was no public market for our common stock. The following table sets forth on a per share basis, for the periods indicated, the low and high sale prices of our common stock as reported by the NYSE.

Year Ended December 31, 2014	High	Low
Fourth quarter (beginning November 6)	$ 39.37	$ 25.00

Holders of Record

At March 2, 2015, there were approximately 3,507 stockholders of record of our common stock, and the closing price per share of our common stock was $44.19. 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. Additionally, the terms of our credit facility with Capital Royalty Partners prohibit us from paying cash dividends on our capital stock without their prior consent. 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.

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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 New York Stock Exchange, 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, 2014
Nevro Corp. (NVRO)	$ 100.00	$ 153.51
S&P 500 (GSPC)	$ 100.00	$ 101.36
S&P Healthcare Equipment (SPSIHE)	$ 100.00	$ 106.98

Recent Sales of Unregistered Securities

From January 1, 2014 through December 31, 2014, we sold and issued the following unregistered securities:

1. Prior to filing our registration statement on Form S-8 in November 2014, we granted stock options and stock awards to employees, directors and consultants under our 2007 Stock Incentive Plan, as amended, covering an aggregate of 696,603 shares of common stock, at a weighted average exercise price of $11.95 per share. Of these, options covering an aggregate of 4,707 shares were cancelled without being exercised.

2. Prior to filing our registration statement on Form S-8 in November 2014, we sold an aggregate of 450,941 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of $1.1 million upon the exercise of stock options and stock awards.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (1) and (2) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

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Initial Public Offering

Use of Proceeds

In November 2014, we completed our IPO and issued 8,050,000 shares of our common stock, including the underwriter s exercise of their over-allotment option, at an initial offering price to the public of $18.00. We received net proceeds from the IPO of approximately $131.6 million, after deducting underwriting discounts and commissions of approximately $10.1 million and estimated offering costs of approximately $3.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. The underwriters were J.P. Morgan, Morgan Stanley, Leerink Partners and JMP Securities.

Shares of our common stock began trading on the New York Stock Exchange on November 6, 2014. The shares were registered under the Securities Act on registration statement on Form S-1 (Registration No. 333-199156), which was declared effective by the SEC on November 5, 2014.

We expect to use the proceeds from the IPO to fund our activities related to seeking U.S. regulatory approval and preparing for the commercial launch of Senza in the United States, and for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated November 5, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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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 Report. The selected consolidated statements of income data for each of the three years in the period ended December 31, 2014, and the consolidated balance sheet data as of December 31, 2014, 2013 and 2012 have been derived from our audited consolidated financial statements.

(in thousands, except per share data)	2014	2013	2012
Selected Consolidated Statements of Income Data:			
Revenue:	$ 32,573	$ 23,500	$ 18,150
Cost of revenue:	11,278	9,473	7,527
Gross profit	21,295	14,027	10,623
Operating expenses:			
Research and development	19,824	20,345	15,659
Sales, general and administrative	29,777	18,833	14,094
Total operating expenses	49,601	39,178	29,753
Loss from operations	(28,306)	(25,151)	(19,130)
Interest and other income (expense), net	(1,896)	(501)	325
Loss before income taxes	(30,202)	(25,652)	(18,805)
Income tax provision	478	362	162
Net loss	$ (30,680)	$ (26,014)	$ (18,967)
Basic and diluted net loss per common share	$ (6.94)	$ (29.84)	$ (38.59)
Shares used in computing basic and diluted net loss per common share	4,440,663	876,932	494,066

	As of December 31,		
	2014	2013	2012
Selected Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 25,287	$ 12,409	$ 5,618
Short-term investments	$ 151,521	$ 44,123	$ 24,997
Working capital	$ 190,327	$ 66,870	$ 43,572
Total assets	$ 202,496	$ 75,411	$ 49,111
Notes payable	$ 19,511	$	$
Total stockholders equity (deficit)	$ 172,070	$ (85,790)	$ (61,794)

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

This Annual Report on Form 10-K 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 for the next 12 months; the impact of recent changes in accounting standards; 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, 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

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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 Report under Part I, Item 1A. *Risk Factors*. All forward-looking statements and reasons why results may differ included in this Report are made as of the date of the filing of this 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 Report.

Overview

We are a medical device company that has developed and commercialized an innovative neuromodulation platform for the treatment of chronic pain. Our Senza system is the only spinal cord stimulation, or SCS, system that delivers our proprietary HF10 therapy. Our SENZA-RCT U.S. pivotal study, a non-inferiority study, met its primary and secondary endpoints, and our post-hoc statistical analysis supports the superiority of HF10 therapy over traditional SCS therapies for treating both leg and back pain. While SCS therapy is indicated and reimbursed for treating back and leg pain, it has limited efficacy in back pain and is utilized primarily for treating leg pain, which has limited its market adoption. In our pivotal study, HF10 therapy was demonstrated to provide significant and sustained back pain relief in addition to leg pain relief. Additionally, HF10 therapy was demonstrated to provide pain relief without paresthesia, a constant tingling sensation that is the basis of traditional SCS therapy. By utilizing anatomical lead placement instead of relying on paresthesia, HF10 therapy is designed to reduce variability in the operating procedure, providing meaningful benefits to both patients and physicians. We believe we are positioned to transform and grow the approximately $1.5 billion existing global SCS market under current reimbursement by treating back pain in addition to leg pain and by eliminating paresthesia.

Senza received a CE Mark in 2010, and full commercialization commenced in Europe and Australia in 2011 and is reimbursed under existing SCS codes. We market our products to physicians and sell to hospitals and outpatient surgery centers through both a direct sales organization and distributors in Australia, and Europe. During 2011, we established our international sales organizations to support our product launch outside of the United States. Senza is not currently approved for sale in the United States and we have not generated any sales revenue within the United States. We submitted our PMA to the FDA in June 2014, and, in January 2015, we received a letter from the FDA informing us of the approvability of our PMA, subject to satisfaction of regulatory inspections and audits of manufacturing facilities, methods and controls for Senza, as well as finalization of the products labeling with the FDA. We are working to satisfy the conditions of approval and anticipate initial commercial availability in the U.S. by mid-2015, if approved by the FDA, but there can be no assurance we will receive FDA approval within this timeframe or at all.

Since our inception, we have financed our operations primarily through equity financings and borrowings under our debt facility. Our accumulated deficit as of December 31, 2014 was $122.0 million. A significant amount of our capital resources has been used to support the development of Senza and our HF10 therapy, including, our pivotal clinical trial, SENZA-RCT, which we initiated in May 2012. We intend to make a significant investment building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives for U.S. commercialization. We also intend to continue to make significant investments in research and development to develop Senza to treat other chronic pain indications, including conducting clinical trials to support our future regulatory submissions. As a result of these and other factors, we expect to continue to incur net losses for the next several years and we expect to require substantial additional funding, 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. Many of these suppliers are currently single source suppliers. 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

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inventory impairment charges. In particular, as we prepare for our commercial launch of Senza in the U.S., we intend to substantially increase our levels of inventory in order to meet our estimated demand 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 obsolesce comparatively.

On November 5, 2014, our registration statement on Form S-1 relating to our initial public offering (IPO) of common stock became effective. Our IPO closed on November 12, 2014 at which time we issued 8,050,000 shares of our common stock, which included 1,050,000 shares issued pursuant to the exercise in full by the underwriters of their over-allotment option. We received cash proceeds of approximately $131.6 million from the IPO, net of underwriting discounts and commissions and estimated offering costs paid by us.

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.

We Do Not Expect Our Revenue Growth Rate in International Markets to Continue at Historic Rates

Our revenue increased from $18.2 million to $23.5 million to $32.6 million in the fiscal years 2012, 2013 and 2014, respectively. Revenue increased as a result of our sales of Senza in Europe and Australia; however, we do not expect to continue this rate of revenue growth in these international markets given our existing penetration in these markets. Due to governmental reimbursements constraints in the European SCS market limiting the number of annual SCS implants and our current penetration in these markets, we expect to grow less rapidly in the future than we have in the past in this market.

Significant Investment in U.S. Sales Organization

We have started to make significant investments in building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives for U.S. commercialization. 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 require significant investment by us in advance of PMA approval. 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.

Importance of Physician Awareness and Acceptance of Senza

We continue to invest in programs to educate international 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. 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.

Access to Hospital Facilities

In the United States, in order for physicians to use Senza, the hospital facilities where these physicians treat patients typically will require us to enter into purchasing contracts. This process can be lengthy and time-consuming and

require extensive negotiations and management time. In Europe, we may be required to engage in a contract bidding process in order to sell Senza product, which processes are only open at certain periods of time, and we may not be successful in the bidding process.

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Inventory Buildup

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, as we prepare for our commercial launch of Senza in the U.S., we intend to substantially increase our levels of inventory. As a result, we will incur significant expenditures associated with the increases in our inventory, which will include satisfying certain minimum purchase obligations, as demand for Senza in the U.S. is developing. Further, the manufacturing process for Senza requires lengthy lead times, during which components may become obsolete. We may also over- or under-estimate 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. 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 research and development 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. In the future, we expect to initiate clinical trials to support the development of Senza and HF10 therapy for the treatment of other chronic pain conditions. We believe that our continuing clinical research and regulatory efforts will continue to drive adoption of Senza. While research and development and clinical testing are time consuming and costly, we believe that clinical data demonstrating efficacy, safety and cost effectiveness is critical to increasing the adoption of HF10 therapy.

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, or US 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 of Notes to Consolidated Financial Statements in Part II, Item 8 of this Report.

Revenue

We recognize revenue when all of the following criteria are met:

- persuasive evidence of an arrangement exists;

the sales price is fixed or determinable;

collection of the relevant receivable is probable at the time of sale; and

delivery has occurred or services have been rendered.

For a majority of sales, where our sales representative delivers our product at the point of implantation at hospitals or medical facilities, we recognize revenue upon completion of the procedure and authorization, which represents satisfaction of the required revenue recognition criteria. For the remaining sales, which are sent from

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our distribution centers directly to hospitals and medical facilities, as well as distributor sales where product is ordered in advance of an implantation procedure and a valid purchase order has been received, we recognize revenue at the time of shipment of the product, which represents the point in time when the customer has taken ownership and assumed the risk of loss and the required revenue recognition criteria are satisfied. Such customers are obligated to pay within specified terms regardless of when or if they ever they sell or use the products. We do not offer rights of return or price protection and we have no post-delivery obligations.

