

NEVRO CORP
Form 10-Q
November 06, 2017
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

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 (I.R.S. Employer
incorporation or organization) 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)

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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 No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 31, 2017 there were 29,628,207 shares of the registrant’s common stock, par value \$0.001 per share, outstanding.

Nevro Corp.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Nevro Corp.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share data)

	September 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	\$ 44,042	\$ 41,406
Short-term investments	227,312	234,951
Accounts receivable, net of allowance for doubtful accounts of \$952 and \$1,008 at September 30, 2017 and December 31, 2016, respectively	53,409	52,818
Inventories	95,575	85,221
Prepaid expenses and other current assets	6,259	5,895
Total current assets	426,597	420,291
Property and equipment, net	7,187	7,132
Other assets	3,346	2,354
Restricted cash	806	806
Total assets	\$ 437,936	\$ 430,583
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 17,800	\$ 16,162
Accrued liabilities	30,696	26,028
Other current liabilities	110	8
Total current liabilities	48,606	42,198
Long-term debt	143,260	138,140
Other long-term liabilities	1,831	1,211
Total liabilities	193,697	181,549
Commitments and contingencies (Note 5)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at September 30, 2017 and December 31, 2016; zero shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value, 290,000,000 shares authorized at September 30, 2017 and December 31, 2016; 29,603,852 and 28,886,862 shares issued and	30	29

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outstanding at September 30, 2017 and December 31, 2016, respectively

Additional paid-in capital	498,354	470,869
Accumulated other comprehensive loss	(612)	(678)
Accumulated deficit	(253,533)	(221,186)
Total stockholders' equity	244,239	249,034
Total liabilities and stockholders' equity	\$ 437,936	\$ 430,583

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

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,	
	2017	2016	2017	2016
Revenue	\$82,256	\$60,922	\$228,711	\$157,973
Cost of revenue	24,316	19,235	70,530	53,741
Gross profit	57,940	41,687	158,181	104,232
Operating expenses				
Research and development	9,381	7,923	27,617	22,453
Sales, general and administrative	52,977	35,636	157,971	98,591
Total operating expenses	62,358	43,559	185,588	121,044
Loss from operations	(4,418)	(1,872)	(27,407)	(16,812)
Interest income	808	556	2,264	1,066
Interest expense	(2,497)	(2,381)	(7,386)	(3,995)
Other income (expense), net	251	259	1,198	96
Loss on extinguishment of debt	—	—	—	(1,268)
Loss before income taxes	(5,856)	(3,438)	(31,331)	(20,913)
Provision for income taxes	374	448	1,016	1,040
Net loss	(6,230)	(3,886)	(32,347)	(21,953)
Other comprehensive loss:				
Changes in foreign currency translation adjustment	165	(100)	(41)	(446)
Changes in unrealized gains on short-term investments, net	13	(507)	107	(296)
Net change in other comprehensive loss	178	(607)	66	(742)
Comprehensive loss	\$(6,052)	\$(4,493)	\$(32,281)	\$(22,695)
Net loss per share, basic and diluted	\$(0.21)	\$(0.14)	\$(1.10)	\$(0.77)
Weighted average number of common shares used to				

compute basic and diluted net loss per share	29,513,842	28,542,760	29,342,883	28,373,430
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The accompanying notes are an integral part of these condensed consolidated financial statements.

Nevro Corp.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities		
Net loss	\$(32,347)	\$(21,953)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,774	1,234
Stock-based compensation expense	18,867	10,428
Accretion of discount on short-term investments	(168)	(148)
Non-cash loss on extinguishment of debt	—	1,156
Payment of original issue discount	—	(1,500)
Provision for doubtful accounts	(85)	562
Write-down of inventory	3,675	2,759
Non-cash interest expense	5,120	2,037
Unrealized (gains) losses on foreign currency transactions	(1,074)	939
Changes in operating assets and liabilities		
Accounts receivable	288	(19,249)
Inventories	(13,399)	(13,997)
Prepaid expenses and other current assets	(296)	(2,837)
Other assets	(988)	(557)
Accounts payable	1,791	(8,928)
Accrued liabilities	4,392	6,583
Other long-term liabilities	620	610
Net cash used in operating activities	(11,830)	(42,861)
Cash flows from investing activities		
Purchases of short-term investments	(206,891)	(266,839)
Proceeds from sales of short-term investments	5,993	—
Proceeds from maturity of short-term investments	208,811	128,100
Purchases of property and equipment	(2,475)	(2,414)
Net cash provided by (used in) investing activities	5,438	(141,153)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	—	172,500
Convertible notes initial issuance discount and debt issuance costs	—	(6,171)
Proceeds from issuance of warrants	—	33,120
Purchase of convertible note hedges	—	(45,092)
Repayment of debt	—	(19,500)
Minimum tax withholding paid on behalf of employees for net share settlement	(732)	—
Proceeds from issuance of common stock to employees	9,337	5,234
Net cash provided by financing activities	8,605	140,091
Effect of exchange rate changes on cash and cash equivalents	423	(380)
Net increase (decrease) in cash and cash equivalents	2,636	(44,303)

Cash and cash equivalents		
Cash and cash equivalents at beginning of period	41,406	87,036
Cash and cash equivalents at end of period	\$44,042	\$42,733
Significant non-cash transactions		
Purchases of property and equipment in accounts payable	\$79	\$1,385
Vesting of early-exercised stock options	\$7	\$40

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

Nevro Corp.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Formation and Business of the Company

Nevro Corp. (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, 2016, the Company incurred a net loss of \$31.8 million and used \$58.5 million of cash in operations. For the nine months ended September 30, 2017, the Company incurred a net loss of \$32.3 million and used \$11.8 million of cash in operations. At September 30, 2017 and December 31, 2016, the Company had an accumulated deficit of \$253.5 million and \$221.2 million, respectively. The Company has financed operations to date primarily through private placements of equity securities, borrowings under a debt agreement, the issuance of common stock in its November 2014 initial public offering, its June 2015 underwritten public offering and its June 2016 underwritten public offering of convertible senior notes due 2021. The Company's ability to continue to meet its obligations and to achieve its business objectives for the foreseeable future is dependent upon, amongst other things, generating sufficient revenues and its ability to continue to control expenses. Failure to increase sales of its products, manage discretionary expenditures or raise additional financing, if 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, 2017 and for the nine months ended September 30, 2017 and 2016, 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 in the United States (U.S. GAAP) for interim financial information and on the same basis as the audited financial statements included on the Company's Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (SEC) on February 23, 2017. 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, 2017, and the results of its operations and cash flows for the nine months ended September 30, 2017 and 2016. All such adjustments are of a normal and recurring nature. The interim financial data as of September 30, 2017 is not necessarily indicative of the results to be expected for the year ending December 31, 2017, 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, 2016 included in the Annual Report.

2. Summary of Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. The condensed consolidated financial statements include the Company's accounts and those of its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Segments

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

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Revenue by geography is based on the billing address of the customer. The United States was the only country with revenue accounting for more than 10% of the total revenue in any of the periods presented, as follows:

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
United States	81 %	78 %	80 %	74 %

Long-lived assets and operating income 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) on 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 and comprehensive loss. The Company recorded net unrealized and net realized foreign currency transaction gains (losses) during the periods presented as follows (in thousands):

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
Net unrealized foreign currency gain (loss)	\$(223)	\$615	\$1,092	\$(663)
Net realized foreign currency gain (loss)	518	(310)	254	918

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 consolidated financial

statements include items such as allowances for doubtful accounts; warranty obligations; clinical accruals; stock-based compensation; depreciation and amortization periods; inventory valuation; and 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 and is 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, 2017 and December 31, 2016. The Company also held cash in foreign banks of approximately \$3.4 million at September 30, 2017 and \$3.3 million at December 31, 2016 that was not federally insured. The Company has not experienced any losses on its deposits of cash and cash equivalents.

In the international markets in which the Company participates, the Company uses both a direct sales force and distributors to sell its products, while in the United States the Company utilizes a direct sales force. 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 and nine months ended September 30, 2017 and 2016, no single customer accounted for 10% or more of the Company's revenue. As of September 30, 2017 and December 31, 2016, no single customer accounted for 10% or more of the accounts receivable balance.

The Company is subject to risks common to 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, continued reimbursement from third-party payors, uncertainty of market acceptance of products and the need to obtain additional financing. The Company is dependent on third-party manufacturers and suppliers, which, in some cases, are sole- or single-source suppliers.

There can be no assurance that the Company's products or services will continue to be accepted in its existing marketplaces, 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 may choose to raise additional funds to further enhance its research and development efforts, for product expansion opportunities or to acquire a new business or products that are complementary to its business. 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 \$28.7 million and \$35.5 million as of September 30, 2017 and December 31, 2016, respectively. At September 30, 2017 and December 31, 2016, 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.

Restricted Cash

Restricted cash as of September 30, 2017 and December 31, 2016 consists of a letter of credit of \$0.6 million representing collateral for the Company's Redwood City, California building lease pursuant to an agreement dated March 5, 2015 and certificates of deposit of \$0.2 million collateralizing payment of charges related to the Company's credit cards.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments with original maturities greater than three months at the date of purchase and remaining maturities of less than 12 months are considered short-term investments. Those investments with remaining maturities greater than 12 months at the date of purchase are also classified as short-term investments as management considers them to be available for current operations if needed. The Company's investment securities classified as available-for-sale are recorded at fair value. 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 (accrued) 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 net realizable value of such inventory. Cost is determined using the standard cost method which approximates the first-in, first-out basis. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. 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 has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory that 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 using the same lower of cost or net realizable value approach that has been 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. As a result of these evaluations, the Company recognized total write downs of \$0.3 million and \$1.1 million of its inventories for the three months ended September 30, 2017 and 2016, respectively, and \$3.7 million and \$2.8 million for the nine months ended September 30, 2017 and 2016, respectively. The Company's estimation of the future demand for any given 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.

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 reasonably assured 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.

Allowance for Doubtful Accounts

The Company makes estimates of the collectability of accounts receivable. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance of doubtful accounts.

Warranty Obligations

The Company has a limited one- to five-year warranty to most customers and warrants that its products will operate substantially in conformity with product specifications. The Company records an estimate for the provision for warranty claims in cost of revenue when the related revenues are recognized. The estimate is based on historical and anticipated rates of warranty claims, the cost per claim and the number of units sold. The Company regularly assesses the adequacy of its recorded warranty obligations and adjusts the amounts as necessary.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment, other than leasehold improvements, is computed using the straight-line method over the assets' estimated useful lives of three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the life of the lease. Upon retirement or sale, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss, 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 or asset group might not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is 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, 2017.

