

**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 March 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38701

SI-BONE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

26-2216351
(I.R.S. Employer
Identification Number)

471 El Camino Real, Suite 101, Santa Clara, California

(Address of principal executive offices)

95050

(Zip Code)

Registrant's telephone number, including area code: **(408) 207-0700**

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 every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the 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
Smaller reporting company

Accelerated filer
Emerging growth company

Non-accelerated filer

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 7(a)(2)(B) of the Securities Act.

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

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	SIBN	NASDAQ Global Market

The number of shares outstanding of the registrant's Common Stock, par value \$.0001 per share, was 24,563,506 as of May 6, 2019.

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In this Quarterly Report on Form 10-Q, “we,” “our,” “us,” “SI-BONE,” and “the Company” refer to SI-BONE, Inc. The SI-BONE logo and other trade names, trademarks or service marks of SI-BONE are the property of SI-BONE, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected properties, performance and impact on healthcare costs, the expected timeline for achievement of our clinical milestones, the timing of, and potential results from, clinical and other trials, marketing authorization from the U.S. Food and Drug Administration, or FDA, or regulatory authorities in other jurisdictions, coverage and reimbursement for procedures using our product candidates, if approved, research and development costs, timing of regulatory filings and feedback, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements include, but are not limited to, statements about the following:

- our expectation that, for the foreseeable future, a significant portion of our revenues will be derived from sales of the iFuse Implant System, or iFuse;
- our ability to expand our sales and marketing capabilities to increase demand for iFuse, expand geographically, and obtain favorable coverage and reimbursement determinations from third-party payors;
- our estimates of our market opportunity;
- developments or disputes concerning our intellectual property or other proprietary rights;
- competition in the markets we serve;
- our expectations of the reliability and performance of iFuse;
- our expectations of the benefits to patients, providers, and payors of iFuse;
- our reliance on a limited number of suppliers, including sole source suppliers, which may impact the availability of replacement instruments and materials;
- the factors we believe drive demand for iFuse and our ability to sustain or increase such demand;
- our ability to develop additional revenue opportunities, including new devices;
- our expectations regarding the benefits of the scope of protection we establish and maintain for intellectual property rights covering iFuse and any other device we may develop;
- our estimates regarding our costs and risks associated with our international operations and international expansion;
- our expectations regarding our ability to retain and recruit key personnel and expand our sales force;
- our expectations regarding acquisitions and strategic operations;
- our ability to fund our working capital requirements;
- our compliance with, and the cost of, federal, state, and foreign regulatory requirements;
- the factors that may impact our financial results; and

- anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements are based on management's current expectations, estimates, forecasts, and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this report may turn out to be inaccurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this report. These statements, like all statements in this report, speak only as of their date. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future, except as may be required by law.

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements

SI-BONE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,561	25,120
Short-term investments	102,748	97,103
Accounts receivable, net of allowance for doubtful accounts of \$262 and \$263, respectively	8,411	8,486
Inventory	3,516	3,343
Prepaid expenses and other current assets	2,161	1,990
Total current assets	129,397	136,042
Property and equipment, net	2,336	2,154
Other non-current assets	321	325
TOTAL ASSETS	\$ 132,054	138,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,811	\$ 2,146
Accrued liabilities and other	7,097	6,860
Total current liabilities	9,908	9,006
Long-term borrowings	39,028	38,963
Other long-term liabilities	363	360
TOTAL LIABILITIES	49,299	48,329
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 24,497,566 and 24,450,757 shares issued and outstanding, respectively	3	3
Additional paid-in capital	248,829	246,927
Accumulated other comprehensive income	445	439
Accumulated deficit	(166,522)	(157,177)
TOTAL STOCKHOLDERS' EQUITY	82,755	90,192
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 132,054	\$ 138,521

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

SI-BONE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenue	\$ 14,991	\$ 12,712
Cost of goods sold	1,526	1,048
Gross profit	13,465	11,664
Operating expenses:		
Sales and marketing	15,815	10,967
Research and development	1,683	1,206
General and administrative	4,766	2,408
Total operating expenses	22,264	14,581
Loss from operations	(8,799)	(2,917)
Interest and other income (expense), net:		
Interest income	744	62
Interest expense	(1,230)	(1,275)
Other expense, net	(60)	(71)
Net loss	(9,345)	(4,201)
Other comprehensive income (loss):		
Changes in foreign currency translation	(19)	(21)
Unrealized gain on marketable securities	25	—
Comprehensive loss	\$ (9,339)	\$ (4,222)
Net loss per share, basic and diluted	\$ (0.38)	\$ (1.17)
Weighted-average number of common shares used to compute basic and diluted net loss per share	24,390,648	3,593,658

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

SI-BONE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK
AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Three months ended March 31, 2019								
Balance at December 31, 2018	—	\$ —	24,450,757	\$ 3	\$ 246,927	\$ 439	\$ (157,177)	\$ 90,192
Issuance of common stock upon exercise of stock options, net of shares withheld	—	—	46,809	—	125	—	—	125
Stock-based compensation	—	—	—	—	1,871	—	—	1,871
Vesting of early exercised stock options	—	—	—	—	66	—	—	66
Additional accrual of IPO related cost	—	—	—	—	(160)	—	—	(160)
Foreign currency translation	—	—	—	—	—	(19)	—	(19)
Unrealized gain of marketable securities	—	—	—	—	—	25	—	25
Net loss	—	—	—	—	—	—	(9,345)	(9,345)
Balance at March 31, 2019	—	\$ —	24,497,566	\$ 3	\$ 248,829	\$ 445	\$ (166,522)	\$ 82,755
Three months ended March 31, 2018								
Balance at December 31, 2017	11,871,578	\$118,548	3,603,140	\$ 1	\$ 9,943	\$ 402	\$ (139,724)	\$ (129,378)
Issuance of common stock upon exercise of stock options	—	—	4,207	—	18	—	—	18
Stock-based compensation	—	—	—	—	391	—	—	391
Vesting of early exercised stock options	—	—	—	—	20	—	—	20
Foreign currency translation	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(4,201)	(4,201)
Balance at March 31, 2018	11,871,578	\$118,548	3,607,347	\$ 1	\$ 10,372	\$ 381	\$ (143,925)	\$ (133,171)

SI-BONE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (9,345)	\$ (4,201)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	193	168
Stock-based compensation	1,871	392
Change in fair value of redeemable convertible preferred stock warrants	—	79
Loss on sale and disposal of property and equipment	97	40
Amortization of debt discount	65	65
Short-term investment accretion	(479)	—
Changes in operating assets and liabilities		
Accounts receivable	87	233
Inventory	(165)	(221)
Prepaid expenses and other assets	(167)	(281)
Accounts payable	451	82
Accrued liabilities and other	314	(767)
Net cash used in operating activities	<u>(7,078)</u>	<u>(4,411)</u>
Cash flows from investing activities		
Purchases of short-term investments	(22,741)	—
Maturities of short-term investments	17,600	—
Purchases of property and equipment	(412)	(218)
Net cash used in investing activities	<u>(5,553)</u>	<u>(218)</u>
Cash flows from financing activities		
Proceeds from the exercise of stock options	125	20
Net cash provided by financing activities	125	20
Effect of exchange rate changes on cash and cash equivalents	(53)	(7)
Net decrease in cash and cash equivalents	<u>\$ (12,559)</u>	<u>\$ (4,616)</u>
Cash and cash equivalents at		
Beginning of period	25,120	22,408
End of period	<u>\$ 12,561</u>	<u>\$ 17,792</u>
Supplemental disclosure of non-cash information		
Vesting of early exercised stock options	\$ 66	\$ 18
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 140	\$ —
Public offering costs included in accounts payable	\$ 167	\$ —

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

1. The Company and Nature of Business

SI-BONE, Inc. (the “Company”) was incorporated in the state of Delaware on March 18, 2008 and is headquartered in Santa Clara, California. The Company is a medical device company that has pioneered a proprietary minimally invasive surgical implant system to fuse the sacroiliac joint for treatment of the most common types of sacroiliac joint disorders that cause lower back pain. The Company introduced its iFuse Implant System, or iFuse, in 2009 in the United States, in 2010 in certain countries in the European Union, and in 2015 in certain countries in the rest of the world.

Reverse Stock Split

In October 2018, the Company's board of directors and stockholders approved a 1-for-18 reverse stock split of the Company's common stock and redeemable convertible preferred stock, which was effected on October 4, 2018. The par value of the common stock and redeemable convertible preferred stock was not adjusted as a result of the reverse split. All issued and outstanding share and per share amounts of common stock, redeemable convertible preferred stock, stock options, and warrants included in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all periods presented.

Initial Public Offering

On October 16, 2018, the Company's Registration Statement on Form S-1 (File No. 333-227445) relating to the initial public offering (IPO) of its common stock was declared effective by the Securities and Exchange Commission (SEC). Pursuant to such Registration Statement, the Company sold 8,280,000 shares at an initial public offering price of \$15.00 per share for net proceeds of \$113.4 million to the Company, net of underwriting discounts and commissions and offering costs. Upon the closing of the IPO, the Company's outstanding shares of redeemable convertible preferred stock were automatically converted into an aggregate of 12,066,654 shares of common stock and the Company's outstanding warrants to purchase 156,550 shares of redeemable convertible preferred stock were automatically converted into warrants to purchase an aggregate of 160,657 shares of common stock, resulting in reclassification of the related redeemable convertible preferred stock warrant liability of \$1.2 million in additional paid-in-capital.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) and applicable rules and regulations of the Securities and Exchange Commission (“SEC”) regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2018 has been derived from the audited consolidated financial statements at that date but does not include all of the information required by GAAP for complete financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments that are necessary for a fair statement of the Company's consolidated financial information. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other interim period or for any other future year.

The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2018 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant accounting estimates and management judgments reflected in the consolidated financial statements include: fair value of assets and liabilities; analysis of the allowance for doubtful accounts; inventory valuation; valuation of deferred tax assets, including related valuation allowances; fair value of common stock and redeemable convertible preferred stock warrants; stock-based compensation; and useful lives of long lived assets. Estimates are based on historical experience, where applicable and other assumptions believed to be reasonable by the management. Actual results could differ from those estimates.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. There have been no material changes to these accounting policies.

JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company has elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies.

Segments

The chief operating decision makers for the Company are the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"). The CEO and the CFO review financial information presented on a consolidated basis, accompanied by information about revenue by geographic region, for purposes of evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level. Accordingly, the Company has determined that it has a single reportable and operating segment structure.

The Company derives substantially all of its revenue from sales to customers in the United States. Revenue by geography is based on billing address of the customer. No single country outside the United States accounts for more than 10% of the total revenue during the periods presented. Long-lived assets held outside the United States are immaterial. The table below summarizes the Company's revenue by geography (in thousands):

	Three Months Ended March	
	31,	
	2019	2018
Domestic	\$ 13,450	\$ 11,295
International	1,541	1,417
	\$ 14,991	\$ 12,712

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents are deposited with financial institutions in the United States and in Europe; the majority of the Company's cash and cash equivalents are deposited with a single financial institution in the United States. Deposits in this institution exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's revenue and accounts receivable are spread across a large number of customers, primarily in the United States, and no one customer accounts for more than 10% of total revenue or gross accounts receivable in any period presented.