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.

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 assesses 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 goods sold 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 on a straight-line basis over the requisite service period of the award, which is generally the vesting term of four years.

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:

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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. Because of the limitations on the sale or transfer or our common stock as a privately held company, we do not believe our historical exercise pattern is indicative of the pattern we will experience as a publicly traded company. We have consequently used the Staff Accounting Bulletin, or SAB, 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period. We plan to continue to use the SAB 110 simplified method until we have sufficient trading history as a publicly traded company.

Volatility. We determine 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. 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 intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer 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.

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 net deferred tax assets as of December 31, 2014 and 2013. We intend to maintain a full valuation allowance on the federal, state and foreign deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

As of December 31, 2014, we had federal and state net operating loss carryforwards, or NOLs, of $108.2 million and $31.7 million, respectively, available to offset future taxable income, due to prior period losses, which if not utilized will begin to expire in 2026 and 2016 for federal and state purposes, respectively. 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, or 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, an 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 more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws.

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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 may in the future experience a Section 382 ownership change. If so, or if we do not generate sufficient taxable income, we may not be able to utilize a material portion of our NOLs and tax credits even if we achieve profitability. 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 and penalties related to income taxes have been recognized in the statements of operations and comprehensive loss in 2014 and 2013.

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 $6.6 million, net of allowance of $10,000 as of December 31, 2014, and $6.6 million, net of allowance for doubtful accounts of $0.2 million, as of December 31, 2013.

Components of Results of Operations

Revenue

Our revenue is generated from sales to two types of customers: hospitals and outpatient medical facilities served through a direct sales force, and third-party distributors. Sales to hospitals and medical facilities represent the majority of our revenue. Product sales to hospitals and medical facilities are billed to and paid by the hospitals 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 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 fluctuates based on the selling price of the system, as the sales price of a system varies among jurisdictions, and the mix of sales by jurisdiction. In addition, our revenue may fluctuate based on the ratio of trials to permanent implants. 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 that we sell our products in. We recognized net foreign currency transaction losses of $1.7 million, $0.6 million, and $0.2 million, during the year ended December 31, 2014, 2013 and 2012, respectively which are recorded within other income (expense), net in the consolidated statement of operations.

We expect our revenue to fluctuate from quarter to quarter due to a variety of factors, including seasonality, as we have historically experienced lower sales in the summer months and around the holidays, and the impact of the buying patterns and implant volumes of our hospitals and medical facilities, and third party distributors.

Cost of Revenue

We utilize contract manufactures for production of Senza. Cost of revenue consists primarily of acquisition costs of the components of Senza, allocated 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.

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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, primarily by our costs to have our products manufactured for us, the ratio of trials to permanent implants, the period of time between a trial and the related permanent implant, and, to a lesser extent, the percentage of products we sell to distributors as compared to those sold directly to hospitals and medical facilities as our gross margin is typically higher on products we sell directly as compared to products we sell through distributors. 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 research and development, sales, general and administrative expense. Personnel costs are the most significant component of operating expenses and consist of salaries, benefits, stock-based compensation, and sales commissions. We expect operating expenses to increase in absolute dollars as we continue to invest to grow our business.

Research and Development. Research and development, or 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 research and development expenses 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. 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. Sales, general and administrative, or SG&A, expenses consist 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 services 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 24 months, we significantly increased the size of our sales presence internationally and increased marketing spending to generate sales opportunities. We expect SG&A expenses to significantly increase as we build up our sales and marketing personnel in anticipation of approval and launch 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 fiscal 2014, our administrative expenses increased as we prepared to become a public company. We expect our administrative expenses will continue to increase as we increase our headcount and expand our facility and information technology to support our operations as a public company. Additionally, we anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, director and officer insurance premiums and investor relations costs associated with being a public company. Our SG&A expenses may fluctuate from period to period due to the seasonality of our revenue and the timing and extent of our SG&A expenses.

Interest Income (Expense), Net

Interest income (expense) consists primarily of interest income earned on our investments and interest paid on our outstanding debt.

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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.

Income Tax Expense

Income tax expense consists primarily of income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including net operating loss carryforwards and research and development credits and other 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 Report.

Comparison of the Years Ended December 31, 2014 and 2013

Revenue, Cost of Revenue, Gross Profit and Gross Margin

	Year Ended December 31,		
(in thousands)	**2014**	**2013**	**Change**
Revenue	$ 32,573	$ 23,500	$ 9,073
Cost of revenue	11,278	9,473	1,805
Gross profit	21,295	14,027	7,268
Gross margin	65%	60%	5%

Revenue. In 2014, revenue increased to $32.6 million from $23.5 million in 2013, an increase of $9.1 million, or 39%, due to increased acceptance of Senza in Europe and Australia. We established our international sales operations in 2011, and materially expanded our sales forces in those countries during 2012 and 2013 to support our revenue growth.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $1.8 million, or 19%, in 2014 as compared to 2013 due to higher personnel costs of $1.0 million, an increase in the costs for manufactured goods of $0.6 million related to the increased production of units due to the increase in sales volume, as well as an increase in our shipping costs of $0.2 million. Gross profit increased $7.3 million, or 52%, to $21.3 million, in the year ended 2014 as compared to 2013 due to higher sales volume, while our gross profit as a percentage of sales increased by 5%.

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Operating Expenses

	Year Ended December 31,				
	2014		2013		
(in thousands)	Amount	% of Total Revenue	Amount	% of Total Revenue	Change Amount
Operating expenses:					
Research and development	$ 19,824	61%	$ 20,345	87%	$ (521)
Sales, general and administrative	29,777	91	18,833	80	10,944
Total operating expenses	$ 49,601	152%	$ 39,178	167%	$ 10,423

Research and Development Expenses. R&D expenses decreased $0.5 million, or 3%, in 2014 as compared to 2013. Our clinical trial expenses declined by $2.8 million in 2014 to $1.1 million as compared to $3.9 million during 2013 due to the completion of the enrollment in our clinical trial in February 2013. Our development costs were $4.5 million in both 2013 and 2014 due to our continued investment in preclinical activities for our products and our preparation of the PMA submission for Senza. We submitted our completed PMA in June 2014 to the FDA. The overall decline in our R&D expenses was offset by an increase in personnel costs of $1.8 million as we increased our headcount to support continued investment in our products, as well as increased facilities related expenses of $0.6 million.

Sales, General and Administrative Expenses. SG&A expenses increased $10.9 million, or 58%, in 2014 as compared to 2013, primarily due to an increase in personnel costs of $5.5 million as we increased sales and administrative headcount to support growth, as well as increased facilities related expenses of $0.9 million. Our professional consulting expenses increased by $3.0 million during 2014 as compared to 2013 as a result of our expenses related to preparing to become a public company. In addition our travel-related expense increased $0.7 million as a result of our larger sales team and support for the expansion in foreign markets.

Interest Income, Other Income (Expense), Net and Income Tax Expense

	Year Ended December 31,		
(in thousands)	2014	2013	Change
Interest income (expense), net	$ (16)	$ 153	$ (169)
Other income (expense), net	(1,880)	(654)	(1,226)
Income tax	(478)	(362)	(116)

Interest Income (Expense, net). Interest income (expense), net decreased to an expense of $16,000 during 2014 from interest income in 2013 of $0.2 million, primarily due to an increase in our average outstanding debt balances during the year 2014. We entered into a credit line during 2014 under which we drew down $20.0 million in December 2014, whereas during the year ended December 31, 2013 we did not have any debt outstanding.

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 to the U.S. dollar. We recorded such expense of $1.7 million during the year ended December 31, 2014, and expense of $0.7 million

during the same period in 2013. Our remeasurement gains and losses are affected by changes in the foreign currency translation rates of the different countries that we do business in.

Income Tax Expense. Income tax expense was $0.5 million in 2014, compared to an income tax expense of $0.4 million in 2013. We incur income tax expense primarily due to foreign taxes. We continue to generate tax losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We have a full valuation allowance for our deferred tax assets. The change in income tax expense was due to changes in foreign income taxes on profits realized by our foreign subsidiaries as we expanded internationally.

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Comparison of the Years Ended December 31, 2013 and 2012

Revenue, Cost of Revenue, Gross Profit and Gross Margin

	Year Ended December 31,		
(in thousands)	**2013**	**2012**	**Change**
Revenue	$ 23,500	$ 18,150	$ 5,350
Cost of revenue	9,473	7,527	1,946
Gross profit	14,027	10,623	3,404
Gross margin	60%	59%	1%

Revenue. In the year ended December 31, 2013, revenue increased to $23.5 million from $18.2 million in the prior year, an increase of $5.4 million, or 29%, due to increased acceptance of Senza in Europe and Australia. We established our international sales operations in 2011, and materially expanded our sales forces in those countries during 2012 and 2013 to support our revenue growth.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $2.0 million, or 26%, in 2013 as compared to 2012 due to higher costs for manufactured goods of $1.3 million related to the increased production of units due to the increase in sales volume, as well as an increase in our write-off of obsolete inventory of $0.9 million. Gross profit increased $3.4 million, or 32%, to $14.0 million, in the year ended December 31, 2013 as compared to the prior year due to higher sales volume, while our gross profit as a percentage of sales remained essentially the same in each year.

Operating Expenses

	Year Ended December 31,				
	2013		2012		
(in thousands)	**Amount**	**% of Total Revenue**	**Amount**	**% of Total Revenue**	**Change Amount**
Operating expenses:					
Research and development	$ 20,345	87%	$ 15,659	86%	$ 4,686
Sales, general and administrative	18,833	80	14,094	78	4,739
Total operating expenses	$ 39,178	167%	$ 29,753	164%	$ 9,425

Research and Development Expenses. R&D expense increased $4.7 million, or 30%, in the year ended December 31, 2013 compared to the year ended December 31, 2012, primarily due to an increase in personnel costs of $2.2 million as we increased our headcount to support continued investment in our products, as well as increased external consulting costs of $1.2 million, and an increase in facilities related expenses of $0.6 million. Our clinical trial expenses declined to $3.9 million during 2013 as compared to $6.7 million during 2012 due to the completion of the enrollment in our clinical trial in February 2013. Our development costs increased from $1.7 million during 2012 to $4.5 million during 2013 due to our continued investment in preclinical activities for our products and our preparation of the PMA submission for Senza throughout 2013. We submitted our completed PMA in June 2014 to the FDA.

