NEVRO CORP
Form 424B4
June 03, 2015
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Filed Pursuant to Rule 424(b)(4)
Registration Statement No. 333-204270 and 333-204662

Prospectus

4,705,880 Shares

Common Stock

Nevro Corp. is offering 1,764,705 shares of its common stock. The selling stockholders identified in this prospectus are offering 2,941,175 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 June 2, 2015 was $51.45 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	$ 51.00	$ 239,999,880
Underwriting discounts and commissions(1)	$ 3.06	$ 14,399,993
Proceeds to Nevro Corp., before expenses	$ 47.94	$ 84,599,958
Proceeds to selling stockholders	$ 47.94	$ 140,999,929

(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 705,882 shares of common stock.

The underwriters expect to deliver the shares against payment in New York, New York on or about June 8, 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**

June 2, 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® 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. 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	1,764,705 shares
Common stock the selling stockholders are offering	2,941,175 shares
Common stock to be outstanding after the offering	26,661,216 shares (27,367,098 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 705,882 shares of our common stock from us.
Use of proceeds	The net proceeds to us from this offering will be approximately $83.9 million, or approximately $117.7 million if the underwriters exercise their option to purchase additional shares in full, 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. We will not receive any proceeds from the sale of any shares by the selling stockholders.
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:

- 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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SUMMARY CONSOLIDATED FINANCIAL DATA

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.

	Years Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
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
Operating expenses					
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[1]	$ (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[1]	494,066	876,932	4,440,663	1,075,932	24,849,229

	As of March 31, 2015[2]	
	Actual	As Adjusted
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 159,216	$ 243,101
Working capital	174,363	258,248
Total assets	192,220	276,105
Accumulated deficit	(136,037)	(136,037)
Total stockholders equity	$ 159,118	$ 243,003

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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 1,764,705 shares of common stock offered by us in this offering at the public offering price of $51.00 per share, after deducting 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.

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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

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