Other Risks and Uncertainties

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, the ability to obtain adequate coverage and 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, in some cases single source suppliers. The Company currently has limited long term contracts with its key suppliers and is subject to risks such as manufacturing failures, non-compliance with regulatory requirements, price fluctuations, inability to properly meet demand and third-party supplier discontinuation of operations.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers, which required an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for fiscal years beginning after December 15, 2017 for public companies, and for fiscal years beginning after December 15, 2018, and interim periods beginning after December 15, 2019, for private companies. Early application is permitted. The standard permits the use of either the retrospective or cumulative effect transition method. In March 2016, the FASB issued ASU 2016-08, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, which relates 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. In November 2018, the FASB issued ASU 2018-18, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB’s revenue standard, Topic 606. These ASUs have the same effective date and transition date as ASU 2014-09.

The Company continues to evaluate the impact of adoption of the new standard on its accounting policies, processes, and system requirements and has assigned internal resources, in addition to the engagement of third party service providers, to assist in the evaluation. At this time, as it relates to product sales where the Company’s sales representative delivers the product at the point of implantation at hospital or other medical facilities, the Company expects revenue to continue to be recognized upon completion of the procedure and authorization by the customer. Additionally, the new standard requires the capitalization of costs to obtain a contract, primarily sales commissions, and amortization of these costs over the contract period or estimated customer life. The Company expects to continue expensing all sales commissions as incurred. Management will adopt the standard using the modified retrospective method for the fiscal year ending December 31, 2019.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires that lessee's recognize a right-of-use asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. A lease liability is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset is an asset that represents the lessee’s right to use, or control use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the adoption date. In July 2018, the FASB issued ASU 2018-10 and ASU 2018-11, which provides clarification on the narrow aspects of the guidance and provide an additional transition method to adopt the new leases standard. The new transition method allows an entity to recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In December 2018, FASB issued ASU 2018-20, which provides guidance and clarification with respect to lessor accounting associated with (i) certain taxes collected from lessees, (ii) certain lessor costs, and (iii) the recognition of variable payments for contracts with lease and non-lease components. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. The new guidance is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018 for public companies and beginning after December 15, 2019 for private companies. Early adoption is permitted for any interim or annual financial statements not yet issued. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing and operating leases) must apply a modified retrospective approach for all leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact of this standard on its consolidated financial statements and anticipates adopting the standard for the fiscal year ending December 31, 2020.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), which provides guidance on the following eight specific cash flow classification issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. Current GAAP does not include specific guidance on these eight cash flow classification issues. The amendments of this ASU are effective for reporting periods beginning after December 15, 2017 for public companies, and fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019 for private companies, with early adoption permitted. The Company has adopted this standard for the fiscal year ending December 31, 2019, which did not have any material impact on the Company’s consolidated financial statements.

SI-BONE, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public business entities, the amendments in Part I of this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. Since at the time of the IPO, all of the Company's redeemable preferred stock were automatically converted to common stock and all redeemable preferred stock warrants were automatically converted to common stock warrants, the Company currently does not have financial instruments with characteristics of liabilities and equity. The Company will evaluate the impact this new standard may have on its consolidated financial statements, as applicable at the time of adoption. The Company anticipates adopting the standard for the fiscal year ending December 31, 2020.

In February 2018, the FASB issued ASU 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220). This update provides companies with the option to reclassify stranded tax effects caused by the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act) from accumulated other comprehensive income to retained earnings. This standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company has adopted this standard for the fiscal year ending December 31, 2019, which did not have any material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Improvements to Non-employee Share-Based Payment Accounting. ASU 2018-07 expands the scope of Topic 718, Compensation-Stock Compensation, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, Equity-Equity-Based Payments to Non-Employees. For public business entities, the amendments are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. The Company is currently evaluating the impact that the adoption of this standard will have on the consolidated financial statements, and anticipates adopting the standard for the fiscal year ending December 31, 2020.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurements, which eliminates, adds or modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year, with early adoption permitted to adopt either the entire standard or only the provisions that eliminate or modify the requirements. The Company is currently evaluating the impact that the adoption of this standard will have on the consolidated financial statements and anticipates adopting the standard for the fiscal year ending December 31, 2020.

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3. Marketable Securities

The table below summarizes the marketable securities as of March 31, 2019 and December 31, 2018 (in thousands). Unrealized gains and losses on marketable securities are recorded in accumulated other comprehensive loss.

	March 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	\$ 76,601	\$ 12	\$ —	\$ 76,613
Corporate bonds	17,144	23	—	17,167
Commercial paper	8,968	—	—	8,968
Short-term investments	102,713	35	—	102,748
Money market funds	9,921	—	—	9,921
Cash equivalents	9,921	—	—	9,921
Total marketable securities	\$ 112,634	\$ 35	\$ —	\$ 112,669

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	\$ 65,491	\$ 2	\$ (4)	\$ 65,489
Corporate bonds	19,708	15	(3)	19,720
Commercial paper	11,894	—	—	11,894
Short-term investments	97,093	17	(7)	97,103
U.S. treasury securities	1,000	—	—	1,000
Commercial paper	6,635	—	—	6,635
Money market funds	15,223	—	—	15,223
Cash equivalents	22,858	—	—	22,858
Total marketable securities	\$ 119,951	\$ 17	\$ (7)	\$ 119,961

4. Fair Value Measurement

Carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate fair value due to their relatively short maturities and market interest rates, if applicable. The carrying value of the Company's long-term debt also approximates fair value based on management's estimation that a current interest rate would not differ materially from the stated rate.

The table below summarizes the fair value of the Company's marketable securities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands). There were no other financial assets and liabilities other than discussed above that requires fair value hierarchy measurements and disclosures for the periods presented.

	March 31, 2019			
	Level 1	Level 2	Level 3	Total
Marketable securities				
Money market funds ^[1]	\$ 9,921	\$ —	\$ —	\$ 9,921
U.S. treasury securities	76,613	—	—	76,613
Corporate bonds	—	17,167	—	17,167
Commercial paper	—	8,968	—	8,968
Total marketable securities	<u>\$ 86,534</u>	<u>\$ 26,135</u>	<u>\$ —</u>	<u>\$ 112,669</u>
	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Marketable securities				
Money market funds ^[1]	\$ 15,223	\$ —	\$ —	\$ 15,223
U.S. treasury securities	66,489	—	—	66,489
Corporate bonds	—	19,720	—	19,720
Commercial paper	—	18,529	—	18,529
Total marketable securities	<u>\$ 81,712</u>	<u>\$ 38,249</u>	<u>\$ —</u>	<u>\$ 119,961</u>

[1] Included in cash and cash equivalents on the consolidated balance sheet.

5. Balance Sheet Components

Inventory

As of March 31, 2019 and December 31, 2018, inventory consisted entirely of finished goods.

Property and Equipment, net (in thousands):

	March 31, 2019	December 31, 2018
Machinery and equipment	\$ 4,045	\$ 3,785
Construction in progress	778	\$ 730
Computer and office equipment	423	\$ 407
Leasehold improvements	481	\$ 448
Furniture and fixtures	154	\$ 148
	<u>5,881</u>	<u>5,518</u>
Less: Accumulated depreciation and amortization	(3,545)	\$ (3,364)
	<u>\$ 2,336</u>	<u>\$ 2,154</u>

Depreciation expense was \$0.2 million and \$0.2 million for the three months ended March 31, 2019 and 2018, respectively.

Accrued Liabilities and Other (in thousands):

	March 31, 2019	December 31, 2018
Accrued compensation and related expenses	\$ 4,548	\$ 5,425
Accrued interest	1,150	—
Accrued professional services	458	583
Sales tax payable	436	388
Liability for early exercise of unvested stock options	265	331
Others	240	133
	<u>\$ 7,097</u>	<u>\$ 6,860</u>

6. Commitments and Contingencies

Operating Leases

The Company has an existing seven-year non-cancelable operating lease for an office building space in Santa Clara, California which commenced in April 2018. Also, the Company has non-cancelable operating leases for its office building space in Gallarate, Italy and Mannheim, Germany which both expire in November 2024. Further, the Company also leases vehicles under operating lease arrangements for certain of its sales personnel in Europe which expire various times in 2019 to 2021.

Rent expense is recorded over the lease terms on a straight-line basis. Rent expense charged to operations under operating leases was \$0.3 million and \$0.3 million for three months ended March 31, 2019 and 2018, respectively.

The table below summarizes aggregate future minimum lease payments under all leases as of March 31, 2019 (in thousands):

Remainder of 2019	\$ 800
2020	1,040
2021	919
2022	844
2023	833
Thereafter	1,183
	<u>\$ 5,619</u>

Purchase Commitments and Obligations

The Company has certain purchase commitments related to inventory used in normal course of business. These commitments amounted to \$0.3 million and \$0.2 million at March 31, 2019 and December 31, 2018, respectively. The amounts paid under these arrangements may be less in the event that the arrangement is renegotiated or canceled.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Legal Proceedings

On February 6, 2019, a putative class action captioned Eric B. Fromer Chiropractic, Inc. v. SI-BONE, Inc. (Civil Action No. 5:19-cv-633-SVK), was filed in the United States District Court, Northern District of California. The complaint alleges violations of the Telephone Consumer Protection Act (the "TCPA") on behalf of an individual and putative classes of persons alleged to be similarly situated. The complaint alleges that the Company sent invitations to an educational dinner event to health care providers by way of facsimile transmission. The TCPA prohibits using a fax machine to send unsolicited advertisements not including proper opt-out instructions or to send unsolicited advertisements to persons with whom the sender did not have an established business relationship. The Company believes that it has meritorious defenses and intends to vigorously defend itself in the action. On March 28, 2019, the Company filed a motion to dismiss or, in the alternative, to stay the action pending resolution of the PDR Network, LLC v. Carlton & Harris Chiropractic Inc. case currently before the U.S. Supreme Court, the outcome of which may affect this case. It is too early in this matter to reasonably predict the probability of the outcomes or to estimate the range of possible loss, if any.

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.

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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 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.

7. Borrowings

The Company had \$39.0 million and \$39.0 million of outstanding debt, net of debt discounts, as of March 31, 2019 and December 31, 2018, respectively. The outstanding debt is related to a term loan entered by the Company with Biopharma Credit Investments IV Sub L.P.I, or Pharmakon, in October 2017 for total loan proceeds of \$40.0 million. The total debt issuance costs of \$1.3 million were recorded as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet, and are being amortized over the period of the term loan using the effective interest method to interest expense in the consolidated statement of operations. The term loan includes an interest-only period for 35 months through September 2020 and is then repaid in equal quarterly principal payments plus interest through December 2022, and is classified as long-term borrowings on the consolidated balance sheet. The term loan carries a fixed interest rate of 11.5% and a closing fee of 1.5% of the funded amount, or \$0.6 million. The term loan includes a prepayment fee equal to the interest due for the first 30 months of the agreement if it is prepaid within the first 30 months, a 2% prepayment penalty for months 31-48, and a 1% penalty for months 49-60. The term loan requires the Company to maintain a minimum cash balance of \$5.0 million and beginning with the three months ended March 31, 2019, the Company is required to meet either minimum net sales or trailing 12-month consolidated EBITDA targets as discussed in detail in Note 7 of Notes to Consolidated Financial Statements in the Annual Report on Form 10-K filed with the SEC on March 14, 2019. Under the loan agreement, the Company also had a second tranche of \$10.0 million available through January 2019, contingent upon the achievement of certain revenue milestones. The Company did not draw upon the second tranche. The loan is a senior obligation secured with a blanket first lien on the assets of the Company. For the three months ended March 31, 2019 and 2018, the effective interest rate was 12.2%. The Company was in compliance with all debt covenants as of March 31, 2019.

