

NEVRO CORP  
Form S-1/A  
June 01, 2015  
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As filed with the Securities and Exchange Commission on June 1, 2015.

Registration No. 333-204270

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

AMENDMENT NO. 1  
TO  
FORM S-1  
REGISTRATION STATEMENT  
*UNDER*  
*THE SECURITIES ACT OF 1933*

Nevro Corp.

(Exact name of Registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>3841</b> (Primary Standard Industrial Classification Code Number)	<b>56-2568057</b> (I.R.S. Employer Identification Number)
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**4040 Campbell Avenue, Menlo Park, CA 94025, (650) 251-0005**

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**Michael DeMane**

**Chief Executive Officer**

**Nevro Corp.**

**4040 Campbell Avenue, Menlo Park, CA 94025, (650) 251-0005**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

**Anthony J. Richmond, Esq.**

**Brian J. Cuneo, Esq.**

**Latham & Watkins LLP**

**140 Scott Drive**

**Menlo Park, CA 94025**

**Telephone: (650) 328-4600**

**Facsimile: (650) 463-2600**

**Michael W. Hall, Esq.**

**General Counsel**

**Nevro Corp.**

**4040 Campbell Avenue**

**Menlo Park, CA 94025**

**Telephone: (650) 251-0005**

**Facsimile: (650) 251-9415**

**Alan F. Denenberg, Esq.**

**Davis Polk & Wardwell LLP**

**1600 El Camino Real**

**Menlo Park, CA 94025**

**Telephone: (650) 752-2000**

**Facsimile: (650) 752-2111**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. "

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

Subject to completion, dated June 1, 2015

**Prospectus**

**3,934,681 Shares**

**Common Stock**

Nevro Corp. is offering 1,475,506 shares of its common stock. The selling stockholders identified in this prospectus are offering 2,459,175 shares of our common stock. We will not receive any proceeds from the sale of any shares by the selling stockholders.

Our common stock is listed on the New York Stock Exchange under the symbol **NVRO**. The last reported sale price of our common stock on the New York Stock Exchange on May 29, 2015 was \$50.83 per share.

We are an emerging growth company, as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See [Risk Factors](#) beginning on page 10.

	Per Share	Totals
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$

Proceeds to Nevro Corp., before expenses	\$	\$
Proceeds to selling stockholders	\$	\$

(1) See Underwriting for additional disclosure regarding underwriting discounts and commissions and estimated offering expenses.

We have granted the underwriters an option for a period of 30 days to purchase from us up to an additional 590,202 shares of common stock.

The underwriters expect to deliver the shares against payment in New York, New York on or about \_\_\_\_\_, 2015.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

**J.P. Morgan**

**Morgan Stanley**

**Leerink Partners**

**JMP Securities**

, 2015

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Neither we nor the selling stockholders have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we may authorize to be delivered or made available to you. We and the selling stockholders take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the selling stockholders are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

**No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in any such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.**

Nevro, Senza, HF10 and our logo are some of our trademarks used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® and symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

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**PROSPECTUS SUMMARY**

This summary highlights the information contained or incorporated by reference in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before buying our common stock. Therefore, you should read the entire prospectus carefully, including the information in our filings with the Securities and Exchange Commission, or SEC, incorporated by reference in this prospectus, before deciding to invest in our common stock. Investors should carefully consider the information set forth under Risk Factors beginning on page 10 of this prospectus and those identified in our Annual Report on Form 10-K for the year ended December 31, 2014, or our 2014 Annual Report, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, or our March 2015 Quarterly Report. In this prospectus, unless the context otherwise requires, references to the Company, we, us, our, or Nevro refer to Nevro Corp. and its consolidated subsidiaries.

**Overview**

We are a medical device company that has developed and commercialized an innovative neuromodulation platform for the treatment of chronic pain. Our Senza<sup>®</sup> system is the only spinal cord stimulation, or SCS, system that delivers our proprietary HF10 therapy. On May 8, 2015, our premarket approval, or PMA, application for our Senza SCS system, or Senza, was approved by the U.S. Food and Drug Administration, or FDA.

