NEVRO CORP
Form 10-Q
November 09, 2015
Table of Contents

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 September 30, 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.)**

1800 Bridge Parkway

Redwood City, CA

(Address of principal executive offices)

94065

(Zip Code)

(650) 251-0005

(Registrant s telephone number, including area code)

(former address of Registrant)

4040 Campbell Avenue

Menlo Park, CA, 94025

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 x 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 October 31, 2015 there were 27,936,964 shares of the registrant s common stock, par value $0.001 per share, outstanding.

Table of Contents

Nevro Corp.

TABLE OF CONTENTS

	Page
PART I FINANCIAL INFORMATION	
Item 1. Condensed Consolidated Financial Statements (unaudited)	3
Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014	3
Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014	4
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014	5
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3. Quantitative and Qualitative Disclosures About Market Risk	30
Item 4. Controls and Procedures	30
PART II OTHER INFORMATION	
Item 1. Legal Proceedings	31
Item 1A. Risk Factors	31
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	65
Item 3. Defaults Upon Senior Securities	66
Item 4. Mine Safety Disclosures	66
Item 5. Other Information	66
Item 6. Exhibits	67
SIGNATURES	68

Table of Contents

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)

	September 30, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 87,558	$ 25,287
Short-term investments	134,994	151,521
Accounts receivable, net of allowance for doubtful accounts of $72 and $10 at September 30, 2015 and December 31, 2014, respectively	10,525	6,610
Inventories, net	42,651	14,856
Prepaid expenses and other current assets	3,463	2,851
Total current assets	279,191	201,125
Property and equipment, net	5,686	647
Other assets	1,901	424
Restricted cash	906	300
Total assets	$ 287,684	$ 202,496
Liabilities and stockholders equity		
Current liabilities		
Accounts payable	$ 12,912	$ 4,460
Accrued liabilities	10,492	6,268
Other current liabilities	92	70
Total current liabilities	23,496	10,798
Notes payable	19,689	19,511
Other long-term liabilities	158	117
Total liabilities	43,343	30,426
Commitments and contingencies (Note 5)		
Stockholders equity		

Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2015 and December 31, 2014; zero shares issued and outstanding at September 30, 2015 and December 31, 2014		
Common stock, $0.001 par value, 290,000,000 shares authorized at September 30, 2015 and December 31, 2014; 27,933,992 and 24,865,491 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	28	25
Additional paid-in capital	419,649	293,945
Accumulated other comprehensive income (loss)	(119)	77
Accumulated deficit	(175,217)	(121,977)
Total stockholders equity	244,341	172,070
Total liabilities and stockholders equity	$ 287,684	$ 202,496

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

Table of Contents

Nevro Corp.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ 15,402	$ 8,668	$ 36,482	$ 22,858
Cost of revenue	5,968	2,737	15,349	8,257
Gross profit	9,434	5,931	21,133	14,601
Operating expenses				
Research and development	5,247	5,236	15,508	15,082
Sales, general and administrative	21,896	7,193	54,848	20,719
Total operating expenses	27,143	12,429	70,356	35,801
Loss from operations	(17,709)	(6,498)	(49,223)	(21,200)
Interest income	185	20	399	93
Interest expense	(739)		(2,093)	
Other expense, net	(922)	(1,270)	(1,757)	(888)
Loss before income taxes	(19,185)	(7,748)	(52,674)	(21,995)
Provision for income taxes	269	137	566	374
Net loss	(19,454)	(7,885)	(53,240)	(22,369)
Accretion of redeemable convertible preferred stock to redemption value		(44)		(131)
Net loss attributable to common stockholders	(19,454)	(7,929)	(53,240)	(22,500)
Other comprehensive loss:				
Changes in foreign currency translation adjustment	(188)	(36)	(191)	(40)
Changes in losses on short-term investments, net	(89)	(2)	(4)	(9)
Net change in other comprehensive loss	(277)	(38)	(195)	(49)
Comprehensive Loss	$ (19,731)	$ (7,967)	$ (53,435)	$ (22,549)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (5.96)	$ (2.04)	$ (19.04)

Weighted average number of common shares used to compute basic and diluted net loss per share	27,861,523	1,329,610	26,102,679	1,181,511

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

Table of Contents

Nevro Corp.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities		
Net loss	$ (53,240)	$ (22,369)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	287	65
Stock-based compensation expense	5,083	1,234
Amortization (accretion) of premium (discount) on short-term investments	(324)	263
Provision for doubtful accounts	58	
Write-down of inventory	2,071	457
Non-cash interest expense	179	
Changes in operating assets and liabilities		
Accounts receivable	(4,338)	929
Inventories	(29,542)	(2,458)
Prepaid expenses and other current assets	(646)	775
Other assets	(1,483)	(1,825)
Accounts payable	7,994	319
Accrued liabilities	3,851	605
Other long-term liabilities	41	5
Net cash used in operating activities	(70,009)	(22,000)
Cash flows from investing activities		
Purchases of short-term investments	(127,924)	(20,767)
Proceeds from maturity of short-term investments	144,772	45,361
Restricted cash	(606)	
Purchases of property and equipment	(4,310)	(236)
Net cash provided by investing activities	11,932	24,358
Cash flows from financing activities		
Proceeds from issuance of common stock in underwritten public offering	118,440	
Proceeds from issuance of common stock from stock option exercises	2,145	955
Payment of deferred offering costs		(1,246)
Net cash provided by (used in) financing activities	120,585	(291)

Effect of exchange rate on cash and cash equivalents	(237)	
Net increase in cash and cash equivalents	62,271	2,067
Cash and cash equivalents		
Cash and cash equivalents at beginning of period	25,287	12,409
Cash and cash equivalents at end of period	$ 87,558	$ 14,476
Significant non-cash transactions		
Unpaid deferred offering costs	$	$ 532
Property and equipment in accounts payable	$ 1,016	$
Vesting of early-exercised stock options	$ 39	$ 128

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

Table of Contents

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 nine months ended September 30, 2015, the Company incurred a net loss of $53.2 million and used $70.0 million of cash in operations. At September 30, 2015 and December 31, 2014, the Company had an accumulated deficit of $175.2 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 its initial public offering (IPO) completed in November 2014 and underwritten public offering completed in June 2015 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 revenue 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 September 30, 2015 and for the nine months ended September 30, 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 (consisting of normal recurring adjustments) necessary to state fairly the Company s financial position as of September 30, 2015, and the results of its operations and cash flows for the nine months ended September 30, 2015 and 2014. All such adjustments are of a normal and recurring nature. The interim financial data as of September 30, 2015 is 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

Table of Contents

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.

Historically, the Company derived substantially all of its revenue from sales to customers in Australia and Europe, and, commencing in the second quarter of 2015, has 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
United States	29%		12%	
Australia	24%	35%	27%	34%
United Kingdom	15%	19%	17%	18%
Germany	14%	17%	17%	17%

Long-lived assets located 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. 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 condensed consolidated statements of operations. The Company recorded net unrealized and net realized foreign currency transaction gain (loss) during the periods presented as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net unrealized foreign currency gain (loss)	$ 293	$ (1,291)	$ 958	$ (473)
Net realized foreign currency gain (loss)	(1,170)	32	(2,576)	(363)

As the Company s international operations grow, its risks associated with fluctuations in currency rates will become greater, and the Company will continue to reassess its approach to managing this risk. In addition, currency fluctuations or a weakening 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

Table of Contents

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 September 30, 2015 and December 31, 2014. The Company also held cash in foreign banks of approximately $3.4 million at September 30, 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.