Income Taxes

During the three and nine months ended September 30, 2017 and 2016, 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. The provision for income taxes for the three and nine months ended September 30, 2017 and 2016 is primarily comprised of foreign and state taxes based upon income earned during the period with no tax benefit recorded for the loss jurisdictions.

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. The Company's policy is to recognize interest and penalties related to income taxes as a component of income tax expense. No interest or penalties related to income taxes have been recognized in the statements of operations and comprehensive loss for the three and nine months ended September 30, 2017 and 2016.

Comprehensive Income (Loss)

Comprehensive income (loss) represents all changes in the stockholders' equity except those resulting from distributions to stockholders. The Company's changes in unrealized gains and losses on 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 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 Accounting Standards Codification (ASC) 718, Compensation - Stock Compensation. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all share-based payments including stock options.

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-09, Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting, which the Company adopted on January 1, 2017. Under ASU 2016-09, entities are permitted to make an accounting policy

election to either estimate forfeitures on share-based payment awards, as previously required, or to recognize forfeitures as they occur. The Company has elected to continue to estimate forfeitures expected to occur to determine the amount of compensation cost recognized in each period. ASU 2016-09 also requires that entities recognize, on a prospective basis, all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement as discrete items in the reporting period in which they occur. The adoption did not result in a cumulative-effect adjustment to accumulated deficit as of January 1, 2017 using the modified retrospective method. Additionally, under ASU 2016-09, excess tax benefits are classified as an operating activity in the statement of cash flows. The Company has elected the presentation of excess tax benefits in the statement of cash flows using the prospective transition method.

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

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

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

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

The Company accounts for stock-based compensation for restricted stock units at their fair value, based on the closing market price of the Company's common stock on the grant date. These costs are recognized on a straight-line basis over the requisite service period, which is generally the vesting term of four years.

The Company also issues stock options and restricted stock units with vesting based upon completion of performance goals. The fair value for these performance-based awards is recognized over the period during which the goals are to be achieved. Stock-based compensation expense recognized at fair value includes the impact of estimated probability that the goals would be achieved, which is assessed prior to the requisite service period for the specific goals.

Upon adoption of ASU 2016-09 as described above, excess tax benefits or deficiencies from share-based award activity are reflected in the consolidated statements of operations as a component of the provision for income taxes, whereas they were previously recognized as additional paid-in capital.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss 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 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 restricted stock units and options to purchase shares of common stock are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

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

customer contracts, including significant judgments, changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In March 2016, the FASB amended the principal-versus-agent implementation guidance and illustrations in the new standard. In April 2016, the FASB amended the guidance related to identifying performance obligations and the implementation guidance on licensing. In May 2016, the FASB issued guidance related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. ASU 2014-09 and the related amendments (collectively, the new revenue standard) may be applied retrospectively to each prior period presented (full retrospective) or retrospectively with the cumulative effect recognized as of the date of initial application (modified retrospective). The Company will be adopting the new revenue standard using the modified retrospective approach in the first quarter of 2018. The Company has developed a project plan, established steering and working committees for implementing the guidance, classified customers with varying characteristics into different categories and evaluated contracts with customers from which revenue was recognized in the first half of 2017. The Company will continue to assess additional customer contracts throughout 2017 and will continue to design changes to business processes and controls, as needed, to comply with the relevant accounting guidelines and additional required disclosures under the new revenue standard. Although the Company is still in the process of evaluating the full impact the new

revenue standard will have on its consolidated financial statements, the Company does not expect the impact to be material based on its initial assessment, as the majority of the Company's revenue arrangements generally consists of a single performance obligation and the transfer of promised goods or services that allows the Company to recognize revenue at a point in time. However, assuming all other revenue recognition criteria have been met, the Company may recognize revenue earlier for arrangements where certain documents needed for revenue recognition under the current standard are considered administrative and incidental under the new revenue standard. As the Company continues its evaluation of the new revenue standard, new information may arise that could change the Company's current understanding of the impact to revenue and expenses to be recognized under the new revenue standard. The Company will adjust its assessment and implementation plans accordingly.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company has not determined the potential effects of this ASU on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). This update requires an entity to recognize assets and liabilities for leases with lease terms of more than 12 months on the balance sheet. ASU 2016-02 is effective for public entities for fiscal years beginning after December 15, 2018. Although the Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures, the Company expects that all of its operating lease commitments with a term will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon adoption.

In August, 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force). The update clarifies the classification of certain cash receipts and cash payments in the statement of cash flows, including debt prepayment or extinguishment costs, settlement of contingent consideration arising from a business combination, insurance settlement proceeds and distributions from certain equity method investees. ASU 2016-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other than Inventory. This update is intended to reduce the complexity and diversity in practice related to the tax consequences of certain types of intra-entity asset transfers. Under this ASU, a selling entity is required to recognize a current tax expense or benefit upon the transfer of the asset. Similarly, the purchasing entity is required to recognize a deferred tax asset or liability, as well as the related deferred tax benefit or expense, upon receipt of the asset. This ASU does not apply to intra-entity transfers of inventory, where the income tax consequences from the sale of inventory from one member of a consolidated entity to another will continue to be deferred until the inventory is sold to a third party. ASU 2016-16 is effective for public entities for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Early adoption is permitted. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, a consensus of the FASB Emerging Issues Task Force. The update requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 is effective for public entities for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In February 2017, the FASB issued ASU No. 2017-05, Other Income – Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for

Partial Sales of Nonfinancial Assets. This update clarifies that a financial asset is within the scope of Subtopic 610-20 if it is deemed an “in substance non-financial asset.” The effective date and transition methods of ASU 2017-05 are aligned with ASU 2014-09 described above. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In March 2017, the FASB issued ASU No. 2017-08, Receivables – Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities. This update shortens the premium amortization period for certain purchased callable debt securities held at a premium. ASU 2017-08 is effective for public entities for annual periods beginning after December 15, 2018. The Company has not determined the potential effects of the guidance on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting. This update amends the scope of modification accounting for share-based payment awards. Specifically, companies would not apply modification accounting if the fair value, vesting conditions and classification of the award remain the same despite a change in terms or conditions. ASU 2017-09 is effective for public entities for annual periods beginning after December 15, 2017, with early adoption permitted. The Company has not determined the potential effects of the guidance on its consolidated financial statements and is currently expecting to adopt the new guidance effective January 1, 2018.

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. The Company's money market funds are classified within Level 1 of the fair value hierarchy and are valued based on quoted prices in active markets for identical securities. The Company's short-term investments are comprised of commercial paper and corporate notes. All short-term investments have been classified within Level 1 or Level 2 of the fair value hierarchy because of the sufficient observable inputs for revaluation. The Company's Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry-standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs. The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

Balance as of September 30, 2017	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (i)	\$28,699	\$—	\$ —	\$28,699
Commercial paper (ii)	—	75,408	—	75,408
Corporate notes (ii)	—	151,904	—	151,904
Total assets	\$28,699	\$227,312	\$ —	\$256,011

Balance as of December 31, 2016	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (i)	\$35,510	\$—	\$ —	\$35,510
Commercial paper (ii)	—	160,582	—	\$160,582
Corporate notes (ii)	—	74,369	—	\$74,369

Total assets	\$35,510	\$234,951	\$ —	\$270,461
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(i) Included in cash and cash equivalents on the condensed consolidated balance sheets.

(ii) Included in short-term investments on the condensed consolidated balance sheets.

Convertible Senior Notes

As of September 30, 2017 and December 31, 2016, the fair value of the 1.75% convertible senior notes due 2021 was \$204.8 million and \$183.8 million, respectively. The fair value was determined on the basis of market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy (See Note 6).

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, excluding investments in money market funds (in thousands):

	September 30, 2017			
	Gross		Gross	
		Unrealized	Unrealized	
	Amortized	Holding	Holding	Aggregate
	Cost	Gains	Losses	Fair Value
Investment Securities				
Commercial paper	\$75,432	\$ 2	\$ (26)	\$75,408
Corporate notes	151,981	5	(82)	151,904
Total securities	\$227,413	\$ 7	\$ (108)	\$227,312

	December 31, 2016			
	Gross		Gross	
		Unrealized	Unrealized	
	Amortized	Holding	Holding	Aggregate
	Cost	Gains	Losses	Fair Value
Investment Securities				
Commercial paper	\$160,729	\$ 6	\$ (153)	\$160,582
Corporate notes	74,430	3	(64)	74,369
Total securities	\$235,159	\$ 9	\$ (217)	\$234,951

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 amount of realized gains and realized losses on investments recorded for the periods presented has not been material.

The contractual maturities of the Company's investment securities as of September 30, 2017 were as follows (in thousands):

	Amortized	Fair
	Cost	Value
Amounts maturing within one year	\$188,749	\$188,690

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Amounts maturing after one year through five years	38,664	38,622
Total investment securities	\$ 227,413	\$ 227,312

Inventories (in thousands)

	September 30, 2017	December 31, 2016
Raw materials	\$ 45,593	\$ 44,862
Finished goods	49,982	40,359
Total inventories	\$ 95,575	\$ 85,221

Property and Equipment, Net (in thousands)

	September 30, 2017	December 31, 2016
Laboratory equipment	\$ 2,241	\$ 1,567
Computer equipment and software	4,978	2,388
Furniture and fixtures	2,196	2,051
Leasehold improvements	1,221	1,214
Construction in process	687	2,274
Total	11,323	9,494
Less: Accumulated depreciation and amortization	(4,136)	(2,362)
Property and equipment, net	\$ 7,187	\$ 7,132

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

	Three Months Ended		Nine Months Ended	
	September 30, 2017	2016	September 30, 2017	2016
Depreciation and amortization expense	\$ 666	\$ 465	\$ 1,774	\$ 1,234

Accrued Liabilities (in thousands)

	September 30, 2017	December 31, 2016
Accrued payroll and related expenses	\$ 21,043	\$ 17,732
Accrued professional fees	2,409	1,067
Accrued taxes	2,488	2,110
Accrued clinical and research expenses	1,022	1,545
Accrued interest	998	243
Accrued warranty	603	645
Accrued other	2,133	2,686
Total accrued liabilities	\$ 30,696	\$ 26,028

5. Commitments and Contingencies

Operating Leases

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. In December 2016, the Company entered into a first amendment to the lease for an additional approximately 50,000 square feet of office space adjacent to the premises under the original lease (the Expansion Premises), with initial annual payments of \$1.2 million, increasing to \$2.9 million in the final year of the amended lease term. The lease for the Expansion Premises commences on the earlier of (i) the date the Company commences business operations in the Expansion Premises, or (ii) the date upon which the Landlord substantially completes certain improvements to, and permitting for, the Expansion Premises (the Commencement Date). The first amendment also extends the lease term for the original premises to terminate on the same date as the amended lease. Under the first amendment, if the Company is unable to move into the Expansion Premises before the Scheduled Delivery Date, as defined in the amendment, the Company may terminate the lease for the Expansion Premises. In April 2017, the Company entered into a second amendment to the lease for a temporary space for a period beginning in May 2017 and ending on the Commencement Date of the Expansion Premises. As of September 30, 2017, the Commencement Date of the Expansion Premises has not occurred.