Key highlights of our SENZA PMA are as follows:

First U.S. commercial approval for an SCS system supported by a prospective, randomized, controlled, comparative study.

HF10 therapy is the first and only SCS therapy approved by FDA with superiority labeling.

HF10 therapy is the first and only SCS therapy that is approved by FDA to deliver paresthesia-free pain relief.

HF10 therapy is the first and only SCS therapy approved by the FDA to be used without patient restrictions on motor vehicle operation while receiving therapy.

Senza is the first fully implantable SCS system approved by the FDA with labeling for 3T conditional MRI compatibility.

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.

While traditional 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. 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, a constant tingling

sensation that is the basis of traditional SCS therapy.

Our SENZA-RCT U.S. pivotal study, a non-inferiority study, met its primary and secondary endpoints, and demonstrated the superiority of HF10 therapy over traditional SCS therapies for treating both leg and back pain. 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. HF10 therapy is also designed to reduce variability in the operating procedure, providing meaningful benefits to both patients and physicians.

We hold 76 issued patents globally and over 100 pending patent applications in the United States and international jurisdictions. Our revenue increased from \$23.5 million for the year ended December 31, 2013 to \$32.6 million for the year ended December 31, 2014, with a net loss of \$26.0 million and \$30.7 million in these



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periods, respectively. We have a history of significant net losses and we expect to continue to incur losses for the foreseeable future. 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.

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 substantial experience in the neuromodulation field. With what we believe are compelling efficacy data for both leg and back pain compared to traditional SCS therapy, we aim to drive adoption of Senza 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.

### **SENZA-RCT Pivotal Study**

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.

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, the study results demonstrated 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.

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.

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.

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.

The study results demonstrated the superiority 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 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 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.

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### **Market Overview**

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. About 1.5 billion people suffer from chronic pain worldwide, including approximately 100 million Americans. Back pain is the most common manifestation of chronic pain, with an estimated 84 million patients in the United States experiencing chronic back pain. 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.

#### *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. Failed Back Surgery Syndrome 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.

#### *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, and are also known to present a high risk of addiction.

#### *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 that utilizes low frequency stimulation, typically between 40 Hz and 60 Hz (therapeutic pulses per second), to induce paresthesia that overlaps the distribution of pain with the intent of masking pain perception. 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. 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 considered to be a minimally invasive, reversible therapy that may provide greater long-term benefits over more invasive surgical approaches or opioids.

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. The global market for traditional SCS therapy is projected to grow to approximately \$1.8 billion in 2017, with the United States comprising approximately 80% of this global market. 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. 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,

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interventional pain specialists and orthopedic spine surgeons. However, only approximately half of chronic pain patients are considered candidates for traditional SCS therapy. 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. 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.

### **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.

**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 variability in the procedure and a complicated anesthesia management process, impacting the physician's schedule and patient comfort.

### **Our Solution for Chronic Pain**

Our HF10 therapy is designed to overcome many of the limitations of traditional SCS therapy, offering benefits to patients, physicians and hospitals. Compared to traditional SCS therapy, HF10 therapy delivers spinal cord stimulation at a lower amplitude and a higher frequency waveform of 10,000 Hz (therapeutic pulses per second). We believe the advantages of our proprietary HF10 therapy over traditional SCS include:

**Compelling efficacy data for both leg and back pain.** 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.

**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.

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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.** 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.

## **Our Growth Strategy**

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

Drive adoption of HF10 therapy through a world-class sales and marketing organization.

Communicate what we believe is the compelling clinical efficacy of HF10 therapy to patients, physicians and payors globally.

Expand the existing SCS market by treating back pain.

Develop HF10 therapy for use in other chronic pain indications.

Invest in research and development to drive innovation.