Sales, General and Administrative Expenses. SG&A expense increased $4.7 million, or 34%, in 2013 compared to 2012, primarily due to an increase in personnel costs of $2.8 million as we increased sales and administrative headcount to support growth. Travel-related expense increased $0.9 million and our marketing and promotional expenses increased by $0.4 million as a result of our larger sales team and support for the expansion in foreign markets. In addition our professional consulting expenses increased by $0.6 million during the year ended December 31, 2013 over the comparable period in 2012.

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Interest Income, Other Income (Expense), Net and Income Tax Expense

(in thousands)	Year Ended December 31, 2013	2012	Change
Interest income	$ 153	$ 139	$ 14
Other income (expense), net	(654)	186	(840)
Income tax	(362)	(162)	(200)

Interest Income. Interest income increased to $0.2 million during 2013 from $0.1 million during the prior year, primarily due to an increase in our average investment balances during the year.

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 to the U.S. dollar. We recorded income of $0.2 million during the year ended December 31, 2012, and a loss of $0.7 million during the same period in 2013.

Income Tax Expense. Income tax expense was $0.4 million in 2013, compared to an income tax expense of $0.2 million in 2012. We incur income tax expense primarily due to foreign taxes. We continue to generate tax losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We have a full valuation allowance for our deferred tax assets. The change in income tax expense was due to changes in foreign income taxes on profits realized by our foreign subsidiaries as we expanded internationally.

Liquidity, Capital Resources and Plan of Operations

Since our inception through December 31, 2014, we have financed our operations through private placements of preferred stock and issuance of common stock in our IPO. At December 31, 2014, we had cash and cash equivalents and investments of $176.8 million. Based on our current operating plan, we expect that our cash on hand, together with the anticipated funds from our operations and the remaining funds available under our credit facility will be sufficient to fund our operations through at least the next twelve months.

In October 2014, we entered into a credit facility with Capital Royalty Partners and certain of its affiliates, which we refer to as our credit facility, whereby we have access to borrow up to $50.0 million principal amount of senior secured term loan financing in up to three draws on or before September 30, 2015. We borrowed $20.0 million on December 12, 2014. We are eligible to draw a second tranche in a principal amount of $10.0 million on or prior to June 29, 2015 and a third tranche in a principal amount of $20.0 million on or prior to September 30, 2015, in each case, upon meeting certain conditions and continued compliance with the covenants in the credit facility.

We expect to incur substantial expenditures in the foreseeable future in connection with the expansion of our U.S. commercial infrastructure and sales force in anticipation of our commercial launch of Senza in the United States, if approved. In addition, we intend to make investment in the development of Senza and HF10 therapy for the treatment of other chronic pain conditions, including ongoing research and development programs and clinical trials. If Senza is approved for commercialization in the United States, we expect that additional funding will be required in order to build the associated sales, marketing and distribution infrastructure.

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. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the outcome, timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities, including the potential for the FDA and other regulatory authorities to require that we perform more studies or product tests than we currently expect;

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- the scope and timing of our investment in our U.S. commercial infrastructure and sales force;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- the costs of commercialization activities including product sales, marketing, manufacturing and distribution;
- the amount and timing of any draws we make under our credit facility;
- the degree and rate of market acceptance of Senza;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- 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 if we enter the U.S. market. For example, our major competitors, Medtronic, Inc., Boston Scientific Corporation and St. Jude Medical, Inc., have each 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 additional 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:

	Year Ended December 31,

	2014	2013	2012
Net cash (used in) provided by:			
Operating activities	$ (31,148)	$ (21,095)	$ (22,467)
Investing activities	(108,055)	(19,899)	15,276
Financing activities	152,081	47,785	1,532
Net increase (decrease) in cash	$ 12,878	$ 6,791	$ (5,659)

Cash Used in Operating Activities. Net cash used in operating activities was $31.1 million and $21.1 million for the years ended December 31, 2014 and 2013, respectively, primarily due to the net losses during the periods of $30.7 million and $26.0 million, respectively. The cash used in operating activities in the year ended December 31, 2014 was affected by changes in operating assets and liabilities, including an increase of $3.0 million in accounts payable and accrued liabilities and non-cash stock based compensation expense of $2.0 million, offset by an increase in our prepaid expenses and other current assets of $1.3 million, and an increase in our inventory balances by $5.5 million. The increase in cash used in operations during the year ended December 31, 2013 was primarily due to changes in our operating assets and liabilities, including a decrease in our outstanding prepaid and other assets of $1.2 million, an increase of $3.1 million in accounts payable and

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accrued liabilities, and non-cash stock based compensation expense of $1.6 million, which were offset in part by an increase in our accounts receivable balances of $0.7 million and an increase in our inventory balance by $1.6 million.

Net cash used in operating activities was for the year ended December 31, 2012 was $22.5 million, primarily due to the net loss of $19.0 million. The cash used in operating activities in the year ended December 31, 2012 was affected by changes in operating assets and liabilities, including an increase of $1.7 million in accounts payable and accrued liabilities and non-cash stock based compensation expense of $1.1 million, offset by an increase in our prepaid expenses and other current assets of $1.0 million, an increase in accounts receivable of $2.2 million, and an increase in our inventory balances by $3.6 million.

Cash Used in Investing Activities. Investing activities consisted primarily of changes in investment balances, including purchases and maturities of short-term investments. During the year ended December 31, 2014 and 2013 we made net purchases of $107.4 million and $19.6 million of investments, respectively. During the year ended December 31, 2012 a total of $15.4 million of investments matured.

Cash Provided by Financing Activities. Cash provided by financing activities in the year ended December 31, 2014 was $152.1 million, primarily from the $131.6 million in net proceeds received in the IPO, as well as borrowing under our note payable of $19.5 million, which consisted of borrowings of $20.0 million, and closing fees of $0.5 million. Cash provided by financing activities for 2013 consisted of $47.7 million in net proceeds from the issuance of Series C convertible preferred stock in March 2013 and $0.1 million received upon exercise of common stock options. Cash provided by financing activities was $1.5 million for 2012, primarily from the proceeds received upon the exercise of common stock options.

Credit Facility

On October 24, 2014, we entered into a credit facility with Capital Royalty Partners and certain of its affiliates, which we refer to as our credit facility, whereby, subject to certain conditions, we have access to borrow up to $50.0 million principal amount of senior secured term loan financing in up to three draws on or before September 30, 2015. The credit facility provides for quarterly interest only payments at a fixed rate of 11.5% per annum on outstanding loans until the quarterly payment date three years after the first borrowing, followed by three years of quarterly interest payments at a fixed rate of 11.5% per annum and quarterly principal payments in equal installments. The final principal payment will also include a cash payment of 5% of the principal amount drawn. We made the first draw in a principal amount of $20.0 million on December 12, 2014, net of closing fees of $0.5 million. In March 2015, we entered into a First Amendment under the credit facility extending the draw-down deadline for the second tranche of $10.0 million from March 31, 2015 to June 29, 2015, upon meeting certain conditions. We may also draw a third tranche in a principal amount of $20.0 million, at our election, on or prior to September 30, 2015, upon, among other conditions, raising $30.0 million in net proceeds from a private equity financing or receiving FDA approval of our PMA for Senza. At our election, 3.5% per annum of interest payments that are owed during the three year period following the first draw under the credit facility is payable in-kind, which, if so selected, would be added to the outstanding principal amount of the loans; the remaining 8.0% per annum must be paid in cash. Upon the satisfaction of certain conditions precedent on or prior to September 30, 2016, including the receipt of FDA approval of our PMA for Senza, the interest only period will be extended so that the outstanding principal amount of the terms loans will be payable in a single installment at maturity (the 24th quarterly payment date after the first borrowing). The credit facility contains customary events of default, including in the event of bankruptcy or upon the occurrence of a material adverse change. Our obligations under the credit facility are collateralized by substantially all of our assets, including our intellectual property.

The credit facility includes affirmative and negative covenants, including certain minimum financial covenants for pre-specified liquidity and revenue requirements. In particular, we are required to maintain a minimum of $5.0 million of cash and certain cash equivalents, and we must achieve minimum revenue of

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$25.0 million in 2015, $30.0 million in 2016, $40.0 million in 2017, $50.0 million in 2018 and $70.0 million in 2019. In addition, the credit facility prohibits the payment of cash dividends on our capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. As of December 31, 2014, we were in compliance with all applicable covenants.

Contractual Obligations and Commitments

We have lease obligations consisting of operating leases for our principal offices that expire in 2015. The following table summarizes our contractual obligations as of December 31, 2014 (in thousands):

		Payments due by period			
	Total	**Less than 1 year**	**1 to 3 years**	**4 to 5 years**	**After 5 years**
			(in thousands)		
Lease obligations	$359	$359	$	$	$
Total	$359	$359	$	$	$

Subsequent to December 31, 2014, we entered into a lease agreement for approximately 50,000 square feet of office space located in Redwood Shores, 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 in the final year of the lease term. In March 2015, we entered into supply agreements with certain of our suppliers that require an aggregate upfront payment of $1.8 million, along with certain minimum annual purchase commitments that total an aggregate of $80.2 million, with $35.2 million due in 2015, and the remainder due within 1 to 3 years.

Off-Balance Sheet Arrangements

Through December 31, 2014, 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 5 to the consolidated financial statements within Part II, Item 8 of this 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, 2014, we had cash and cash equivalents of $25.3 million consisting of cash and money market funds and investments of $151.5 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, 2014 and held cash in foreign banks of approximately $5.7 million and $4.3 million at December 31, 2013 and 2014 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

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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, all of our revenue and a portion of our 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. We recognized net foreign currency transaction losses of $1.7 million, $0.6 million, and $0.2 million, during the year ended December 31, 2014, 2013 and 2012, respectively. A hypothetical 10% favorable or unfavorable change in the weighted-average foreign exchange rates for the year ended December 31, 2014 would have affected the annualized consolidated foreign-currency-denominated operating loss by approximately 5% for the year. 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.