Historically, substantially 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 direct sales forces and distributors to sell its products. Recently, the Company began deriving revenue from customers in the United States, accounting for approximately $4.5 million of its $15.4 million of revenue for the three months ended September 30, 2015. 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 months and nine months ended September 30, 2015 and 2014, no single customer accounted for more than 10% of the Company s revenue. As of September 30, 2015 and December 31, 2014, no single customer accounted for 10% of the 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 will continue to be accepted in its existing marketplaces, nor can there be any assurance that any future products or services can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products or services will be successfully marketed, if at all.

The Company expects to incur substantial operating losses for the next several years and may 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 $22.4 million and $10.6 million as of September 30, 2015 and December 31, 2014, respectively. At September 30, 2015 and December 31, 2014, the Company s cash equivalents were held at institutions in the United States and include deposits in a money market fund which was unrestricted as to withdrawal or use.

Table of Contents

Restricted Cash

Restricted cash as of September 30, 2015 consists of a certificate of deposit of $0.3 million collateralizing payment of charges related to the Company s credit cards and a letter of credit of $0.6 million representing collateral for the Company s Redwood City building lease pursuant to an agreement dated as of March 5, 2015. Restricted cash as of December 31, 2014 represents a certificate of deposit of $0.3 million collateralizing payment of charges related to the Company s corporate credit cards.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities 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 accumulated 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 writes down inventory that is no longer saleable, has a cost basis in excess of its expected net realizable value or is 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 with the same lower of cost or market approach used to value inventory. The Company also periodically evaluates inventory quantities in consideration of actual loss experience. In addition, the Company determines at times that there may be certain inventory that does not meet its product requirements. For the three and nine months ended September 30, 2015, an analysis of inventory resulted in a write down of inventory of $0.3 million and $1.6 million, respectively, for inventory that did not meet its product requirements, as compared to none for the three and nine months ended September 30, 2014. As a result of these inventory evaluations, as well as inventory shrinkage, the Company recognized a total write down for Senza inventories of $0.5 million and $0.2 million for the three months ended September 30, 2015 and 2014, respectively, and $2.1 million and $0.5 million for the nine months ended September 30, 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 of inventory values in any particular period.

Shipping and Handling Costs

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

Table of Contents

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- to five-year warranty to most customers in the markets in which it operates. 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 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 September 30, 2015.

Income Taxes

During the three and nine months ended September 30, 2015 and 2014, the Company calculated its interim tax provision to record taxes incurred on a discrete basis due to the variability of taxable income in the jurisdictions in which it operates. 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 provision for income taxes for the three and nine months ended September 30, 2015 and 2014, is primarily comprised of foreign taxes based upon income earned during the period with no tax benefit recorded for the loss jurisdictions.

Table of Contents

The Company operates in various tax jurisdictions and is subject to audit by various tax authorities. To date, taxes paid by the Company 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 changes in 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.

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.

Table of Contents

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 July 2015, the Financial Accounting Standards Board (FASB) issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, which permits companies to measure inventory at the lower of cost and realizable value. ASU 2015-11 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, 2016. Early adoption is permitted. The Company is in the process of evaluating whether the adoption of ASU 2015-11 will have a material effect on its consolidated financial statements.

In April 2015, the 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 August 2015, the FASB issued ASU No. 2015-15, *Interest Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated With Line-of-Credit Arrangements Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting*, which clarified that the SEC would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement. 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

Table of Contents

from costs incurred to obtain or fulfill a contract. In August 2015, FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which effectively delayed the adoption date by one year, to an effective date for public entities for annual and interim periods beginning after December 15, 2017. 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 and commercial paper that is classified as Level 2 in 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 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):

Table of Contents

Balance as of September 30, 2015	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (i)	$ 22,359	$	$	$ 22,359
Commercial paper (ii)		192,993		192,993
Total assets	$ 22,359	$ 192,993	$	$ 215,352

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

(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 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):

	September 30, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investment Securities				
Commercial paper (i)	$ 192,791	$ 202	$	$ 192,993

(i) Includes $58.0 million of commercial paper that is classified as cash and cash equivalents on the consolidated balance sheet.

	December 31, 2014			
	Amortized Cost	Gross Unrealized Holding	Gross Unrealized Holding	Aggregate Fair Value

		Gains	Losses	
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 (expense), net as incurred. The cost of securities sold is determined based on the specific identification method. The Company has not recorded any realized gains or losses on its investments during the periods presented.

The contractual maturities of the Company s investment securities were all within one year as of September 30, 2015 and December 31, 2014.

Table of Contents

Inventories (in thousands)

	September 30, 2015	December 31, 2014
Raw materials	$ 16,151	$ 7,960
Finished goods	26,500	6,896
Total inventories	$ 42,651	$ 14,856

Property and Equipment, Net (in thousands)

	September 30, 2015	December 31, 2014
Laboratory equipment	$ 735	$ 390
Computer equipment and software	1,218	125
Furniture and fixtures	1,827	112
Leasehold improvements	1,094	22
Construction in process	1,188	333
Total	6,062	982
Less: Accumulated depreciation and amortization	(376)	(335)
Property and equipment, net	$ 5,686	$ 647

The Company recognized depreciation and amortization expense on property and equipment as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Depreciation and amortization expense	$ 157	$ 26	$ 287	$ 65

Accrued Liabilities (in thousands)

	September 30, 2015	December 31, 2014
Accrued payroll and related expenses	$ 6,846	$ 4,268
Accrued professional fees	374	184
Accrued taxes	1,891	998
Accrued clinical and research expenses	342	613
Accrued other	1,039	205
Total accrued liabilities	$ 10,492	$ 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, California as amended in 2012 to extend the period of the lease until May 31, 2015. In March 2015, the Company again extended the lease through September 30, 2015, at which time the lease terminated. 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.

Table of Contents

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 on June 30, 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.

The Company recognized rent expense during the periods indicated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Rent expense	$ 851	$ 173	$ 1,260	$ 455

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 September 30, 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.

Table of Contents

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.

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.

The Company recognized royalty expense during the periods indicated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Royalty expense	$ 153	$ 87	$ 363	$ 229

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. Under the original agreement, the Company was eligible to enter into a second term loan for a principal amount of $10.0 million on or prior to March 31, 2015 and a third term loan for a principal amount of $20.0 million on or prior to September 30, 2015, in each case, 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. In June 2015, the Company entered into a Second

Amendment to extend the draw-down deadline of the second draw from June 29, 2015 to September 30, 2015. Upon the satisfaction of certain conditions precedent on or prior to September 30, 2016, the interest only period on the first draw 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. As of September 30, 2015, the Company did not elect to enter into the second or third draw, and the option to do so expired as of September 30, 2015.

Table of Contents

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 September 30, 2015, the Company was in compliance with all applicable covenants.

As of September 30, 2015, future minimum payments for the notes are as follows (in thousands):

	Term Loans
2015	$ 588
2016	2,338
2017	3,739
2018	7,977
2019 and beyond	14,960
Total minimum payments	29,602
Less: Amount representing interest	(8,602)
Less: Amount representing closing and repayment fees	(1,000)
Present value of minimum payments	20,000
Less: Unamortized debt discount	(431)
Plus: Accretion of closing and repayment fees	120
Notes payable, net	19,689
Less: Notes payable, current portion	
Non-current portion of notes payable	$ 19,689

7. Convertible Preferred Stock

Prior to the IPO, the Company had 15,208,048 shares of convertible preferred stock outstanding. 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 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 classified 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 $44,000 and $131,000 during the three months and nine months ended September 30, 2014,

respectively.