Scale our business to achieve cost and production efficiencies.

## **Risks Associated With Our Business**

Our business is subject to numerous risks, as more fully described in the section entitled **Risk Factors** immediately following this prospectus summary. These risks include, among others:

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

We are substantially dependent on market acceptance in the United States for our HF10 therapy, and the failure of our HF10 therapy to gain such market acceptance will negatively impact our business.

If we are unable to protect, enforce and maintain our intellectual property, our business will be negatively affected.

We must educate physicians on the safe and effective use of our HF10 therapy and demonstrate its merits compared to the SCS systems of our competitors.

We face significant competition from larger, well established companies with substantially greater resources and who have a long history of competing in the SCS market, which we believe will intensify now that we have received FDA approval and intend to launch in the U.S. market.

### **Corporate Information**

We were incorporated in March 2006 as a Minnesota corporation under the name NBI Development, Inc. and in October 2006 reincorporated in Delaware. In June 2007, we changed our corporate name to Nevro Corp. 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. Our principal executive offices are located at 4040 Campbell Avenue, Menlo Park, California 94025, and our telephone number is (650) 251-0005. Our website address is [www.nevro.com](http://www.nevro.com). The information on, or that can be accessed through, our website is not part of this prospectus. We have included our website address as an inactive textual reference only.



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We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) December 31, 2019 (the last day of the fiscal year following the fifth anniversary of our initial public offering), (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, (3) the last day of the fiscal year 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 (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startup Act of 2012 herein as the JOBS Act, and references herein to emerging growth company shall have the meaning associated with it in the JOBS Act.

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**THE OFFERING**

Common stock we are offering	1,475,506 shares
Common stock the selling stockholders are offering	2,459,175 shares
Common stock to be outstanding after the offering	26,372,017 shares (26,962,219 shares if the underwriters exercise their option to purchase additional shares in full)
Underwriter's option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to an additional 590,202 shares of our common stock from us.
Use of proceeds	<p>We estimate that the net proceeds to us from this offering will be approximately \$69.8 million, or approximately \$98.0 million if the underwriters exercise their option to purchase additional shares in full, at an assumed public offering price of \$50.83 per share, which was the last reported sale price of our common stock on the New York Stock Exchange on May 29, 2015, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering to support our commercial launch of Senza in the United States, and for working capital and general corporate purposes, including research and development. See Use of Proceeds.</p> <p>We will not receive any proceeds from the sale of any shares by the selling stockholders.</p>
Risk factors	You should read the Risk Factors section of this prospectus and our 2014 Annual Report and our March 2015 Quarterly Report, incorporated by reference herein, for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Symbol on the New York Stock Exchange	NVRO
The number of shares of common stock to be outstanding after this offering is based on 24,896,511 shares of common stock outstanding as of March 31, 2015, and excludes the following, in each case as of such date:	

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3,315,947 shares of common stock issuable upon the exercise of outstanding stock options having a weighted-average exercise price of approximately \$9.69 per share;

2,316,800 shares of common stock reserved for issuance pursuant to future equity awards under our 2014 Equity Incentive Award Plan, as well as any future increases in the number of shares of our common stock reserved for future issuance under this plan; and

445,320 shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, as well as any future increases in the number of shares of our common stock reserved for future issuance under this plan.

Unless otherwise indicated, the number of shares of our common stock described above assumes no exercise of the underwriters' option to purchase additional shares.

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The following table presents summary consolidated financial data for our business. We derived the following statements of operations data for the years ended December 31, 2012, 2013, and 2014 from our audited financial statements incorporated by reference in this prospectus from our 2014 Annual Report and we derived the following statements of operations data for the three months ended March 31, 2014 and 2015 and the balance sheet data as of March 31, 2015 from our unaudited interim financial statements incorporated by reference in this prospectus from our March 2015 Quarterly Report. You should read this data together with our consolidated financial statements and related notes, as well as the information under the captions **Selected Financial Data** and **Management's Discussion and Analysis of Financial Condition and Results of Operations**, appearing in our 2014 Annual Report, which is incorporated by reference herein. Our historical results are not necessarily indicative of our future results and results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for the full year.