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 Report.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Nevro Corp.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock, redeemable convertible preferred stock and stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Nevro Corp. and its subsidiaries (the Company) at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits of these consolidated statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 18, 2015

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Nevro Corp.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 25,287	$ 12,409
Short-term investments	151,521	44,123
Accounts receivable, net of doubtful accounts of $10 and $182 at December 31, 2014 and 2013, respectively	6,610	6,605
Inventories, net	14,856	10,123
Prepaid expenses and other current assets	2,851	1,514
Total current assets	201,125	74,774
Property and equipment, net	647	117
Other assets	424	220
Restricted cash	300	300
Total assets	$ 202,496	$ 75,411
Liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders equity (deficit)		
Current liabilities		
Accounts payable	$ 4,460	$ 3,177
Accrued liabilities	6,268	4,536
Other current liabilities	70	191
Total current liabilities	10,798	7,904
Notes payable	19,511	
Other long-term liabilities	117	62
Total liabilities	30,426	7,966
Commitments and contingencies (Note 5)		
Series A convertible preferred stock, par value $0.001 zero shares and 130,508,081 shares authorized at December 31, 2014 and 2013, respectively; zero shares and 5,437,826 shares issued and outstanding at December 31, 2014 and 2013, respectively;		47,217
Series B and C redeemable convertible preferred stock, par value $0.001 zero shares and 234,485,750 shares authorized at December 31, 2014 and 2013, respectively; zero shares and 9,770,222 shares issued and outstanding at December 31, 2014 and 2013, respectively		106,018
Stockholders equity (deficit)		

Preferred stock, $0.001 par value, 10,000,000 shares and zero shares authorized at December 31, 2014 and 2013, respectively; zero shares issued and outstanding at December 31, 2014 and 2013, respectively		
Common stock, $0.001 par value, 290,000,000 and 472,000,000 shares authorized at December 31, 2014 and 2013, respectively; 24,865,491 and 1,120,416 shares issued and outstanding at December 31, 2014 and 2013, respectively	25	1
Additional paid-in capital	293,945	5,331
Accumulated other comprehensive income	77	28
Accumulated deficit	(121,977)	(91,150)
Total stockholders equity (deficit)	172,070	(85,790)
Total liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders equity (deficit)	$ 202,496	$ 75,411

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

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Nevro Corp.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year Ended December 31,		
	2014	2013	2012
Revenue	$ 32,573	$ 23,500	18,150
Cost of revenue	11,278	9,473	7,527
Gross profit	21,295	14,027	10,623
Operating expenses			
Research and development	19,824	20,345	15,659
Sales, general and administrative	29,777	18,833	14,094
Total operating expenses	49,601	39,178	29,753
Loss from operations	(28,306)	(25,151)	(19,130)
Interest income (expense), net	(16)	153	139
Other income (expense), net	(1,880)	(654)	186
Loss before income taxes	(30,202)	(25,652)	(18,805)
Provision for income taxes	478	362	162
Net loss	(30,680)	(26,014)	(18,967)
Accretion of redeemable convertible preferred stock to redemption value	(147)	(153)	(98)
Net loss attributable to common stockholders	(30,827)	(26,167)	(19,065)
Other comprehensive income (loss):			
Changes in foreign currency translation adjustment	(147)		
Changes in gains (losses) on short-term investments, net	196	23	(15)
Net change in other comprehensive income (loss)	49	23	(15)
Comprehensive loss	$ (30,778)	$ (26,144)	$ (19,080)
Net loss per share attributable to common stockholders, basic and diluted	$ (6.94)	$ (29.84)	(38.59)
Weighted-average number of common shares used to compute basic and diluted net loss per share	4,440,663	876,932	494,066

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

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Nevro Corp.

Consolidated Statements of Convertible Preferred Stock, Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)

(in thousands, except share data)

	Series A Convertible Preferred Stock		Series B and C Redeemable Convertible Preferred Stock		Common Stock		Additional		Accumulated Other	
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	Total
alances at anuary 1, 012	5,437,826	$ 47,217	5,450,578	$ 58,093	641,324	$ 1	$ 1,192	$ (45,918)	$ 20	$ (44,705
ccretion of edeemable onvertible referred stock suance costs				98				(98)		(98
xercise of ommon stock ptions					435,661		601			601
esting of arly exercised tock options							265			265
tock based ompensation xpense							1,125			1,125
et loss								(18,967)		(18,967
ther omprehensive come (loss)									(15)	(15
alances at ecember 31, 012	5,437,826	47,217	5,450,578	58,191	1,076,985	1	3,183	(64,983)	5	(61,794
suance of eries C edeemable onvertible referred stock February and arch 2013 at 11.11 per hare for cash,			4,319,644	47,674						

et of issuance osts of 326,623										
ccretion of edeemable onvertible referred stock ssuance costs				153				(153)		(153
xercise of ommon stock ptions					43,431		111			111
esting of arly exercised tock options							460			460
tock based ompensation xpense							1,577			1,577
et loss								(26,014)		(26,014
ther omprehensive come (loss)									23	23
alances at ecember 31, 013	5,437,826	47,217	9,770,222	106,018	1,120,416	1	5,331	(91,150)	28	(85,790
ccretion of edeemable onvertible referred stock ssuance costs				147				(147)		(147
onversion of referred stock common tock	(5,437,826)	(47,217)	(9,770,222)	(106,165)	15,208,048	15	153,367			153,382
ssuance of ommon stock pon initial ublic offering, et of issuance osts					8,050,000	8	131,609			131,617
ssuance of ommon stock connection ith license greement					20,833		523			523
xercise of ommon stock ptions					466,194	1	963			964
esting of arly exercised tock options							154			154

tock based ompensation xpense				1,998			1,998
et loss					(30,680)		(30,680)
ther omprehensive come (loss)						49	49
alances at ecember 31, 014	$	$	24,865,491	$ 25	$ 293,945	$ (121,977)	$ 77	$ 172,070

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

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Nevro Corp.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2014	2013	2012
Cash flows from operating activities			
Net loss	$ (30,680)	$ (26,014)	$ (18,967)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	96	47	39
Provision for doubtful accounts	(172)	2	180
Stock-based compensation expense	1,998	1,577	1,125
Noncash research and development expense	523		
Amortization (accretion) of premium (discount) on short term investments	82	540	538
Non-cash interest expense	11		
Write down of inventory	754	1,066	
Changes in operating assets and liabilities			
Accounts receivable	167	(750)	(2,427)
Inventories	(5,487)	(1,600)	(3,597)
Prepaid expenses and other current assets	(1,337)	1,246	(994)
Other assets	(204)	(138)	(35)
Accounts payable	1,283	1,227	624
Accrued liabilities	1,763	1,888	1,082
Other long term liabilities	55	(186)	(35)
Net cash used in operating activities	(31,148)	(21,095)	(22,467)
Cash flows from investing activities			
Purchases of short-term investments	(159,265)	(70,404)	(40,350)
Proceeds from maturity of short-term investments	51,835	50,760	55,706
Restricted cash		(200)	(50)
Purchase of property and equipment	(625)	(55)	(30)
Net cash provided by (used) in investing activities	(108,055)	(19,899)	15,276
Cash flows from financing activities			
Proceeds from issuance of notes payable	19,500		
Proceeds from issuance of convertible preferred stock, net		47,674	
Proceeds from issuance of common stock in initial public offering, net	131,617		
Proceeds from issuance of common stock from stock option exercises	964	111	1,532
Net cash provided by financing activities	152,081	47,785	1,532
Net increase (decrease) in cash and cash equivalents	12,878	6,791	(5,659)

Cash and cash equivalents			
Cash and cash equivalents at beginning of period	12,409	5,618	11,277
Cash and cash equivalents at end of period	$ 25,287	$ 12,409	$ 5,618
Supplemental disclosures of cash flow information Cash paid for income taxes	$ 243	$ 179	$ 32
Significant non-cash transactions			
Vesting of early exercised stock options	$ 154	$ 460	$ 265

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

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Nevro Corp.

Notes to Consolidated Financial Statements

1. Formation and Business of the Company

We were 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, we were 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, 2014, the Company incurred a net loss of $30.7 million and used $31.1 million of cash in operations. At December 31, 2014, the Company had an accumulated deficit of $122.0 million and does not expect to experience positive cash flows in the near future. The Company has financed operations to date primarily through private placements of equity securities, the issuance of common stock in the initial public offering completed in November 2014, and borrowings under a debt agreement. The Company s ability to continue to meet its obligations and to achieve its business objectives is dependent upon, amongst other things, obtaining U.S. Food and Drug Administration (FDA) approval and commercializing in the United States, generating sufficient revenues and its ability to continue to control expenses, if necessary, to meet its obligations as they become due for the foreseeable future. Failure to increase sales of its products, obtain U.S. FDA approval, manage discretionary expenditures or raise additional financing, as required, may adversely impact the Company s ability to achieve its intended business objectives.

Initial Public Offering

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 estimated offering costs; 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.

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 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 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. 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.

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The Company derives all of its revenues from sales to customers in Australia and Europe, and has not yet received approval to sell its products in the Unites States. Revenue by geography is based on the billing address of the customer. The following table sets forth revenue by geographic area for countries with revenue accounting for more than 10% of the total revenue during the periods presented:

	Years ended December 31,		
	2014	**2013**	**2012**
Australia	35%	30%	28%
United Kingdom	18%	19%	15%
Germany	17%	18%	14%
Netherlands	7%	9%	11%
Ireland	4%	7%	12%

Long-lived assets and operating income outside the U.S. 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 United States Dollars using the current exchange rates in effect at the balance sheet date and equity accounts are translated into United States dollars 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 gain or loss of $1.1 million, $0.3 million and $0.2 million during the years ended December 31, 2014, 2013 and 2012, respectively. Additionally, realized gains and losses resulting from transactions denominated in currencies other than the local currency are recorded in other income (expense), net in the consolidated statements of operations. The Company recorded realized foreign currency transaction losses of $0.6 million, $0.2 million, and $34,000, during the year ended December 31, 2014, 2013 and 2012, respectively.

As the Company s international operations grow, its risks associated with fluctuation 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; clinical accruals; stock-based compensation; depreciation and amortization lives; inventory valuation; valuation of investments and deferred tax assets, including valuation allowances. Estimates are based on historical experience,

where applicable, and other assumptions believed to be reasonable by the management. Actual results may differ from those estimates under different assumptions or conditions.