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):

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (19,454)	$ (7,885)	$ (53,240)	$ (22,369)
Accretion of redeemable convertible preferred stock to redemption value		(44)		(131)
Net loss attributable to common stockholders	$ (19,454)	$ (7,929)	$ (53,240)	$ (22,500)
Weighted average shares outstanding	27,881,302	1,372,211	26,126,145	1,232,439
Less: weighted average shares subject to repurchase	(19,779)	(42,601)	(23,466)	(50,928)
Weighted average shares used to compute basic and diluted net loss per share	27,861,523	1,329,610	26,102,679	1,181,511
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (5.96)	$ (2.04)	$ (19.04)

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:

	September 30,	
	2015	2014
Convertible preferred stock		15,208,048
Options to purchase common stock	2,907,426	2,561,827
Total	2,907,426	17,769,875

9. Employee Benefit Plans

401(k) 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.

Employee Stock Purchase Plan

Concurrent with the effectiveness of the Company s registration statement on Form S-1 in November 2014, the Company s 2014 Employee Stock Purchase Plan (ESPP) became effective. The ESPP allows eligible employees to purchase shares of the Company s Class A common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP generally provides for six-month offering periods, and at the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company s Class A common stock on the first trading day of the offering period or on the last trading day of the offering period.

There were no sales under the ESPP during the three and nine months ended September 30, 2015 and 2014. Shares available for future purchase under the ESPP were 0.4 million at September 30, 2015.

Table of Contents

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 began U.S. commercialization of the Senza system in May 2015. In order to maintain our PMA approval in the United States, 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 met its primary and secondary non-inferiority endpoints. The analysis also demonstrated the superiority of HF10 therapy over traditional SCS therapies for treating both back and leg 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 September 30, 2015 was $175.2 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 continue to make a significant investment building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives as we ramp up our commercial launch in the United States. We also intend to continue to make significant investments in research and development (R&D) to develop Senza to treat other chronic pain indications,

Table of Contents

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 may 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 continue 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.

On November 5, 2014, our registration statement on Form S-1 relating to the initial public offering (IPO) of common stock became effective. The IPO closed in November 2014 at which time we issued 8,050,000 shares of our common stock, which included 1,050,000 shares issued pursuant to the exercise in full by the underwriters of their option to purchase additional shares. We received cash proceeds of approximately $131.6 million from the IPO, net of underwriting discounts and commissions and offering costs paid by us. In June 2015, we completed an underwritten public offering of our common stock, which included shares of our common stock held by certain of our stockholders, at which time we issued 2,470,587 shares of common stock, including 705,882 shares issued pursuant to the exercise in full by the underwriters of their option to purchase additional shares. We received cash proceeds of approximately $118.4 million, net of underwriting discounts and commissions and offering costs paid by us.

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.

Significant Investment in U.S. Sales Organization

We are continuing 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.

Table of Contents

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.

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 continue with our commercial launch of Senza in the United States, 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. There may also be times in which we determine that our inventory does not meet our product requirements, as was the case in the nine months ended September 30, 2015, wherein we recorded a write down of inventory of $1.6 million for inventory that did not meets our product requirements. 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 statements. There have been no significant or material changes in our critical accounting policies during the three months ended September 30, 2015.

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.

Table of Contents

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 in which we sell our products.

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. In addition, in the second quarter of 2015, we commenced commercial sales of Senza in the United States and have recorded revenue of approximately $4.5 million for the nine months ended September 30, 2015 for sales in the United States. We anticipate that our total revenue will increase as we continue our commercial launch in the United States.

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. While costs are primarily incurred in U.S. dollars, international revenue may be impacted by the appreciation or depreciation of the U.S. dollar, which may impact our overall gross margin. We expect our gross margin to be positively affected over time to the extent we are successful in reducing manufacturing costs as our sales volume increases. However, our gross margin may fluctuate from period to period.

Operating Expenses

Our operating expenses consist of R&D, 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 expense to increase in absolute dollars as we continue to develop product enhancements to Senza and develop our HF10 therapy to treat other chronic pain indications, including conducting additional clinical studies. Our R&D expenses may fluctuate from period to period due to the timing and extent of our R&D and clinical trial expenses.

Sales, General and Administrative. SG&A expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation expenses for our sales and marketing personnel, including sales commissions, and for administrative personnel that support our general operations, such as information technology, executive

management, financial accounting, customer 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.

Table of Contents

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 expense to continue to significantly increase as we build up our sales and marketing personnel as we launch Senza in the United States, continue to increase the size of our sales and marketing organizations, increase our international presence and develop and assist our channel partners.

For the nine months ended September 30, 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, including compliance under the Sarbanes-Oxley Act of 2002 as a large accelerated filer, director and officer insurance premiums and investor relations costs associated with being a public company. Our SG&A expense may fluctuate from period to period due to the seasonality of our revenue and the timing and extent of our SG&A expense.

Interest Income and Interest Expense

Interest Income consists primarily of interest income earned on our investments and Interest Expense consists of interest paid on our outstanding debt.

Other Income (Expense), Net

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

Provision for Income Taxes

The provision for income taxes is calculated on a discrete basis due to the variability of taxable income in the jurisdictions in which we operate. The provision for income taxes consists primarily of income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for our 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 September 30, 2015 and 2014

Revenue, Cost of Revenue, Gross Profit and Gross Margin

(in thousands)	Three months ended September 30,		
	2015	2014	Change
Revenue	$ 15,402	$ 8,668	$ 6,734
Cost of revenue	5,968	2,737	3,231
Gross profit	$ 9,434	$ 5,931	$ 3,503

Gross margin	61%	68%	(7)%

Revenue. Revenue increased to $15.4 million in the three months ended September 30, 2015 from $8.7 million in the three months ended September 30, 2014, an increase of $6.7 million, or 78%. The net revenue increase was primarily due to sales of the Senza system in the United States, which began in May 2015, of approximately $4.5 million and continued adoption of the Senza system in international markets where it has historically been sold.

Table of Contents

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased to $6.0 million in the three months ended September 30, 2015 from $2.7 million in the three months ended September 30, 2014, an increase of $3.2 million, or 118%. This was primarily due to a $2.5 million increase in the acquisition costs of manufactured product components as sales volumes increased in the most recent period, as well as a $0.3 million increase in inventory-related charges. Gross profit increased to $9.4 million in the three months ended September 30, 2015 from $5.9 million in the three months ended September 30, 2014, an increase of $3.5 million, or 59%. Gross profit as a percentage of revenue, or gross margin, decreased to 61% in the three months ended September 30, 2015 compared to 68% in the three months ended September 30, 2014. Gross margins decreased year-over-over partly as a result of costs incurred in association with ramping our operational infrastructure in response to the U.S. product launch. Additionally, while costs were primarily incurred in U.S. dollars, international revenue was negatively impacted by the appreciation of the U.S. dollar, which negatively impacted the overall gross margin for the period.

Operating Expenses

	Three Months Ended September 30,				
	2015		2014		
(in thousands)	Amount	% of Total Revenue	Amount	% of Total Revenue	Change Amount
Operating expenses:					
Research and development	$ 5,247	34%	$ 5,236	60%	$ 11
Sales, general and administrative	21,896	142%	7,193	83%	14,703
Total operating expenses	$ 27,143	176%	$ 12,429	143%	$ 14,714

Research and Development Expense. R&D expense increased by approximately $11,000 in the three months ended September 30, 2015, thus remaining at approximately $5.2 million in the three months ended September 30, 2015 and 2014. The R&D expense reflects an increase in headcount and related personnel and consulting costs of $0.6 million, offset by a decrease in clinical and development expenses of $0.5 million.