	<b>Years Ended December 31,</b>			<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2014</b>	<b>2015</b>
	<b>(in thousands, except share and per share data)</b>				
<b>Consolidated Statements of Operations Data:</b>					
Revenue	\$ 18,150	\$ 23,500	\$ 32,573	\$ 6,664	\$ 9,662
Cost of revenue	7,527	9,473	11,278	2,999	3,873
Gross profit	10,623	14,027	21,295	3,665	5,789
<b>Operating expenses</b>					
Research and development	15,659	20,345	19,824	4,696	4,998
Sales, general, and administrative	14,094	18,833	29,777	6,210	13,130
Total operating expenses	29,753	39,178	49,601	10,906	18,128
Loss from operations	(19,130)	(25,151)	(28,306)	(7,241)	(12,339)
Interest and other income (expense), net	325	(501)	(1,896)	278	(1,579)
Loss before income taxes	(18,805)	(25,652)	(30,202)	(6,963)	(13,918)
Provision for income taxes	162	362	478	93	142
Net loss	\$ (18,967)	\$ (26,014)	\$ (30,680)	\$ (7,056)	\$ (14,060)
Accretion of redeemable convertible preferred stock to redemption value	(98)	(153)	(147)	(43)	
Net loss attributable to common stockholders per share, basic and diluted <sup>(1)</sup>	\$ (38.59)	\$ (29.84)	\$ (6.94)	\$ (6.60)	\$ (0.57)
Weighted-average number of common shares used to compute basic and diluted net loss per share <sup>(1)</sup>	494,066	876,932	4,440,663	1,075,932	24,849,229

	<b>As of March 31, 2015<sup>(2)</sup></b>	
	<b>Actual</b>	<b>As Adjusted<sup>(3)</sup></b>
<b>(in thousands)</b>		
<b>Consolidated Balance Sheet Data:</b>		
Cash, cash equivalents and short-term investments	\$ 159,216	\$ 229,001
Working capital	174,363	244,148
Total assets	192,220	262,005
Accumulated deficit	(136,037)	(136,037)
 Total stockholders' equity	 \$ 159,118	 \$ 228,903

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- (1) See Notes 2 and 10 to our consolidated financial statements appearing in our 2014 Annual Report and Note 2 to our unaudited condensed consolidated financial statements appearing in our March 2015 Quarterly Report, each of which is incorporated by reference herein, for an explanation of the calculations of our basic and diluted net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.
  
- (2) The as-adjusted balance sheet data reflects the sale of 1,475,506 shares of common stock offered by us in this offering at an assumed public offering price of \$50.83 per share, which was the last reported sale price of our common stock on the New York Stock Exchange on May 29, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from any sale of shares of our common stock in this offering by the selling stockholders; accordingly, there is no impact upon the adjusted consolidated balance sheet for these sales.
  
- (3) Each \$1.00 increase (decrease) in the assumed public offering price of \$50.83 per share, which was the last reported sale price of our common stock on the New York Stock Exchange on May 29, 2015, would increase (decrease) the as adjusted amount of each of cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' equity by approximately \$1.4 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 100,000 share increase (decrease) in the number of shares offered by us at the assumed public offering price of \$50.83 per share would increase (decrease) the as adjusted amount of each of cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' equity by approximately \$4.8 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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**RISK FACTORS**

Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should carefully consider the risks described below, as well as the other information in this prospectus or incorporated by reference, including our consolidated financial statements and the related notes and the risks and uncertainties discussed under Risk Factors in our 2014 Annual Report and our March 2015 Quarterly Report, which is incorporated by reference herein in its entirety. The occurrence of any of the events or developments described below or incorporated by reference herein could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

**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. In May 2015, the FDA approved our PMA to market Senza in the United States, and we have not yet commercially launched the product in the United States. We expect to continue to incur losses as we 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 \$14.1 million and \$30.7 million for the three months ended March 31, 2015 and the year ended December 31, 2014, respectively, and as of March 31, 2015 our accumulated deficit was \$136.0 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.