The table below summarizes annual future minimum principal payments under the loan agreement as of March 31, 2019 (in thousands):

Remainder of 2019	\$	—
2020		4,444
2021		17,778
2022		17,778
Total future minimum payments		40,000
Less: Amount representing debt discount		(972)
Long-term borrowings	\$	39,028

8. Warrants

The table below summarizes common stock warrants issued and outstanding at both March 31, 2019 and December 31, 2018 (in thousands, except share and per share data):

Date		Number of Shares Underlying Warrants	Price per Share	Fair Value
Issuance	Expiration			
3/1/2017	3/1/2027 [a]	1,388	\$ 5.94	\$ 5 [b]
7/19/2013	7/22/2023 [a]	32,983	9.10	122 [b]
11/26/2014	11/26/2024 [a]	6,680	16.47	49 [b]
10/20/2015	10/20/2025 [a]	41,650	16.47	396 [c]
11/9/2015	11/9/2025 [a]	25,709	16.47	244 [c]
12/22/2016	12/22/2026 [a]	9,712	10.03	45 [c]
		<u>118,122</u>		<u>\$ 861</u>

[a] Common stock warrants will remain outstanding until exercised by the holder.

[b] Fair value at the date of issuance.

[c] Fair value at the date of conversion from redeemable convertible preferred stock to common stock warrants in conjunction with the IPO on October 16, 2018.

9. Stock-Based Incentive Compensation Plans

2018 Equity Incentive Plan

In October 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 EIP"). The number of shares of common stock reserved for issuance under the 2018 Equity Incentive Plan will automatically increase on January 1 of each year, beginning January 1, 2019, and continuing through and including January 1, 2028, by 5% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. On January 1, 2019, the total number of shares of common stock reserved for issuance increased by 1,222,538 shares. The Company filed a Registration Statement on Form S-8 on March 22, 2019 to register these additional shares reserved for issuance under the 2018 EIP. As of March 31, 2019, a total of 2,814,245 shares of common stock are available for future grants under the 2018 EIP.

Stock Options

The table below summarizes the stock option activity under the 2008 Stock Option Plan and 2018 Equity Incentive Plan for the three months ended March 31, 2019:

	Number of Shares	Weighted- Average Exercise Price
Outstanding at December 31, 2018	2,641,198	\$ 4.27
Options granted	468,600	22.00
Options exercised	(46,945)	2.73
Options canceled	(15,723)	9.32
Outstanding at March 31, 2019	<u>3,047,130</u>	<u>\$ 6.99</u>

As of March 31, 2019, there was \$7.3 million of unrecognized compensation cost related to stock options granted. These costs are expected to be recognized over a period of approximately 3.0 years.

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The estimated weighted-average grant date fair value of options granted for the three months ended March 31, 2019 and 2018 was \$10.40 per share and \$2.13 per share, respectively. The grant date fair value of the stock option awards granted to employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Three months ended	
	March 31,	
	2019	2018
Expected term	6.03	5.93
Expected volatility	42%-47%	42%-45%
Risk-free interest rate	2.52%-2.59%	1.64%-2.80%
Dividend yield	—%	—%

Early Exercise of Unvested Stock Options

Early exercises of stock options are subject to a right of repurchase by the Company of any unvested shares. The repurchase rights lapse over the original vesting period of the options. The Company accounts for the cash received in consideration for the early exercised options as a liability included in accrued liabilities, which is then reclassified to stockholders' equity as the options vest. At March 31, 2019 and December 31, 2018, the Company had a total of 59,193 and 74,019 shares of common stock, respectively, subject to repurchase under the 2008 Stock Option Plan and \$0.3 million and \$0.3 million, respectively, of associated liabilities for the repurchase.

Restricted Stock Units

The table below summarizes restricted stock units activity for the three months ended March 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	53,436	\$11.69
Granted	481,893	20.82
Forfeited	(3,660)	19.91
Outstanding at March 31, 2019	<u>531,669</u>	19.90

As of March 31, 2019, there was a total unrecognized compensation cost of \$9.2 million related to the restricted stock units granted. These costs are expected to be recognized over a period of approximately 3.5 years.

Employee Stock Purchase Plan

In October 2018, the Company adopted the 2018 Employee Stock Purchase Plan (the "2018 ESPP" or "ESPP"). The Company allows eligible employees to purchase shares of the Company's common stock through payroll deductions at the price equal to 85% of the lesser of the fair market value of the stock as of the first date or the ending date of each six month offering period. There were 515,307 shares of common stock reserved for issuance under the ESPP. As of March 31, 2019 and December 31, 2018, total accumulated ESPP related employee payroll deductions amounted to \$1.0 million and \$0.4 million, respectively, which were included within accrued compensation and related expenses in the consolidated balance sheets. For the three months ended March 31, 2019, the Company recognized \$0.2 million stock-based compensation expense related to ESPP. As of March 31, 2019, the unrecognized compensation cost for the ESPP was \$0.1 million.

On March 22, 2019, the Company filed a Registration Statement on Form S-8 to register 244,507 additional shares of common stock for issuance under the 2018 ESPP.

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Stock-Based Compensation

The table below presents the detail of stock-based compensation expense amounts included in the consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of goods sold	\$ 42	\$ 6
Sales and marketing	670	127
Research and development	96	39
General and administrative	1,062	219
	<u>\$ 1,870</u>	<u>\$ 391</u>

10. Net Loss Per Share of Common Stock

Basic and Diluted Net Loss per Share

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

	Three Months Ended March 31,	
	2019	2018
Net loss	\$ (9,345)	\$ (4,201)
Weighted-average shares used to compute basic and diluted net loss per share	24,390,648	3,593,658 *
Net loss per share, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (1.17) *</u>

* Calculated based on the 1-for-18 reverse stock split effected October 4, 2018.

Unvested shares for the periods ended March 31, 2019 and 2018 were excluded from the weighted-average shares used to compute basic and diluted net loss per share.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	Three Months Ended March 31,	
	2019	2018
Stock options	3,047,130	3,017,033
Restricted stock units	531,669	—
Shares subject to repurchase	59,193	186,531
Redeemable convertible preferred stock	—	11,871,578
Redeemable convertible preferred stock warrants	—	156,551
Common stock warrants	118,122	124,326
	<u>3,756,114</u>	<u>15,356,019</u>

11. Income Taxes

In determining quarterly provisions for income taxes, the Company uses the annual estimated effective tax rate applied to the actual year-to-date profit or loss, adjusted for discrete items arising in that quarter. The Company updates its estimate of its annual effective tax rate at the end of each quarterly period. The estimate takes into account annual forecasted income (loss) before income taxes, the geographic mix of income (loss) before income taxes and any significant permanent tax items. The Company did not have provision for income taxes for the three months ended March 31, 2019 and 2018. The Company continues to maintain a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding realization of such assets.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return. There had been no changes in the estimated uncertain tax benefits recorded as of December 31, 2018.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q, and with the consolidated financial statements and management's discussion and analysis of our financial condition and results of operations in our Annual Report on Form 10-K filed with the SEC on March 14, 2019. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied, by these forward-looking statements.

Overview

We are a medical device company that has pioneered a proprietary minimally invasive surgical implant system, which we call iFuse, to fuse the sacroiliac joint to treat sacroiliac joint dysfunction that often causes severe lower back pain. Since we introduced iFuse in 2009, more than 38,000 procedures have been performed by over 1,800 surgeons in the United States and 33 other countries. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the sacroiliac joint. We believe iFuse is currently used in the majority of minimally invasive surgical fusions of the sacroiliac joint in the United States.

The two sacroiliac joints are the largest joints in the body and connect the sacrum, near the base of the spine, to the iliac bones, the two major bones of the pelvis. The iFuse system includes a series of patented triangular implants, the instruments we have developed to enable the procedure, as well as the diagnostic and surgical techniques we have developed to enable physicians to perform the procedure. We introduced our second generation implant, the iFuse-3D, in 2017. We market our products with a direct sales force and a number of distributors in the United States, and with a combination of a direct sales force and distributors in other countries.

We have incurred net losses since our inception in 2008. We had net losses of \$9.3 million for the three months ended March 31, 2019 and \$17.5 million and \$23.0 million for the years ended December 31, 2018 and 2017, respectively. As of March 31, 2019, we had an accumulated deficit of \$166.5 million. To date, we have financed our operations primarily through an initial public offering, private placements of equity securities, certain debt-related financing arrangements, and sales of our products. We have devoted substantially all of our resources to research and development of our products, reimbursement-related initiatives, sales and marketing activities, and clinical, quality assurance, and regulatory matters for our products.

In October 2018, we completed our initial public offering, or IPO, by issuing 8,280,000 shares of common stock, at an offering price of \$15.00 per share, for net proceeds of \$113.4 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Factors Affecting Results of Operations

Coverage and Reimbursement

Prior to our launch of iFuse in 2009, Medicare and most private insurance companies reimbursed surgeons routinely for sacroiliac joint fusions, which were primarily invasive. However, effective July 1, 2013, the AMA's ("American Medical Association") Editorial Panel effectively restricted reimbursement for minimally invasive sacroiliac joint fusion because they considered the published clinical evidence at the time to be inadequate.

Subsequently, as a result of the growing number of published clinical studies demonstrating the effectiveness and safety of iFuse, along with the support of several professional medical specialty societies and leading academic surgeons, the AMA Editorial Panel established a new reimbursement code for minimally invasive sacroiliac joint fusion surgery, effective January 1, 2015. However, the new code did not immediately lead to positive coverage decisions by payors-in many cases, the payors wanted additional published evidence before deciding to cover the procedure. As a result, positive reimbursement decisions covering the procedure have occurred over the last few years, and some payors are still in the process of making decisions based on the most recent evidence.

Coverage decisions for this code are made independently by each private insurance company and each of the seven regional Medicare Administrative Contractors that help manage Medicare. The process of obtaining coverage is laborious. As of June 30, 2016, because of the iFuse clinical evidence, all Medicare Administrative Contractors were covering the procedure. At the time, very few private payors were covering.

In 2018, more private payors began covering iFuse based upon our clinical evidence. As of March 31, 2019, U.S. payors covering 266 million lives regularly reimbursed for the iFuse procedures, 131 million lives of which are covered by private payors. Forty-nine of the largest 65 private payors that we track had positive coverage policies for the procedure, were consistently covering the procedure, or had announced coming future coverage. Of these there were 49 private payors, 30 of which have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence. Twenty-four of these exclusive coverage policies have published since January 1, 2018, which we believe has contributed to our recent sales growth.

