NEVRO CORP
Form 10-Q
May 11, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2015

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-36715

Nevro Corp.

(Exact name of registrant as specified in its charter)

Delaware	**56-2568057**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

4040 Campbell Avenue

Menlo Park, CA

(Address of principal executive offices)

94025

(Zip Code)

(650) 251-0005

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of April 30, 2015 there were 24,897,647 shares of the registrant s common stock, par value $0.001 per share, outstanding.

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Nevro Corp.

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PART I FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Nevro Corp.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share data)

	March 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$ 21,984	$ 25,287
Short-term investments	137,232	151,521
Accounts receivable, net of allowance for doubtful accounts of $10 and $10 at March 31, 2015 and December 31, 2014, respectively	7,314	6,610
Inventories, net	18,236	14,856
Prepaid expenses and other current assets	3,026	2,851
Total current assets	187,792	201,125
Property and equipment, net	1,189	647
Other assets	2,333	424
Restricted cash	906	300
Total assets	$ 192,220	$ 202,496
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	$ 8,151	$ 4,460
Accrued liabilities	5,218	6,268
Other current liabilities	60	70
Total current liabilities	13,429	10,798
Notes payable	19,569	19,511
Other long-term liabilities	104	117
Total liabilities	33,102	30,426

Commitments and contingencies (Note 5)		
Stockholders equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2015 and December 31, 2014; zero shares issued and outstanding at March 31, 2015 and December 31, 2014		
Common stock, $0.001 par value, 290,000,000 shares authorized at March 31, 2015 and December 31, 2014; 24,896,511 and 24,865,491 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	25	25
Additional paid-in capital	295,255	293,945
Accumulated other comprehensive income (loss)	(125)	77
Accumulated deficit	(136,037)	(121,977)
Total stockholders equity	159,118	172,070
Total liabilities and stockholders equity	$ 192,220	$ 202,496

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

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Nevro Corp.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2015	2014
Revenue	$ 9,662	$ 6,664
Cost of revenue	3,873	2,999
Gross profit	5,789	3,665
Operating expenses		
Research and development	4,998	4,696
Sales, general and administrative	13,130	6,210
Total operating expenses	18,128	10,906
Loss from operations	(12,339)	(7,241)
Interest income	104	40
Interest expense	(673)	
Other income (expense), net	(1,010)	238
Loss before income taxes	(13,918)	(6,963)
Provision for income taxes	142	93
Net loss	(14,060)	(7,056)
Accretion of redeemable convertible preferred stock to redemption value		(43)
Net loss attributable to common stockholders	(14,060)	(7,099)
Other comprehensive income (loss):		
Changes in foreign currency translation adjustment	(123)	
Changes in gains (losses) on short-term investments, net	(79)	(13)
Net change in other comprehensive loss	(202)	(13)
Comprehensive loss	$ (14,262)	$ (7,112)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (6.60)

Weighted average number of common shares used to compute basic and diluted net loss per share	24,849,229	1,075,932

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

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Nevro Corp.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (14,060)	$ (7,056)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	46	16
Stock-based compensation expense	1,218	405
Amortization (accretion) of premium (discount) on short-term investments	(71)	102
Write down of inventory	264	24
Non-cash interest expense	58	
Changes in operating assets and liabilities		
Accounts receivable	(704)	80
Inventories	(3,644)	8
Prepaid expenses and other current assets	(175)	(796)
Other assets	(1,909)	(23)
Accounts payable	3,496	133
Accrued liabilities	(1,335)	(968)
Other long-term liabilities	(13)	(25)
Net cash used in operating activities	(16,829)	(8,100)
Cash flows from investing activities		
Purchases of short-term investments	(3,741)	(11,939)
Proceeds from maturity of short-term investments	18,022	23,121
Restricted cash	(606)	
Purchases of property and equipment	(228)	(109)
Net cash provided by investing activities	13,447	11,073
Cash flows from financing activities		
Proceeds from issuance of common stock	79	29
Net cash provided by financing activities	79	29

Net increase (decrease) in cash and cash equivalents	(3,303)	3,002
Cash and cash equivalents		
Cash and cash equivalents at beginning of period	25,287	12,409
Cash and cash equivalents at end of period	$ 21,984	$ 15,411
Significant non-cash transactions		
Property and equipment in accounts payable	$ 360	$ 33
Vesting of early-exercised stock options	$ 13	$ 114

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

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Nevro Corp.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Formation and Business of the Company

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

Since inception, the Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2014, the Company incurred a net loss of $30.7 million and used $31.1 million of cash in operations. For the three months ended March 31, 2015, the Company incurred a net loss of $14.1 million and used $16.8 million of cash in operations. At March 31, 2015 and December 31, 2014, the Company had an accumulated deficit of $136.0 million and $122.0 million, respectively, and does not expect to experience positive cash flows in the near future. The Company has financed operations to date primarily through private placements of equity securities, the issuance of common stock in the initial public offering (IPO) completed in November 2014 and borrowings under a debt agreement. On May 8, 2015, the Company s Senza spinal cord stimulation product was approved for commercialization in the United States by the U.S. Food and Drug Administration (FDA). The Company s ability to continue to meet its obligations and to achieve its business objectives is dependent upon, amongst other things, commercializing its products in the United States, generating sufficient revenues and its ability to continue to control expenses, if necessary, to meet its obligations as they become due for the foreseeable future. Failure to increase sales of its products, manage discretionary expenditures or raise additional financing, as required, may adversely impact the Company s ability to achieve its intended business objectives.