*We are substantially dependent on market acceptance in the United States for our HF10 therapy, and 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 March 31, 2015, our total revenue was \$91.6 million and was derived entirely from sales of Senza in Europe and Australia. We have incurred and will in the future incur significant costs, including costs to build our sales force, in order to commercially launch in the United States. If we are unable to achieve significant market acceptance in the United States, our results of operations will be adversely affected as the United States is expected to be the principal market for this product. 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 additional regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to our HF10 therapy or the other factors discussed in these risk factors, we would lose our only source of revenue, and our business will be materially adversely affected.

*We may 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.



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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 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 (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

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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. For example, on May 11, 2015, we learned that Boston Scientific Neuromodulation Corporation intended to file with the USPTO two petitions for inter partes review challenging the validity of our U.S. Patent No. 8,359,102. We may also need to initiate infringement claims or litigation. Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly, or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and/or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

We may also be forced to enter into cross-license agreements with competitors in order to manufacture, use, sell, import and/or export products or services that are covered by our competitors' intellectual property rights. If we need to use our intellectual property to enter such cross-license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, import and/or export our patented technology.

For additional information regarding risks related to our intellectual property, see [Risks Related to Intellectual Property](#).

***We must 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.

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***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, we must build a substantial direct sales force. As we initiate our commercial launch and increase our marketing efforts, we will need to retain, develop and grow the number of direct sales personnel that we employ. We intend to make a significant investment in recruiting and training sales representatives and clinical representatives as we ramp up to commercially launch in the United States. 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 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 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 May 2015, one of our principal competitors, Boston Scientific Neuromodulation Corporation, filed with the USPTO two petitions for inter partes review challenging the validity of our U.S. Patent No. 8,359,102. We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States.

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

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

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

The FDA requires manufacturers of medical devices to maintain regulatory approval by filing timely reports and complying with numerous regulations. There can be no assurance that approval will be maintained. For example:

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

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we may fail to comply with the requisite guidelines by FDA and other agencies to maintain our PMA approval; and

the manufacturing process and facilities we use may not meet applicable requirements to maintain our PMA approval.

In addition, although the FDA has approved our PMA for Senza, we may suffer from product liability or other issues that impact our ability to continue to market the Senza system in the United States.

Failing to maintain 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 improve or augment manufacturing processes, collect and provide data on the quality or safety of our product, or issue us a warning letter relating to matters that may result in removal of our product from the market. Additionally, we will be required to obtain FDA approval prior to making any modification to the device, and the FDA may revoke the approval or impose other restrictions if post-market data demonstrates safety issues or lack of effectiveness. If we are unable to obtain and maintain the necessary regulatory approvals, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited.

We are currently conducting clinical trials for Senza to explore the potential for HF10 therapy to treat other chronic pain indications, including 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. Senza may not be approved for these additional indications.

***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, including Senza, will have to compete for market acceptance and market share. We believe that the primary competitive factors in the neuromodulation market are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects

and salesforce experience and relationships. We face significant competition in the United States and internationally, which we believe will intensify as 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



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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;

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 only just received approval to market Senza in the United States, 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 (EU), plus Norway, Liechtenstein and Iceland. It was also approved by the Australia Therapeutic Goods Administration (TGA), in 2011. In May 2015, the FDA approved our PMA to market Senza in the United States, and we have not yet commercially launched sales in the United States. As a result, we have a limited history of commercializing our product generally and no history of selling Senza in the United States. We also 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. As an organization, we have never commercially launched a product in the United States, nor commenced a sales representative training program or conducted a launch of a similar expected size. A commercial launch and training program of this size is a significant undertaking that requires substantial financial and managerial resources. We may be unable to gain broader market acceptance in the countries in which we have already begun to commercialize Senza or 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;