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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 of America in excess of federally insured limits. The Company maintained investments in money market funds that were not federally insured during the year ended December 31, 2014 and 2013 and held cash in foreign banks of approximately $4.3 million and $5.7 million at December 31, 2014 and 2013, respectively, that was not federally insured. The Company has not experienced any losses on its deposits of cash and cash equivalents.

All of the Company s revenue has been derived from sales of its products in international markets, principally Australia and Europe. In the international markets in which the Company participates, the Company uses both a direct sales force and distributors to sell its products. The Company performs ongoing credit evaluation of its direct customers and distributors, does not require collateral, and maintains allowances for potential credit losses on customer accounts when deemed necessary.

During the year ended December 31, 2014, no customers accounted for more than 10% of our revenues or the Company s accounts receivable balance as of December 31, 2014. During the year ended December 31, 2013, no customers accounted for more than 10% of the Company s revenue. As of December 31, 2013, one customer accounted for 11% of our accounts receivable balance. During the year ended December 31, 2012, two customers accounted for 11% and 11%, respectively, of the Company s revenue.

The Company is subject to risks common to early-stage 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 s products require approval from the U.S. Food and Drug Administration prior to commencing commercial sales in the U.S. There can be no assurance that the Company s products will receive all of the required approvals. If the Company is denied such approvals or such approvals are delayed, it may have a material adverse impact on the Company s results of operations, financial position and liquidity.

The Company expects to incur substantial operating losses for the next several years and will 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 and debt 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

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the amount of $10.6 million and $2.4 million as of December 31, 2014 and 2013, respectively. At December 31, 2014 and 2013, the Company s cash equivalents were held in institutions in the U.S. and include deposits in a money market fund which was unrestricted as to withdrawal or use.

Restricted Cash

Restricted cash of $0.3 million and $0.3 million as of December 31, 2014 and 2013, respectively, represents certificates of deposit collateralizing payment of charges related to the Company s corporate credit cards.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company s investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of comprehensive income or 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 market value of such inventory. Cost is determined using the standard cost method which approximates the first-in, first-out basis. Market value is determined as the lower of replacement cost or net realizable value. 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 net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective 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 market approach as that has been used to value the inventory. The Company also periodically evaluates inventory quantities in consideration of actual loss experience. As a result of these evaluations, for the year ended December 31, 2014 and 2013, the Company recognized a total write down of $0.8 million and $1.1 million for Senza inventories. The Company s estimation of the future demand for a particular component of the Senza product 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 recognizes revenue when all of the following criteria are met:

persuasive evidence of an arrangement exists;

the sales price is fixed or determinable;

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collection of the relevant receivable is probable at the time of sale; and

delivery has occurred or services have been rendered.

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 satisfaction of the required revenue recognition criteria. 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 procedure and a valid purchase order has been received, the Company recognizes revenue at the time of shipment of the product, which represents the point in time when the customer has taken ownership and assumed the risk of loss and the required revenue recognition criteria are satisfied. The Company s 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 and it has no post-delivery obligations.

The Company has a limited one-year warranty to most customers. Estimated warranty obligations are recorded at the time of sale and to date, warranty costs have been insignificant.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment 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, 2014.

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, all of the Company s revenues have been derived outside of the United States, and the taxes paid have been predominantly due to income taxes in foreign 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.

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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.

Comprehensive Income (Loss)

Comprehensive income (loss) represents all changes in the stockholders equity (deficit) 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, or R&D, costs, 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 ASC 718, C*ompensation 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.

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, expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends.

The fair value 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.

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.

Estimating the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is

recognized. These inputs are subjective and generally require significant analysis and judgment to develop. For all stock options granted to date, we estimated the volatility data based on a study of publicly traded industry peer companies. For purposes of identifying these peer companies, we considered the industry, stage of development, size and financial leverage of potential comparable companies. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the equity-settled award.

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The Company recognizes a benefit from stock-based compensation as additional paid-in capital if an incremental tax benefit is realized by following the with-and-without approach. In addition, the company has also elected to ignore the indirect tax effects of stock-based compensation deductions for financial and accounting reporting purposes.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders 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 the net loss attributable to common stockholders 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, redeemable convertible preferred stock 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 May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU s effective date will be the first quarter of fiscal year 2017 using one of two retrospective application methods. The Company is in the process of determining the potential effects of this ASU on its consolidated financial statements.

In June 2014, the FASB issued ASU 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*. ASU 2014-12 requires that a performance target that affects vesting and could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for the Company in its first quarter of 2016 with early adoption permitted. The Company does not expect its pending adoption of ASU 2014-12 to have a material impact on its consolidated financial statements and disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern,* to provide guidance on management s responsibility in evaluating whether there is substantial doubt about a company s ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for the Company in the first quarter of 2017 with early adoption permitted. The Company does not expect its pending adoption of ASU 2014-15 to have an impact on its consolidated financial statements and disclosures.

3. 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.

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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 are comprised of 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 market pricing convention for identical assets that the Company has the ability to access. The Company s short-term investments are comprised of commercial paper, corporate notes and U.S. government agency obligations. All short-term investments 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 and 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, 2014	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds[(i)]	$ 10,590	$	$	$ 10,590
Commercial paper[(ii)]		140,484		140,484
Corporate notes[(ii)]		19,037		19,037
Total	$ 10,590	$ 159,521	$	$ 170,111

Balance as of December 31, 2013	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds[(i)]	$ 2,372	$	$	$ 2,372
Commercial paper[(ii)]		15,246		15,246
Corporate notes[(ii)]		30,377		30,377
Total	$ 2,372	$ 45,623	$	$ 47,995

(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.

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4. 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, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investment Securities				
Commercial paper[(i)]	$ 140,273	$ 211	$	$ 140,484
Corporate notes	19,040		(3)	19,037
Total securities	$ 159,313	$ 211	$ (3)	$ 159,521

(i) Includes $8.0 million of commercial paper that is classified as cash and cash equivalents on the consolidated balance sheet.

	December 31, 2013			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investment Securities				
Commercial paper[(i)]	$ 15,231	$ 15	$	$ 15,246
Corporate notes	30,379	2	(4)	30,377
Total securities	$ 45,610	$ 17	$ (4)	$ 45,623

(i) Includes $1.5 million of commercial paper that is classified as cash and cash equivalents on the consolidated balance sheet.

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 Company has not recorded any realized gains, realized losses or impairment on its investments during the periods presented.

The contractual maturities of the Company s investment securities were all within one year as of December 31, 2014 and 2013.

Inventories, Net (in thousands)

	December 31	
	2014	**2013**
Raw materials	$ 7,960	$ 4,595
Finished goods	6,896	5,528
	$ 14,856	$ 10,123

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Property and Equipment, Net (in thousands)

	December 31	
	2014	2013
Laboratory equipment	$ 390	$ 105
Computer equipment and software	125	79
Furniture and fixtures	112	95
Leasehold improvements	22	22
Construction in process	333	55
Total	982	356
Less: Accumulated depreciation and amortization	(335)	(239)
Property and equipment, net	$ 647	$ 117

Depreciation and amortization expense for the years ended December 31, 2014, 2013 and 2012 was $96,000, $47,000 and $39,000, respectively. During the year ended December 31, 2013, the Company retired equipment having an original cost of $0.1 million, and removed the cost and the related accumulated depreciation from the consolidated balance sheet.

Accrued Liabilities (in thousands)

	December 31	
	2014	2013
Accrued payroll and related expenses	$ 4,268	$ 2,545
Accrued professional fees	184	186
Accrued taxes	998	929
Accrued clinical and research expenses	613	454
Accrued other	205	422
Total accrued liabilities	$ 6,268	$ 4,536

5. Commitments and Contingencies

Operating Leases

The Company entered into a non-cancellable operating lease effective May 1, 2010 for facilities in Menlo Park, as amended in 2012 to extend the period of the lease until May 31, 2015. In March 2015, the Company extended the lease through September 30, 2015 and is obligated to pay approximately $275,000 in additional rent payments. 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 is obligated to pay approximately $100,000 in lease payments over the term of the lease.

In February 2015, the Company entered into a lease agreement for approximately 50,000 square feet of office space located in Redwood Shores, 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.

Rent expense for the years ended December 31, 2014, 2013 and 2012 was $0.7 million, $0.5 million and $0.3 million, respectively.

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Future minimum lease payments under the operating leases as of December 31, 2014 are as follows (in thousands):

	Operating Leases
Year ending December 31,	
2015	359
	$ 359

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 or disclosure at December 31, 2014 and 2013.

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, 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.

License Agreement

In March 2006, the Company entered into an amended and restated license agreement with the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, and Venturi Group LLC, or 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 anytime 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.

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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 will be 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.

Retainer fees paid and recognized as research and development expenses during the years ended December 31, 2013 and 2012 was $18,000 and $40,000, respectively. Royalties paid during the years ended December 31, 2014, 2013 and 2012 were $0.3 million, $0.2 million and $0.2 million, respectively.

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

6. Notes Payable

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 may enter into three term loan agreements totaling $50.0 million with the lenders on or before September 30, 2015. Under the credit facility, each term loan is to be paid over 24 quarterly payment periods, with the first payment due on the last day of the calendar quarter during the period for which the term loan is made. The first twelve quarterly payments will be interest only payments, and the last twelve quarterly payments will be equal installments in which interest and principal amounts are paid. Interest is calculated at a fixed rate of 11.5% per annum. During the interest only period for the first twelve quarterly payments under each term loan, the Company may elect to make the 11.5% interest payment by making a cash payment for the 8.0% per annum of interest and making a payment in kind for the remaining amount, for which the 3.5% per annum of interest would be added to the outstanding principal amount of the loans. The Company has initially chosen not to elect the payment in kind option. The final payment will also include an additional amount for closing and repayment fees equivalent to 5% of the term loan agreement. The Company entered into the first term loan for $20.0 million on December 12, 2014, and incurred closing fees of $0.5 million. The Company is eligible to enter into a second term loan for a principal amount of $10.0 million on or prior to March 31, 2015, upon meeting certain conditions. In March 2015, the Company entered into a First Amendment under its credit facility with Capital Royalty Partners to extend the draw-down deadline of the second draw from March 31, 2015 to June 29, 2015. The Company may also enter into a third term loan for a principal amount of $20.0 million on or prior to September 30, 2015, upon, among other conditions, raising $30.0 million in net proceeds from a private equity financing or receiving FDA approval of the Company s PMA for Senza. Upon the satisfaction of certain conditions precedent on or prior to September 30, 2016, including the receipt of FDA approval of the Company s PMA for Senza, the interest only period will be extended so that the outstanding principal amount of the

terms loans will be payable in a single installment at maturity (the 24th quarterly payment date after the first borrowing). The credit facility contains customary events of default, including in the event of bankruptcy or upon the occurrence of a material adverse change. The Company s obligations under the credit facility are collateralized by substantially all of its assets, including its intellectual property.