There are a number of large and small private payors, including Aetna, Cigna, Humana, and Anthem, that are not yet reimbursing for the procedure. In the most recent review cycle, all four of the aforementioned large payors continued their experimental policies. These non-covering payors reevaluate coverage annually based upon the most recently published clinical data. There can be no assurance they will reach positive coverage decisions in the future.

Medical Affairs and Education

Our medical affairs team focuses on both internal and external education. Internally, specialized medical knowledge and practical experience with iFuse are used to help train our sales, marketing, quality, reimbursement, clinical, regulatory, engineering, and product development teams. This same specialized medical knowledge and practical experience allow us to create and execute a wide variety of programs to train the relevant external medical community, to assist them in identifying and diagnosing patients with sacroiliac joint dysfunction and in performing the iFuse procedure. The medical affairs team is led by a board-certified fellowship trained orthopedic spine surgeon. As of March 31, 2019, our U.S. faculty consisted of 83 surgeons, 24 pain management physicians, 17 nurse practitioners/physician's assistants, and 92 physical therapists. These third-party consultants educate surgeons, physician's assistants, nurses, physical therapists, and other healthcare professionals regarding sacroiliac joint diagnosis and the iFuse procedure.

Our surgeon training programs are for orthopedic spine surgeons, neurosurgeons, general orthopedic surgeons, and orthopedic trauma surgeons. Since its introduction, over 1,800 surgeons around the world have been trained and treated patients with iFuse. We also have a large number of educational programs for the broader medical community including primary care physicians and other healthcare practitioners that may manage a sacroiliac joint patient non-surgically, such as physical therapists, pain management physicians, and chiropractors. Our medical affairs programs focus on working with leading spine surgeons to educate other surgeons on the differential diagnosis of sacroiliac joint disorders and the use of iFuse. We also work closely with medical societies to raise the awareness of and the appropriate diagnosis of sacroiliac joint dysfunction and the associated treatment options.

Our Sales Force

We market and sell iFuse primarily through a direct sales force and a number of third-party distributors. Our target customer base includes approximately 7,500 U.S. surgeons who perform spine and/or pelvic surgery, including orthopedic spine surgeons, neurosurgeons, general orthopedic surgeons, and orthopedic trauma surgeons.

Our direct sales organization in the United States has grown from seven to ten sales regions. In each region there is a number of territory sales managers who act as the primary customer contact. Our territory sales managers have extensive training and experience selling medical devices for spine problems and pain management, generally focusing on emerging technologies and markets. As of March 31, 2019, our territory sales managers were led by ten regional sales directors who reported to our Vice President of U.S. Sales. The Vice President of U.S. Sales reports to our Chief Commercial Officer. As of March 31, 2019, our U.S. sales force consisted of 49 sales representatives directly employed by us and 34 third-party distributors.

In addition to general sales and marketing training, we provide our sales organization with comprehensive, hands-on cadaveric and dry-lab training sessions focusing on the clinical benefits of our products and how to use them. We believe our robust training and professional development programs have been an important component of our success to date and will help support our anticipated future growth. We expect to continue to increase the size of our sales organization in order to increase sales and market penetration and to provide the significant, ongoing level of customer support required by our sales and marketing strategy.

As of March 31, 2019, we had 32 employees working in our European operations, and have established operations in Italy (2010), Germany (2014), and the United Kingdom (2015). As of March 31, 2019, our international sales force consisted of 16 sales representatives directly employed by us and 27 exclusive third-party distributors, which together had sales in 33 countries through March 31, 2019. We anticipate continuing to build our operations in the major European countries while establishing distributor arrangements in smaller ones. We intend to follow a similar model in Europe to the one established in the United States, working with internationally recognized healthcare professional experts as we expand our training and reimbursement activities. As of March 31, 2019, beyond Europe and the United States, surgeons had performed the first iFuse procedures in Australia, Cayman Islands, Hong Kong, Israel, Japan, Kuwait, New Zealand, Saudi Arabia, Taiwan and Turkey.

We have in the past and expect in the future to enter into different compensation arrangements with our sales professionals, which may include minimum guaranteed commissions. This has impacted our compensation expenses in the past and we expect it will in the future.

Components of Results of Operations

Revenue

We derive substantially all our revenue from sales of iFuse. Revenue from sales of iFuse fluctuate based on volume of cases (procedures performed), discounts, mix of international and U.S. sales, and the number of implants used for a particular patient. Similar to other orthopedic companies, our case volume can vary from quarter to quarter due to a variety of factors including reimbursement, sales force changes, physician activities, and seasonality. In addition, our revenue is impacted by changes in average selling price as we respond to the competitive landscape. Further, revenue results can differ based upon the mix of business between U.S. and international sales. Our revenue from international sales is impacted by fluctuations in foreign currency exchange rates between the U.S. dollar (our reporting currency) and the local currency.

Cost of Goods Sold, Gross Profit, and Gross Margin

We utilize third-party manufacturers for production of iFuse implants and instrument sets. Cost of goods sold consists primarily of costs of the components of iFuse implants and instruments, scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs. We anticipate that our cost of goods sold will increase as case levels increase.

Our gross profit and gross margin have been and will continue to be affected by factors impacting revenue and cost of goods sold. In addition, our gross margins are typically higher on products we sell directly as compared to products we sell through third-party distributors. As a result, changes in the mix of direct versus distributor sales can directly influence our gross margins.

In accordance with the Patient Protection and Affordable Care Act, effective January 1, 2013, we began to incur an excise tax on sales of medical devices in the United States. Effective December 2015, the Act was amended to include a provision to suspend the tax on medical devices through 2017. In January 2018, the suspension on the tax on medical devices was further extended through 2019.

Operating Expenses

Our operating expenses consist of sales and marketing, research and development, and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consist of salaries, sales commissions and other cash and stock-based compensation related expenses. We expect operating expenses to increase as we continue to invest and grow our business.

Sales and Marketing Expenses

Sales and marketing expenses primarily consist of salaries, stock-based compensation expense, and other compensation related costs, for personnel employed in sales, marketing, medical affairs, reimbursement and professional education departments. In addition, our sales and marketing expenses include commissions and bonuses, generally based on a percentage of sales, to our sales directors, direct territory sales managers, and third-party distributors. We expect our sales and marketing expenses to increase with the continued commercialization of our current and future products and continued investment in our global sales organization, including broadening our relationships with third-party distributors, expanding exclusivity commitments among them and increasing the number of our direct sales representatives, especially with increased reimbursement and adoption in the United States. Our sales and marketing expenses may fluctuate from period to period due to the seasonality of our business and as we continue to add direct territory sales managers in new territories.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, clinical and regulatory expenses (including clinical study expenses), and consulting services, outside prototyping services, outside research activities, materials, depreciation, and other costs associated with development of our products. Research and development expenses also include related personnel and consultants' compensation and stock-based compensation expense. We expense research and development costs as they are incurred. We expect research and development expense to increase as we develop new products, add research and development personnel, and undergo clinical activities, including more clinical studies to gain additional regulatory clearances and wider surgeon adoption.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, stock-based compensation expense, and other costs for finance, accounting, legal, compliance, and administrative matters. We expect our general and administrative expenses to increase to support the growth of our business. We also expect to incur additional general and administrative expenses as a result of operating as a public company, including but not limited to: expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and those of the Nasdaq Global Market on which our securities are traded; additional insurance expenses; investor relations activities; and other administrative and professional services.

Interest Income

Interest income is related to our investments of excess cash in money market funds and marketable securities.

Interest Expense

Interest expense is related to borrowings and amortization of debt issuance costs. Prior to our initial public offering, interest expense also included the amortization of debt discounts derived from the issuance of warrants.

Other Income (Expense), Net

Other income (expense), net consists primarily of net foreign exchange gains (losses) on foreign transactions. Prior to our initial public offering, other income (expense), net included changes in fair value of our preferred stock warrant liability. In connection with our initial public offering, our preferred stock warrant liability was reclassified to equity upon conversion of preferred stock warrants to common stock warrants.

Results of Operations

We operate as one operating and reportable segment. The table below summarizes our results of operations for the periods presented, which we derived from the accompanying condensed consolidated financial statements (in thousands, except for percentages):

	Three Months Ended March 31,			
	2019		2018	
Consolidated Statements of Operations Data:				
Revenue	\$ 14,991	100 %	\$ 12,712	100 %
Cost of goods sold	1,526	10 %	1,048	8 %
Gross profit	13,465	90 %	11,664	92 %
Operating expenses:				
Sales and marketing	15,815	106 %	10,967	86 %
Research and development	1,683	11 %	1,206	9 %
General and administrative	4,766	32 %	2,408	20 %
Total operating expenses	22,264	149 %	14,581	115 %
Loss from operations	(8,799)	(59)%	(2,917)	(23)%
Interest and other income (expense), net:				
Interest income	744	5 %	62	— %
Interest expense	(1,230)	(8)%	(1,275)	(10)%
Other income (expense), net	(60)	— %	(71)	(1)%
Net loss	\$ (9,345)	(62)%	\$ (4,201)	(34)%

We derive the majority of our revenue from sales to customers in the United States. Revenue by geography is based on billing address of the customer. No single country outside the United States accounts for more than 10% of the total revenue during the periods presented. The table below summarizes our revenue by geography (in thousands except for percentages):

	Three Months Ended March 31,			
	2019		2018	
United States	13,450	90%	11,295	89%
International	1,541	10%	1,417	11%
	\$ 14,991	100%	\$ 12,712	100%

Comparison of the Three Months Ended March 31, 2019 and 2018

Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin

	Three Months Ended March 31,			
	2019	2018	\$ Change	% Change
(in thousands, except for percentages)				
Revenue	\$ 14,991	\$ 12,712	\$ 2,279	18%
Cost of goods sold	1,526	1,048	478	46%
Gross profit	\$ 13,465	\$ 11,664	\$ 1,801	15%
Gross margin	90%	92%		

Revenue. Revenue increased \$2.3 million or 18%, for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. The increase is primarily due to an increase of \$2.2 million as a result of growth of domestic case volumes. U.S. case volumes increased from higher sales force productivity, higher numbers of sales personnel, and more active surgeons due to improving U.S. reimbursement coverage. The remaining \$0.1 million increase in our revenue was due to growth of our international case volumes.

Cost of Goods Sold, Gross Profit, and Gross Margin. Total cost of goods sold increased \$0.5 million, or 46%, for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. The increase in cost of goods sold is primarily due to higher sales volume and implant costs. Higher net revenue resulted in increased gross profit of \$1.8 million, or 15%. Gross margin decreased to 90% for the three months ended March 31, 2019 as compared to 92% for the three months ended March 31, 2018 due to an increase in personnel in operations to support the growth of the business.