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limitations in our ability to demonstrate differentiation and advantages of our product compared to competing products and the relative safety, efficacy and ease of use of our product;

the limited size of our sales force and the learning curve required to gain experience selling our product;

the inability to obtain sufficient supply of the components for Senza or secure second-source suppliers if our main suppliers are unable to fulfill our orders;

insufficient financial or other resources to support our commercialization efforts necessary to reach profitability; and

the introduction and market acceptance of new, more effective or less expensive competing products and technologies.

Moreover, physicians and hospitals may not perceive the benefits of our products and may be unwilling to change from the SCS devices they are currently using. Communicating the benefits of Senza and HF10 therapy to these physicians and hospitals requires a significant commitment by our marketing team and sales organization. Physicians and hospitals may be slow to change their practices because of perceived risks arising from the use of new products. Physicians may not recommend or use Senza until there is more long-term commercial experience to convince them to alter their existing treatment methods, or until they receive additional recommendations from other physicians that our product is effective. We cannot predict when, if ever, physicians and hospitals may adopt use of our product. If we are unable to educate physicians and hospitals about the advantages of our HF10 therapy 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.

***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 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, competitive dynamics, market size, 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 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.

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***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.

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

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

Sales of Senza outside the United States represented all of our revenue from Senza sales. 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 March 31, 2015, 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;

foreign currency exchange rate fluctuations;

a shortage of high-quality sales people and distributors;

third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of Senza;

competitive disadvantage to competition with established business and customer relationships;

the imposition of additional U.S. and foreign governmental controls or regulations;

economic instability;

changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

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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:

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;

we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;

our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of Senza, impacting our ability to maintain our PMA approval, or cause delays in shipment, impacting our ability to meet demand in the U.S. or international markets;

we may have difficulty locating and qualifying alternative suppliers;

switching components or suppliers may require product redesign and possibly submission to FDA, EEA Notified Bodies, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;

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

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



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our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to sufficiently quickly establish additional or alternative suppliers for commercialization in the United States if necessary, in part because we may need to undertake additional activities to 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 implantable pulse generator (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.

***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.

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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.

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

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

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

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.

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***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. In May 2015, the FDA approved our PMA to market Senza in the United States, and we have not yet commercially launched the product in the United States. As an organization, we have never commercially launched a product in the United States, nor commenced a sales representative training program or conducted a launch of a similar expected size. A commercial launch and training program of this size is a significant undertaking that requires substantial financial and managerial resources. We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force in the United States requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

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

***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

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disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed.

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

Manufacturing and marketing 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 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 (IRBs), Ethics Committees, EU Competent Authorities or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;

patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;

patients or investigators do not comply with study protocols;

patients do not return for post-treatment follow-up at the expected rate;

patients experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our products such as the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;

sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;

difficulties or delays associated with establishing additional clinical sites;

third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or perform in a manner inconsistent with the investigator agreement, clinical study protocol, good clinical practices, other FDA, IRB or Ethics Committee requirements, and EEA Member State or other foreign regulations governing clinical trials;

third-party organizations do not perform data collection and analysis in a timely or accurate manner;

regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;



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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 FDA refusing to accept the data as support for our future applications. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

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

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

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

In 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

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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.

***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.

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**Table of Contents****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 Corporation, 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. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

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

stop selling, making, using, or exporting products that use the disputed intellectual property;

obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;

incur significant legal expenses;

pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;

if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;

pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;

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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.