Sales, General and Administrative Expense. SG&A expense increased to $21.9 million in the three months ended September 30, 2015 from $7.2 million in the three months ended September 20, 2014, an increase of $14.7 million, or 204%. This increase was primarily due to an increase in personnel costs of $10.2 million in relation to an increase in headcount for SG&A personnel in support of our U.S. commercial launch, increased travel, training, marketing and associated supplies costs of $1.8 million, increased legal and other professional services costs associated with being a public company of $1.3 million and additional facilities costs of $0.7 million.

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

	Three months ended September 30,		
(in thousands)	2015	2014	Change
Interest income	$ 185	$ 20	$ 165

Interest expense	(739)		(739)
Other income (expense), net	(922)	(1,270)	348
Provision for income taxes	(269)	(137)	(132)

Interest Income. Interest income increased to $185,000 in the three months ended September 30, 2015 from $20,000 in the three months ended September 30, 2014, primarily as a result of the increase in average investment balances.

Interest Expense. Interest expense increased to $0.7 million in the three months ended September 30, 2015 from zero in the three months ended September 30, 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.

Table of Contents

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. In the three months ended September 30, 2015, we recorded a loss of $0.9 million, compared to the corresponding period in the prior year when we recorded a loss of $1.3 million.

Provision for Income Taxes. Income tax expense was $0.3 million and $0.1 million in the three months ended September 30, 2015 and 2014, respectively, and was primarily 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.

Comparison of the nine months ended September 30, 2015 and 2014

Revenue, Cost of Revenue, Gross Profit and Gross Margin

(in thousands)	Nine months ended September 30, 2015	2014	Change
Revenue	$ 36,482	$ 22,858	$ 13,624
Cost of revenue	15,349	8,257	7,092
Gross profit	$ 21,133	$ 14,601	$ 6,532
Gross margin	58%	64%	(6)%

Revenue. Revenue increased to $36.5 million in the nine months ended September 30, 2015 from $22.9 million in the nine months ended September 30, 2014, an increase of $13.6 million, or 60%. This increase was primarily due to sales of the Senza system in the United States, which began in May 2015 of approximately $4.5 million, and continued adoption of the Senza system in international markets where it has historically been sold.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased to $15.3 million in the nine months ended September 30, 2015 from $8.3 million in the nine months ended September 30, 2014, an increase of $7.1 million, or 86%. This was primarily due to a $5.0 million increase in the acquisition costs of manufactured product components as sales volumes increased in the most recent period, as well as a $1.6 million increase in inventory-related charges. Gross profit increased to $21.1 million in the nine months ended September 30, 2015 from $14.6 million in the nine months ended September 30, 2014, an increase of $6.5 million, or 45%. Gross profit as a percentage of revenue, or gross margin, decreased to 58% in the nine months ended September 30, 2015 compared to 64% in the nine months ended September 30, 2014. Gross margins decreased year-over-over partly as a result of costs incurred in association with ramping our operational infrastructure in response to the U.S. product launch, as well as the $1.6 million increase in inventory-related charges in the nine-month period ended September 30, 2015. Additionally, while costs were primarily incurred in U.S. dollars, international revenue was negatively impacted by the appreciation of the U.S. dollar, which negatively impacted the overall gross margin for the period.

Operating Expenses

Nine Months Ended September 30,

(in thousands)	2015 Amount	2015 % of Total Revenue	2014 Amount	2014 % of Total Revenue	Change Amount
Operating expenses:					
Research and development	$ 15,508	43%	$ 15,082	66%	$ 426
Sales, general and administrative	54,848	150%	20,719	91%	34,129
Total operating expenses	$ 70,356	193%	$ 35,801	157%	$ 34,555

Table of Contents

Research and Development Expense. R&D expense increased to $15.5 million in the nine months ended September 30, 2015 from $15.1 million in the nine months ended September 30, 2014, an increase of $0.4 million, or 3%. The increase was primarily due to an increase in headcount and related personnel and consulting costs of $1.4 million, offset by a decrease in clinical and development expenses of $0.9 million associated with our preclinical and regulatory costs in preparation for our June 2014 PMA submission, as well as a decrease in facilities-related costs of $0.2 million.

Sales, General and Administrative Expense. SG&A expense increased to $54.8 million in the nine months ended September 30, 2015 from $20.7 million in the nine months ended September 30, 2014, an increase of $34.1 million, or 165%. This increase was primarily due to an increase in personnel costs of $22.4 million in relation to an increase in headcount for SG&A personnel in support of our U.S. commercial launch, increased travel, training, marketing and associated supplies costs of $6.6 million, increased legal and other professional services costs associated with being a public company of $2.6 million and additional facilities-related costs of $1.7 million.

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

	Nine months ended September 30,		
	2015	2014	Change
(in thousands)			
Interest income	$ 399	$ 93	$ 306
Interest expense	(2,093)		(2,093)
Other income (expense), net	(1,757)	(888)	(869)
Provision for income taxes	(566)	(374)	(192)

Interest Income. Interest income increased to $0.4 million in the nine months ended September 30, 2015 from $93,000 in the nine months ended September 30, 2014, primarily as a result of the increase in average investment balances.

Interest Expense. Interest expense increased to $2.1 million in the nine months ended September 30, 2015 from zero in the nine months ended September 30, 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. Related to these two items, in the nine months ended September 30, 2015 we recorded a loss of $1.8 million, compared to the corresponding period in prior year in which we recorded a loss of $0.9 million.

Provision for Income Taxes. Income tax expense was $0.6 million and $0.4 million in the nine months ended September 30, 2015 and 2014, respectively, and was associated primarily with foreign income 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 September 30, 2015, we have financed our operations through private placements of preferred stock, the issuance of common stock in the initial public offering (IPO) in November 2014 and our underwritten public offering in June 2015, and a borrowing under our credit facility. At September 30, 2015, we had

cash and cash equivalents and investments of $222.6 million. Based on our current operating plan, we expect that our cash on hand, together with the anticipated funds from our operations, will be sufficient to fund our operations through at least the next twelve months.

As of September 30, 2015, we did not elect to enter into the second or third draw of $10.0 million and $20.0 million, respectively, under our credit facility with Capital Royalty Partners and the option to do so expired as of such date. We currently have outstanding a term loan with a principal balance of $20.0 million under the facility.

Table of Contents

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 continuing 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 may 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 may 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 force in connection with commercialization of Senza in the United States;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- the degree and rate of market acceptance of Senza in the United States and elsewhere;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the amount and timing of any draws we make under our credit facility;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

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

If we are unable to raise 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:

	Nine months ended September 30,	
	2015	**2014**
(in thousands)		
Net cash provided by (used in)		
Operating activities	$ (70,009)	$ (22,000)
Investing activities	11,932	24,358
Financing activities	120,585	(291)
Effect of exchange rate on cash flows	(237)	
Net increase in cash and cash equivalents	$ 62,271	$ 2,067

Table of Contents

Cash Used in Operating Activities. Net cash used in operating activities was $70.0 million in the nine months ended September 30, 2015, compared to $22.0 million in the nine months ended September 30, 2014, primarily as a result of the net losses recorded in the periods of $53.2 million and $22.4 million, respectively. In the nine months ended September 30, 2015, net cash used in operations was also affected by changes in our operating assets and liabilities, including increases in our inventories of $29.5 million as we build inventories as part of our U.S. commercial launch, accounts receivable of $4.3 million and long-term assets of $1.5 million. These increases were partially offset by an increase of $11.8 million in accounts payable and accrued liabilities due primarily to increases in headcount-related liabilities as well as amounts owed in association with our increase in inventories, as well as the recording of non-cash stock based compensation expense of $5.1 million and inventory write-downs of $2.1 million. In the nine months ended September 30, 2014, the net cash used in operations was affected by changes in our operating assets and liabilities, including an increase in our inventories of $2.5 million and other assets of $1.8 million, offset by a decrease in accounts receivable of $0.9 million and prepaid and other current assets of $0.8 million, as well as an increase in accounts payable and accrued liabilities of $0.9 million and the recording of non-cash stock based compensation expense of $1.2 million.