The accompanying interim condensed consolidated financial statements as of March 31, 2015 and for the three months ended March 31, 2015 and 2014, and the related interim information contained within the notes to the financial statements, are unaudited. The unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and on the same basis as the audited financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which include only normal recurring adjustments necessary to state fairly the Company s financial position as of March 31, 2015, and the results of its operations and cash flows for the three months ended March 31, 2015 and 2014. Such adjustments are of a normal and recurring nature. The results for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015, or for any future period.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2014 included in the Company s Annual Report filed on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 18, 2015.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Segments

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

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

	Three Months Ended March 31,	
	2015	**2014**
Australia	27%	27%
United Kingdom	22%	15%
Germany	18%	15%
Netherlands	7%	14%

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

Foreign Currency Translation

The Company s consolidated financial statements are prepared in U.S. dollars (USD). Its foreign subsidiaries use their local currency as their functional currency and maintain their records in the local currency. Accordingly, the assets and liabilities of these subsidiaries are translated into USD using the current exchange rates in effect at the balance sheet date and equity accounts are translated into USD using historical rates. Revenues and expenses are translated using the monthly average exchange rates during the period when the transaction occurs. The resulting foreign currency translation adjustments from this process are recorded in accumulated other comprehensive income (loss) in the consolidated balance sheets. Unrealized foreign exchange gains and losses from the remeasurement of assets and liabilities denominated in currencies other than the functional currency of the reporting entity are recorded in Other income (expense), net. The Company recorded net unrealized foreign currency transaction gain (loss) of $(0.5) million and $0.2 million during the three months ended March 31, 2015 and 2014, respectively. Additionally, realized gains and losses resulting from transactions denominated in currencies other than the local currency are recorded in Other income (expense), net in the consolidated statements of operations. The Company recorded realized foreign currency transaction gain (loss) of $(0.5) million, and $61,000, during the three months ended March 31, 2015 and 2014, respectively.

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

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Significant accounting estimates and management judgments reflected in the condensed consolidated financial statements include items such as allowances for doubtful accounts; clinical accruals; stock-based compensation; depreciation and amortization periods; inventory valuation; valuation of investments and deferred tax assets, including valuation allowances. Estimates are based on historical experience, where applicable, and other assumptions believed to be reasonable by the management. Actual results may differ from those estimates under different assumptions or conditions.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The majority of the Company s cash is held by one financial institution in the United States of America in excess of federally insured limits. The Company maintained investments in money market funds that were not federally insured during the periods ended March 31, 2015 and December 31, 2014 and held cash in foreign banks of approximately $5.1 million at March 31, 2015 and $4.3 million at December 31, 2014 that was not federally insured. The Company has not experienced any losses on its deposits of cash and cash equivalents.

All of the Company s revenue has been derived from sales of its products in international markets, principally Australia and Europe. In the international markets in which the Company participates, the Company uses both a direct

sales force and distributors to sell its products. The Company performs ongoing credit evaluations of its direct customers and distributors, does not require collateral and maintains allowances for potential credit losses on customer accounts when deemed necessary.

During the three-month period ended March 31, 2015, no customers accounted for more than 10% of the Company s revenue, and during the three-month period ended March 31, 2014, one customer accounted for 14% of the Company s revenue. As of March 31, 2015, one customer accounted for 12% of the accounts receivable balance. As of December 31, 2014, no customer accounted for more than 10% of the Company s accounts receivable balance.

The Company is subject to risks common to early-stage medical device companies, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, manufacturing quality and scaling, uncertainty of market acceptance of products and the need to obtain additional financing. The Company is dependent on third-party manufacturers and suppliers, in some cases sole- or single-source suppliers.

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

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The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any products or product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

Fair Value of Financial Instruments

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

Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include money market funds in the amount of $10.0 million and $10.6 million as of March 31, 2015 and December 31, 2014, respectively. At March 31, 2015 and December 31, 2014, the Company s cash equivalents were held in institutions in the United States and include deposits in a money market fund which was unrestricted as to withdrawal or use.

Restricted Cash

Restricted cash of $0.3 million as of December 31, 2014 represents a certificate of deposit collateralizing payment of charges related to the Company s corporate credit cards. Restricted cash as of March 31, 2015 represents $0.3 million of a certificate of deposit collateralizing payment of charges related to the Company s credit cards and also includes $0.6 million representing collateral for a letter of credit related to the Company s lease entered into in March 2015.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities of less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company s investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of comprehensive income (loss).