The credit facility includes affirmative and negative covenants, including certain minimum financial covenants for pre-specified liquidity and revenue requirements. In particular, the Company is required to maintain a minimum of $5.0 million of cash and certain cash equivalents, and the Company must achieve

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minimum revenue of $25.0 million in 2015, $30.0 million in 2016, $40.0 million in 2017, $50.0 million in 2018 and $70.0 million in 2019. In addition, the credit facility prohibits the payment of cash dividends on the Company s capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. As of December 31, 2014, the Company was in compliance with all applicable covenants.

As of December 31, 2014, future minimum payments for the notes are as follows (in thousands):

	Term Loans
2015	$ 2,332
2016	2,338
2017	3,739
2018	7,977
2019 and beyond	14,960
Total minimum payments	31,346
Less: Amount representing interest	(10,346)
Less: Amount representing closing and repayment fees	(1,000)
Present value of minimum payments	20,000
Less: Unamortized debt discount	(495)
Plus: Accretion of closing and repayment fees	6
Notes payable, net	19,511
Less: Notes payable, current portion	
Non-current portion of notes payable	$ 19,511

7. Convertible Preferred Stock

Prior to the 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 million shares of the Company s common stock.

The Company recorded the Series B and C redeemable convertible preferred stock at fair value on the dates of issuance. The Company classifies the Series B and C redeemable convertible preferred stock outside of stockholders deficit because the shares contain liquidation features that are not solely within the Company s control. The Series B and C redeemable convertible preferred shares were originally issued with a contingent redemption feature, which allowed the holders to redeem their shares five years following the issuance date of the Series B and C redeemable preferred shares. Accordingly, the Company is accreting the Series B and C redeemable convertible preferred stock for change in redemption value with a change to accumulated deficit at the end of each reporting period. Accordingly, the Company has accreted $0.1 million and $0.2 million during the years ended December 31, 2014 and 2013,

respectively.

8. Stock-Based Compensation

Summary of Plans

The Company s Board of Directors, or 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) and the 2014 Employee Stock Purchase Plan. 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 Company s 2007 Stock Incentive Plan, as amended (the 2007

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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. 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. As of December 31, 2014, no stock had been issued under the 2014 Employee Stock Purchase Plan.

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.

Options granted under the 2014 Plan may be either incentive stock options, nonstatutory stock options, restricted stock awards 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. Upon the exercise of options, the Company issues new common stock from its authorized shares. 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 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% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. The vesting provisions of individual options may vary but provide for vesting of at least 20% per year.

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 29,613 at December 31, 2014, and 57,202 and 184,960 at December 31, 2013 and 2012, respectively, 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, 2014 and 2013 cash received related to unvested shares totaled $0.1 million and $0.2 million, respectively. Amounts recorded are transferred into common stock and additional paid-in-capital as the shares vest.

Restricted Stock

In March 2011, the Company issued 416,983 common shares under a restricted stock agreement to one of the officers of the Company at a purchase price of $1.44 per share. Under the terms of the agreement, the holder was entitled to purchase the shares in exchange for a promissory note. All the shares were purchased in March 2011 in exchange for a promissory note aggregating to $0.6 million. The restricted stock agreement granted the Company repurchase rights which lapsed upon attainment of full vesting by the stockholder. The restricted common shares vested 33% one year from the vesting start date and monthly thereafter over the next two years. The note bore interest at 0.54% per annum compounded annually. The principal amount of the note along with accrued interest was discharged on a quarterly basis in arrears on a pro rata basis over a period of three years conditioned upon the holder continuing to provide services to the Company. The Company accounted for the grant of the restricted common stock as stock-based

compensation based on the fair value of the shares on the

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original grant date, and recognized expense over the three-year vesting period. The Company recorded stock-based compensation expenses of $48,000 and $0.3 million for the years ended December 31, 2014 and 2013, respectively. At December 31, 2014 and 2013, zero and 34,749 shares of common stock were subject to repurchase by the Company, respectively.

Activity under the Stock Plans was as follows:

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balances at January 1, 2012	278,314	1,962,900	$ 2.64		
Additional shares reserved	537,136				
Options granted	(584,550)	584,550	$ 3.60		
Options exercised		(435,661)	$ 3.60		
Options cancelled	133,920	(133,920)	$ 3.60		
Balances at December 31, 2012	364,820	1,977,869	$ 2.65	8.4	$ 1,741
Additional shares reserved	1,014,289				
Options granted	(915,458)	915,458	$ 3.60		
Options exercised		(43,431)	$ 2.64		
Options cancelled	117,934	(117,934)	$ 3.60		
Balances at December 31, 2013	581,585	2,731,962	$ 2.88	8.0	$ 1,655
Additional shares reserved	1,854,166				
Options granted	(753,102)	753,102	$ 13.50		
Options exercised		(498,565)	$ 2.26		
Options cancelled	12,767	(12,767)	$ 3.60		
Balances at December 31, 2014	1,695,416	2,973,732	$ 5.77	7.9	$ 97,832
Options exercisable as of December 31, 2014		1,449,417	$ 3.00	6.8	$ 51,707
Options vested, exercisable, or expected to vest December 31, 2014		2,919,086	$ 5.35	7.8	$ 97,252

The options outstanding and vested under the Stock Plans by exercise price, at December 31, 2014, are as follows:

	Options Outstanding				Options Vested		
Exercise Price	Number Outstanding	Weighted Average Remaining	Aggregate Intrinsic Value	Number Exercisable	Weighted Average Exercise	Aggregate Intrinsic Value	

		Contractual Life (in Years)			Price		
			(in thousands)				(in thousands)
$0.96	64,242	3.48	$ 2,423	66,064	$ 0.96	$	2,491
$1.44	328,926	5.42	12,246	342,453	$ 1.44		12,750
$1.92	69,052	6.37	2,538	62,715	$ 1.92		2,305
$3.60	2,030,147	7.99	71,196	968,092	$ 3.60		33,951
$10.08	37,745	9.70	1,079	208	$ 10.08		6
$18.00	387,121	9.85	8,002	9,885	$ 18.00		204
$32.51	56,499	9.95	348		$ 32.51		
	2,973,732		$ 97,832	1,449,417		$	51,707

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The aggregate pretax intrinsic value of options exercised during the years ended December 31, 2014 and 2013, was $68,000 and $45,000, respectively. The intrinsic value is the difference between the estimated fair value of the Company s common stock at the date of exercise and the exercise price for in-the-money options. The aggregate fair value of shares vested during the years ended December 31, 2014 and 2013 was $0.1 million, and $1.1 million, respectively. The weighted-average grant-date fair value of options granted during the years ended December 31, 2014 and 2013 was $11.33, and $1.92 per share, respectively.

Employee Stock-Based Compensation

Stock-based compensation expense recognized during the years ended December 31, 2014, 2013 and 2012 for stock-based awards granted to employees based on the grant date fair value estimated in accordance with the provisions of ASC 718 was $2.0 million, $1.6 million and $1.1 million, respectively. As of December 31, 2014, there were total unrecognized compensation expenses of $5.7 million, net of estimated forfeitures, related to these stock options that is expected to be recognized over a weighted-average amortization period of 3.6 years.

The Company estimated the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following weighted average assumption:

	Years Ended December 31,		
	2014	2013	2012
Expected term (in years)	5.3 - 6.1	5.9 - 6.1	5.8 - 6.1
Expected volatility	57% - 63%	62% - 63%	63% - 66%
Risk-free interest rate	1.7% - 2.0%	1.1% - 1.8%	0.8% - 1.3%
Dividend yield	0%	0%	0%

Expected Term. The expected term of stock options represents the weighted-average period that the stock options are expected to remain outstanding. The Company has opted to use the simplified method for estimating the expected term of the options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected Volatility. The Company determined the share price volatility for options granted based on an analysis of the volatility used by a peer group of publicly traded medical device companies. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size. In future periods, the Company expects to utilize its own stock trading volatility to determine stock based compensation expense.

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 options.

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.

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The following table sets forth the stock-based compensation expense recorded under ASC 718:

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Cost of revenue	$ 131	$ 10	$ 8
Research and development	677	349	277
Sales, general and administrative	1,190	1,218	840
	$ 1,998	$ 1,577	$ 1,125

9. Income Taxes

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

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Domestic	$ (31,807)	$ (26,574)	$ (19,450)
Foreign	1,605	922	645
Total income (loss) before income taxes	$ (30,202)	$ (25,652)	$ (18,805)

The components of income tax expense are as follows (in thousands):

	Years Ended December 31,		
	2014	2013	2012
Current:			
Federal	$	$	$
State	2	(6)	(5)
Foreign	476	368	167
Total current	478	362	162
Deferred:			
Federal			
State			
Foreign			
Total deferred			
Total income tax expense	$ 478	$ 362	$ 162

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

	Years Ended December 31,		
	2014	**2013**	**2012**
Tax at statutory federal rate	34.0%	34.0%	34.0%
State tax, net of federal benefit	0.0%	0.0%	0.0%
Others	(5.3)%	(3.4)%	(5.4)%
Foreign rate differential	0.2%	(0.2)%	0.3%
Tax credits	2.0%	4.2%	0.2%
Change in valuation allowance	(32.5)%	(36.0)%	(30.0)%
Total	(1.6)%	(1.4)%	(0.9)%

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

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Net operating loss carryforwards	$ 37,977	$ 29,491	$ 22,122
Tax credits	3,713	2,937	1,681
Depreciation	29	8	6
Stock-based compensation	471	371	224
Accruals and reserves	1,215	1,363	279
Others	262	98	
	43,667	34,268	24,312
Valuation allowance	(43,667)	(34,268)	(24,312)
Net deferred tax assets	$	$	$

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of these assets.