In August 2014, the Company entered into a 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, at which time the lease terminated.

The Company entered into a separate non-cancellable facility lease for warehouse space beginning on March 1, 2017 through February 28, 2022, under which it is obligated to pay approximately \$0.4 million in lease payments over the term of the lease.

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

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
Rent expense	\$ 653	\$ 593	\$ 1,864	\$ 1,800

Warranty Obligations

The Company warrants that its products will operate substantially in conformity with product specifications and has a limited one- to five-year warranty to most customers. Activities related to warranty obligations were as follows (in thousands):

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
Beginning balance	\$656	\$514	\$645	\$394
Provision for warranty	352	230	945	638
Utilization	(405)	(154)	(987)	(442)
Ending balance	\$603	\$590	\$603	\$590

License Agreement

In October 2006, the Company entered into an amended and restated license agreement with the Mayo Foundation for Medical Education and Research (Mayo) and the 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 expiration of (1) the last to expire of the licensed patents or (2) the Company's obligations to pay royalties, whichever is later, unless terminated earlier. The agreement can be terminated by the Company, Mayo or VGL upon 60 days' notice of a party's material breach if such breach remains uncured after such 60-day period.

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		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Royalty expense	\$ 665	\$ 606	\$1,831	\$1,571

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities related to, for example, employment matters and patent issues. 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 were no contingent liabilities requiring accrual at September 30, 2017 and December 31, 2016.

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.

Legal Matters

On November 28, 2016, the Company filed a lawsuit for patent infringement against Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, Boston Scientific). The lawsuit, filed in the United States District Court for the Northern District of California, asserts that Boston Scientific is infringing the Company's patents covering inventions relating to the Senza system and HF10 therapy. The lawsuit seeks preliminary and permanent injunctive relief against further infringement as well as damages and attorney's fees.

On December 9, 2016, Boston Scientific filed a patent infringement lawsuit alleging the Company's manufacture, use and sale of the Senza system infringes certain of Boston Scientific's patents covering spinal cord stimulation technology related to stimulation leads, rechargeable batteries and telemetry. The lawsuit, filed in the United States District Court for the District of Delaware, seeks unspecified damages and attorney's fees, as well as preliminary and permanent injunctive relief against further infringement. As of September 30, 2017, the Company is unable to determine an outcome or potential range of loss. In relation to this lawsuit, on July 21, 2017, the Company filed two petitions for inter partes review of U.S. Patent No. 6,895,280 (the '280 patent) and one petition for inter partes review of U.S. Patent No. 7,437,193 (the '193 patent) at the U.S. Patent and Trademark Office challenging certain asserted claims of the '280 patent and the '193 patent, respectively. The Company also filed a petition for inter partes review of U.S. Patent No. 7,587,241 (the '241 patent) at the U.S. Patent and Trademark Office on July 31, 2017 challenging certain asserted claims of the '241 patent.

The Company is and may from time to time continue to be involved in various legal proceedings of a character normally incident to the ordinary course of its business, including several pending European patent oppositions at the European Patent Office (EPO) initiated by the Company's competitors Medtronic and Boston Scientific, which the Company does not believe to be material to its business and consolidated financial statements at this stage.

6. Long-term Debt

1.75% Convertible Senior Notes and Convertible Note Hedge and Warrant Transactions

In June 2016, the Company issued \$150.0 million aggregate principal amount of 1.75% convertible senior notes due 2021 in a registered underwritten public offering and an additional \$22.5 million aggregate principal amount of such notes pursuant to the exercise in full of the over-allotment options of the underwriters (the 2021 Notes). The interest rates are fixed at 1.75% per annum and are payable semi-annually in arrears on June 1 and December 1 of each year, commencing on December 1, 2016. The total net proceeds from the debt offering, after deducting initial purchase discounts and debt issuance costs, were approximately \$166.2 million.

Each \$1,000 principal amount of the 2021 Notes will initially be convertible into 10.3770 shares of the Company's common stock, which is equivalent to an initial conversion price of approximately \$96.37 per share, subject to adjustment upon the occurrence of specified events. The 2021 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding December 1, 2020, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on September 30, 2016 (and only during such calendar quarter), if the last reported sale

price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period (the measurement period) in which the trading price (as defined in the indenture to the 2021 Notes) per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events. On or after December 1, 2020 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2021 Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. If the Company undergoes a fundamental change prior to the maturity date, holders of the notes may require the Company to repurchase for cash all or any portion of their notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if specific corporate events occur prior to the applicable maturity date, the Company will increase the conversion rate for a holder who elects to convert their notes in connection with such a corporate event in certain circumstances. It is the Company's current intent and policy to settle conversions through combination settlement with a specified dollar amount per \$1,000 principal amount of notes of \$1,000. During the three months ended September 30, 2017, the conditions allowing holders of the 2021 Notes to convert have not been met. The 2021 Notes are therefore not convertible during the three months ended December 31, 2017 and are classified as long-term debt. Should the sale price condition be met in a future quarter, the 2021 Notes will be convertible at the holders' option during the immediately following quarter. As of September 30, 2017, the if-converted value of the 2021 Notes did not exceed the principal value of those notes.

In accounting for the issuance of the convertible senior notes, the Company separated the 2021 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar debt instrument that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was \$32.9 million and was determined by deducting the fair value of the liability component from the par value of the 2021 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense over the term of the 2021 Notes expense at an effective interest rate of 6.29% over the contractual terms of the notes.

In accounting for the debt issuance costs of \$6.2 million related to the 2021 Notes, the Company allocated the total amount incurred to the liability and equity components of the 2021 Notes based on their relative values. Issuance costs attributable to the liability component were \$5.0 million and will be amortized to interest expense using the effective interest method over the contractual terms of the 2021 Notes. Issuance costs attributable to the equity component were netted with the equity component in stockholders' equity.

The net carrying amount of the liability component of the 2021 Notes was as follows (in thousands):

	September 30, 2017	December 31, 2016
Principal	\$ 172,500	\$ 172,500
Unamortized discount	(25,280)	(29,783)
Unamortized issuance cost	(3,960)	(4,577)
Net carrying amount	\$ 143,260	\$ 138,140

The net carrying amount of the equity component of the 2021 Notes was as follows (in thousands):

	September 30, 2017	December 31, 2016
Debt discount related to value of conversion option	\$ 32,945	\$ 32,945
Debt issuance cost	(1,179)	(1,179)
Net carrying amount	\$ 31,766	\$ 31,766

The following table sets forth the interest expense recognized related to the 2021 Notes (in thousands):

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	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Contractual interest expense	\$755	\$755	\$2,264	\$898
Amortization of debt discount	1,528	1,438	4,504	1,710
Amortization of debt issuance costs	212	188	616	223
Total interest expense related to the 2021 Notes	\$2,495	\$2,381	\$7,384	\$2,831

In connection with the offering of the 2021 Notes, the Company entered into convertible note hedge transactions with certain bank counterparties in which the Company has the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of the Company's common stock at a price of approximately \$96.37 per share. The total cost of the convertible note hedge transactions was \$45.1 million. In addition, the Company sold warrants to certain bank counterparties whereby the holders of the warrants have the option to purchase initially (subject to adjustment for certain specified events) a total of approximately 1.8 million shares of the Company's common stock at a price of \$127.28 per share. The Company received \$33.1 million in cash proceeds from the sale of these warrants. Taken together, the purchase of the convertible note hedges and the sale of warrants are intended to offset any actual dilution from the conversion of these notes and to effectively increase the overall conversion price from \$96.37 to \$127.28 per share. As these transactions meet certain accounting criteria, the convertible note hedges and warrants are recorded in stockholders' equity and are not accounted for as derivatives. The net cost of \$12.0 million incurred in connection with the convertible note hedge and warrant transactions was recorded as a reduction to additional paid-in capital on the consolidated balance sheet.

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 could enter into three term loan agreements totaling \$50.0 million with the lenders on or before September 30, 2015. In June 2016, the Company paid the outstanding principal and repayment fees totaling \$21.0 million to the lenders, and the credit facility terminated and is now no longer in effect.

7. Net Loss Per Share

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

	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Net loss, basic and diluted	\$(6,230)	\$(3,886)	\$(32,347)	\$(21,953)
Weighted average shares outstanding	29,513,842	28,547,789	29,343,291	28,382,147
Less: weighted average shares subject to repurchase	—	(5,029)	(408)	(8,717)
Weighted average shares used to compute				
basic and diluted net loss per share	29,513,842	28,542,760	29,342,883	28,373,430
Net loss per share, basic and diluted	\$(0.21)	\$(0.14)	\$(1.10)	\$(0.77)

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and dilutive common stock equivalents outstanding for the period, if inclusion of these is dilutive. Since the Company expects to settle the principal amount of its outstanding convertible senior notes in cash, the Company uses the treasury stock method for calculating any potential dilutive effect of the conversion spread on diluted net income per share, if applicable. The conversion spread will have a dilutive impact on diluted net income per share of common stock when the average market price of the Company's common stock for a given period exceeds the conversion price of \$96.37 per share for the 2021 Notes. 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, as the effect would be anti-dilutive:

	September 30,	
	2017	2016
Unreleased restricted stock	520,267	276,081
Options to purchase common stock	2,342,965	2,928,391
Total	2,863,232	3,204,472

8. 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. In June 2016, the Company adopted a policy to match a portion of employee contributions for all qualified employees participating in the 401(k) plan. For the nine months ended September 30, 2017 and 2016, the Company recorded an expense of \$2.0 million and \$1.1 million, respectively, for matching contributions.