Operating Expenses

	Three Months Ended March 31,		\$ Change	% Change
	2019	2018		
	(in thousands, except for percentages)			
Sales and marketing	\$ 15,815	\$ 10,967	\$ 4,848	44%
Research and development	1,683	1,206	477	40%
General and administrative	4,766	2,408	2,358	98%
Total operating expenses	\$ 22,264	\$ 14,581	7,683	53%

Sales and Marketing Expenses. Sales and marketing expenses increased \$4.8 million, or 44%, for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. The increase was primarily due to an increase of \$1.8 million in salaries and other employee related costs, an increase of \$0.5 million in travel expense, and an increase of \$0.5 million in facilities and other related expenses as a result of an increase in headcount to further expand of our sales and marketing department, \$0.7 million in commissions due to increased sales, \$0.6 million in stock-based compensation expense due to increase in headcount and issuance of stock grants with higher market value, \$0.7 million in training, advertising and marketing costs due to continued commercialization of our current and future products and continued investment in our global sales organization.

Research and Development Expenses. Research and development expenses increased \$0.5 million, or 40%, for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. The increase was primarily related to an increase of \$0.2 million in salaries and other employee related costs and \$0.1 million in stock-based compensation expense as a result of an increase in headcount. Facilities and other expenses also increased by \$0.2 million mainly due to increased research and development activities as well as higher headcount.

General and Administrative Expenses. General and administrative expenses increased \$2.4 million, or 98%, for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. The increase was primarily due to higher stock-based compensation of \$0.8 million from an increase in headcount and issuance of stock grants with higher market value, \$0.3 million in salaries and employee related costs due to increases in headcount, \$0.8 million in consulting and professional services due to additional regulatory and other compliance services required for a public company, and \$0.5 million in facilities and other expenses due to expansion of our general and administrative department.

Interest and Other Income (Expense), Net

	Three Months Ended March 31,		\$ Change	% Change
	2019	2018		
	(in thousands except for percentages)			
Interest income	\$ 744	\$ 62	\$ 682	1100 %
Interest expense	(1,230)	(1,275)	45	(4)%
Other expense, net	(60)	(71)	11	(15)%

Interest Income. Interest income increased \$0.7 million for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018, due to an increase of investments of excess cash in marketable securities.

Interest Expense. Interest expense remained relatively unchanged for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

Other Expense, Net. Other expense, net, remained relatively unchanged for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

Liquidity and Capital Resources

As of March 31, 2019, we had cash and cash equivalents of \$12.6 million and short-term investments of \$102.7 million, compared to cash and cash equivalents of \$25.1 million and short-term investments of \$97.1 million as of December 31, 2018. We have financed our operations through our initial public offering, debt financing arrangements, and the sale of our products. As of March 31, 2019 and December 31, 2018, we had \$39.0 million and \$39.0 million principal amount of outstanding debt, net of debt discounts, respectively.

As of March 31, 2019, we had an accumulated deficit of \$166.5 million. During the three months ended March 31, 2019, we incurred a net loss of \$9.3 million. During the years ended December 31, 2018 and 2017, we incurred a net loss of \$17.5 million and \$23.0 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date. The debt covenants associated with our current debt agreement require us to maintain a minimum cash balance and meet either minimum net sales or trailing 12-month consolidated EBITDA targets as discussed in detail below. If we do not comply with these covenants, the debt will immediately become due.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. We continue to face challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to: (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products; (e) changes we may make in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our sales and marketing efforts, research and development activities, or other operations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we are unable to raise capital, we will need to delay, reduce, or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

Borrowings

The outstanding debt is related to a term loan we entered with Biopharma Credit Investments IV Sub L.P.I, or Pharmakon, in October 2017 for total loan proceeds of 40.0 million. The term loan includes an interest-only period for 35 months through September 2020 and is then repaid for equal principal payments plus interest through December 2022. The term loan carries a fixed interest rate of 11.5% and a closing fee of 1.5% of the funded amount, or \$0.6 million. The term loan includes a pre-payment fee of the remaining interest payable for the first 30 months of the agreement if it is prepaid within the first 30 months, a 2% prepayment penalty for months 31-48, and a 1% penalty for months 49-60. The term loan required us to maintain a minimum cash balance of \$5.0 million.

Beginning with the three months ended March 31, 2019, we are required to meet either minimum net sales or trailing 12-month consolidated EBITDA targets. We need to meet one or the other, but not both. If we do not meet either the minimum net sales or trailing 12-month consolidated EBITDA targets, the debt will immediately become due. The minimum net sales and trailing 12-month consolidated EBITDA targets are as follows (in thousands):

Twelve Months Ending	Minimum Net Sales		Trailing 12-Month Consolidated EBITDA	
March 31, 2019	\$	52,000	or	\$ (5,000)
June 30, 2019	\$	53,500	or	\$ (3,500)
September 30, 2019	\$	54,500	or	\$ (2,000)
December 31, 2019	\$	56,000	or	\$ —
March 31, 2020	\$	57,500	or	\$ 1,000
June 30, 2020	\$	58,500	or	\$ 2,000
thereafter, as applicable	\$	60,000	or	\$ 3,000

The term loan is collateralized by all of our assets, including intellectual property.

As of December 31, 2018 and March 31, 2019, we were in compliance with all of our debt obligations and covenants.

Contractual Obligations

During the three months ended March 31, 2019, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from December 31, 2018.

Cash Flows

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

	Three Months Ended March 31,		\$ Change	% Change
	2019	2018		
(in thousands, except for percentages)				
Net cash (used in) provided by:				
Operating activities	\$ (7,078)	\$ (4,411)	\$ (2,667)	60%
Investing activities	(5,553)	(218)	(5,335)	2447%
Financing activities	125	20	105	525%
Effects of exchange rate changes on cash and cash equivalents	(53)	(7)	(46)	657%
Net decrease in cash and cash equivalents	<u>\$ (12,559)</u>	<u>\$ (4,616)</u>	<u>\$ (7,943)</u>	

Cash Used in Operating Activities

Net cash used in operating activities increased \$2.7 million, or 60%, from the three months ended March 31, 2018 to the three months ended March 31, 2019. The increase was primarily due to an increase of \$5.1 million in our net loss, partially offset by an increase of \$1.0 million in non-cash charges and decrease in changes in operating assets and liabilities of \$1.5 million. The increase in net loss resulted from higher operating expenses from expansion of the business, partially offset by higher revenue. The increase in non-cash charges was mainly due to an increase in stock-based compensation expense, partially offset by accretion of our short-term investments. The decrease in changes in operating assets and liabilities was mainly due to the timing of payments of our accounts payable, accrued expenses and other liabilities.

Cash Used in Investing Activities

Net cash used in investing activities in the three months ended March 31, 2019 was \$5.6 million compared to net cash used in investing activities of \$0.2 million in the three months ended March 31, 2018. Cash used in investing activities for the three months ended March 31, 2019 consisted of purchases of short-term investments of \$22.7 million and purchases of property and equipment of \$0.4 million, which were partially offset by maturities of our short-term investments of \$17.6 million. Net cash used in investing activities for the three months ended March 31, 2018 consisted of purchases of property and equipment.

Cash Provided by Financing Activities

Cash provided by financing activities increased \$0.1 million, from the three months ended March 31, 2018 to the three months ended March 31, 2019. The increase was due to higher proceeds from the exercises of stock options.

Critical Accounting Policies, Significant Judgments, and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated, and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

Our critical accounting policies and estimates are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" in our Annual Report on Form 10-K filed with the SEC on March 14, 2019. There had been no material changes to these accounting policies. See Note 2 of Notes to Unaudited Condensed Consolidated Financial Statements for related discussions on updates on recently issued accounting pronouncements.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2019, 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.

Seasonality

Our business is affected by seasonal variations. For instance, we have historically experienced lower sales in the summer months and higher sales in the last quarter of the fiscal year. However, taken as a whole, seasonality does not have a material impact on our financial results.

JOBS Act Accounting Election

In April 2012, the JOBS Act was enacted. Section 107(b) of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

See Note 2 of Notes to Unaudited Condensed Consolidated Financial Statements for related discussions on updates on recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable to a smaller reporting company.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit pursuant to the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2019, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline, and our stockholders may lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business and Our Industry

We have incurred significant operating losses since inception, we expect to continue to incur operating losses in the future, and we may not be able to achieve or sustain future profitability.

We have incurred net losses since our inception in 2008. For the three months ended March 31, 2019, we had net loss of \$9.3 million. For the years ended December 31, 2018 and 2017, we had net losses of \$17.5 million and \$23.0 million, respectively. As of March 31, 2019, we had an accumulated deficit of \$166.5 million. To date, we have financed our operations primarily through the proceeds of our initial public offering of our common stock, or IPO, private placements of equity securities, certain debt-related financing arrangements, and from sales of our products. We have devoted substantially all of our resources to research and development of our products, sales and marketing activities, investments in training and educating surgeons and other healthcare providers, and clinical and regulatory matters for our products. There can be no assurances that we will be able to generate sufficient revenue from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flows. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance, and commercialize our existing and new products and incur additional operational and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives.

Our expected future capital requirements may depend on many factors including expanding our surgeon base, the expansion of our sales force, and the timing and extent of spending on the development of our technology to increase our product offerings. We may need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations.

If hospitals, surgeons, and other healthcare providers are unable to obtain coverage and reimbursement from third-party payors for procedures performed using our products, adoption of our products may be delayed, and it is unlikely that they will gain further acceptance.

Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Hospitals, surgeons, and other healthcare providers that purchase or use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices.

Adequate coverage and reimbursement for procedures performed with our products is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage, continue to deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. For example, our sales decreased significantly after minimally invasive sacroiliac joint fusion was assigned to a Category III Current Procedure Terminology, or CPT, code effective July 1, 2013. After implementation of this Category III CPT Code, surgeons were no longer able to consistently obtain reimbursement for procedures performed using our products. However, effective January 1, 2015, minimally invasive sacroiliac joint fusion was assigned to a Category I CPT Code.

Many private payors refer to coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines for setting their coverage and reimbursement policies. By December 31, 2016, all Medicare Administrative Contractors were regularly reimbursing for minimally invasive sacroiliac joint fusion. Private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures performed with our products. Private commercial payors have been slower to adopt positive coverage policies for minimally invasive sacroiliac joint fusion, and many private payors still have policies that treat the procedure as experimental or investigational and do not regularly reimburse for the procedure. Future action by CMS or third-party payors may further reduce the availability of payments to physicians, outpatient surgery centers, and/or hospitals for procedures using our products.

The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they chose to cover. For example, several Blue Cross Blue Shield payors have recently adopted policies that treat 3D-printed orthopedic implants that come in standard sizes, rather than customized to the patient's anatomy, such as our iFuse-3D implant, as experimental and investigational and therefore not eligible for reimbursement. There can be no guarantee that we will be able to provide the scientific and clinical data necessary to overcome these policies. Such policies may contribute to a decrease in sales of our iFuse-3D implants. Payors may adopt policies in the future restricting access to medical technologies like ours and/or the procedures performed using such technologies. Therefore, we cannot be certain that the procedures performed with each of our products will be reimbursed. There can be no guarantee that, should we introduce additional products in the future, payors will cover those products or the procedures in which they are used.