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

Inventories

Inventories are stated at the lower of cost to purchase or manufacture the inventory or the market value of such inventory. Cost is determined using the standard cost method which approximates the first-in, first-out basis. Market value is determined as the lower of replacement cost or net realizable value. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate.

The Company s policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on the Company s estimates of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, the Company may increase the write down for excess inventory for that component and record a charge to inventory impairment in the accompanying consolidated statements of operations and comprehensive loss. The Company periodically evaluates the carrying value of inventory on hand for potential excess amounts over demand using the same lower of cost or market approach as that has been used to value the inventory. The Company also periodically evaluates inventory quantities in consideration of actual loss experience. As a result of these evaluations, the Company recognized a total write down for Senza inventories of $0.3 million and $24,000 for the three months ended March 31, 2015 and 2014, respectively. The Company s estimation of the future demand for a particular component of the Senza product may vary and may result in changes in estimates in any particular period.

Shipping and Handling Costs

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

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Revenue Recognition

The Company recognizes revenue when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- the sales price is fixed or determinable;
- collection of the relevant receivable is probable at the time of sale; and
- delivery has occurred or services have been rendered.

For a majority of sales, where the Company s sales representative delivers its product at the point of implantation at hospitals or medical facilities, the Company recognizes revenue upon completion of the procedure and authorization, which represents satisfaction of the required revenue recognition criteria. For the remaining sales, which are sent from the Company s distribution centers directly to hospitals and medical facilities, as well as distributor sales, where product is ordered in advance of an implantation procedure and a valid purchase order has been received, the Company recognizes revenue at the time of shipment of the product, which represents the point in time when the customer has taken ownership and assumed the risk of loss and the required revenue recognition criteria are satisfied. The Company s customers are obligated to pay within specified terms regardless of when or if they ever sell or use the products. The Company does not offer rights of return or price protection and it has no post-delivery obligations.

The Company has a limited one-year warranty to most customers in the international markets in which it operates. Warranty terms may vary once the Company has commercialized in the United States. Estimated warranty obligations are recorded at the time of sale and to date, warranty costs have been insignificant.

Property and Equipment

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group s carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. There were no impairment charges or changes in estimated useful lives recorded through March 31, 2015.

Income Taxes

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

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

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

Comprehensive Income (Loss)

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

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Research and Development

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

Stock-Based Compensation

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

The Company s determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option-pricing model and is impacted by its common stock price as well as changes in assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends.

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

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

Estimating the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. For all stock options granted to date, the Company estimated the volatility data based on a study of publicly traded industry peer companies. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the equity-settled award.

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

Net Loss per Share of Common Stock

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

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability, consistent with debt discounts. ASU 2015-03 applies to all business entities and is effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. The Company does not expect that the adoption of ASU 2015-03 will have a material effect on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a

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contract. The ASU is effective for public entities for annual and interim periods beginning after December 15, 2016. In April 2015, the FASB proposed to defer for one year the effective date of the new revenue standard, with an option that would permit companies to adopt the standard as early as the original effective date. Early adoption prior to the original effective date is not permitted. The Company has not determined the potential effects of this ASU on its consolidated financial statements.

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

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties About an Entity s Ability to Continue as a Going Concern*. The new standard provides guidance around management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company s consolidated financial statements.

3. Fair Value Measurements

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

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

Level 1 Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Cash Equivalents and Short-Term Investments

The Company s cash equivalents are comprised of investments in money market funds that are classified as Level 1 of the fair value hierarchy. To value its money market funds, the Company values the funds at $1 stable net asset value, which is the market pricing convention for identical assets that the Company has the ability to access. The Company s short-term investments are comprised of commercial paper, time deposits and corporate notes. All short-term investments have been classified within Level 2 of the fair value hierarchy because of the sufficient observable inputs

for revaluation. The Company s Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry-standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs. The following table sets forth the Company s financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

Balance as of March 31, 2015	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds (i)	$ 9,997	$	$	$ 9,997
Time deposits (ii)	10,001			10,001
Commercial paper (ii)		131,171		131,171
Total assets	$ 19,998	$ 131,171	$	$ 151,169

Balance as of December 31, 2014	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds (i)	$ 10,590	$	$	$ 10,590
Commercial paper (ii)		140,484		140,484
Corporate notes (ii)		19,037		19,037
Total assets	$ 10,590	$ 159,521	$	$ 170,111

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

4. Balance Sheet Components

Investments

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

	March 31, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investment Securities				
Commercial paper (i)	$ 131,044	$ 127	$	$ 131,171
Time deposits	10,000	1		10,001
Total securities	$ 141,044	$ 128	$	$ 141,172

(i) Includes $3.9 million of commercial paper that are classified as cash and cash equivalents on the consolidated balance sheet.