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 zero and 44,999 shares of common stock issued under the ESPP for the three and nine months ended September 30, 2017, respectively. There were zero and 42,613 shares of common stock issued under the ESPP for the three and nine months ended September 30, 2016, respectively. Shares available for future purchase under the ESPP were 864,898 at September 30, 2017.

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 (Quarterly Report) and with our audited consolidated financial statements and notes thereto for the year ended December 31, 2016, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 23, 2017.

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," "strategy," "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 global medical device company focused on providing innovative products that improve the quality of life of patients suffering from chronic pain. We have developed and commercialized the Senza spinal cord stimulation (SCS) system, an evidence-based neuromodulation platform for the treatment of chronic pain. Our proprietary paresthesia-free HF10 therapy, delivered by our Senza system, was demonstrated in our SENZA-RCT study to be superior to traditional SCS therapy, with Senza being nearly twice as successful in treating back pain and 1.5 times as successful in treating leg pain when compared to traditional SCS therapy. Comparatively, traditional SCS therapy has limited efficacy in treating back pain and is used primarily for treating leg pain, limiting its market adoption. Our SENZA-RCT study, along with our European studies, represents what we believe is the most robust body of clinical evidence for any SCS therapy. We believe the superiority of HF10 therapy over traditional SCS therapies will allow us to capitalize on and expand the approximately \$1.6 to \$1.8 billion existing global SCS market by treating both back and leg pain without paresthesia.

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We launched Senza commercially in the United States in May 2015, after receiving a label from the U.S. Food and Drug Administration (FDA) supporting the superiority of our HF10 therapy over traditional SCS. The Senza system has been commercially available in certain European markets since November 2010 and in Australia since August 2011. We have experienced significant revenue growth in the United States since commercial launch and, effective January 1, 2016, received a transitional pass-through payment under the Medicare hospital outpatient prospective payment system. In addition, Senza is reimbursed by all of the major insurance providers. In early 2017, we commenced a controlled commercial launch of our surgical lead, marketed as the Surpass surgical lead, which we believe will provide us access to approximately an additional 30% of the U.S. SCS market that we previously did not address. The tables below set forth our revenue from U.S. sales, international sales and total sales revenue since the first quarter of 2015 on a quarterly basis and total revenue for each of the past three years and the nine months ended September 30, 2017.

	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017
	(in millions)										
Revenue from U.S. sales	N/A	\$0.1	\$4.5	\$19.8	\$29.5	\$40.6	\$47.2	\$56.0	\$53.1	\$63.0	\$66.3
Revenue from international sales	9.7	11.3	10.9	13.3	12.2	14.8	13.7	14.5	15.3	15.0	16.0
Total sales revenue	\$9.7	\$11.4	\$15.4	\$33.1	\$41.7	\$55.4	\$60.9	\$70.5	\$68.4	\$78.0	\$82.3

Nine
Months
Ended

September
30, 2017

2014 2015 2016
(in millions)

Total revenue \$32.6 \$69.6 \$228.5 \$ 228.7

Since inception, we have financed our operations primarily through equity and debt financings and borrowings under a debt facility. Our accumulated deficit as of September 30, 2017 was \$253.5 million. A significant amount of our capital resources has been used to support the development of Senza and our HF10 therapy and we have also made a significant investment building our U.S. commercial infrastructure and sales force to support our commercialization efforts in the United States. We intend to continue to make significant investments in our U.S. commercial infrastructure, as well as in research and development (R&D) to develop Senza to treat other chronic pain indications, including conducting clinical trials to support our future regulatory submissions. In order to further enhance our R&D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to raise additional funds, 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. During 2015, 2016 and 2017, we entered into and/or amended several supply agreements in an effort to reinforce our supply chain. 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, we have substantially increased our levels of inventory in order to meet our estimated demand in the United States 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 obsolescence.

Our initial public offering (IPO) closed in November 2014 at which time we received cash proceeds of approximately \$131.6 million, 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 and we received cash proceeds of approximately \$118.4 million, net of underwriting discounts and commissions and offering costs paid by us. In June 2016, we issued \$172.5 million aggregate principal amount of 1.75% convertible senior notes due 2021 (the 2021 Notes) in a registered underwritten public offering for total net proceeds, after deducting transaction costs, of approximately \$166.2 million.

In November 2016, we filed a lawsuit for patent infringement against Boston Scientific, asserting that Boston Scientific is infringing our patents covering inventions related to our HF10 therapy and the Senza system. In December 2016, Boston Scientific, filed its own lawsuit alleging that we infringed Boston Scientific's patents covering technology related to stimulation leads, batteries and telemetry units. Each of the lawsuits seek preliminary and permanent injunctive relief against further infringement as well as damages and attorney fees. In relation to our defense of Boston Scientific's allegations, we filed three petitions for inter partes review at the U.S. Patent and Trademark Office on July 21, 2017, and one petition for inter partes review on July 31, 2017, challenging certain asserted claims of Boston Scientific's patents. We believe pursuing our lawsuit and defending ourselves against Boston Scientific's lawsuit will require significant cash resources over the immediate and near long term.

Important Factors Affecting our Results of Operations

We believe that the following factors have impacted, and we expect will continue to impact, our results of operations.

Importance of Physician Awareness and Acceptance of Senza

We continue to invest in programs to educate 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. Further, 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.

Reimbursement and Coverage Decisions by Third-Party Payors

Healthcare providers in the United States generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to cover and reimburse all or part of the cost of Senza and the related implant procedure for patients. The revenue we are able to generate from sales of Senza depends in large part on the availability of reimbursement from such payors. While we currently have a favorable reimbursement decision from federal Medicare, decisions of coverage and reimbursement for Senza and the related implant procedure from private health insurance providers can vary. In general, these decisions require that such payors perform analyses to determine if the procedure is medically necessary and if our technology is covered under their existing coverage policies. These payors may deny reimbursement if they determine that the device or procedure was not used in accordance with the payor's coverage policy, is subject to individual plan benefit limitations or is investigational and/or experimental. A significant component of our commercial efforts include working with private payors to ensure positive coverage and reimbursement decisions for Senza. While favorable reimbursement decisions from federal Medicare and certain commercial payors, such as Aetna, Cigna, Humana and Kaiser, have contributed to our increase in revenue to date, certain regional Blue Cross Blue Shield plans have historically denied coverage for Senza on the basis that high-frequency neuromodulation is investigational and/or experimental. We continue to engage in efforts to educate payors on the advantages of HF10 therapy, and as a result of these efforts, the Blue Cross Blue Shield Association updated their policy earlier this year, stating that high-frequency stimulation "results in a meaningful improvement in net health outcomes." Although the largest commercial payors and federal Medicare cover Senza, there can be no assurance that all private health insurance plans will cover the product. A significant number of negative coverage and reimbursement decisions by private insurers may impair our ability or delay our ability to grow our revenue.

Inventory Buildup and Supply Chain Management

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, since our commercial launch of Senza in the United States, we have continued to add suppliers to fortify our supply chain and we have substantially increased our levels of inventory. As a result, we have incurred significant uses of cash associated with the increases in our inventory, which includes 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 for the nine months ended September 30, 2017 and the year ended December 31, 2016, wherein we recorded a write down of inventory of \$3.4 million and \$3.7 million, respectively. Further, the manufacturing process for Senza requires lengthy lead times, during which components may become obsolete. We may also over- or under-estimate the quantities of required components, 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. For example, in early 2017, we commenced a controlled commercial launch of Surpass, our surgical lead product, and we

are currently investing in product improvements to Senza, including enhanced MRI capabilities and a next generation IPG. While R&D and clinical testing are time consuming and costly, we believe expanding into new indications, implementing product improvements and continuing to demonstrate HF10 efficacy, safety and cost effectiveness through clinical data are all critical to increasing the adoption of HF10 therapy.

Significant Investment in U.S. Sales Organization

We are continuing to make significant investments in building our U.S. commercial infrastructure and recruiting and training our U.S. sales force. 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. 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. As we gain U.S. market share, we expect that growth rates will moderate.

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 Senza, where the bidding processes are only open at certain periods of time, and we may not be successful in the bidding process.

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

Our revenue from international markets has increased from \$18.2 million for the year ended December 31, 2012 to \$55.2 million for the year ended December 31, 2016. 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. Despite our growth in international markets, international revenue was negatively impacted by the appreciation of the U.S. dollar. Further, due to governmental reimbursement 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.

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 condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. 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, 2017.

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. This type of product sales are billed to, and paid by, the hospitals and medical facilities as part of their normal payment processes, with payment received by us in the form of an electronic transfer, check or credit card payment. Product sales to distributors are billed to and paid by the distributors as part of their normal payment processes, with payment received by us in the form of an electronic transfer.

Revenue from sales of Senza fluctuate based on the selling price of the system, as the average sales price of a system varies geographically, and based on the mix of sales by geography. 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. Additionally, around holidays, the impact of the

buying patterns and implant volumes of hospitals and medical facilities, and third-party distributors may vary. In addition, in the second quarter of 2015, we commenced commercial sales of Senza in the United States and recorded revenue of approximately \$173.3 million and \$24.4 million for the years ended December 31, 2016 and 2015, respectively, for sales in the United States. We anticipate that our total revenue will increase as we continue our commercialization in the United States.

Cost of Revenue

We utilize contract manufacturers 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 the 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 expense, and sales, general and administrative (SG&A) expense. Personnel costs are the most significant component of operating expenses and consist primarily of salaries, bonus incentives, benefits, stock-based compensation and sales commissions. We expect operating expenses to increase in absolute dollars, as we continue to invest in growing 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 such as chronic upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. 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.

In the last two years, we significantly increased the size of our sales presence internationally and increased marketing spending to generate sales opportunities. Additionally, we have made substantial investments in our U.S. commercial infrastructure to support our commercialization efforts in the United States. We expect SG&A expenses to continue to increase as we build up our sales and marketing personnel to support commercialization of Senza in the United States, continue to increase the size of our sales and marketing organizations and increase our international presence and develop and assist our channel partners.