Market acceptance of our products in foreign markets may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. We may not obtain additional international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

If the reimbursement provided by third-party payors to hospitals, surgeons, and other healthcare providers for procedures performed using our products is insufficient, adoption and use of our products and the prices paid for our implants may decline.

When an iFuse procedure is performed, both the surgeon and the healthcare facility, either a hospital or ambulatory surgical center, submit claims for reimbursement to the healthcare payor. Generally, the facility obtains a lump sum payment, or facility fee, for minimally invasive sacroiliac joint fusions. Our products are purchased by the facility, along with other supplies used in the procedure. The facility must also pay for its own fixed costs of operation, including certain operating room personnel involved in the procedure. If these costs exceed the facility fee reimbursement, the facility's managers may discourage or restrict surgeons from performing the procedure in the facility or using certain technologies, such as our iFuse implants, to perform the procedure.

The national average Medicare payment per procedure to hospital outpatient departments increased from \$10,538 to \$14,704 effective January 1, 2017. Effective January 1, 2019, the national average Medicare payment to hospital outpatient departments is \$15,402. Effective January 1, 2019, the Medicare payment to an ambulatory surgical center for a sacroiliac joint fusion is \$12,481. We believe that payments to facilities are generally adequate for these facilities to offer the iFuse procedure. However, there can be no guarantee that these facility fee payments will not decline in the future. The number of iFuse procedures performed and the prices paid for our implants may in the future decline if payments to facilities for minimally invasive sacroiliac joint fusions decline.

Surgeons are reimbursed separately for their professional time and effort to perform a surgical procedure. Prior to reassignment of minimally invasive sacroiliac joint fusion to a Category III CPT Code, the national average Medicare physician fee schedule payment to surgeons for CPT codes commonly used to submit claims for reimbursement for the iFuse procedure was approximately \$1,000 and the procedure was commonly covered by both government and private commercial payors in the United States. In 2015, the national average physician payment for the new Category I CPT Code for minimally invasive sacroiliac fusion was \$574, and we believe that this payment caused adoption of the procedure to slow. Effective January 1, 2016, the national average Medicare payment for the Category I CPT code increased to \$718, and the national average payment effective January 1, 2019, is \$720. Many private payors set their payment amounts with reference to the Medicare payment, often approximately 10% to 33% higher than the Medicare payment for a procedure. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all.

We believe that some surgeons view the current Medicare and commercial reimbursement amount as insufficient for the procedure, given the work effort involved with the procedure, including the time to diagnose the patient and obtain prior authorization from the patient's health insurer if necessary. Many private payors require extensive documentation of a multi-step diagnosis before authorizing minimally invasive sacroiliac joint fusion for a patient. We believe that some private payors apply their own coverage policies and criteria inconsistently, and surgeons may not be able to consistently have minimally invasive sacroiliac fusions approved and covered. The perception by physicians that the reimbursement for minimally invasive sacroiliac joint fusion is insufficient to compensate them for the work required, including diagnosis, documentation, obtaining payor approval for the procedure, and burden on their office staff, may negatively affect the number of procedures performed and may therefore impede the growth of our revenues or cause them to decline. Generally, private commercial insurance payments to physicians are based on the Medicare set payment and are in the range of 20% to 30% higher i.e. a range of \$864 to \$936 depending upon the negotiated price between the provider and the payor.

If healthcare payors reverse decisions to cover minimally invasive sacroiliac joint fusion exclusively when performed with iFuse and choose to reimburse for procedures performed with competitive products, our market share could decline, adversely affecting our revenues.

As of March 31, 2019, 49 of the largest 65 U.S. private payors that we track and target have issued positive coverage policies covering the patented triangular design of our iFuse implants and excluding coverage of other products that are intended to fuse the sacroiliac joint because of the clinical evidence supporting the use of iFuse and the lack of clinical evidence supporting the use of other products. Additionally, the public hospital system in France initiated coverage for iFuse exclusively beginning September 6, 2018. We believe that payors have adopted these exclusive coverage decisions due to the strength of our clinical evidence and in part due to recommendations of specialty benefit managers and healthcare technology assessment organizations. In 2018, AIM Specialty Health, Blue Cross Blue Shield Association Evidence Street, and eviCore Healthcare published positive coverage recommendations to their constituents and payor customers, recommending that iFuse be covered exclusively. Clinical trials of the type and size necessary to offer evidence of the safety and efficacy of competing products could be performed and could show that other products for sacroiliac joint fusion are as effective as, or more effective than, iFuse. Payors could also abandon their decisions to cover iFuse exclusively for other reasons.

We may not be able to convince physicians that iFuse is an attractive alternative to our competitors' products and that our procedure is an attractive alternative to existing surgical and non-surgical treatments of the sacroiliac joint.

Surgeons play the primary role in determining the course of treatment in consultation with their patients and, ultimately, the product that will be used to treat a patient. In order for us to sell our iFuse solution successfully, we must convince surgeons through education and training that treatment with iFuse is beneficial, safe, and cost-effective for patients as compared to our competitors' products. If we are not successful in convincing surgeons of the merits of iFuse, they may not use our product, and we will be unable to increase our sales and achieve or grow profitability.

Historically, most spine surgeons did not include sacroiliac joint pain in their diagnostic work-up because they did not have an adequate surgical procedure to perform for patients diagnosed with the condition. As a result, some patients with lower back pain resulting from sacroiliac joint dysfunction are misdiagnosed. We believe that educating surgeons and other healthcare professionals about the clinical merits and patient benefits of iFuse is an important element of our growth. If we fail to effectively educate surgeons and other medical professionals, they may not include a sacroiliac joint evaluation as part of their diagnosis and, as a result, those patients may continue to receive unnecessary or only non-surgical treatment.

Surgeons may also hesitate to change their medical treatment practices for other reasons, including the following:

- lack of experience with minimally invasive procedures;
- perceived liability risks generally associated with the use of new products and procedures;
- costs associated with the purchase of new products; and
- time commitment that may be required for training.

Furthermore, we believe surgeons will not widely use iFuse unless they determine, based on experience, clinical data, and published peer-reviewed publications, that surgical intervention provides benefits or is an attractive alternative to non-surgical treatments of sacroiliac joint dysfunction. In addition, we believe support of our products relies heavily on long-term data showing the benefits of using our products. If we are unable to provide that data, surgeons may not use our products. In such circumstances, we may not achieve expected sales and may be unable to achieve profitability.

Many patients with sacroiliac joint dysfunction are cared for by pain physicians, who are generally trained as anesthesiologists or physical medicine and rehabilitation specialists. These pain physicians often offer a variety of non-surgical and surgical interventions to sacroiliac joint dysfunction patients, including, but not limited to, steroid injections, radiofrequency ablation of the nerves serving the sacroiliac joint and implantation of neurostimulation devices. Our professional education program seeks to teach pain physicians, and other health care providers, about the benefits of iFuse, in order to prompt these providers to refer their patients with sacroiliac joint dysfunction to surgeons who have been trained to perform the iFuse procedure. These providers may, however, prefer to continue to treat these patients with the interventions they offer. If we are unable to convince potential referring health care providers of the comparative benefits of iFuse, and we are therefore unable to prompt sufficient numbers of these providers to refer their patients with sacroiliac joint dysfunction for treatment by surgeons trained to perform the iFuse procedure, sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

Surgeons and payors may not find our clinical evidence to be compelling, which could limit our sales and revenue, and on-going and future research may prove our products to be less safe and effective than initially anticipated.

The products we currently market in the United States have either received premarket clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, or are exempt from premarket review. Those marketed in the European Union, or EU, have been the subject of a CE Certificate of Conformity. The 510(k) clearance process of the U.S. Food and Drug Administration, or FDA, requires us to document that our product is “substantially equivalent” to another 510(k)-cleared products. The 510(k) process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes, such as a premarket approval, or PMA, and does not usually require pre-clinical or clinical studies. Additionally, to date, we have not been required to complete clinical studies in connection with the sale of our products outside the United States. As a result, while there are a number of published studies relating to iFuse and minimally invasive sacroiliac joint surgery that support the safety and effectiveness of our products and the benefits they offer, our clinical studies may lack the size and scope of randomized controlled clinical trials required to support approval of a PMA. For these reasons, surgeons may be slow to adopt our products, third-party payors may be slow to provide coverage, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by surgeons, significantly reduce our ability to achieve expected sales, and could prevent us from achieving profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension, or withdrawal of FDA clearance, and suspension, variation, or withdrawal of our CE Certificates of Conformity, significant legal liability or harm to our business reputation, which could have a material adverse effect on our results or operations and financial condition. Similar risks apply to product approvals and registrations in other countries outside the United States and the EU as well.

Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the proliferation of “physician-owned distributorships” may impact our ability to sell our product at prices necessary to support our current business strategies.

If competitive forces drive down the prices we are able to charge for our product, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business. The sacroiliac joint fusion market has attracted numerous new companies and technologies. As a result of this increased competition, we believe there will be continuing increased pricing pressure, resulting in lower gross margins, with respect to our products.

Even to the extent our product and procedures using our product are currently covered and reimbursed by third-party private and public payors, adverse changes in coverage and reimbursement policies that affect our products, discounts, and number of implants used may also drive our prices down and harm our ability to market and sell our products.

We are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our products will be justified and incorporated into the overall cost of the procedure. In addition, to the extent there is a shift from inpatient setting to outpatient settings, we may experience increased pricing pressure.

Consolidation in the healthcare industry, including both third-party payors and healthcare providers, could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations, or financial condition. Because healthcare costs have risen significantly over the past several years, numerous initiatives and reforms initiated by legislators, regulators, and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage, and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products, and adversely impact our business, results of operations, or financial condition. As we continue to expand into international markets, we will face similar risks relating to adverse changes in coverage and reimbursement procedures and policies in those markets.

Physician-owned distributorships, or PODs, are medical device distributors that are owned, directly or indirectly, by physicians. These physicians profit from selling or arranging the sale of medical devices for use in procedures they perform on their own patients at hospitals that purchase the devices from the POD. We currently do not engage with PODs. The proliferation of PODs could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.

We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow.

Our currently marketed products are, and any future products we commercialize will likely be, subject to intense competition. Our field is subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors, and are safer, less invasive, and more effective than alternatives available for similar purposes as demonstrated in peer-reviewed clinical publications. Because of the size of the potential market, we anticipate that other companies will dedicate significant resources to developing competing products.

The number of competitors that we are aware of marketing sacroiliac joint fusion products in the United States has grown from zero to 23 since 2008. Many of our current and potential competitors are major medical device companies that have substantially greater financial, technical, and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly longer operating history and more established reputations than we do. Some of these companies sell a broad suite of products that can be used together in the operating room in order to facilitate surgery, such as surgical imaging, navigation and robotic systems, or a large number of implants intended to treat different conditions affecting the spine and pelvis. The ability of these competitors to sell these products together or as part of larger purchasing arrangements may put us at a disadvantage.

In the United States, we believe that our primary competitors currently are Globus Medical, Inc., Medtronic plc, XTant Medical Holdings and RTI Surgical, Inc. Our primary competitors in Europe are Globus Medical, SIGNUS Medizintechnik GmbH, and XTant Medical Holdings. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of the sacroiliac joint that compete directly or indirectly with our products. They may also develop and patent processes or products earlier than we can or obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for competing products in the European Economic Area, or EEA, more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products and our results of operations could be negatively affected.