	December 31, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investment Securities				
Commercial paper (i)	$ 140,273	$ 211	$	$ 140,484
Corporate notes	19,040		(3)	19,037
Total securities	$ 159,313	$ 211	$ (3)	$ 159,521

(i)

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

Realized gains or losses and other-than-temporary impairments, if any, on available-for-sale securities are reported in other income or expense as incurred. The cost of securities sold is determined based on the specific identification method. The Company has not recorded any realized gains on its investments during the periods presented.

The contractual maturities of the Company s investment securities were all within one year as of March 31, 2015 and December 31, 2014.

Inventories (in thousands)

	March 31, 2015	December 31, 2014
Raw materials	$ 8,298	$ 7,960
Finished goods	9,938	6,896
	$ 18,236	$ 14,856

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Property and Equipment, Net (in thousands)

	March 31, 2015	December 31, 2014
Laboratory equipment	$ 315	$ 390
Computer equipment and software	418	125
Furniture and fixtures	112	112
Leasehold improvements	22	22
Construction in process	593	333
Total	1,460	982
Less: Accumulated depreciation and amortization	(271)	(335)
Property and equipment, net	$ 1,189	$ 647

The Company recognized depreciation and amortization expense on property and equipment during the three months ended March 31, 2015 and 2014 of $46,000 and $16,000, respectively.

Accrued Liabilities (in thousands)

	March 31, 2015	December 31, 2014
Accrued payroll and related expenses	$ 2,852	$ 4,268
Accrued professional fees	711	184
Accrued taxes	771	998
Accrued clinical and research expenses	305	613
Accrued other	579	205
Total accrued liabilities	$ 5,218	$ 6,268

5. Commitments and Contingencies

Operating Leases

The Company entered into a non-cancellable operating lease effective May 1, 2010 for facilities in Menlo Park, as amended in 2012 to extend the period of the lease until May 31, 2015. In March 2015, the Company extended the lease through September 30, 2015 and is obligated to pay approximately $0.3 million in additional rent payments. In August 2014, the Company entered into a new facility lease for warehouse space beginning on August 21, 2014 through May 31, 2015. In March 2015, the Company extended the warehouse lease through February 2017 under which it is obligated to pay approximately $0.3 million in lease payments over the remaining term of the lease.

In March 2015, the Company entered into a lease agreement for approximately 50,000 square feet of office space located in Redwood City, California for a period beginning in June 2015 and ending in May 2022, with initial annual

payments of approximately $2.0 million, increasing to $2.4 million annually during the final year of the lease term.

Rent expense for the three months ended March 31, 2015 and March 31, 2014 was $0.2 million and $0.1 million, respectively.

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Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual or disclosure at March 31, 2015 or December 31, 2014.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to the Company s technology. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made.

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

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

License Agreement

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

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

In March 2011, the Company entered into a Phase II License Agreement with Mayo which provides the Company access to the certain know-how and licensed patents owned by Mayo. The licenses granted are exclusive and the Company has the right to sub-license.

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

- Pay a retainer fee of $40,000 per annum starting March 2011 and ending on February 2013; and

- Pay royalties based on the greater of earned royalties or a minimum royalty. The earned royalties are based on a percentage of net sales of licensed products either by the Company or the sub-licensee. The minimum annual royalty payment is $200,000.

Royalties paid during the three months ended March 31, 2015 and March 31, 2014 were $0.1 million and $0.1 million, respectively.

6. Notes Payable

Capital Royalty Term Loan

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

The credit facility includes affirmative and negative covenants, including certain minimum financial covenants for pre-specified liquidity and revenue requirements. In particular, the Company is required to maintain a minimum of $5.0 million of cash and certain cash equivalents, and the Company must achieve minimum revenue of $25.0 million in 2015, $30.0 million in 2016, $40.0 million in 2017, $50.0 million in 2018 and $70.0 million in 2019. In addition, the credit facility prohibits the payment of cash dividends on the Company s capital stock and also places restrictions

on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. As of March 31, 2015, the Company was in compliance with all applicable covenants.

As of March 31, 2015, future minimum payments for the notes are as follows (in thousands):

	Term Loans
2015	$ 1,757
2016	2,338
2017	3,739
2018	7,977
2019 and beyond	14,960
Total minimum payments	30,771
Less: Amount representing interest	(9,771)
Less: Amount representing closing and repayment fees	(1,000)
Present value of minimum payments	20,000
Less: Unamortized debt discount	(474)
Plus: Accretion of closing and repayment fees	43
Notes payable, net	19,569
Less: Notes payable, current portion	
Non-current portion of notes payable	$ 19,569

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7. Convertible Preferred Stock

Prior to the IPO, the Company had outstanding 15,208,048 shares of convertible preferred stock. Each share of preferred stock was convertible to one share of common stock. Upon the closing of the Company s IPO on November 11, 2014, all shares of outstanding redeemable convertible preferred stock were automatically converted to 15,208,048 million shares of the Company s common stock.