Our administrative expenses have increased compared to the same period in the prior year. During 2017, we have experienced a significant increase in legal expenses associated with our pending intellectual property litigation with Boston Scientific, and we anticipate continued expenses associated with these legal activities. We expect our administrative expenses will continue to increase as we increase our headcount and expand our facility and information technology to support our growing operations. Additionally, we continue to incur significant 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 (the Sarbanes-Oxley Act) as a large accelerated filer, director and officer insurance premiums and investor relations costs associated with being a growing 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 and the amortization of debt discount and debt issuance costs.

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 consists primarily of income taxes in foreign jurisdictions in which we conduct business as well as states where we have determined we have state nexus. We maintain a full valuation allowance for our deferred tax assets including net operating loss (NOL) carryforwards and R&D credits and other tax credits.

Allowance for Doubtful Accounts

We make estimates as to the overall collectability of accounts receivable and provide an allowance for accounts receivable considered uncollectible. We specifically analyze accounts receivable based on historical bad debt experience, customer concentrations, customer credit-worthiness, the age of the receivable, current economic trends, and changes in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. We record the adjustment in general and administrative expense.

Consolidated Results of Operations

Comparison of the three months ended September 30, 2017 and 2016

Revenue, Cost of Revenue, Gross Profit and Gross Margin

	Three Months Ended September 30,		
	2017	2016	Change
(in thousands)			
Revenue	\$82,256	\$60,922	\$21,334
Cost of revenue	24,316	19,235	5,081
Gross profit	\$57,940	\$41,687	\$16,253
Gross margin	70%	68%	2%

Revenue. Revenue increased to \$82.3 million in the three months ended September 30, 2017 from \$60.9 million in the three months ended September 30, 2016, an increase of \$21.3 million, or 35%. The revenue increase was primarily due to a period over period increase of Senza system sales in the United States, which was \$66.3 million in the three months ended September 30, 2017, compared to \$47.2 million in the three months ended September 30, 2016, as well as continued adoption of the Senza system in our international markets.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased to \$24.3 million in the three months ended September 30, 2017 from \$19.2 million in the three months ended September 30, 2016, an increase of \$5.1 million, or 26%. This was primarily due to a \$5.6 million increase in the costs of manufactured product components as sales volumes increased in the most recent period, offset by a decrease of \$0.8 million in charges related to inventory-related writedowns. Gross profit increased to \$57.9 million in the three months ended September 30, 2017 from \$41.7 million in the three months ended September 30, 2016, an increase of \$16.3 million, or 39%. Gross profit as a percentage of revenue, or gross margin, increased to 70% in the three months ended September 30, 2017, compared to 68% in the three months ended September 30, 2016. The gross margin increase is primarily attributed to a decrease in charges related to inventory-related writedowns.

Operating Expenses

Three Months Ended September 30,				
2017		2016		Change
Amount	% of	Amount	% of	

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	Total		Total		Amount
	Revenue		Revenue		
(in thousands)					
Operating expenses:					
Research and development	\$9,381	11%	\$7,923	13%	\$1,458
Sales, general and administrative	52,977	64%	35,636	58%	17,341
Total operating expenses	\$62,358	76%	\$43,559	71%	\$18,799

Research and Development Expense. R&D expense increased to \$9.4 million in the three months ended September 30, 2017 from \$7.9 million in the three months ended September 30, 2016, an increase of approximately \$1.5 million, or 18%. The increase in R&D expense reflects an increase in headcount and related personnel and consulting costs of \$1.5 million.

Sales, General and Administrative Expense. SG&A expense increased to \$53.0 million in the three months ended September 30, 2017 from \$35.6 million in the three months ended September 30, 2016, an increase of \$17.3 million, or 49%. This increase was primarily due to an increase in personnel costs of \$10.6 million in connection with an increase in headcount to support our continued U.S. commercial launch and increased training and conference-related expense of \$1.1 million. Additionally, there was a net increase

in professional expenses, primarily associated with intellectual property litigation legal fees of \$4.6 million incurred in the three months ended September 30, 2017.

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

	Three Months Ended		
	September 30,		
	2017	2016	Change
(in thousands)			
Interest income	\$808	\$556	\$ 252
Interest expense	(2,497)	(2,381)	(116)
Other income (expense), net	251	259	(8)
Provision for income taxes	374	448	(74)

Interest Income. Interest income increased to \$0.8 million in the three months ended September 30, 2017 from \$0.6 million in the three months ended September 30, 2016, primarily as a result of the increase in average investment balances as well as average investment return rates.

Interest Expense. Interest expense increased to \$2.5 million in the three months ended September 30, 2017 from \$2.4 million in the three months ended September 30, 2016, primarily as a result of the amortization of debt discount and debt issuance costs related to the issuance of the 2021 Notes in September 2016.

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, for which we recorded a gain of \$0.3 million in each of the three months ended September 30, 2017 and 2016.

Provision for Income Taxes. Income tax expense was \$0.4 million in each of the three months ended September 30, 2017 and 2016. The income tax expense for the three months ended September 30, 2017 was principally comprised of foreign income tax and state income tax. We continued 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, 2017 and 2016

Revenue, Cost of Revenue, Gross Profit and Gross Margin

	Nine Months Ended		
	September 30,		
	2017	2016	Change
(in thousands)			
Revenue	\$228,711	\$157,973	\$70,738
Cost of revenue	70,530	53,741	16,789
Gross profit	\$158,181	\$104,232	\$53,949
Gross margin	69%	66%	3%

Revenue. Revenue increased to \$228.7 million in the nine months ended September 30, 2017 from \$158.0 million in the nine months ended September 30, 2016, an increase of \$70.7 million, or 45%. The revenue increase was primarily due to a period over period increase of Senza system sales in the United States, which was \$182.4 million in the nine months ended September 30, 2017, compared to \$117.3 million in the nine months ended September 30, 2016, as well as continued adoption of the Senza system in our international markets.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased to \$70.5 million in the nine months ended September 30, 2017 from \$53.7 million in the nine months ended September 30, 2016, an increase of \$16.8 million, or 31%. This was primarily due to a \$13.5 million increase in the costs of manufactured product components as sales volumes increased in the most recent period, as well as an increase of \$0.9 million in charges related to inventory related write-downs. Gross profit increased to \$158.2 million in the nine months ended September 30, 2017 from \$104.2 million in the nine months ended September 30, 2016, an increase of \$53.9 million, or 52%. Gross profit as a percentage of revenue, or gross margin, increased to 69% in the nine months ended September 30, 2017, compared to 66% in the nine months ended September 30, 2016. The gross margin increase is primarily attributed to a decrease in the underlying cost of components sold.

Operating Expenses

	Nine Months Ended September 30,		2016		Change
	2017	% of	Amount	% of	
	Amount	Total	Revenue	Total	
(in thousands)					
Operating expenses:					
Research and development	\$27,617	12%	\$22,453	14%	\$5,164
Sales, general and administrative	157,971	69%	98,591	62%	59,380
Total operating expenses	\$185,588	81%	\$121,044	77%	\$64,544

Research and Development Expense. R&D expense increased to \$27.7 million in the nine months ended September 30, 2017 from \$22.5 million in the nine months ended September 30, 2016, an increase of \$5.2 million, or 23%. The increase in R&D expense reflects an increase in headcount and related personnel and consulting costs of \$4.9 million.

Sales, General and Administrative Expense. SG&A expense increased to \$158.0 million in the nine months ended September 30, 2017 from \$98.6 million in the nine months ended September 30, 2016, an increase of \$59.4 million, or 60%. This increase was primarily due to an increase in personnel costs of \$37.5 million in relation to an increase in headcount to support our continued U.S. commercial launch, increased training and conference-related expense of \$4.6 million, increased travel, marketing and associated supply costs of \$3.5 million and additional hardware, software, facilities and bad debt expense of \$2.6 million. Additionally, there was an increase in professional expenses, primarily associated with intellectual property litigation legal fees of \$11.0 million incurred in the nine months ended September 30, 2017.

Interest Income, Interest Expense and Other Income (Expense), Net, Loss on Extinguishment of Debt and Provision for Income Taxes

	Nine Months		
	Ended	2016	Change
	September 30,		
(in thousands)	2017	2016	
Interest income	\$2,264	\$1,066	\$1,198
Interest expense	(7,386)	(3,995)	(3,391)
Other income (expense), net	1,198	96	1,102
Loss on extinguishment of debt	—	(1,268)	1,268
Provision for income taxes	1,016	1,040	(24)

Interest Income. Interest income increased to \$2.3 million in the nine months ended September 30, 2017 from \$1.1 million in the nine months ended September 30, 2016, primarily as a result of the increase in average investment balances as well as average investment return rates.

Interest Expense. Interest expense increased to \$7.4 million in the nine months ended September 30, 2017 from \$4.0 million in the nine months ended September 30, 2016, primarily as a result of the amortization of debt discount and debt issuance costs related to the issuance of the 2021 Notes in September 2016.

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, for which we recorded a gain of \$1.3 million in the nine months ended September 30, 2017, compared to a gain of \$0.3 million in the nine months ended September 30, 2016.

Loss on Extinguishment of Debt. We repaid all outstanding obligation under our 2014 credit facility in the nine months ended September 30, 2016. The difference between the total payment to the lenders and the net carrying amount of the obligation recorded on our balance sheet was recorded as a loss on extinguishment of debt.

Provision for Income Taxes. Income tax expense was \$1.0 million in each of the nine months ended September 30, 2017 and 2016. The income tax expense for the nine months ended September 30, 2017 was principally comprised of foreign income tax and state income tax. We continued 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, we have financed our operations through private placements of preferred stock, the issuance of common stock in our IPO in November 2014 and our underwritten public offering in June 2015, borrowing under our credit facility, which we have subsequently repaid, and the issuance of convertible senior notes due 2021 in June 2016. At September 30, 2017, we had cash, cash equivalents and short-term investments of \$271.4 million. Based on our current operating plan, we expect that our cash and cash equivalents on hand, together with the anticipated funds from the collection of our receivables, will be sufficient to fund our operations through at least the next 12 months.

In June 2016, we paid the outstanding principal and repayment fees under our credit facility with Capital Royalty Partners and certain of its affiliates and terminated the credit facility. As of September 30, 2017, we do not have a credit facility in place.