Some of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies. These competitors may enjoy several competitive advantages over us, including:

- greater financial, human, and other resources for product research and development, sales and marketing, and legal matters;
- significantly greater name recognition;
- established relationships with surgeons, hospitals, and other healthcare providers;
- large and established sales and marketing and distribution networks;
- greater experience in obtaining and maintaining domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for products and product enhancements;

- more expansive portfolios of intellectual property rights; and
- greater ability to cross-sell their products or to incentivize hospitals or surgeons to use their products.

New participants have increasingly entered the medical device industry. Many of these new competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our products or that are alternatives to our existing or planned products may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the market generally.

As a result, without the timely introduction of new products and enhancements, our products may become obsolete over time. If we are unable to develop innovative new products, maintain competitive pricing, and offer products that surgeons and other physicians perceive to be as reliable as those of our competitors, our sales or margins could decrease, thereby harming our business.

We currently manufacture and sell products used in a single procedure, which could negatively affect our operations and financial condition.

We do not sell any product other than iFuse and related tools and instruments. Therefore, we are solely dependent on widespread market adoption of iFuse and we will continue to be dependent on the success of this single product for the foreseeable future. There can be no assurance that iFuse will gain a substantial degree of market acceptance among surgeons, patients or healthcare providers. Our failure to successfully increase sales of iFuse or any other event impeding our ability to sell iFuse, would result in a material adverse effect on our results of operations, financial condition and continuing operations.

If we are unable to maintain and expand our network of direct sales representatives and third-party distributors, we may not be able to generate anticipated sales.

As of March 31, 2019, our U.S. sales force consisted of 49 sales representatives directly employed by us and 34 third-party distributors. As of March 31, 2019, our international sales force consisted of 16 sales representatives and 27 exclusive third-party distributors, which together have had sales in 33 countries through March 31, 2019. Our operating results are directly dependent upon the sales and marketing efforts of both our direct sales force and of our third-party distributors.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and third-party distributors with significant technical knowledge in various areas, such as spine health and treatment. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. Our intention is for our direct sales representatives and third-party distributors to develop long-lasting relationships with the surgeons they serve. If our direct sales representatives or third-party distributors fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. Some of our international third-party distributors account for a significant portion of our international sales volume, and if any such third-party distributor were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative third-party distributors or increase our reliance on our direct sales representatives, which may not prevent our sales from being adversely affected. If a direct sales representative or third-party distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified third-party distributors or to hire additional direct sales representatives to work with us. Furthermore, we may not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or third-party distributors would prevent us from expanding our business and generating sales.

In addition, distribution arrangements are complex and time consuming to negotiate and document, especially outside the United States. We may not be able to negotiate distribution arrangements on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our products, delay their potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our products or bring them to market and generate revenue.

If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations, and financial condition.

We have a limited operating history and may face difficulties encountered by early stage companies in new and rapidly evolving markets.

We were formed in 2008. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, investors must consider the risks and difficulties frequently encountered by early stage companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of medical devices. These risks include our inability to:

- increase coverage by third-party, private, and government payors;
- establish and increase awareness of our brand and strengthen customer loyalty;
- obtain domestic and international regulatory clearances or approvals, and CE Certificates of Conformity;
- conform to commercialize new products and enhance our existing products;
- manage rapidly changing and expanding operations;
- grow our direct sales force and increase the number of our third-party distributors to expand sales of our products in the United States and in targeted international markets;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- continue to develop and enhance our products and product candidates;
- expand our presence and commence operations in international markets;
- perform clinical research and trials on our existing products and current and future product candidates; and
- attract and retain qualified personnel.

We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

Our sales volumes and our operating results may fluctuate over the course of the year.

We have experienced and continue to experience meaningful variability in our sales and gross profit from quarter to quarter, as well as within each quarter. Our sales and results of operations will be affected by numerous factors, including, among other things:

- payor coverage and reimbursement;
- the number of products sold in the quarter and our ability to drive increased sales of our products;
- our ability to establish and maintain an effective and dedicated sales force;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products and products in development;
- the mix of our products sold because profit margins differ amongst our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of materials and components;

- the evolving product offerings of our competitors;
- the demand for, and pricing of, our products and the products of our competitors;
- factors that may affect the sale of our products, including seasonality and budgets of our customers;
- domestic and international regulatory clearances or approvals, or CE Certificates of Conformity, and legislative changes affecting the products we may offer or those of our competitors;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- our ability to expand the geographic reach of our sales and marketing efforts;
- the costs of maintaining adequate insurance coverage, including product liability insurance;
- the availability and cost of components and materials;
- the number of selling days in the quarter;
- fluctuation in foreign currency exchange rates; and
- impairment and other special charges.

Some of the products we may seek to develop and introduce in the future will require FDA clearance or approval before commercialization in the United States, and commercialization of such products outside of the United States would likely require additional regulatory approvals, or Certificates of Conformity and import licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. Quarterly comparisons of our financial results may not always be meaningful and should not be relied upon as an indication of our future performance.

If our business strategy proves to be flawed, or if we do not successfully implement our business strategy, our business and results of operations will be adversely affected

Our business strategy was based on assumptions about the market that might prove wrong. We believe that various demographics and industry-specific trends will help drive growth in the market and our business, but these demographics and trends have been and will continue to be uncertain. Actual demand for our products could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments to those offered by our products gain widespread acceptance.

To implement our business strategy we need to, among other things, develop and introduce new products, find new applications for and improve our existing products, obtain new domestic and international regulatory clearances or approvals and CE Certificates of Conformity and domestic and international regulatory clearance or approval for new products and applications, and educate surgeons and payors about the clinical benefits and cost effectiveness of our products. We may not be able to successfully implement our business strategy. Also, our strategy of focusing exclusively on the sacroiliac joint market may limit our ability to grow. In addition, in order to increase our sales, we will need to commercialize additional products and expand our direct and third-party distributor sales forces in existing and new regions, all of which could result in our becoming subject to additional or different foreign and domestic regulatory requirements, with which we may not be able to comply. Moreover, we may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our products obsolete. Any failure to implement our business strategy may adversely affect our business, results of operations, and financial condition.

Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel.

We are dependent upon the continued services of key members of our senior management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our President, Chief Executive Officer, and Chairman, Jeffrey W. Dunn. The loss of members of our senior management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations, and financial condition. We do not maintain “key person” insurance for any of our executives or employees. In addition, several of the members of our executive management team are not subject to non-competition agreements that restrict their ability to compete with us. Accordingly, the adverse effect resulting from the loss of certain executives could be compounded by our inability to prevent them from competing with us.

Although currently subject to lock-up agreements and other restrictions on trading, a portion of the equity of our management team will not contain other contractual transfer restrictions and may become tradable in April 2019 after the expiration of the lock-up agreements entered into with the underwriters in our IPO. This liquidity may represent material wealth to such individuals and impact retention and focus of existing key members of management.

Our products may have undesirable side effects which may require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen adverse events related to our products could arise either during clinical development or, if cleared, approved, or subject to CE Certificate of Conformity, after the product has been marketed. In clinical research, the most common adverse event related to our implant was leg pain resulting from misplacement. The most common adverse event for our implant procedure has been minor wound infections. Additional adverse effects from iFuse or any of our other products could arise either during clinical development or, if approved, cleared, or subject to CE Certificate of Conformity, after the product has been marketed.

If we or others later identify adverse events caused by our products:

- sales of the product may decrease significantly, and we may not achieve the anticipated market share;
- regulatory authorities or our Notified Body may require changes to the labeling of our product. This may include the addition of labeling statements, specific warnings, and contraindications and issuing field alerts to physicians and patients;
- we may be required to change instructions regarding the way the product is implanted or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- regulatory authorities may require us to take our approved product off the market (temporarily or permanently) or to conduct other field safety corrective actions;
- we may be required to modify our product;
- we may be subject to litigation fines or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

Various factors outside our direct control may adversely affect manufacturing, sterilization, and distribution of our products.

The manufacture, sterilization, and distribution of our products is challenging. Changes that our suppliers may make outside the purview of our direct control can have an impact on our processes, quality of our products, and the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include:

- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk;
- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment, or other forms of disruption to business operations affecting our manufacturers or suppliers; and

- latent defects that may become apparent after products have been released and that may result in a recall of such products.

If any of these risks were to materialize, our ability to provide our products to customers on a timely basis would be adversely impacted.

We are dependent on a limited number of third-party suppliers, some of them single-source and some of them in single locations, for most of our products and components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials in a timely and cost-effective manner, could materially adversely affect our business.

We rely on third-party suppliers to supply substantially all of our products. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable prices, and on a timely basis. We do not have long-term supply contracts for some of our suppliers, and in some cases, even where we do have agreements in place, we purchase important parts of the iFuse Implant System from a single supplier. Therefore, we cannot assure investors that we will be able to obtain sufficient quantities of product in the future.

In addition, our anticipated growth could strain the ability of our suppliers to deliver an increasingly large supply of products, materials, and components. Suppliers often experience difficulties in scaling up production, including financial issues, or problems with production yields and quality control and assurance. For example, from time to time, we have experienced certain delays and may experience delays from our suppliers in the future.

We generally use a small number of suppliers for our instruments and rely on one supplier, Orchid Bio-Coat, a division of Orchid Orthopedic Solutions LLC, for the coating of our first-generation iFuse implants and one supplier, rms Company, for our second-generation iFuse-3D implants. Our dependence on such a limited number of suppliers exposes us to risks, including, among other things:

- third-party contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the safety or effectiveness of our products or cause delays in shipments of our products;
- third-party contract manufacturers or suppliers may fail to maintain good manufacturing practices, leading to quality control problems or regulatory findings that could cause disruptions in their manufacturing processes and lead to delays in shipments of our products;
- we or our third-party manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
- we or our third-party manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- we or our third-party manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- we may experience delays in delivery by our third-party manufacturers and suppliers due to changes in demand from us or their other customers;
- fluctuations in demand for products that our third-party manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our third-party manufacturers and suppliers may wish to discontinue supplying components or services to us for risk management reasons;
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our third-party manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

If any one or more of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products. If we are unable to satisfy commercial demand for our system in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products. Additionally, we could be forced to seek alternative sources of supply.

In addition, most of our supply and manufacturing agreements do not have minimum manufacturing or purchase obligations. As such, with many of our suppliers, we have no obligation to buy any given quantity of products, and the suppliers have no obligation to sell us or to manufacture for us any given quantity of components or products. As a result, our ability to purchase adequate quantities of components or our products may be limited and we may not be able to convince suppliers to make components and products available to us in some instances. Our suppliers may also encounter problems that limit their ability to supply components or manufacture products for us, including financial difficulties, damage to their manufacturing equipment or facilities, product discontinuations or adverse findings in quality audits. As a result, there is a risk that certain components could be discontinued and no longer available to us. We may be required to make significant “last time” purchases of component inventory that is being discontinued by the supplier to ensure supply continuity. If we fail to obtain sufficient quantities of high quality components to meet demand for our products in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Securing a replacement third-party manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our iFuse system that are subject to domestic and international regulatory clearances or approvals and the review of our Notified Body.