The Company recorded the Series B and C redeemable convertible preferred stock at fair value on the dates of issuance. The Company classifies the Series B and C redeemable convertible preferred stock outside of stockholders deficit because the shares contain liquidation features that are not solely within the Company s control. The Series B and C redeemable convertible preferred shares were originally issued with a contingent redemption feature, which allowed the holders to redeem their shares five years following the issuance date of the Series B and C redeemable preferred shares. Accordingly, the Company accreted the Series B and C redeemable convertible preferred stock for change in redemption value with a change to accumulated deficit at the end of each reporting period. Accordingly, the Company has accreted $43,000 during the three-month period ended March 31, 2014.

8. Net Loss Per Share Attributable to Common Stockholders

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

	Three Months Ended March 31,	
	2015	2014
Net loss	$ (14,060)	$ (7,056)
Accretion of convertible preferred stock to redemption value		(43)
Net loss attributable to common stockholders	$ (14,060)	$ (7,099)
Weighted average shares outstanding	24,876,383	1,123,683
Less: weighted average shares subject to repurchase	(27,154)	(47,751)
Weighted average shares used to compute basic and diluted net loss per share	24,849,229	1,075,932
Net loss attributable to common stockholders per share, basic and diluted	$ (0.57)	$ (6.60)

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities,

if inclusion of these is dilutive. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computation of diluted shares outstanding:

	March 31,	
	2015	**2014**
Convertible preferred stock		15,208,048
Options to purchase common stock	3,315,947	2,791,132
Total	3,315,947	17,999,180

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9. Employee Benefit Plan

In 2007, the Company adopted a 401(k) plan for its employees whereby eligible employees may contribute up to the maximum amount permitted by the Internal Revenue Code. Under the plan, the Company does not provide matching contributions to employees.

10. Subsequent Events

On May 8, 2015, the FDA approved the Company s PMA for marketing the Senza spinal cord stimulation product in the United States.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following management s discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes thereto for the year ended December 31, 2014, included in our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 18, 2015.

Special note regarding forward-looking statements

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Forward-looking statements are often identified by the use of words such as, but not limited to, anticipate, believe, can, continue, could, estimate, expect, intend, may, plan, project, seek, should, st and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled Risk Factors included under Part II, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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 (SCS), system that delivers our proprietary HF10 therapy. On May 8, 2015, our premarket approval (PMA) application for our Senza SCS system, or Senza, was approved by the U.S. Food and Drug Administration (FDA). Accordingly, we expect to begin U.S. commercialization of the Senza system in May 2015. In order to maintain our PMA approval in the U.S. we need to comply with applicable laws and regulations from the FDA and other relevant regulatory agencies. The Senza system received a CE Mark in 2010, and commercialization commenced in Europe in 2010 and Australia in 2011 where the system is reimbursed under existing SCS codes. We market our products to physicians in Europe and Australia and sell to hospitals and outpatient surgery centers through both a direct sales organization and distributors. Beginning in 2010, we established our international sales organizations to support our product launch outside of the United States.

Our SENZA-RCT U.S. pivotal study, a non-inferiority study, met its primary and secondary endpoints, and our post-hoc statistical analysis supports the superiority of HF10 therapy over traditional SCS therapies for treating both leg and back pain. While SCS therapy is indicated and reimbursed for treating back and leg pain, it has limited efficacy in back pain and is utilized primarily for treating leg pain, which has limited its market adoption. In our pivotal study, HF10 therapy was demonstrated to provide significant and sustained back pain relief in addition to leg pain relief. Additionally, HF10 therapy was demonstrated to provide pain relief without paresthesia, a constant tingling sensation that is the basis of traditional SCS therapy. By utilizing anatomical lead placement instead of relying on paresthesia, HF10 therapy is designed to reduce variability in the operating procedure, providing meaningful benefits to both patients and physicians. We believe we are positioned to transform and grow the

approximately $1.5 billion existing global SCS market under current reimbursement by treating back pain in addition to leg pain and by eliminating paresthesia.

Since our inception, we have financed our operations primarily through equity financings and borrowings under our debt facility. Our accumulated deficit as of March 31, 2015 was $136.0 million. A significant amount of our capital resources has been used to support the development of Senza and our HF10 therapy, including, our pivotal clinical trial, SENZA-RCT, which we initiated in May 2012. We intend to make a significant investment building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives for U.S. commercialization. We also intend to continue to make significant investments in research and development (R&D), to develop Senza to treat other chronic pain indications, including conducting clinical trials to support our future regulatory submissions. As a result of these and other factors, we expect to continue to incur net losses for the next several years and require substantial additional funding, which may include future equity and debt financings.