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

We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. Two of our competitors, Boston Scientific Corporation, and Medtronic, Inc., have filed oppositions in the European Union with respect to certain of our patents. In addition, on May 11, 2015, we learned that Boston Scientific Neuromodulation Corporation intended to file with the USPTO two petitions for inter partes review challenging the validity of our U.S. Patent No. 8,359,102. We do not anticipate that we will have a final result in the USPTO for at

least 12 to 18 months. However, defending our position in these proceedings will require management's time and attention, as well as financial costs. An unfavorable outcome in this inter partes review could cause us to lose certain valuable intellectual property rights. Given the competitive environment in which we operate, we expect additional challenges to our intellectual property portfolio as we commence commercialization of Senza in the U.S. An unfavorable outcome in these or any other such proceedings could cause us to lose valuable intellectual property rights and/or be unable to enforce our intellectual property rights.



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***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 (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 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

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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 (the Mayo License), with the Mayo Foundation for Medical Education and Research (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 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.

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

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

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

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

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

## **Risks Related to our Financial and Operating Results**

***We 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. In particular, we believe that we will continue to expend substantial resources for the

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foreseeable future on the commercialization of Senza in the United States, including sales and marketing efforts and sales representative training, seeking additional foreign regulatory approvals, the preparation and submission of regulatory filings and the clinical development of any other product candidates we may choose to pursue. These expenditures will include costs associated with manufacturing and supply as well as marketing and selling Senza in the United States and elsewhere, as well as any other future products approved for sale, research and development, conducting preclinical studies and clinical trials and obtaining regulatory approvals.

We believe that our growth will depend, in part, on our ability to fund our commercialization efforts, particularly in the United States, and our efforts to develop Senza and our HF10 therapy for the treatment of 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. For the three months ended March 31, 2015, our net cash used in operating activities was \$16.8 million and, as of March 31, 2015, our working capital was \$174.4 million. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

the costs of commercialization activities related to commercializing Senza in the United States and elsewhere, including product sales, marketing, manufacturing and distribution;

the scope and timing of our investment in our U.S. commercial infrastructure and sales force in connection with commercialization of Senza in the United States;

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 degree and rate of market acceptance of Senza in the United States and elsewhere;

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

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.

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.



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

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

physician and payor acceptance of Senza and our HF10 therapy;

the timing, expense and results of our commercialization efforts in the United States and elsewhere, 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 obsolescence comparatively. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire and its value would become impaired and we would be required to record an impairment charge. For example, during the year ended December 31, 2014 and 2013, we recorded charges of \$0.8 million and \$1.0 million, respectively, and for the three months ended March 31, 2015 we recorded charges of \$0.3 million, 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 obsolescence risk. In the event that a substantial portion of our inventory becomes obsolete or expires, or in the event we experience a supply chain imbalance as described above, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

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***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, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating loss (NOL) carryforwards and other tax attributes, such as research and development tax credits to offset 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 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.

**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

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EEA Member State Competent Authorities. The FDA and other U.S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

design, development and manufacturing;

testing, labeling, content and language of instructions for use and storage;

clinical trials;

product safety;

marketing, sales and distribution;

pre-market regulatory clearance and approval;

conformity assessment procedures;

record-keeping procedures;

advertising and promotion;

recalls and other field safety corrective actions;

post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;

post-market studies; and

product import and export.

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

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

***Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to 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.

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

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

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. 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 (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.

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

In the EEA, Senza must comply with the Essential Requirements laid down in Annex I to the EU Active Implantable Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to Senza, without which 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 (BSI)), which could impair our ability to market products in the EEA in the future.

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

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

Physicians may also misuse our product or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA determines that our promotional materials, training or physician support activities constitute promotion of an off-label use, it could request that we modify our training,

promotional materials or physician support activities or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative

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penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Further, regulators or legislators may also enhance the enforcement of, and attempt to curtail, any off-label use by physicians of medical devices in the future. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Further, the advertising and promotion of our products is subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices (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 (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 (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 (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 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.

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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 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 (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 (HITECH), and their respective implementing regulations, which impose requirements on certain

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covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;

the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. 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.

***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.



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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 of 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 (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.

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 (the Exchange Act), and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (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.