Cash Provided by Investing Activities. Investing activities consisted primarily of changes in investment balances, including purchases and maturities of short-term investments. We had net proceeds from the maturity of investments of $16.8 million in the nine months ended September 30, 2015, compared to $24.6 million for the corresponding period in prior year. We additionally purchased $4.3 million and $0.2 million of property and equipment in the nine months ended September 30, 2015 and 2014, respectively.

Cash Provided by Financing Activities. Cash provided by financing activities was $120.6 million in the nine months ended September 30, 2015, primarily due to the cash received from the issuance of common stock in our underwritten public offering in June 2015 totaling $118.4 million and cash received from the exercise of common stock options of $2.1 million. Cash used in financing activities was $0.3 million in the nine months ended September 30, 2014, primarily due to payment of deferred offering costs of $1.2 million as the Company prepared for its initial public offering, offset by cash received from the exercise of common stock options of $1.0 million.

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, and extended the lease for office space in Menlo Park, California through September 2015, at which time that lease expired. 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 one of the agreements.

Off-Balance Sheet Arrangements

Through September 30, 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.

29

Table of Contents

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 September 30, 2015, we had cash and cash equivalents of $87.6 million, consisting of cash, money market funds and commercial paper, and short-term investments of $135.0 million, consisting of commercial paper. We maintained investments in money market funds that were not federally insured in the nine months ended September 30, 2015 and held cash in foreign banks of approximately $3.4 million at September 30, 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, substantially 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. As a component of other income (expense), we recognized net foreign currency transaction losses of $1.6 million and $0.8 million in the nine months ended September 30, 2015 and 2014, respectively. A hypothetical 10% favorable or unfavorable change in the weighted average foreign exchange rates for the nine months period ended September 30, 2015 would have affected the annualized consolidated foreign-currency-denominated operating loss by approximately 3% 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.

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 September 30, 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.

Table of Contents

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

On May 14, 2015, Boston Scientific Neuromodulation Corporation, a unit of Boston Scientific Corporation, filed with the U.S. Patent and Trademark Office two petitions for inter partes review (IPR) alleging that certain claims of U.S. Patent No. 8,359,102 (the 102 patent) are invalid due to prior art references. Through the IPR petitions, Boston Scientific seeks to invalidate the challenged claims. The 102 patent is one of Nevro s 55 issued U.S. patents directed to Nevro s innovations in the neuromodulation field.

The same unit of Boston Scientific Corporation has filed four European Oppositions at the European Patent Office, alleging all the claims of Nevro s EU Patent Nos. EP 2403589 (the 589 patent), EP 2421600 (the 600 patent), EP 2243510 (the 510 patent), and EP 2630984 (the 984 patent) are invalid. These oppositions were filed on November 4, 2014; December 4, 2014; January 8, 2015; and April 7, 2015, respectively, and seek to invalidate all the claims of the listed patents. The 589 patent, the 600 patent, the 510 patent and the 984 patent are four of Nevro s nine EU patents directed to Nevro s innovations in the neuromodulation field. In addition, Medtronic plc filed three European Oppositions at the European Patent Office, alleging all the claims of the 589 patent, the 510 patent, and the 984 patent are invalid. The Medtronic plc oppositions were filed on October 13, 2014; January 8, 2015; and March 17, 2015, respectively, and seek to invalidate all the claims of the listed patents.

Nevro intends to vigorously defend its intellectual property in these matters.

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 materialize, 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. We expect to continue to incur losses as we build our U.S. commercial sales force and ramp up 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 $53.2 million and $30.7 million for the nine months ended September 30, 2015 and the year ended December 31, 2014, respectively, and as of September 30, 2015 our accumulated deficit was $175.2 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 equity and working capital. If our revenue grows more slowly than we anticipate, or if our operating expenses are higher than we expect, we may not be able to achieve profitability and our financial condition could suffer. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

31

Table of Contents

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 September 30, 2015, our total revenue of $118.4 million was derived nearly entirely from sales of Senza in Europe and Australia, although we have recorded revenue in the United States of $4.5 million for the nine months ended September 30, 2015. We have incurred and will in the future incur significant costs, including costs to build our sales force, in order to continue our 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.

- 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

Table of Contents

certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the U.S. Patent and Trademark Office (USPTO), to determine priority of invention in the United States. There may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.

Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors products and services, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, including interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions oppositions, nullity actions, or other patent proceedings. For example, two of our competitors, Boston Scientific Neuromodulation Corporation and Medtronic plc, have filed oppositions in the European Union with respect to certain of our patents. In addition, on May 14, 2015, Boston Scientific Neuromodulation Corporation filed with the USPTO two petitions for inter partes review challenging the validity of our U.S. Patent No. 8,359,102. We may also need to initiate infringement claims or litigation. Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

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

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

Table of Contents

For additional information regarding risks related to our intellectual property, see Risks Related to Intellectual Property.

We must demonstrate to physicians the merits of our HF10 therapy compared to those of our competitors.

Physicians play a significant role in determining the course of a patient s treatment and 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 successfully commercialize Senza in the United States, we must build a substantial direct sales force. As we continue our commercial launch and increase our marketing efforts, we will need to retain, develop and grow the number of direct sales personnel that we employ. We intend to continue to make a significant investment in recruiting and training sales representatives and clinical representatives as we ramp up our commercial 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 continue our commercial launch in the United States our competitors will take aggressive action to protect their current market position. For example, in May 2015, a unit of Boston Scientific Neromodulation Corporation, one

of our principal competitors, filed with the USPTO two petitions for inter partes review challenging the validity of our U.S. Patent No. 8,359,102. 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

Table of Contents

many successful implants using the neuromodulation products made by these competitors may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try and subsequently adopt our product, then our revenue growth will slow or decline.

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

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

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

- we may not be able to maintain to the FDA s satisfaction that our product is safe and effective for its intended use;
- we may fail to comply with the guidelines required by FDA and other agencies to maintain our PMA approval; and
- the manufacturing processes and facilities we and our vendors 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 FDA approval could result in unexpected and significant costs for us and consume management s time and other resources. The FDA could ask us to improve or augment manufacturing processes, collect and provide data on the quality or safety of our product, or issue us a warning letter relating to matters that may result in removal of our product from the market. Additionally, we will be required to obtain FDA approval prior to making any modification to the device, and the FDA may revoke the approval or impose other restrictions if post-market data demonstrates safety issues or lack of effectiveness. If we are unable to obtain and maintain the necessary regulatory approvals, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited.