We expect to incur continued expenditures in the future in connection with the expansion of our U.S. commercial infrastructure and sales force in connection with commercializing Senza in the United States. In addition, we intend to continue to make investments in the development of Senza and HF10 therapy for the treatment of other chronic pain conditions, including ongoing R&D programs and conducting clinical trials. Further, we expect to expend significant cash resources pursuing and defending our ongoing lawsuits with Boston Scientific. In order to further enhance our R&D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to raise additional funds.

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. Should we choose to raise additional capital, the requirements 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 cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including, in particular, the costs of enforcing our patent rights in the action we filed against Boston Scientific and in defending against Boston Scientific's action against us;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business;
- 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;
- 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, Boston Scientific and Abbott Laboratories (through its recent acquisition of St. Jude Medical), 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, or have access to, sufficient 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,	
	2017	2016
(in thousands)		
Net cash provided by (used in)		
Operating activities	\$(11,830)	\$(42,861)
Investing activities	5,438	(141,153)
Financing activities	8,605	140,091
Effect of exchange rate on cash flows	423	(380)
Net increase (decrease) in cash and cash equivalents	\$2,636	\$(44,303)

Cash Used in Operating Activities. Net cash used in operating activities was \$11.8 million in the nine months ended September 30, 2017, compared to \$42.9 million in the nine months ended September 30, 2016. In the nine months ended September 30, 2017, net cash used in operations was primarily a result of the net losses recorded during the period of \$32.3 million, as well as increases in inventories of \$13.4 million. These changes were partially offset by the recording of non-cash stock based compensation expense of \$18.9 million, increases in accounts payable and accrued liabilities of \$6.2 million, non-cash interest expense of \$5.1 million and write-downs of inventory of \$3.7 million. In the nine months ended September 30, 2016, net cash used in operations was primarily a result of the net losses recorded during the period of \$22.0 million, as well as increases in our prepaid expenses and other current assets of \$2.8 million and net decreases in our accounts payable and accrued liabilities of \$2.3 million. We also had increases in our accounts receivable of \$19.2 million and our inventories of \$14.0 million as we build inventories, both in relation to our continued U.S. commercial launch. These changes were partially offset by the recording of non-cash stock based compensation expense of \$10.4 million, write-downs of inventory of \$2.8 million and non-cash interest expense of \$2.0 million.

Cash Provided by (Used in) Investing Activities. Investing activities consisted primarily of changes in investment balances, including purchases and maturities of short-term investments. We had net proceeds of investments of \$7.9 million in the nine months ended September 30, 2017, compared to net purchases of investments of \$138.7 million in the nine months ended September 30, 2016, primarily from the proceeds received from the issuance of convertible debt. We additionally purchased \$2.5 million and \$2.4 million of property and equipment in the nine months ended September 30, 2017 and 2016, respectively.

Cash Provided by Financing Activities. Cash provided by financing activities was \$8.6 million in the nine months ended September 30, 2017 due to cash received from the exercise of options to purchase shares of common stock. Cash provided by financing activities was \$140.1 million in the nine months ended September 30, 2016. The majority of this cash was provided by the issuance of convertible debt of \$172.5 million. Additionally, we received proceeds of \$5.2 million from the issuance of common stock from stock option exercises. The cash received from these activities was offset by a net \$12.0 million cost of convertible note hedge and warrant transactions, which included the \$45.1 million purchase of convertible note hedges and proceeds of \$33.1 million related to the sale of warrants. Convertible debt issuance costs were \$6.2 million, and \$19.5 million was used in relation to the repayment of the credit facility.

Contractual Obligations and Commitments

We have lease obligations consisting of operating leases for our principal offices, which expire as set forth below, and for our warehouse space that expire in 2022, as well as for office space in Switzerland that expire in 2019.

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 December 2016, we entered into a first amendment to the lease for an additional approximately 50,000 square feet of office space adjacent to the premises under the original lease (the Expansion Premises) with initial annual payments of \$1.2 million, increasing to \$2.9 million in the final year of the amended lease term. The lease for the Expansion Premises commences on the earlier of the following dates (the Commencement Date): (i) the date we commence business operations in the Expansion Premises or (ii) the date upon which the landlord for the Expansion Premises substantially completes certain improvements to, and permitting for, the Expansion Premises. The first amendment also extends the lease term for the original premises to terminate on the same date as the amended lease, which is the last day of the calendar month following the date that is 84 months after the Commencement Date. Under the first amendment, if we are unable to move into the Expansion Premises before the Scheduled Delivery Date, as defined in the amendment, we may terminate the lease for the Expansion Premises. In April 2017, we entered into a second amendment to the lease for a temporary space for a period beginning in May 2017

and ending on the Commencement Date of the Expansion Premises. As of September 30, 2017, the Commencement Date of the Expansion Premises has not occurred. See Note 5, Commitments and Contingencies, to the condensed consolidated financial statements for additional information.

In August 2014, we entered into a facility lease for warehouse space beginning on August 21, 2014 through May 31, 2015. In March 2015, we extended our warehouse lease through February 2017, at which time the lease terminated.

In February 2017, we entered into a separate non-cancellable facility lease for warehouse space beginning March 1, 2017 through February 28, 2022, under which we are obligated to pay approximately \$0.4 million in lease payments over the term of the lease.

We have entered into supply agreements with certain of our suppliers that required certain minimum annual purchase agreements. As of September 30, 2017, we had minimum annual purchase commitments \$2.3 million remaining due in 2017, \$5.7 million due in each of 2018 and 2019, \$5.6 million due in 2020 and \$5.5 million due in 2021.

As of September 30, 2017, our contractual obligations related to the 2021 Notes are interest payments of \$1.5 million remaining in 2017 and \$3.0 million due each year from 2018 through 2020, as well as payments in interest and principal totaling \$174.0 million due in 2021.

Off-Balance Sheet Arrangements

Through September 30, 2017, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. For information regarding indemnification obligations, refer to Note 5 to the condensed consolidated financial statements within this report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

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

We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of September 30, 2017, we had cash and cash equivalents of \$44.0 million, consisting of cash and money market funds, and short-term investments of \$227.3 million, consisting of commercial paper and corporate notes. We maintained investments in money market funds that were not federally insured in the nine months ended September 30, 2017 and additionally held cash in foreign banks of approximately \$3.4 million at September 30, 2017 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, a portion of our revenue and 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 gain of \$1.3 million in the nine months ended September 30, 2017 and gains of \$0.3 million in the nine months ended September 30, 2016. A hypothetical 10% favorable or unfavorable change in the weighted average foreign exchange rates for the three months ended September 30, 2017 would have affected the Company's net loss by approximately 18%. 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 nor changes in prices had a significant impact on our results of operations for any periods presented in our consolidated financial statements.

Market Risk and Market Interest Risk

In June 2016, we issued \$172.5 million aggregate principal amount of 1.75% convertible senior notes due 2021. The fair value of our convertible senior notes is subject to interest rate risk, market risk and other factors due to the convertible feature. The fair value of the convertible senior notes will generally increase as our common stock price increases and will generally decrease as our common stock price declines in value. The interest and market value changes affect the fair value of our convertible senior notes but do not impact our financial position, cash flows or results of operations due to the fixed nature of the debt obligation. Additionally, we carry the convertible senior notes at face value less unamortized discount on our balance sheet, and we present the fair value for required disclosure purposes only.

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, 2017, the end of the period covered by this Quarterly Report. 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 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

On November 28, 2016, we filed a lawsuit for patent infringement against Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, “Boston Scientific”). The lawsuit, filed in the United States District Court for the Northern District of California, asserts that Boston Scientific is infringing our patents covering inventions relating to our Senza system and HF10 therapy. The lawsuit seeks preliminary and permanent injunctive

relief against further infringement as well as damages and attorney's fees.

On December 9, 2016, Boston Scientific filed a patent infringement lawsuit alleging our manufacture, use and sale of the Senza system infringes certain of Boston Scientific's patents covering SCS technology related to stimulation leads, rechargeable batteries and telemetry. The lawsuit, filed in the United States District Court for the District of Delaware, seeks unspecified damages and attorney's fees, as well as preliminary and permanent injunctive relief against further infringement. In relation to this lawsuit, on July 21, 2017, we filed two petitions for inter partes review of U.S. Patent No. 6,895,280 (the '280 patent) and one petition for inter partes review of U.S. Patent No. 7,437,193 (the '193 patent) at the U.S. Patent and Trademark Office challenging certain asserted claims of the '280 patent and the '193 patent, respectively. We also filed a petition for inter partes review of U.S. Patent No. 7,587,241 (the '241 patent) at the U.S. Patent and Trademark Office on July 31, 2017 challenging certain asserted claims of the '241 patent.

We are, and may from time to time continue to be, involved in various legal proceedings of a character normally incident to the ordinary course of our business, including several pending European patent oppositions at the European Patent Office initiated by our competitors Medtronic and Boston Scientific, which we do not believe to be material to our business and consolidated financial statements at this stage.

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 Quarterly Report, 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 have no assurance that we will achieve profitability. In May 2015, the FDA approved our PMA to market Senza in the United States and we commenced commercial sales in the United States in mid-2015. We expect to continue to incur losses as we build our U.S. commercial sales force and continue 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 \$32.3 million for the nine months ended September 30, 2017 and net losses of \$31.8 million and \$67.4 million for the years ended December 31, 2016 and 2015, respectively. As of September 30, 2017, our accumulated deficit was \$253.5 million. Our prior losses have had, and will continue to have, 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. For example, we have recently filed a complaint against Boston Scientific alleging patent infringement, and Boston Scientific Corporation followed by filing a complaint against us alleging patent infringement. These lawsuits may result in substantial legal expenses. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We are substantially dependent on continued market acceptance in the United States for our HF10 therapy, and the failure of our HF10 therapy to continue to gain 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. Prior to mid-2015, our revenue was derived nearly entirely from sales of Senza in Europe and Australia. Although we received approval of our PMA in May 2015, we are still in the relatively early stages of our commercialization efforts in the United States and have a limited history of commercializing our product in the United States. We have incurred, and anticipate we will in the future incur, significant costs, including costs to continue to build our sales force in order to sustain our commercial sales in the United States. If we are unable to continue 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 Senza. Because we do not have any other products currently in development, if we are unsuccessful in our continuing efforts to commercialize 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 also have relatively limited experience engaging in commercial activities and limited established relationships with physicians and hospitals as well as third-party suppliers on whom we depend for the manufacture of our product. We may be unable to gain broader market acceptance in the countries in which we have already begun to commercialize Senza, including 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 continue to gain market acceptance of our product, 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.