Our deferred tax assets do not include the excess tax benefit related to stock-based compensation that are a component of our federal and state net operating loss carryforwards in the amount of $1.9 million as of December 31, 2014. The excess tax benefit reflected in our net operating loss carryforwards will be accounted for as a credit to shareholders equity, if and when realized. In determining if and when excess tax benefits have been realized, we have elected to utilize the with-and-without approach with respect to such excess tax benefits. We have also elected to ignore the indirect tax effects of stock-based compensation deductions for financial and accounting reporting purposes, and specifically to recognize the full effect of the research tax credit in income from operations.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $9.4 million and $10.0 million for the years ending December 31, 2014 and 2013, respectively.

As of December 31, 2014, the Company had net operating loss carryforwards, or NOLs, for federal and California state income tax purposes of approximately $108.2 million and $31.7 million, respectively. The federal NOLs begin expiring in 2026, and the state NOLs begin expiring in 2016.

As of December 31, 2014, the Company had research and development credit carryforwards of approximately $2.3 million and $1.6 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, an 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 more than 50

percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. The Company may in the future experience, one or more Section 382 ownership changes. 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 has not provided residual U.S. tax on a portion of its foreign subsidiary unremitted earnings as of December 31, 2014 because it is anticipated that the majority of the deferred tax liability on the earnings, if remitted, would be offset by a foreign tax credit deferred tax asset. The impact, if any, to the net deferred taxes stated in the above table would be insignificant due to the small difference between the U.S. and foreign tax rate on the remitted earnings. The timing of any potential remittance of these earning is uncertain at December 31, 2014.

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The Company had unrecognized tax benefits (UTBs) of approximately $2.0 million as of December 31, 2014. All of 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 January 1, 2012	$ 565
Increases related to current year tax provisions	89
Balance at December 31, 2012	654
Increases related to current year tax provisions	228
Increases related to prior year tax provisions	183
Balance at December 31, 2013	1,065
Increases related to current year tax provisions	220
Increases related to prior year tax provisions	677
Balance at December 31, 2014	$ 1,962

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

In accordance with ASC 740-10-50, the Company is classifying interest and penalties as a component of tax expense. There was no interest or penalties accrued at December 31, 2014, December 31, 2013, and December 31, 2012.

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.

10. Net Loss Per Share Attributable to Common Stockholders

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share data):

	Years ended December 31,		
	2014	**2013**	**2012**
Net loss	$ (30,680)	$ (26,014)	$ (18,967)
Accretion of convertible preferred stock to redemption value	(147)	(153)	(98)
Net loss attributable to common stockholders-basic and diluted	$ (30,827)	$ (26,167)	$ (19,065)
Weighted-average shares outstanding	4,486,569	1,090,731	902,742

Less: weighted average shares subject to repurchase	(45,906)	(213,799)	(408,676)
Weighted average shares used to compute basic and diluted net loss per share	4,440,663	876,932	494,066
Net loss per share attributable to common stockholders, basic and diluted	$ (6.94)	$ (29.84)	$ (38.59)

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Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, 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,		
	2014	**2013**	**2012**
Preferred stock		15,208,048	10,888,404
Options to purchase common stock	2,973,732	2,748,367	1,994,274
Total	2,973,732	17,956,415	12,882,678

11. 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. Under the Plan, the Company does not provide matching contributions to employees.

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12. Selected Quarterly Financial Information (Unaudited)

	Three Months Ended			
	December 31, 2014	September 30, 2014	June 30, 2014	March 31, 2014
	(In thousands, except per share data)			
Total revenue	$ 9,715	$ 8,668	$ 7,526	$ 6,664
Gross profit	$ 6,695	$ 5,931	$ 5,004	$ 3,665
Loss from operations	$ (7,106)	$ (6,498)	$ (7,461)	$ (7,241)
Net loss	$ (8,310)	$ (7,885)	$ (7,429)	$ (7,056)
Accretion of redeemable convertible preferred stock to redemption value	$ (16)	$ (44)	$ (44)	$ (43)
Net loss attributable to common stockholders	$ (8,326)	$ (7,929)	$ (7,473)	$ (7,099)
Net loss per common share, basic and diluted	$ (0.59)	$ (5.96)	$ (6.58)	$ (6.60)
Shares used in computing net income per common share, basic and diluted	14,229,775	1,329,610	1,136,259	1,075,932

	Three Months Ended			
	December 31, 2013	September 30, 2013	June 30, 2013	March 31, 2013
	(In thousands, except per share data)			
Total revenue	$ 6,196	$ 6,198	$ 5,699	$ 5,407
Gross profit	$ 3,644	$ 3,728	$ 3,382	$ 3,273
Loss from operations	$ (6,535)	$ (5,362)	$ (6,191)	$ (7,063)
Net loss	$ (6,740)	$ (5,016)	$ (6,889)	$ (7,369)
Accretion of redeemable convertible preferred stock to redemption value	$ (41)	$ (41)	$ (40)	$ (31)
Net loss attributable to common stockholders	$ (6,782)	$ (5,057)	$ (6,929)	$ (7,399)
Net loss per common share, basic and diluted	$ (7.27)	$ (5.54)	$ (8.29)	$ (9.68)
Shares used in computing net income per common share, basic and diluted	933,008	912,838	835,734	764,493

13. Subsequent Events

In March 2015, the Company entered into a lease agreement for approximately 50,000 square feet of office space located in Redwood Shores, California for a period beginning in June 2015 through May 2022 with annual payments of approximately $2.0 million in the first year of the lease, increasing on a yearly basis up to approximately $2.4 million for the final year of the lease term. The lease also provides for certain limited rent abatements in the second year of the lease term, and a tenant improvement allowance of $2.3 million.

In March 2015, the Company extended its current headquarters lease agreement to extend the termination date of the lease agreement to September 30, 2015.

In March 2015, the Company entered into a First Amendment under its credit facility with Capital Royalty Partners to extend the draw-down deadline of the second draw from March 31, 2015 to June 29, 2015.

In March 2015, the ***Company*** entered into a First Amendment to the Product Supply and Development Agreement (the ***Amendment***) to amend the Company s Product Supply and Development Agreement, dated as of April 5, 2009 (the ***Agreement***), with its battery manufacturer used in its implantable pulse generator. The Amendment commits the Company to specified minimum purchase amounts over the course of the term of the Agreement and adjusts the battery manufacturer 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

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the Company or the battery manufacturer provides notice of its intent not to renew prior to the commencement of such renewal term. The Amendment further provides the Company with the right to place a final order of batteries following termination of the Agreement, as amended and modifies certain warranty and assignment terms and the parties limitations of liability.

The Company relies upon a single-source manufacturer of implantable pulse generators (IPGs). In April 2012, the Company entered into its original supply agreement, which was later amended in March 2013 and June 2014. In connection with entry into the new supply agreement, the existing supply agreement, which was to expire by its terms on March 31, 2015, was terminated.

In March 2015, the Company entered into a new multi-year supply agreement, pursuant to which its current single-source IPG manufacturer has agreed to manufacture and supply IPGs, chargers, trial simulators and programmer wands (collectively, the Products). The Company is obligated to purchase specified minimum purchase quantities of IPGs during the first two-years of the supply agreement and thereafter specified increasing percentages of IPGs, unless such IPGs are not able to be manufactured at similar quantities to those contemplated in the agreement. In addition, if the Company seeks to have a third-party manufacture any products, components and materials not currently produced as of the effective date of this supply agreement, the Company is obligated to provide its IPG manufacturer the opportunity to bid for the supply of such products, components and materials.

The supply agreement continues for ten years unless terminated earlier. The term of the supply 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 applicable renewal period. In the event of a change in control, the supply agreement may be terminated by the Company or the applicable acquirer, subject to payment of a termination fee of between $50.0 million and $75.0 million and other conditions, upon no earlier than six years after the effective date of the supply agreement. The supply agreement may also be terminated by the Company, subject to payment of a termination fee of $50.0 million, upon six months prior written notice if the Company determines that it will discontinue the sale of the IPG; provided that the effective date of any such termination may not occur prior to the date that is 5 years after the effective date of the supply agreement. In addition, the supply 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.

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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 Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive 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, 2014, the end of the period covered by this Annual Report on Form 10-K. 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

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the Company s independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

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 on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

On March 13, 2015, we entered into a multi-year supply agreement with Centro de Construccion de Cardioestimuladores del Uruguay S.A. (CCC), a subsidiary of Greatbatch Ltd., as our single-source manufacturer of our implantable pulse generator (IPG). Under the supply agreement, CCC has agreed to manufacture and supply IPGs, chargers, trial simulators and programmer wands (collectively, the Products). We have agreed to pay an upfront payment to CCC in connection with the agreement.

We are obligated to purchase from CCC specified minimum purchase quantities of IPGs during the first two years of the Supply Term and thereafter specified increasing percentages of IPGs, unless CCC is unable to manufacture such IPGs, at similar quantities to those contemplated in the agreement. Beginning on the fifth calendar year of the Supply Term, we may, upon written notice and payment of a preset fee, reduce the minimum purchase quantities within certain thresholds. In addition, if we seek to have a third-party manufacture any

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products, components and materials not currently produced by CCC as of the effective date of this supply agreement, we are obligated to provide CCC with the opportunity to bid for the supply of such products, components and materials.

At our option, and subject to certain conditions and increases in the specified minimum purchase quantities, CCC has agreed to provide us with qualified exclusivity. Subject to certain exceptions and limitations, neither CCC nor any affiliate of CCC may develop, manufacture, market, distribute, or sell any complete device in a certain field of use that requires regulatory approval to any entity other than us.

The supply agreement is effective immediately and continues for ten years unless terminated earlier (the Supply Term). The Supply Term 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 applicable renewal period. In the event of a change in control, the supply agreement may be terminated by us or the applicable acquirer, subject to payment of a termination fee of between $50.0 million and $75.0 million and other conditions, upon no earlier than six years after the effective date of the supply agreement. The supply agreement may also be terminated by us, subject to payment of a termination fee of $50.0 million, upon six months prior written notice if we determine that we will discontinue the sale of the IPG; provided that the effective date of any such termination may not occur prior to the date that is 5 years after the effective date of the supply agreement. In addition, the supply 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.

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 Supply Term, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions.

The foregoing description of the material terms of the Agreement is subject to, and is qualified in its entirety by, reference to the supply agreement, which is filed as an exhibit to this Annual Report on Form 10-K. We are seeking confidential treatment for certain portions of the agreement pursuant to a Confidential Treatment Request submitted to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

In connection with the entry into the new supply agreement, our existing supply agreement with CCC, which was to expire by its terms on March 31, 2015, was terminated.