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

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

An important part of our sales process includes the education of physicians on the safe and effective use of our HF10 therapy and Senza, particularly because Senza and high frequency neuromodulation treatment is relatively new as compared to existing low frequency traditional SCS systems. In addition, we will need to spend substantial time educating physicians using traditional SCS systems on the value of our HF10 therapy as demonstrated by our pivotal U.S. clinical data. Physicians typically need to perform several procedures to become comfortable using HF10 therapy and Senza. If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to continue to use our product or to recommend it to other physicians. It is critical to the success of our commercialization efforts that we educate physicians on the proper use of Senza, and 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.

Table of Contents

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 plc, 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 to provide relief for chronic pain 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.

Table of Contents

We only recently began commercializing Senza in the EEA and Australia, and only recently initiated commercial sales 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 as such, we have just recently launched sales in the United States. As a result, we have a limited history of commercializing our product generally and limited 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 only recently commercially launched a product in the United States and commenced a sales representative training. 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;
- 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.

Table of Contents

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.

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 have represented substantially 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 September 30, 2015, we sell Senza directly in Austria, Switzerland, United Kingdom, Sweden, Australia, Belgium, Luxembourg, Norway 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;

Table of Contents

pricing pressure that we may experience internationally;

foreign currency exchange rate fluctuations;

a shortage of high-quality sales people and distributors;

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

relative disadvantages compared to competitors with established business and customer relationships;

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

economic instability;

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

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

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

laws and business practices favoring local companies;

longer payment cycles;

difficulties in maintaining consistency with our internal guidelines;

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

the imposition of costly and lengthy new export licensing requirements;

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

- the imposition of new trade restrictions.

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

We are dependent upon third-party manufacturers and suppliers, in some cases sole- or single-source suppliers, making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business.

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

Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;

- we may not be able to obtain adequate supplies from one or more vendors in a timely manner or on commercially reasonable terms;

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

Table of Contents

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

- we may have difficulty locating and qualifying alternative suppliers;

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

- one or more of our sole- or single-source suppliers may be unwilling or unable to supply components of Senza, or may supply products that do not meet our product requirements;

- other customers may use fair or unfair negotiation tactics and/or pressures to impede our use of the supplier;

- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and

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

We may not be able to quickly establish additional or alternative suppliers for commercialization in the United States if necessary, in part because we may need to undertake additional activities to qualify such suppliers as required by the regulatory approval process. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain single-source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available.

We rely upon third-party, single-source, and in certain cases sole-source, suppliers for many of the components and materials used in Senza, and for critical manufacturing and packaging services, and the loss of any of these suppliers could harm our business.

A number of the critical components used in Senza are supplied to us from single-source, or in certain cases sole-source, suppliers, including 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

Table of Contents

replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality and on a timely basis, the continued commercialization of Senza would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

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

We believe that establishing and strengthening the Nevro and Senza brands is critical to achieving widespread acceptance of HF10 therapy, particularly because of the highly competitive nature of the market for SCS products. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product for successful treatment of chronic leg and back pain. Given the established nature of our competitors, and our lack of full 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 will, among other things, need to reduce the per-unit manufacturing cost of Senza. This cannot be achieved without increasing the volume of components that we purchase in order to take advantage of volume-based pricing discounts, 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.

Table of Contents

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

To achieve our revenue goals, we must successfully increase manufacturing output to meet expected customer demand. In the future, we may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate 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, the hospital facilities where these physicians treat patients typically require us to enter into purchasing contracts. The process of securing a satisfactory contract can be lengthy and time-consuming and require extensive negotiations and management time. In the 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

Table of Contents

contracts or tender successful bids, our sales may stagnate or decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

We rely in part on a small group of third-party distributors to effectively distribute our products outside the United States.

We depend in part on medical device distributors for marketing and sales of our products in certain territories in Europe. We depend on these distributors efforts to market our products, yet we are unable to control their efforts completely. These distributors typically sell a variety of other, non-competing products that may limit the resources they dedicate to selling Senza. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell Senza, in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offering requires significant time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed.

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

Manufacturing and marketing 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 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 can take many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards (IRBs), Ethics Committees, EU Competent Authorities or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;

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

patients or investigators do not comply with study protocols;

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

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

Table of Contents

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

difficulties or delays associated with establishing additional clinical sites;

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

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

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

changes in federal, state, or foreign governmental statutes, regulations or policies;

interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;

the study design is inadequate to demonstrate safety and efficacy; or

the statistical endpoints are not met.

Clinical failure can occur at any stage of the testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or non-clinical studies in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of any of our devices would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that device or indication for use.

We could also encounter delays if the FDA concludes that our financial relationships with investigators results in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the FDA refusing to accept the data as support for our future applications. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

Even if our products are approved in the United States, Australia and the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries.

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, Australia or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

Table of Contents

In addition, many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate.

Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and employees in the neuromodulation and medical device industry are subject to strict non-compete or confidentiality agreements with their employers, including our main competitors Medtronic plc, Boston Scientific Corp. and St. Jude Medical, Inc. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us. Boston Scientific Corp., for example, initiated a lawsuit in 2014 against one of our employees alleging that the employee cannot work for us without inevitably disclosing Boston Scientific s proprietary information. Although we are not a party to this lawsuit, and it has since been resolved, it impeded our ability to utilize this employee. It is likely that we will experience similar aggressive tactics by our competitors as they seek to protect their market position, particularly as we enter the U.S. market.

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

In October 2014, we entered into a term loan agreement with Capital Royalty Partners and certain of its affiliates, which we refer to as our credit facility. In December 2014, we drew down $20.0 million under this facility. Our credit facility also contains various covenants that limit our ability to engage in specified types of transactions. Subject to limited exceptions, these covenants limit our ability to, among other things:

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

In addition, our credit facility contains certain financial covenants, including certain minimum pre-specified liquidity and revenue requirements. In particular, we are required to maintain a minimum of $5.0 million of cash and certain cash equivalents, and we must achieve minimum revenue of $25.0 million in 2015, $30.0 million in 2016, $40.0 million in 2017, $50.0 million in 2018 and $70.0 million in 2019. The covenants in our credit facility may limit our ability to take certain actions and, in the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding and foreclose on the collateral granted to it to collateralize such indebtedness, which includes our intellectual property. As of September 30, 2015, we did not elect to enter into any additional drawdowns under the facility and the option to do so has expired.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing, and distribution. We use

Table of Contents

enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions, or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors, or catastrophic events. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption, or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

Risks Related to Intellectual Property

We may in the future become involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.

Our success depends in part on not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical industry. Whether merited or not, it is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and/or export our products. For example, our major competitors, Medtronic plc, Boston Scientific Corporation and St. Jude Medical, Inc., each have significant patent portfolios covering systems, sub-systems, methods, and manufacturing processes. These competitors may have one or more patents for which they can threaten and/or initiate patent infringement actions against us and/or any of our third-party suppliers. Our ability to defend ourselves and/or our third-party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages, and/or attorneys fees. From time to time and in the ordinary course of business, we may develop noninfringement and/or invalidity positions with respect to third-party patents, which may or not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation.

Any potential intellectual property litigation also could force us to do one or more of the following:

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

Table of Contents

incur significant legal expenses;

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

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

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

find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory clearance;

find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; and/or

redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

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

our products, or our suppliers may be forced to stop providing us with products.