We are currently, and 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 grow sales of our Senza system or commercialize future products, if any. 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, including the pending lawsuit filed by Boston Scientific 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 broadly enough to prevent others from marketing products and services similar to ours. Similarly, others may simply design around our patents. For example, third parties may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the U.S. Patent and Trademark Office (USPTO), to determine priority of invention in the United States. There may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

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

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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. For example, in November 2016, we filed a complaint against Boston Scientific in order to enforce certain of our patents, and may in the future seek to enforce our patents or other proprietary rights against other potential infringements. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, including interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions, or other patent proceedings. We may also need to initiate infringement claims or litigation. Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

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

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

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

We must continue to educate physicians and demonstrate to them 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. 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. As a result, our success depends, in large part, on effectively marketing our HF10 therapy to physicians, including the results of our pivotal SENZA-RCT study. 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. 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. Educating physicians on the proper use of Senza is critical to the success of our commercialization efforts. If we are not successful in educating physicians and convincing them 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 receiving support of our products from 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. It is also 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.

Our competitors are large, well-established companies with substantially greater resources than we have 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 have. We estimate the existing global SCS market to be approximately \$1.6 to \$1.8 billion, 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 work to increase our market position and penetration 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, 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 (the '102 patent), which the Patent Trial and Appeals Board (PTAB) at the USPTO denied in November 2015, and, in December 2016, filed another lawsuit against us in the U.S. District Court for the District of Delaware alleging that we infringed their patents covering technology related to stimulation leads, batteries and telemetry units. We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States.

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

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

If 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 continue to intensify as we grow our presence in the U.S. market. For example, our major competitors, Medtronic, Boston Scientific and Abbott Laboratories, which recently acquired St. Jude Medical, each has approved neuromodulation systems in at least the United States, Europe, and Australia and have been established for several years. In addition, in October 2016, St. Jude Medical (now a part of Abbott Laboratories) obtained FDA approval for a SCS system that offers an alternate low frequency waveform called BurstDR, and in February 2016, the company gained approval for a neuromodulation system that stimulates the dorsal root ganglion for treatment of focal pain and complex regional pain syndrome. Additionally, we believe that Boston Scientific is in the later stages of a randomized clinical trial of high-frequency SCS therapy. In addition to these major competitors, we may also face competition from smaller companies such as Nuvectra, Saluda and Stimwave. Additionally, there are other emerging competitors 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;

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greater financial and human resources for product development, sales, and marketing; and greater experience in and resources for conducting R&D, 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 we do, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than we do 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 we are in these matters, our business may be harmed.

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.

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.

We believe that SCS procedures using Senza are adequately described by existing CPT, HCPCS II and ICD-10-CM codes for the implantation of spinal cord stimulators and related leads performed in various sites of care, although such codes generally do not specifically describe procedures using either low-frequency or high-frequency stimulation. In the United States, CMS has approved a transitional pass-through payment for High-Frequency Stimulation under the Medicare hospital outpatient prospective payment system effective as of January 1, 2016. This pass-through payment (HCPCS C1822) for HF10 therapy is in addition to the established reimbursement for spinal cord stimulation devices; however, this additional pass-through payment is proposed to end on December 31, 2017.

We believe that some of our target customers may be unwilling to adopt Senza over more established or lower-cost therapeutic alternatives already available or that may subsequently become available. Further, any decline in the amount payors are willing to reimburse our customers for SCS procedures using Senza could make it difficult for new customers to adopt Senza and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. While favorable reimbursement decisions from federal Medicare and certain commercial payors, such as Aetna, Cigna, Humana and Kaiser, have contributed to our increase in revenue to date, certain regional Blue Cross Blue Shield plans have historically denied coverage for Senza on the basis that high-frequency neuromodulation is investigational and/or experimental. We continue to engage in efforts to educate payors on the advantages of HF10 therapy, and as a result of these efforts, the Blue Cross Blue Shield Association updated their policy earlier this year, stating that high-frequency stimulation “results in a meaningful improvement in net health outcomes.” However, there can be no assurance that all private health insurance plans will cover the product. A significant number of negative coverage and reimbursement decisions by private insurers may impair our ability or delay our ability to grow our revenue. 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 develop and retain an effective direct sales force in the United States, our business could suffer.

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 continue 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, or 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, our new sales representatives will usually be subject to restrictive covenants with their former employers, including non-competition, non-solicitation and/or confidentiality provisions. As a result, 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. We and certain of our new sales representatives have been, continue to be, and may in the future be, subject to allegations that these new hires have violated the non-competition clauses, been improperly solicited or divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business.

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 from international markets has increased from \$18.2 million for the year ended December 31, 2012 to \$55.2 million for the year ended December 31, 2016 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 our revenue to stay stable in these international markets and not grow at the rate it did historically. Furthermore, given our relatively recent commercialization in the United States, we have not developed an extended history of payment and therefore we may encounter difficulties in collecting receivables related to our U.S. sales.

In addition, the characteristics of these international 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 markets 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.

If we fail to maintain FDA 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. While we have received FDA approval of our Senza PMA application, 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.

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In addition, 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 warning letters 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 upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. 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.

Traditional SCS has been available for almost 50 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 and in the United States since May 2015. Because we have a relatively limited commercial track record compared to our competitors and Senza has been implanted in patients for significantly less time than our competitors' products, physicians may be slower to adopt or recommend Senza. Further, while we believe our international commercial experience and relatively recent U.S. 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.

In 2010, we began selling Senza in Europe and, in August 2011, we began selling Senza in Australia. As of September 30, 2017, 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 United States and foreign governmental trade, import and export and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors, or any of our third-party suppliers;
- reduced or varied protection for intellectual property rights in some countries;
- pricing pressure that we may experience internationally;
- foreign currency exchange rate fluctuations;
- a shortage of high-quality sales people and distributors;

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- 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 international 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.

The enactment of legislation in the United States implementing changes in taxation or the adoption of other U.S. tax reform or trade policies may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. Among other things, proposed tax reforms in the United States may result in significant changes to current U.S. tax rules and regulations. These potential changes may have an adverse effect on our business, financial conditions and results of operations.

We are unable to predict whether such changes in tax law will occur and, if so, the impact of such changes. Proposals for tax and other reform which could have significant (and adverse) effects on us are under evaluation by various legislative and administrative bodies, making it nearly impossible to accurately determine the overall impact of such proposals. Changes in U.S. tax or other laws (including changes to or new regulations promulgated by the U.S. Internal Revenue Service and the U.S. Department of the Treasury) and U.S. trade policies could materially and adversely impact our effective tax rate, increase our costs and reduce the competitiveness of our products.

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;

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- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of Senza, impacting our ability to maintain our PMA approval, or cause delays in shipment, impacting our ability to meet demand in the 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, European Economic Area (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 leads, lead extenders, surgical leads, neurostimulator components and telemetry modules. Our ability to supply Senza commercially depends, in part, on our ability to obtain a supply of these components that have 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 some 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 or otherwise. 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 the needs of 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. In addition, from time to time, certain of our suppliers experience interruptions and variances in their manufacturing processes, including suppliers of our leads and batteries. Because we are reliant on these single source suppliers, we are particularly susceptible to supply shortages and, if one of our suppliers were to experience an ongoing or continued manufacturing problem, and, in particular, our leads and battery

suppliers, our ability to meet our forecasted commercial demand could be materially and negatively impacted.

If our third-party suppliers fail to deliver the required commercial quantities of materials, or the level of services we require, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued commercialization of Senza would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

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

We believe that establishing and strengthening the Nevro and Senza brands is critical to achieving widespread acceptance of HF10 therapy, particularly because of the highly competitive nature of the market for SCS products. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product for successful treatment of chronic leg and back pain. Additionally, we believe the quality and reliability of our product is critical to building physician support of this new therapy in the United States and any negative publicity regarding the quality or reliability of Senza could significantly damage our reputation in the market. Further, given the established nature of our competitors, and our relatively recent commercial launch 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, improving manufacturing efficiency or increasing 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 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 relatively recently commercially launched our 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 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 European Union (EU), from time to time, certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may 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 the 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 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 Medical Device Amendments of 1976 to the FDCA 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 Senza 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 upper limb and neck pain, painful neuropathies and non-surgical refractory back pain. We will likely need to conduct additional clinical studies in the future to support regulatory approval for the use of Senza to treat some of 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;

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

• difficulties or delays associated with establishing additional clinical sites;

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

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

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- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the statistical endpoints are not met.

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

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

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

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

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

In addition, many of our employees have become, or will soon become, vested in a substantial amount of Company stock or be able to exercise a substantial 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 other employees in the neuromodulation and medical device industry are subject to strict non-competition, non-solicitation and/or confidentiality agreements with their employers, including our main competitors Medtronic plc, Boston Scientific and Abbott Laboratories (which recently acquired St. Jude Medical). Our competitors may allege breaches of, and seek to enforce, such non-competition, non-solicitation and/or

confidentiality agreements or initiate litigation based on such agreements, particularly now that we have entered the U.S. market. Such litigation, whether or not meritorious, may impede our ability to attract, hire or utilize executive officers and other key employees who have been or are currently employed by our competitors.

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

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing,

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

Risks Related to Intellectual Property

We currently are, and 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. For example, on December 9, 2016, Boston Scientific filed a patent infringement lawsuit alleging our manufacture, use and sale of the Senza system infringes certain of Boston Scientific's patents covering technology related to stimulation leads, batteries and telemetry units. 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, Boston Scientific and Abbott Laboratories (which recently acquired St. Jude Medical), 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 non-infringement and/or invalidity positions with respect to third-party patents, which may or not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

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

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

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

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;

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- find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory clearance;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; and/or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. In particular, on November 28, 2016, we filed a lawsuit for patent infringement against units of Boston Scientific asserting that Boston Scientific is infringing our patents covering inventions relating to our Senza system and HF10 therapy. For more information, see the section titled “Legal Proceedings” included under Part II, Item 1 of this Quarterly Report. 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 and the value of the 1.75% convertible senior notes due 2021 (the 2021 Notes). 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. For example, two of our competitors, Boston Scientific and Medtronic, have filed oppositions in the EU with respect to certain of our patents. Defending our position in proceedings such as these will require management’s time and attention, as well as financial costs. Given the competitive environment in which we operate, we expect additional challenges to our intellectual property portfolio as we continue 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, which could invite increased competition thereby materially harming our business.