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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:

delays in the commercialization of Senza or any future product candidates;

announcements of new products by us or our competitors;

achievement of expected product sales and profitability;

manufacture, supply or distribution shortages;

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

our operating results;

results from, or any delays in, clinical trial programs relating to our product candidates;

changes or developments in laws or regulations applicable to our products;

any adverse changes in our relationship with any manufacturers or suppliers;

the success of our efforts to acquire or develop additional products;

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

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

actual or anticipated fluctuations in our operating results;

FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the United States;

changes in financial estimates or recommendations by securities analysts;

trading volume of our common stock;

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

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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.

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

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

***We 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

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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.

***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 March 31, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates held approximately 61% 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;

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



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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;

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.

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**Risks Related to this Offering**

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

Investors purchasing shares of common stock in this offering will pay a price per share that substantially exceeds the as-adjusted book value per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing shares of common stock in this offering will incur immediate dilution of \$42.15 per share, based on an assumed public offering price of \$50.83 per share, which was the last reported sale price of our common stock on the New York Stock Exchange on May 29, 2015, and our as-adjusted net tangible book value as of March 31, 2015 after giving effect to this offering. For information on how the foregoing amounts were calculated, see Dilution.

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering, and the exercise of stock options granted to our employees. In addition, as of March 31, 2015, we had outstanding options to purchase approximately 3.3 million shares of our common stock; the exercise of any of these or future options, equity incentive awards or warrants would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

***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 March 31, 2015, we had outstanding a total of approximately 24.9 million shares of common stock. Of these shares, the 8,050,000 shares of our common stock sold in the IPO are freely tradable, without restriction (except as otherwise applicable), in the public market.

In addition, the lock-up agreements pertaining to our IPO expired on May 4, 2015, following which approximately 16.8 million additional shares of common stock became eligible for sale in the public market, approximately 9.6 million of which shares were held by current directors, executive officers and other affiliates and may be subject to Rule 144 under the Securities Act.

Based upon the number of shares of common stock outstanding as of March 31, 2015, upon the closing of this offering we will have outstanding a total of approximately 26.4 million shares of common stock. Our directors, executive officers and the selling stockholders have entered into lock-up agreements with the underwriters of this offering that will expire 90 days from the date of this prospectus, following which approximately 9.5 million shares of common stock will be eligible for sale in the public market, subject to the limitations of Rule 144 under the Securities Act, to the extent applicable. J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, in their sole discretion, may release the common stock subject to these lock-up agreements at any time.

Furthermore, as of March 31, 2015, approximately 6.1 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of up to approximately 16.5 million shares of our outstanding common stock as of March 31, 2015 were entitled to rights with respect to the registration of their shares under the Securities Act, subject 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.

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*We will receive only a portion of the proceeds from this offering, will have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.*

We will receive only a portion of the proceeds from this offering, as a significant portion of the proceeds from this offering will be received by the selling stockholders. We expect to receive net proceeds of \$69.8 million from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us

Our management will have broad discretion over the use of proceeds received by us this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from this offering to support the commercial launch of Senza in the United States, and for working capital and general corporate purposes, including research and development. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated herein by reference contain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as aim, anticipate, assume, believe, contemplate, continue, could, due, estimate, expect, goal, in plan, predict, potential, positioned, seek, should, target, will, would, and other similar expressions that of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

the timing, scope and phasing of our U.S. commercial launch of Senza;

the scope of protection we are able to establish and maintain for intellectual property rights covering HF10 therapy and Senza, along with any product enhancements;

our expectations regarding the potential market size and the size of the patient populations for our products;

our development plans with respect to Senza, including potential future indications or chronic pain conditions for which we may develop HF10 therapy and seek regulatory approval;

our ability to manufacture Senza in sufficient quantities to meet demand;

whether the results of our trials will be sufficient to support domestic or global regulatory approval for the treatment of any future indications or chronic pain conditions;

the timing or likelihood of regul