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

We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. Two of our competitors, Boston Scientific Corporation and Medtronic plc, have filed oppositions in the European Union with respect to certain of our patents. In addition, on May 14, 2015, Boston Scientific

Table of Contents

Neuromodulation Corporation filed with the USPTO two petitions for inter partes review challenging the validity of our U.S. Patent No. 8,359,102. We may not have a final result in the USPTO actions until the second half of 2016, or possibly later. However, defending our position in these proceedings will require management s time and attention, as well as financial costs. An unfavorable outcome in this inter partes review could cause us to lose certain valuable intellectual property rights. Given the competitive environment in which we operate, we expect additional challenges to our intellectual property portfolio as we commence commercialization of Senza in the United States. An unfavorable outcome in these or any other such proceedings could cause us to lose valuable intellectual property rights and/or be unable to enforce our intellectual property rights.

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act), was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a first-to-invent system to a first-to-file system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to

properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

Table of Contents

We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

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

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

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. In addition, six of our nine executive officers and key employees, including our Chief Executive Officer, have worked for our major competitors (or companies acquired by these competitors), which include Boston Scientific Corporation, Medtronic plc and St. Jude Medical, Inc. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used

or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire

Table of Contents

employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

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

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

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

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

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

Risks Related to our Financial and Operating Results

We may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we continue to build a commercial sales force in the United States, investigate the use of our HF10 therapy for the treatment of other chronic pain conditions, continue to grow our business and continue to operate as

Table of Contents

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

We believe that our growth will depend, in part, on our ability to fund our commercialization efforts, particularly in the United States, and our efforts to develop Senza and our HF10 therapy for the treatment of chronic pain and technology complementary to our current products. Our existing resources may not allow us to conduct all of the activities that we believe would be beneficial for our future growth. As a result, we may need to seek funds in the future. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the year ended December 31, 2014, our net cash used in operating activities was $31.1 million as compared to $21.1 million for the year ended December 31, 2013. For the nine months ended September 30, 2015, our net cash used in operating activities was $70.0 million and, as of September 30, 2015, our working capital was $255.7 million. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the costs of commercialization activities related to commercializing Senza in the United States and elsewhere, including product sales, marketing, manufacturing and distribution;
- the scope and timing of our investment in our U.S. commercial infrastructure and sales force in connection with commercialization of Senza in the United States;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- the degree and rate of market acceptance of Senza in the United States and elsewhere;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the amount and timing of any draws we make under our credit facility;
- our need to implement additional infrastructure and internal systems;

our ability to hire additional personnel to support our operations as a public company; and

the emergence of competing technologies or other adverse market developments.

To finance these activities, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, or at all.

The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If we borrow additional funds or issue debt securities, these securities could have rights superior to holders of our common stock and could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates, or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively and the growth of our business will be harmed.

Table of Contents

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

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

- physician and payor acceptance of Senza and our HF10 therapy;
- the timing, expense and results of our commercialization efforts in the United States and elsewhere, research and development activities, clinical trials and regulatory approvals;
- fluctuations in our expenses associated with inventory buildup or write-downs from analyzing our inventory for obsolesce or conformity with our product requirements;
- Fluctuations in expenses as a result of expanding our commercial operations and operating as a public company;
- the introduction of new products and technologies by our competitors;
- the productivity of our sales representatives;
- supplier, manufacturing or quality problems with our products;
- the timing of stocking orders from our distributors;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers; and
- changes in coverage amounts or government and third-party payors reimbursement policies.

Because of these and other factors, it is likely that in some future period our operating results will not meet investor expectations or those of public market analysts.

Any unanticipated change in revenues or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could cause a decline in our stock price.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

As a result of the need to maintain substantial levels of inventory, we are subject to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges. Our products consist of a substantial number of individual components. In order to market and sell Senza effectively, we often must maintain high levels of inventory. In particular, as we continue our commercial launch of Senza in the United States, we intend to substantially increase our levels of inventory in order to meet our estimated demand and, as a result, incur significant expenditures associated with such increases in our inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of inventory obsolesce comparatively. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire and its value would become impaired and we would be required to record an impairment charge. In addition, we have also experienced inventory write-downs as a result of inventory that did not meet our product requirements. If our estimates of required inventory are too high, we may be exposed to further inventory obsolesce risk. In the event that a substantial portion of our inventory becomes obsolete or expires, or in the event we experience a supply chain imbalance as described above, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. During the three and nine months ended September 30, 2015, we recorded total inventory write-down charges of $0.5 million and $2.1 million.

Table of Contents

The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results.

Our revenue fluctuates on a seasonal basis, which affects the comparability of our results between periods. For example, in certain years we have historically experienced lower sales in the summer months and around the holidays, primarily due to the buying patterns and implant volumes of our distributors, hospitals and clinics. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable, which introduce additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited history commercializing our products has, in part, made our seasonal patterns more difficult to discern, making it more difficult to predict future seasonal patterns.

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

All of our current business is located outside the United States and, as a result, we generate revenue and incur expenses denominated in currencies other than the U.S. dollar, a majority of which is denominated in Euros and Australian Dollars. In the first half of 2015, and all of 2014 and 2013, nearly all of our total revenue was denominated in foreign currencies. As a result, changes in the exchange rates between such foreign currencies and the U.S. dollar could materially impact our reported results of operations and distort period to period comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-U.S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common stock could be adversely affected.

In the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations.

Our ability to use our net operating losses and tax credits to offset future taxable income and taxes may be subject to certain limitations.

In general, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating loss (NOL) carryforwards and other tax attributes, such as research and development tax credits to offset future taxable income and taxes.

As a result of our June 2015 underwritten public offering, we have experienced a Section 382 ownership change. We currently estimate that this ownership change will not inhibit our ability to utilize our NOLs. However, as a result of any potential future ownership changes, or if we do not generate sufficient taxable income in the future, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability. If we are limited in our ability to use our NOLs and tax credits in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits. This could materially and adversely affect our results of operations. As of December 31, 2014, we had federal and state NOLs of $108.2 million and $31.7 million, respectively, available to offset future taxable income due to prior period losses, which if not utilized will begin to expire in 2026 for federal purposes and 2016 for state purposes.

Risks Related to Regulation of our Industry

Senza is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the EU legislative bodies and the EEA Member State Competent Authorities. The FDA and other U.S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

Table of Contents

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- pre-market regulatory clearance and approval;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

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

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

Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to introduce new or improved products.

Our products must comply with regulatory requirements imposed by the FDA in the United States and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include:

the Federal Food, Drug, and Cosmetic Act and the FDA s implementing regulations (Title 21 CFR);

European Union CE mark requirements;

Medical Device Quality Management System Requirements (ISO 13485:2003);

Occupational Safety and Health Administration requirements; and

California Department of Health Services requirements.

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

Table of Contents

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

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

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

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

If adopted, the Medical Devices Regulation is expected to enter into force in 2016 and become applicable three years thereafter. In its current form it would, among other things, also impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a qualified person responsible for regulatory compliance, and provide for more strict clinical evidence requirements. While we believe that the Medical Device Regulation, if adopted in its current form, would likely require reassessment of Senza, the actual impact on Senza remains uncertain unless and until the adoption of a final Medical Device Regulation.

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

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

relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Table of Contents

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

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

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

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

Physicians may also misuse our product or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA determines that our promotional materials, training or physician support activities constitute promotion of an off-label use, it could request that we modify our training, promotional materials or physician support activities or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Further, regulators or legislators may also

enhance the enforcement of, and attempt to curtail, any off-label use by physicians of medical devices in the future. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Further, the advertising and promotion of our products is subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices (the EU Medical Devices Directive), Directive 2006/114/EC

Table of Contents

concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. EEA Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

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

The FDA, EEA Competent Authorities and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use (IFU), or if a deficiency in a device is found or suspected. A government-mandated recall or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. Recalls, which include certain notifications and corrections as well as removals, of Senza could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation with customers, and reduce our ability to achieve expected revenue.