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

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 and may affect patent litigation. The changes also switched the United States patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the

Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

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

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

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, many of our executive officers and key employees, as well as our Chairman of the Board, have worked for our major competitors (or companies acquired by these competitors), which include Boston Scientific, Medtronic and Abbott Laboratories (which recently acquired St. Jude Medical). Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such

technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

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

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

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

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

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, 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 choose, or need, 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 otherwise grow our business and continue to operate as 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, as well as the growth of our 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 or indications we may choose to pursue. These expenditures will also include costs associated with manufacturing and supply as well as marketing and selling Senza in the United States and elsewhere, and any other future products approved for sale, R&D, 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 additional chronic pain indications and develop technology complementary to our current product. In order to further enhance our R&D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to seek additional funds. If we are unable to raise funds on favorable terms, or at all, the long-term growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the costs of commercializing Senza in the United States and elsewhere, including costs associated with product sales, marketing, manufacturing and distribution;
 - the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including, in particular, the costs of enforcing our patent rights in the action we filed against Boston Scientific and in defending against Boston Scientific's action against us;
- the R&D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue;
- whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business;
- 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;
- 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 the 2021 Notes and could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates, or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively and the growth of our business will be harmed.

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

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

- physician and payor acceptance of Senza and our HF10 therapy;
- the timing, expense and results of our commercialization efforts in the United States and elsewhere, R&D activities, clinical trials and regulatory approvals;
- fluctuations in our expenses associated with inventory buildup or write-downs from analyzing our inventory for obsolescence or conformity with our product requirements;
- difficulties in collecting receivables related to our sales in the United States;
 - fluctuations in the expenses related to pursuing and defending our ongoing lawsuits with Boston Scientific;
- 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;

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• 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 obsolescence comparatively. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire and its value would become impaired and we would be required to record an impairment charge. 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 obsolescence risk. In the event that a substantial portion of our inventory becomes obsolete or expires, or in the event we experience a supply chain imbalance as described above, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

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.

A portion of our 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, British Pounds 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 and the value of the 2021 Notes 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 believe 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, 2016, we had federal and state NOLs of \$224.7 million and \$77.3 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 begin to expire in 2017 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:

- 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 expand the potential indications for which Senza is approved or 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:

- FFDCA 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.

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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation remains unclear. We could also be subject to new international, federal, state or local regulations that could affect our R&D 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the “two-for-one” provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the “two-for-one” provisions may apply not only to agency regulations, but also to significant agency

guidance documents. Moreover, on February 24, 2017, an Executive Order was issued requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation and the In-Vitro Diagnostic Medical Devices Regulation, which repeal and replace the Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable,

i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States.

The Medical Devices Regulation and In-Vitro Diagnostic Devices Regulation, among other things, are intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation. However, the Medical Devices Regulation, which is the regulation directly applicable to our products, will only become fully applicable three years following entry into force. Once applicable, the Medical Devices Regulation will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an impact on the way we conduct our business in the EEA.

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.

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 the 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 sale, advertising and promotion of our products is currently subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices (the EU Medical Devices Directive). After May 25, 2020, the EU Medical Devices Directive will be replaced by the EU Medical Device Regulation, which restructures the EU’s medical device regulatory framework and may impose increased compliance obligations for us to access the EU market. We are also subject to Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. EEA Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products and may impose limitations on our promotional activities with healthcare professionals.

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

The FDA, EEA Competent Authorities and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use, or 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 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 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.

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.

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; 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, 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;

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

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 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 included, 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. Subsequently, a two-year moratorium was implemented effective January 1, 2016, such that medical device sales in 2016 and 2017 are exempt from the medical device excise tax. Unless there is further legislative action, the tax will be automatically reinstated for sales of medical devices on or after January 1, 2018. If it were to be reinstated, this excise tax would result 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 ACA, 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. These changes included an aggregate reduction in Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 (MACRA), repealed the formula by which Medicare

made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For instance, on January 20, 2017, President Trump signed an Executive Order stating it is his Administration's policy to seek prompt repeal of the ACA and directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 12, 2017, President Trump signed another Executive Order directing federal agencies to expand access to alternative health plans and health reimbursement arrangements, and the U.S. Department of Health and Human

Services announced that it would immediately cease making Cost-Sharing Reduction (CSR) payments to issuers of qualified health plans. Congress also could consider subsequent legislation to replace elements of the ACA that may be repealed, or could appropriate funding for CSR payments. At this time, the full effect that the ACA, the Executive Orders, the halting of CSR payments, and any subsequent legislation would have on our business remains unclear. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payor insurance plans could impact demand for our product.

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 products or additional pricing pressures.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, additional chronic pain indications for Senza 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 expand the chronic pain indications for which Senza may be used and/or develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for expanded indications or 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 Securities

Our stock price may be volatile and as a result our stockholders may not be able to resell shares of our common stock at or above the price they paid and such volatility may also adversely impact the value of the 2021 Notes.

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 Quarterly Report and others such as:

- delays or setbacks in the commercialization of Senza or the expansion of indications for which Senza is approved;
- 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 obsolescence 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;

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- 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, including our pending lawsuits with Boston Scientific;
- 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;
- trading activity in our common stock by the option counterparties to our convertible note hedge transactions to unwind or modify their hedge positions;
- 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.

Because the 2021 Notes are convertible into shares of common stock, volatility or depressed market prices of our common stock could have a similar effect on the value of the 2021 Notes. Holders who receive shares of our common stock upon conversion of the 2021 Notes will also be subject to the risk of volatility and depressed market prices of our common stock. Similarly, the liquidity of the trading market in the 2021 Notes and the market price quoted for the 2021 Notes, may be adversely affected by changes in the overall market for this type of security and by changes in our financial performance or prospects or in the prospects for companies in our industry generally.

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 and the value of the 2021 Notes. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the 2021 Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Recent and future regulatory actions and other events may adversely affect the value and liquidity of the 2021 Notes.

We expect that many investors in, and potential purchasers of, the 2021 Notes will employ, or seek to employ, a convertible arbitrage strategy with respect to the 2021 Notes. Investors would typically implement such a strategy by selling short the common stock underlying the 2021 Notes and dynamically adjusting their short position while

continuing to hold the 2021 Notes. Investors

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may also implement this type of strategy by entering into swaps on our common stock in lieu of or in addition to short selling the common stock.

The SEC and other regulatory and self-regulatory authorities have implemented various rules and taken certain actions, and may in the future adopt additional rules and take other actions, that may impact those engaging in short selling activity involving equity securities (including our common stock). Such rules and actions include Rule 201 of SEC Regulation SHO, the adoption by the Financial Industry Regulatory Authority, Inc. and the national securities exchanges of a “Limit Up-Limit Down” program, the imposition of market-wide circuit breakers that halt trading of securities for certain periods following specific market declines, and the implementation of certain regulatory reforms required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the Dodd-Frank Act). Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, the 2021 Notes to effect short sales of our common stock, borrow our common stock or enter into swaps on our common stock could adversely affect the value and the liquidity of the 2021 Notes.

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 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 Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), and the Dodd-Frank Act, as well as rules and regulations subsequently implemented by the SEC and the NYSE, 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, our management and other personnel divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which has increased now that we are no longer an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). We continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we will incur in order to remain compliant with our public company reporting requirements 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.

If we are unable to 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 and the value of the 2021 Notes 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 provide a management report on internal control over financial reporting. 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. The process of designing and implementing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting are effective, or 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 and the value of the 2021 Notes 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.

The accounting method for convertible debt securities that may be settled in cash, such as the 2021 Notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options (ASC 470-20). Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the 2021 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the 2021 Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet, and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the 2021 Notes. As a result, we are required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2021 Notes to their face amount over the term of the 2021 Notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's non-convertible interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the value of the 2021 Notes.

In addition, under certain circumstances, convertible debt instruments (such as the 2021 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the 2021 Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the 2021 Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the 2021 Notes, then our diluted earnings per share would be adversely affected.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price and the value of the 2021 Notes 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 and the value of the 2021 Notes may decline.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price and the value of the 2021 Notes to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock and the value of the 2021 Notes could decline. As of September 30, 2017, we had outstanding a total of approximately 29.6 million shares of common stock and approximately 6.7 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 and the value of the 2021 Notes could decline.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

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- 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. The repurchase right under the 2021 Notes in connection with a fundamental change and any increase in the conversion rate in connection with a make-whole fundamental change could also discourage a potential acquirer.

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

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

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

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

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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;

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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. 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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

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Item 6. Exhibits

Exhibit Number	Description of Document	Incorporated by Reference			
		Form	Date	Number	Filed Herewith
3.1	<u>Amended and Restated Certificate of Incorporation.</u>	8-K	11/12/2014	3.1	
3.2	<u>Amended and Restated Bylaws.</u>	8-K	11/12/2014	3.2	
4.1	<u>Reference is made to Exhibits 3.1 through 3.2.</u>				
4.2	<u>Form of Common Stock Certificate.</u>	S-1/A	10/27/2014	4.2	
4.3	<u>Indenture, dated as of June 13, 2016, by and between the Company and Wilmington Trust, National Association.</u>	8-K	6/13/2016	4.1	
4.4	<u>First Supplemental Indenture, dated as of June 13, 2016, by and between the Company and Wilmington Trust, National Association.</u>	8-K	6/13/2016	4.2	
4.5	<u>Form of 1.75% Convertible Senior Note Due 2021.</u>	8-K	6/13/2016	4.3	
10.1	<u>Third Amendment to the Product Supply and Development Agreement, dated as of September 15, 2017, by and between the Company and EaglePicher Medical Power, LLC.</u>				X
10.2*	<u>First Amendment to the Manufacturing and Supply Agreement, dated as of September 30, 2017, by and between the Company and Vention Medical Design and Development, Inc.</u>				X
31.1	<u>Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).</u>				X
31.2	<u>Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).</u>				X
32.1**	<u>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)</u>				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X

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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

*Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the Securities and Exchange Commission.

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** 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.

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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 6, 2017 /s/ RAMI ELGHANDOUR
Rami Elghandour
Chief Executive Officer

(Principal Executive Officer)

Date: November 6, 2017 /s/ ANDREW H. GALLIGAN
Andrew H. Galligan
Chief Financial Officer

(Principal Financial and Accounting Officer)