We rely on third-party suppliers for all of the components of Senza and for the assembly of the system. Many of these suppliers are currently single-source suppliers. We are also required to maintain high levels of inventory, and, as a result, we are subject to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges. In particular, as we initiate our commercial launch of Senza in the United States, we will be substantially increasing our levels of inventory in order to meet our estimated demand and, as a result, incur significant expenditures associated with such increases in our inventory. Additionally, as compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of inventory obsolesce comparatively.

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Important Factors Affecting our Results of Operations

We believe there are several important factors that have impacted and that we expect will impact our results of operations.

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

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

Significant Investment in U.S. Sales Organization

We have started to make significant investments in building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives for U.S. commercialization. This is a lengthy process that requires recruiting appropriate sales representatives, establishing a commercial infrastructure in the United States, and training our sales representatives, and will require significant investment by us. Following initial training for Senza, our sales representatives typically require lead time in the field to grow their network of accounts and produce sales results. Successfully recruiting and training a sufficient number of productive sales representatives is required to achieve growth at the rate we expect.

Importance of Physician Awareness and Acceptance of Senza

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

Access to Hospital Facilities

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

Inventory Buildup

Our Senza product consists of a substantial number of individual components and, in order to market and sell Senza effectively, we must maintain high levels of inventory. In particular, as we initiate our commercial launch of Senza in the U.S., we will be substantially increasing our levels of inventory. As a result, we will incur significant expenditures associated with the increases in our inventory, which will include satisfying certain minimum purchase obligations, as demand for Senza in the United States is developing. Further, the manufacturing process for Senza requires lengthy

lead times, during which components may become obsolete. We may also over-or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. These factors subject us to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges.

Investment in Research and Clinical Trials

We intend to continue investing in R&D to expand into new indications and chronic pain conditions for Senza, as well as develop product enhancements to improve outcomes and enhance the physician and patient experience. In the future, we expect to initiate clinical trials to support the development of Senza and HF10 therapy for the treatment of other chronic pain conditions. We believe that our continuing clinical research and regulatory efforts will continue to drive adoption of Senza. While R&D and clinical testing are time consuming and costly, we believe that clinical data demonstrating efficacy, safety and cost effectiveness is critical to increasing the adoption of HF10 therapy.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management s discussion and analysis of financial condition and results of operations are based upon our unaudited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial. There have been no significant or material changes in our critical accounting policies during the three months ended March 31, 2015.

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Components of Results of Operations

Revenue

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

Revenue from sales of Senza fluctuate based on the selling price of the system, as the sales price of a system varies among jurisdictions, and the mix of sales by jurisdiction. In addition, our revenue may fluctuate based on the ratio of trials to permanent implants. Our revenue from international sales can also be significantly impacted by fluctuations in foreign currency exchange rates, as our sales are denominated in the local currency in the countries that we sell our products in.

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

Cost of Revenue

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

We calculate gross margin as revenue less cost of revenue divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our costs to have our products manufactured for us, the ratio of trials to permanent implants, the period of time between a trial and the related permanent implant and, to a lesser extent, the percentage of products we sell to distributors as compared to those sold directly to hospitals and medical facilities as our gross margin is typically higher on products we sell directly as compared to products we sell through distributors. We expect our gross margin to be positively affected over time to the extent we are successful in reducing manufacturing costs as our sales volume increases. However, our gross margin may fluctuate from period to period.

Operating Expenses

Our operating expenses consist of R&D, sales, general and administrative expense (SG&A). Personnel costs are the most significant component of operating expenses and consist of salaries, benefits, stock-based compensation and sales commissions. We expect operating expenses to increase in absolute dollars, as we continue to invest to grow our business.

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

enhancements to Senza and develop our HF10 therapy to treat other chronic pain indications, including conducting additional clinical studies. Our R&D expenses may fluctuate from period to period due to the timing and extent of our R&D and clinical trial expenses.

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

In the last 24 months, we significantly increased the size of our sales presence internationally and domestically in anticipation of approval and launch of Senza in the United States and increased marketing spending to generate sales opportunities. We expect SG&A expenses to continue to significantly increase as we build up our sales and marketing personnel in anticipation of approval and launch of Senza in the United States, continue to increase the size of our sales and marketing organizations and increase our international presence and develop and assist our channel partners.

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During the first quarter of fiscal year 2015, our administrative expenses increased as we operated as a public company. We expect our administrative expenses will continue to increase as we increase our headcount and expand our facility and information technology to support our operations as a public company. Additionally, we anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company. Our SG&A expenses may fluctuate from period to period due to the seasonality of our revenue and the timing and extent of our SG&A expenses.

Interest Income (Expense), Net

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

Other Income (Expense), Net

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

Provision for Income Taxes

The Company prepares quarterly estimates of its tax provision using a discrete approach. Provision for income taxes consists primarily of income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including net operating loss carryforwards and R&D credits and other tax credits.