In addition, the manufacturing of our products is subject to extensive post-market regulation by the FDA and foreign regulatory authorities, and any failure by us or our contract manufacturers or suppliers to comply with regulatory requirements could result in recalls, facility closures, and other penalties. We and our suppliers and contract manufacturers are subject to the FDA s Quality System Regulation (QSR), and comparable foreign regulations which govern the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, and servicing of medical devices. These regulations are enforced through periodic inspections of manufacturing facilities. Any manufacturing issues at our or our suppliers or contract manufacturers facilities, including failure to comply with regulatory requirements, may result in warning or untitled letters, manufacturing restrictions, voluntary or mandatory recalls or corrections, fines, withdrawals of regulatory clearances or approvals, product seizures, injunctions, or the imposition of civil or criminal penalties, which would adversely affect our business results and prospects.

We are required to report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting (MDR), regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the EU Medical Devices Directive (Directive 93/42/EEC), an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Table of Contents

A recall of our products, either voluntarily or at the direction of the FDA, an EEA Competent Authority or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities such as the Competent Authorities of the EEA countries have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

We may be subject to federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.

Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid or other third-party payors for our products, we are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could significantly impact our business. In the United States, the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;

the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S.

Table of Contents

Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year;

state and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

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

In March 2010, the ACA was signed into law, which includes, among other things, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, effective January 1, 2013. This excise tax is resulting in a significant increase in the tax burden on our industry, and if any efforts we undertake to offset the excise tax are unsuccessful as we begin to sell the product in the United States, the increased tax burden could have an adverse effect on our results of operations and cash flows. Other elements of the PPACA, including comparative effectiveness research, an independent payment advisory board and payment system reforms, including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit

reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 (the ATRA), was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals.

Table of Contents

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner.

It is important to our business that we build a pipeline of product offerings for treatment of chronic pain. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products, or these products may not be accepted by physicians or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical and clinical studies;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- comply fully with FDA and foreign regulations on marketing of new devices or modified products;
- provide adequate training to potential users of our products; and
- receive adequate coverage and reimbursement for procedures performed with our products.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer.

Risks Related to Our Common Stock

We incur significantly increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and the New York Stock Exchange, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly.

In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the JOBS Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a

Table of Contents

public company or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. We also expect that operating as a public company will make it more difficult and expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers

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

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this Risk Factors section of this document and others such as:

- delays or setbacks in the commercialization of Senza or any future product candidates;
- announcements of new products by us or our competitors;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- fluctuations in our expenses associated with inventory buildup or write-downs from analyzing our inventory for obsolesce or conformity with our product requirements;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- our operating results;
- results from, or any delays in, clinical trial programs relating to our product candidates;
- changes or developments in laws or regulations applicable to our products;
- any adverse changes in our relationship with any manufacturers or suppliers;
- the success of our efforts to acquire or develop additional products;

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

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

actual or anticipated fluctuations in our operating results;

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

changes in financial estimates or recommendations by securities analysts;

trading volume of our common stock;

sales of our common stock by us, our executive officers and directors or our stockholders in the future;

general economic and market conditions and overall fluctuations in the United States equity markets; and

the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for medical device stocks in particular, have experienced volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs

Table of Contents

defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

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

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

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

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We are eligible to remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO in November 2014, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Based on our market capitalization as of June 30, 2015, our status as an emerging growth company will cease on December 31, 2015 and we will be required to comply with, among other requirements, the auditor attestation requirements of Section 404 for our 2015 annual report.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our IPO, which will be for our fiscal year ending December 31, 2015, provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an emerging growth company, as defined by the JOBS Act. We do not expect to have our independent registered public accounting firm attest to our internal control over financial reporting for so long as we are an emerging growth company.

If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are in the process of designing and implementing the internal control over financial reporting required to comply with this obligation, which process will be time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are

Table of Contents

unable to assert that our internal control over financial reporting are effective, or, when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

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

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of legal restrictions on resale, the trading price of our common stock could decline. As of September 30, 2015, we had outstanding a total of approximately 27.9 million shares of common stock. Of these shares, the 8,050,000 shares of our common stock sold in the IPO and the 5,411,762 shares sold by us and certain selling stockholders in our June 2015 underwritten public offering are freely tradable, without restriction (except as otherwise applicable), in the public market.

Furthermore, as of September 30, 2015, approximately 5.5 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of up to approximately 2.7 million shares of our outstanding common stock as of September 30, 2015 were entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

As of September 30, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates held approximately 53% of our outstanding voting stock. These stockholders will have the ability to influence us through this ownership position, and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel

are in their best interest.

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

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

Table of Contents

a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror s own slate of directors or otherwise attempting to obtain control of us.

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

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15%

or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

> we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person s conduct was unlawful;

Table of Contents

we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;

the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and

we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our credit facility prohibit us from paying cash dividends on our capital stock. Therefore, our stockholders are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders have purchased it.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

None.

Use of Proceeds

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

Shares of our common stock began trading on the New York Stock Exchange on November 6, 2014. The shares were registered under the Securities Act of 1933, as amended (the Securities Act), on a registration statement on Form S-1 (Registration No. 333-199156), which was declared effective by the Securities and Exchange Commission (SEC), on November 5, 2014.

We expect to use the proceeds from the IPO to fund the continuing commercial launch of Senza in the United States, the continued development of Senza for additional indications, including clinical trial activities to potentially expand its indications for use, and for working capital and general corporate purposes.

Table of Contents

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Amendment to EaglePicher Supply Agreement

On November 6, 2015, we entered into a Second Amendment to the Product Supply and Development Agreement (the Amendment) with EaglePicher Medical Power LLC (EaglePicher) to amend our Product Supply and Development Agreement, dated as of April 5, 2009 (as amended to date, the EaglePicher Agreement). The Amendment increases our pre-existing specified minimum purchase amounts and increases EaglePicher s production capacity commitments under the EaglePicher Agreement, as well as specifying certain purchasing and purchase order protocol. The Amendment obligates EaglePicher to establish and qualify an additional battery production operation and commits us to fund approximately $1.0 million of such production operation paid in three milestone installments. The Amendment also establishes EaglePicher as our exclusive battery supplier through the initial five year term of the EaglePicher Agreement, ending December 31, 2019.

The foregoing description of the material terms of the Amendment is qualified in its entirety by the full terms of the Amendment, which we intend to file as an exhibit to our Annual Report on Form 10-K for the year ending December 31, 2015. We intend to seek confidential treatment for certain portions of the Amendment pursuant to a Confidential Treatment Request submitted to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Table of Contents

Item 6. Exhibits

Exhibit		Incorporated by Reference			
Number	**Description of Document**	**Form**	**Date**	**Number**	**Filed Herewith**
3.1	Amended and Restated Certificate of Incorporation.	8-K	11/12/2014	3.1	
3.2	Amended and Restated Bylaws.	8-K	11/12/2014	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	10/27/2014	4.2	
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).				X
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).				X
32.1*	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Nevro Corp. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	NEVRO CORP. (Registrant)
Date: November 9, 2015	/s/ MICHAEL DEMANE Michael DeMane Chief Executive Officer (Principal Executive Officer)
Date: November 9, 2015	/s/ ANDREW H. GALLIGAN Andrew H. Galligan Chief Financial Officer (Principal Financial and Accounting Officer)