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PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE*

Executive Officers of the Registrant

The following table sets forth information regarding our executive officers, significant employees and directors, as of March 1, 2015:

Name	Age	Position(s)
Executive Officers		
Michael DeMane	58	Chairman of the Board and Chief Executive Officer
Rami Elghandour	36	President
Andrew H. Galligan	58	Vice President of Finance, Chief Financial Officer
Michael Enxing	48	Vice President of Sales and Marketing
Balakrishnan Shankar	49	Vice President, Operations
Andre Walker	51	Senior Vice President, Research & Development
Significant Employees		
David Caraway, M.D., Ph.D.	58	Chief Medical Officer
Bradford E. Gliner	49	Vice President, Clinical & Regulatory
Tamara F. Rook	43	Vice President, Health Economics & Reimbursement
Michael W. Hall	67	General Counsel
Non-Employee Directors		
Ali Behbahani, M.D.[(2)(3)]	38	Director
Frank Fischer[(3)]	73	Director
Wilfred E. Jaeger, M.D.[(1)(2)]	59	Director
Shawn T McCormick[(1)]	50	Director
Nathan B. Pliam, M.D.[(1)(3)]	63	Director
Brad Vale, Ph.D., D.V.M.[(2)]	62	Director

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

Executive Officers

Michael DeMane joined us in March 2011 and serves as our Chairman of the Board and Chief Executive Officer. Mr. DeMane has served on the board of directors of several private companies since 2009, as well as on the board of directors of eReserach Technology, Inc., a public company specializing in clinical services and customizable medical devices, 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 of directors due to his investment experience, strategic leadership track record, service on other boards of directors of companies in the healthcare industry and his service as our chief executive officer.

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Rami Elghandour joined us in October 2012, has served as our Chief Business Officer and currently serves as our President. 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, Inc.), 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.

Andrew H. Galligan has served as our Vice President of Finance and 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 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.

Michael Enxing has served as our Vice President of Sales and Marketing since December 2012. From 2009 to December 2012, Mr. Enxing served as Vice President of Vertos Medical Inc., a medical device company. From 1990 to 2009, Mr. Enxing held various executive positions at Cardiovascular Systems, Inc. (f/k/a Cardio Vascular Solutions (CSI)), a medical device company, Advanced Neuromodulation Systems, Inc. (acquired by St. Jude Medical, Inc.), a medical device company, Stryker Corporation, a medical technology company, and Tecnol Medical Products, Inc. (acquired by Kimberly Clark), a medical device company. Mr. Enxing is a graduate of Iowa State University with a B.S. in Communications and focus in business administration.

Balakrishnan Shankar has served as our Vice President of Operations since March 2014. From 2008 to 2014, Mr. Shankar held a variety of leadership positions at St. Jude Medical, Inc. with responsibility for the development and manufacturing of its implantable pacemakers and defibrillators, including Vice President, Neurotechnology Development from October 2013 to March 2014, Vice President of Software Development from April 2012 to September 2013, Vice President of Operations from January 2010 to March 2012 and Division Director, Operations from October 2008 to December 2009. Mr. Shankar received a B.S. in Electrical Engineering from the Indian Institute of Technology and an M.S. in Biomedical Engineering from Johns Hopkins University.

Andre Walker has served as our Senior Vice President, Research & Development since February 2007. From 1999 to 2007, Mr. Walker was Vice President of R&D at St. Jude Medical, Inc., responsible for the development of its implantable Defibrillators and Pacemaker products. Mr. Walker has also held leadership positions at Siemens Pacesetter, Inc., a medical device company, and Zilog, Inc., a consumer semiconductor manufacturer. Mr. Walker holds a M.S. in Electrical Engineering from the University of Hasselt in Hasselt, Belgium.

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

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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.

Bradford E. Gliner has served as our Vice President of 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.

Tamara F. Rook has served as our Vice President, Health Economics & Reimbursement since September 2013. From June 2012 to August 2013, Ms. Rook was the Vice President of Reimbursement at Vertos Medical Inc., a medical device company, where she focused on gaining market access for an emerging therapy. From 2006 to June 2012, Ms. Rook worked in the neuromodulation space with Medtronic, Inc. and from 2004 to 2006 she worked at Cyberonics, Inc. where she was focused on managing patient access and initiating coverage for new indications. Ms. Rook received an M.B.A. from the University of Houston and a B.A. in Public Administration from Texas State University.

Michael Hall has served as our General Counsel since January 2015. He was a partner at Latham & Watkins from February 1999 to December 2014. Mr. Hall practiced for a number of years at Wilson, Sonsini, Goodrich & Rosati and was a co-founder of Venture Law Group prior to joining Latham & Watkins. His practice was focused on representation of life science companies primarily in the medical device industry. He also represented underwriters and venture capital firms in both public and private financing transactions. He is a member of the board of San Francisco RBI, a non-profit focused on sports and literacy for underprivileged children in San Francisco. Mr. Hall received a B.A. from California University, Sonoma and a J.D. from the University of California at Berkley, School of Law (Boalt Hall).

Non-Employee Directors

Ali Behbahani, M.D. has served on our board of directors since September 2014. Dr. Behbahani joined New Enterprise Associates, Inc., or NEA, in 2007 and is a 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 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 of directors due to his experience in the life science industry and his investment experience.

Frank Fischer has served on our board of directors 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

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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 of directors due to his operational experience in the life science industry.

Wilfred E. Jaeger, M.D. has served on our board of directors 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, Threshold Pharmaceuticals, Inc., a public pharmaceutical 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 of directors 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 of directors since September 2014. Mr. McCormick currently serves as Chief Financial Officer of Tornier N.V., a public medical device company, a position that he has held since September 2012. 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 has been a director of Entellus Medical, Inc., a public medical device company, since November 2014, and serves as the chairman of the audit committee and as a member of the nominating and corporate governance 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. We believe that Mr. McCormick is qualified to serve on our board of directors due to his financial expertise and operational experience in the medical device industry.

Nathan B. Pliam, M.D. has served on our board of directors since October 2009. Dr. Pliam joined Bay City Capital LLC in January 2007 and has served as a Venture Partner since that time. Since December 2011, Dr. Pliam has also been a Venture Partner at Decheng Capital, a Bay City Capital co-sponsored, Shanghai-based venture fund focused on life sciences investments relevant to the Chinese market. He is a co-founder of Ketai Medical Device Ltd, a China-based orthopedic implant company. Dr. Pliam currently serves on the board of directors of numerous private companies. Dr. Pliam received a B.A. in German literature at the University of California, Berkeley, and the Georg August Universite in Gattingen, Germany, an M.D. from Dartmouth Medical School and a Ph.D. from the University of California, San Francisco. We believe that Dr. Pliam is qualified to serve on our board of directors due to his investment experience, strategic leadership track record and service on other boards of directors of companies in the healthcare industry.

Brad Vale, Ph.D., D.V.M., has served on our board of directors 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.,

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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 of directors 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 2015 Annual Meeting of Stockholders (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.

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.

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PART IV

ITEM 15. ***EXHIBITS and FINANCIAL STATEMENT SCHEDULES***

(a) The following documents are filed as part of this Annual Report on Form 10-K:

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 immediately following the signature page of this Form 10-K.

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SIGNATURES

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

March 18, 2015:

NEVRO CORP.

By: /s/ MICHAEL DEMANE
Michael DeMane

Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael DeMane 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/ MICHAEL DEMANE Michael DeMane	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 18, 2015
/s/ ANDREW H. GALLIGAN Andrew H. Galligan	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting	March 18, 2015

	Officer)	
/s/ ALI BEHBAHANI Ali Behbahani, M.D.	Director	March 18, 2015
/s/ BRAD H. VALE Brad H. Vale, Ph.D., DVM	Director	March 18, 2015
/s/ FRANK FISCHER Frank Fischer	Director	March 18, 2015
/s/ WILFRED E. JAEGER Wilfred E. Jaeger, M.D.	Director	March 18, 2015
/s/ SHAWN T MCCORMICK Shawn T McCormick	Director	March 18, 2015
/s/ NATHAN B. PLIAM Nathan B. Pliam, M.D.	Director	March 18, 2015

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Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference 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	
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 Group, LLC.	S-1/A	10/15/2014	10.1	
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)	
10.3	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.				X
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 therein.	S-1/A	11/04/14	10.6(c)

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
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.				X
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(a)#	Offer Letter, dated as of March 8, 2011, by and between Michael DeMane and the Company.	S-1/A	10/10/2014	10.12(a)	
10.12(b)#	Form of Employment Agreement by and between Michael DeMane and the Company.	S-1/A	10/10/2014	10.12(b)	

10.13#	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#	Offer Letter, dated as of May 12, 2010, by and between Andrew H. Galligan and the Company.	S-1	10/03/2014	10.14

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.15#	Offer Letter, dated as of November 1, 2012, by and between Michael Enxing and the Company.	S-1/A	10/10/2014	10.15	
10.16#	Offer Letter, dated as of February 27, 2014, by and between Balakrishnan Shankar and the Company.	S-1/A	10/10/2014	10.16	
10.17#	Offer Letter, dated as of January 16, 2007, by and between Andre Walker and the Company.	S-1/A	10/10/2014	10.17	
10.18(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)	
10.18(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)	
10.18(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)	
10.19#	Nevro Corp. Non-Employee Director Compensation Program.	S-1/A	10/10/2014	10.19	
10.20#	Form of Change in Control Severance Agreement.	S-1/A	10/10/2014	10.20	
10.21(a)	Term Loan Agreement, dated October 24, 2014, by and between the Company and Capital Royalty Partners II L.P.	S-1/A	10/27/2014	10.21	
10.21(b)	First Amendment to Term Loan Agreement, dated as of March 9, 2015, by and between the Company and Capital Royalty Partners II L.P.				X
10.22*	Supply Agreement, dated March 13, 2015, by and between the Company and Centro de Construccion de Cardioestimuladores del Uruguay S.A.				X
10.23	Lease Agreement, dated as of March 5, 2015, by and between the Company and Westport Office Park, LLC.				X
21.1	List of Subsidiaries.	S-1	10/03/2014	21.1	
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

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
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.
* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the Securities and Exchange Commission.

** 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.