Consolidated Results of Operations

Comparison of the three months ended March 31, 2015 and March 31, 2014

Revenue, Cost of Revenue, Gross Profit and Gross Margin

(in thousands)	Three Months Ended March 31,		
	2015	2014	Change
Revenue	$ 9,662	$ 6,664	$ 2,998
Cost of revenue	3,873	2,999	874
Gross profit	5,789	3,665	2,124
Gross margin	60%	55%	5%

Revenue. During the three months ended March 31, 2015, revenue increased to $9.7 million from $6.7 million during the three months ended March 31, 2014, an increase of $3.0 million, or 45%, despite a significant appreciation of the U.S. dollar compared to foreign currency exchange rates used in the three months ended March 31, 2014. The net revenue increase was primarily attributable to continued adoption of the Senza system.

Cost of Revenue, Gross Profit and Gross Margin. Total cost of revenue increased $0.9 million, or 29%, in the three-month period ended March 31, 2015 compared to the same period of the prior year primarily due to an increase in the costs to purchase manufactured products of $0.5 million and an increase in personnel costs of $0.4 million.

Gross profit increased $2.1 million, or 58%, to $5.8 million, in the three-month period ended March 31, 2015 as compared to $3.7 million in the three-month period ended March 31, 2014. Our product costs as a percent of revenue decreased as our average cost per unit benefited from economies of scale with higher unit volumes compared to the same period last year. While our revenues were reduced in part by the appreciation of the U.S. dollar in the three-month period ended March 31, 2015, our costs were primarily incurred in U.S. dollars, which results in a reduced overall gross margin. During the three-month period ended March 31, 2015 our reduced product costs were only partially offset by the effect of revenues being negatively affecting by a strengthening U.S. dollar, as gross margins increased a net 5% compared to the three-month period ended March 31, 2014.

Operating Expenses

(in thousands)	Three Months Ended March 31, 2015 Amount	2015 % of Total Revenue	2014 Amount	2014 % of Total Revenue	Change Amount
Operating expenses:					
Research and development	$ 4,998	52%	$ 4,696	70%	$ 302
Sales, general and administrative	13,130	136%	6,210	93%	6,920
Total operating expenses	$ 18,128	188%	$ 10,906	163%	$ 7,222

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Research and Development Expenses. R&D expense increased $0.3 million in the three-month period ended March 31, 2015 compared to the same period of the prior year, primarily due to an increase in headcount and related personnel costs of $0.5 million, offset by a decrease in development expenses of $0.2 million in the 2015 period as compared to the prior 2014 period.

Sales, General and Administrative Expenses. SG&A expense increased to $13.1 million in the three-month period ended March 31, 2015 from $6.2 million during the same period in the prior year, an increase of $6.9 million, or 111%, primarily due to an increase in personnel costs of $3.2 million, facilities related expenses of $0.9 million and travel expenses of $1.0 million as we increased sales headcount to support growth. We also had an increase in marketing expenses of $0.8 million and legal and other professional services expenses of $0.9 million to support our commercial growth and due to increased costs associated with being a public company.

Interest Income, Interest Expense and Other Income (Expense), Net and Provision for Income Taxes

	Three Months Ended March 31,		
(in thousands)	**2015**	**2014**	**Change**
Interest income	$ 104	$ 40	$ 64
Interest expense	(673)		(673)
Other income (expense), net	(1,010)	238	(1,248)
Provision for income taxes	142	93	49

Interest Income. Interest income increased from $40,000 during the three-month period ended March 31, 2014 to $104,000 in the three-month period ended March 31, 2015, primarily as a result of the increase in average investment balances during the period ended March 31, 2015 as compared to the prior year period.

Interest Expense. Interest expense increased to $673,000 during the three-month period ended March 31, 2015 from zero in the three-month period ended March 31, 2014, primarily as a result of the increase in debt outstanding during 2015 as a result of borrowing under our credit facility in December 2014.

Other Income (Expense), Net. Other income (expense), net was primarily comprised of foreign currency transaction gains and losses, as well as gains and losses from the remeasurement of foreign-currency denominated balances. During the three-month period ended March 31, 2015, we recorded losses of $1.0 million, whereas during the prior period in 2014 we recorded a gain of $0.2 million.

Provision for Income Taxes. Income tax expense was $0.1 million and $0.1 million during the three months ended March 31, 2015 and 2014, respectively, and was associated with foreign taxes. We continue to generate tax losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We have a full valuation allowance for our deferred tax assets.

Liquidity, Capital Resources and Plan of Operations

Since our inception through March 31, 2015, we have financed our operations through private placements of preferred stock, the issuance of common stock in our initial public offering (IPO), and borrowing under our credit facility. At March 31, 2015, we had cash and cash equivalents and investments of $159.2 million. Based on our current operating plan, we expect that our cash on hand, together with the anticipated funds from our operations and our credit facility, will be sufficient to fund our operations through at least the next twelve months.

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

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

- the 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 forcein connection with commercialization of Senza in the United States;

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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.

Our success depends, in part, upon our ability to establish a competitive position in the neuromodulation market by securing broad market acceptance of our HF10 therapy and Senza for the treatment of chronic pain conditions. Any product we develop that achieves regulatory clearance or approval will have to compete for market acceptance and market share. We face significant competition in the United States and internationally, which we believe will intensify as we enter the U.S. market. For example, our major competitors, Medtronic, Inc., Boston Scientific Corporation and St. Jude Medical, Inc., have each approved neuromodulation systems in at least the United States, Europe and Australia and have been established for several years. In addition to these major competitors, we may also face competition from other emerging competitors and smaller companies with active neuromodulation system development programs that may emerge in the future.

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

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

	Three Months Ended March 31,	
	2015	2014
(in thousands)		
Net cash provided by (used in):		
Operating activities	$ (16,829)	$ (8,100)
Investing activities	13,447	11,073
Financing activities	79	29

Net increase (decrease) in cash and cash equivalents	$	(3,303)	$	3,002

Cash Used in Operating Activities. Net cash used in operating activities for the three months ended March 31, 2015 was $16.8 million compared to $8.1 million for the three months ended March 31, 2014, primarily as a result of the net losses recorded in the periods of $14.1 million and $7.1 million, respectively. During the three months ended March 31, 2015, net cash used in operations was also affected by changes in our operating assets and liabilities, including increases in our outstanding long-term other assets of $1.9 million and inventories of $3.6 million, and an increase in accounts receivable of $0.7 million, partially offset by an increase of $2.2 million in accounts payable and accrued liabilities, as well as non-cash stock based compensation expense of $1.2 million. During the three-month period ended March 31, 2014, the net cash used in operations was affected by changes in our operating assets and liabilities, including a decrease in our outstanding prepaid and other assets of $0.8 million and a decrease of $1.0 million in accrued liabilities, offset by non-cash stock based compensation expense of $0.4 million.

Cash Provided by Investing Activities. Investing activities consisted primarily of changes in investment balances, including purchases and maturities of short-term investments. During the three months ended March 31, 2015, investments of $18.0 million matured and we purchased $3.7 million of new investments as compared to the three months ended March 31, 2014 when $23.1 million of investments matured and we purchased $11.9 million of new investments.

Cash Provided by Financing Activities. Cash provided by financing activities was $79,000 for the three months ended March 31, 2015 due to the cash received from the exercise of common stock options as compared to $29,000 received during the three-month period ended March 31, 2014 as a result of the exercise of common stock options.

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Contractual Obligations and Commitments

In March 2015, we entered into a lease agreement for approximately 50,000 square feet of office space located in Redwood City, California for a period beginning in June 2015 and ending in May 2022, with initial annual payments of approximately $2.0 million, increasing to $2.4 million annually in the final year of the lease term. In March 2015, we extended our warehouse lease through February 2017 under which we are obligated to pay approximately $0.3 million in lease payments over the remaining term of the lease. In March 2015, we entered into supply agreements with certain of our suppliers that require an aggregate upfront payment of $1.8 million, along with certain minimum annual purchase commitments that total an aggregate of $80.2 million, with $35.2 million due in 2015, and the remainder due within one to three years. Additional purchase commitments, which are currently indeterminable, are due in each of the remaining seven years of the agreement.

Off-Balance Sheet Arrangements

Through March 31, 2015, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. For information regarding indemnification obligations, refer to Note 5 to the condensed consolidated financial statements within this report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

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

We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of March 31, 2015, we had cash and cash equivalents of $22.0 million consisting of cash and money market funds and short-term investments of $137.2 million consisting of commercial paper, time deposits and corporate notes during the three months ended March 31, 2015. We maintained investments in money market funds that were not federally insured during the three months ended March 31, 2015 and held cash in foreign banks of approximately $5.1 million at March 31, 2015 that was not federally insured. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 1% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign Currency Exchange Risk

To date, all of our revenue and a portion of our operating expenses are incurred outside the United States and are denominated in foreign currencies and are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Australian dollar, the Euro and the United Kingdom pound sterling. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. We recognized net foreign currency transaction gains (losses) of $(0.5) million and $61,000

during the three months ended March 31, 2015 and 2014, respectively. A hypothetical 10% favorable or unfavorable change in the weighted average foreign exchange rates for the period ended March 31, 2015 would have affected the annualized consolidated foreign-currency-denominated operating loss by approximately 6% for the year. To date, we have not engaged in any foreign currency hedging transactions. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

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Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2015, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this prospectus, including our financial statements and notes thereto, before you invest in our common stock. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

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.

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.

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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. We may need to initiate infringement claims or litigation. Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could place one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against 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.

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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.

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 2012, one of our principal competitors, Boston Scientific Corporation, made a number of allegations regarding the SENZA-RCT U.S. pivotal study, including that we had introduced bias into the study. We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States.

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

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.

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;
- 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.

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

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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 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.

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.

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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;

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;

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- 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
- 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

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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.

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.

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.

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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 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;