Because of the nature of our internal quality control requirements, regulatory requirements, and the custom and proprietary nature of the parts, we may not be able to quickly engage additional or replacement suppliers for many of our critical components. We may also be required to assess any potential new manufacturer’s compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Failure of any of our third-party suppliers to meet our product demand level would limit our ability to meet our sales commitments to our customers and could have a material adverse effect on our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA our Notified Body the competent authorities in the countries of the EEA, or other foreign regulatory authorities, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to delays in obtaining clearances or approvals, regulatory action including warning letters, product recalls, termination of distribution, product seizures, civil, administrative, or criminal penalties and the suspension, variation, or withdrawal of our CE Certificates of Conformity. We could incur delays while we locate and engage qualified alternative suppliers, and we may be unable to engage alternative suppliers on favorable terms or at all. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate sales.

In addition, each of our third-party suppliers operates at a facility in a single location and substantially all of our inventory of component supplies and finished goods is held at these locations. We, and our suppliers, take precautions to safeguard facilities, including acquiring insurance, employing back-up generators, adopting health and safety protocols, and utilizing off-site storage of computer data. However, vandalism, terrorism, or a natural or other disaster, such as an earthquake, fire, or flood, could damage or destroy equipment or our inventory of component supplies or finished products, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our suppliers’ facilities could harm our business, financial condition, and operating results.

As our sales grow, we may encounter problems or delays in the assembly of our products or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results.

To become profitable, we must assemble our products in adequate quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to assemble and test our products will require us to improve internal efficiencies. We may encounter a number of difficulties in increasing our assembly and testing capacity, including:

- managing production yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, federal, and foreign regulations.

If we are unable to satisfy commercial demand for our iFuse solution due to our inability to assemble and test, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use our competitors’ products.

If we do not enhance and broaden our product offerings through our research and development efforts, we may be unable to compete effectively.

In order to increase our market share in the sacroiliac joint fusion market, we must enhance and broaden our product offerings in response to changing customer demands and competitive pressures and technologies. We might not be able to successfully develop, obtain domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for, or market new products, and our future products might not be accepted by the surgeons or the third-party payors who reimburse for many of the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and effectiveness of new products; and
- obtain the necessary domestic and international regulatory clearances or approvals and CE Certificates of Conformity for new products or product enhancements.

If we do not develop and obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

We are required to maintain adequate levels of inventory, the failure of which could consume our resources and reduce our cash flows.

As a result of the need to maintain adequate levels of inventory, we are subject to the risk of inventory obsolescence. Many of our products come in sets, which feature components in a variety of sizes so that the implant or device may be customized to the patient's needs. In order to market our products effectively, we often maintain and provide surgeons and hospitals with back-up products and products of different sizes. For each surgery, fewer than all of the components of the set are used, and therefore certain portions of the set may become obsolete before they can be used. In the event that a substantial portion of our inventory becomes obsolete, 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 size and future growth in the market for iFuse has not been established with precision and may be smaller than we estimate, possibly materially. In addition, our estimates of cost savings to the economy and healthcare system as a result of the iFuse procedure are based on our internal estimates and market research and could also be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market or cost savings, our sales growth may be adversely affected.

We are not aware of an independent third-party study that reliably reports the potential market size for iFuse or cost savings as a result of the iFuse procedure. Therefore, our estimates of the size and future growth in the market for our iFuse products, including cost savings to the economy overall, including patients and employers, and to the healthcare system and the number of people currently suffering from lower back pain who may benefit from and be amenable to our iFuse procedure, is based on a number of internal and third-party studies, surveys, reports, and estimates. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our iFuse products and procedures and health cost savings, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. For example, the surveys we have conducted are based on a small number of respondents and are not statistically significant and may have other limitations. The actual incidence of lower back pain, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions and estimates are incorrect. As a result, our estimates of the size and future growth in the market for our iFuse products may prove to be incorrect. In addition, actual health cost savings to the healthcare system as a result of the iFuse procedure may materially differ from those we expect. If the actual number of people with lower back pain who would benefit from our iFuse products and the size and future growth in the market for iFuse products and related costs savings to the healthcare system is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business.

Our results of operations could suffer if we are unable to manage our planned international expansion effectively.

Expansion into international markets is an element of our business strategy and involves risk. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import, and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly affect us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, and the United Kingdom Bribery Act, or UKBA, anti-boycott laws, anti-money laundering laws, and regulations relating to economic sanctions imposed by the United States, including the Office of Foreign Asset Control of the U.S. Treasury. Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect 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 and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

In addition, some of the countries in which we sell or plan to sell our products are, to some degree, subject to various risks, including:

- exposure to different legal and regulatory standards;
- lack of stringent protection of intellectual property;
- obstacles to obtaining domestic and foreign export, import, and other governmental approvals, permits, and licenses and compliance with foreign laws;
- potentially adverse tax consequences and the complexities of foreign value-added tax systems;
- adverse changes in tariffs and trade restrictions;
- limitations on the repatriation of earnings;
- difficulties in staffing and managing foreign operations;
- transportation delays and difficulties of managing international distribution channels;
- longer collection periods and difficulties in collecting receivables from foreign entities;
- increased financing costs;
- currency risks; and
- political, social, and economic instability and increased security concerns.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation.

Our goal of a successful international expansion depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we plan to do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

In the future our products may become obsolete, which would negatively affect operations and financial condition.

The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices, and products that are more effective than our iFuse system or that would render the iFuse system obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our product. Accordingly, our success will depend in part on our ability to respond quickly to medical and changes through the development and introduction of new products. Product development involves a high degree of risk and there can be no assurance that our new product development efforts will result in any commercially successful products.

If we experience significant disruptions in our information technology systems, our business, results of operations, and financial condition could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage:

- sales and marketing, accounting, and financial functions;

- inventory management;
- engineering and product development tasks; and
- our research and development data.

Our information technology systems are vulnerable to damage or interruption from:

- earthquakes, fires, floods, and other natural disasters;
- terrorist attacks and attacks by computer viruses or hackers;
- power losses; and
- computer systems, or Internet, telecommunications, or data network failures.

The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, and legal liability issues, all of which could have a material adverse effect on our reputation, business, results of operations, and financial condition.

In addition, we accept payments for many of our sales through credit card transactions, which are handled through a third-party payment processor. As a result, we are subject to a number of risks related to credit card payments. As a result of these transactions, we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our products or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our customers' credit card information to our third-party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our customers' credit card information if the security of our third-party credit card payment processor is breached. We and our third-party credit card payment processor are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. If we or our third-party credit card payment processor fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our ability to accept credit card payments from our customers, and there may be an adverse impact on our business.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

From time to time, we expect to consider opportunities to acquire or make investments in other technologies, products, and businesses that may enhance our capabilities, complement our current products, or expand the breadth of our markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including:

- problems assimilating the purchased technologies, products, or business operations;
- issues maintaining uniform standards, procedures, controls, and policies;
- unanticipated costs and liabilities associated with acquisitions;
- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product, or technology into our business or retain any key personnel, suppliers, or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete, and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to successfully integrate any acquired businesses, products, or technologies effectively, our business, results of operations, and financial condition will be materially adversely affected.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenue.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships, or other arrangements to develop products and to pursue new markets. We have not entered into any collaboration arrangements to date. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

Risks Related to Our Legal and Regulatory Environment

We, our suppliers, and our third-party manufacturers are subject to extensive governmental regulation both in the United States and abroad, and 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. The FDA and other U.S. and foreign governmental agencies regulate, 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;
- premarket clearance and approval;
- conformity assessment procedures;
- record keeping procedures;
- advertising and promotion;
- compliance with good manufacturing practices requirements;
- recalls and 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 approval studies; and
- product import and export.

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

Before we can market or sell a new regulated product or make a significant modification to an existing product in the United States, with very limited exception, we must obtain either clearance under Section 510(k) of the FDCA for Class II devices or approval of a premarket approval, or PMA, application from the FDA for a Class III device. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology, and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Both the 510(k) and PMA processes can be expensive and lengthy and require the payment of significant fees, unless exempt. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining domestic and international regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

In the United States, our currently commercialized products have either received premarket clearance under Section 510(k) of the FDCA or are exempt from premarket review. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy, and uncertain PMA process. Although we do not currently market any devices under PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from premarket review, the FDA may require us to submit a 510(k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure investors that we will be able to obtain the 510(k) clearances with respect to those products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that our products are safe and effective for their intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay clearance or approval of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. These studies can be very expensive and time consuming to conduct. Failure to comply with those studies in a timely manner could result in the revocation of the 510(k) clearance for a product that is subject to such a 522 Order and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States.

In the EEA, our medical devices must comply with the Essential Requirements set forth in Annex I to the EU Medical Devices Directive (Council Directive 93/42/EEC), or Essential Requirements. Compliance with these requirements is a prerequisite to be able to affix the CE mark to our medical devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements 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), 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 third-party organization designated by the competent authorities of a EEA country to conduct conformity assessments, known as a Notified Body. The Notified Body would typically audit and examine the medical device's Technical File, the quality system for the manufacture, design and conduct a final inspection of our medical devices before issuing a CE Certificate of Conformity demonstrating compliance with the Essential Requirements or the QSR of the Medical Devices Directive.

Additionally, as part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices to verify that they comply with the relevant Essential Requirements covering safety and performance. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions/ warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from (i) clinical studies conducted on the devices being assessed; (ii) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated; or (iii) both clinical studies and scientific literature. With respect to implantable devices, or devices classified as Class III in the EU, the manufacturer must conduct clinical studies to obtain the required clinical data, unless the relying on existing clinical data from similar devices can be justified. As part of the conformity assessment procedure, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation for the medical device. The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time consuming.

The FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and effectiveness of our products.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- facility closures;
- refusal of the FDA or our Notified Body or other regulator to grant future clearances or approvals or to issue CE Certificates of Conformity;
- withdrawals or suspensions of current clearances or approvals and CE Certificates of Conformity, resulting in prohibitions on sales of our products; and
- in the most serious cases, criminal penalties.

Adverse action by an applicable regulatory agency, our Notified Body or the FDA could result in inability to produce our products in a cost-effective and timely manner, or at all, decreased sales, higher prices, lower margins, additional unplanned costs or actions, damage to our reputation, and could have material adverse effect on our reputation, business, results of operations, and financial condition.

We and our sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to physician kickbacks and false claims for reimbursement, as well as equivalent foreign laws.

Healthcare providers, distributors, physicians, and third-party payors play a primary role in the distribution, recommendation, ordering, and purchasing of any implant or other medical device for which we have or obtain marketing clearance or approval. Through our arrangements with customers and third-party payors, we are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, or third-party distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete, and accurate reporting of financial information or data, other commercial or regulatory laws or requirements, and equivalent foreign rules. We have a compliance program, Code of Conduct, and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and government authorities may conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance despite our good faith efforts to comply.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Our relationships and our distributors' relationships with surgeons, other healthcare professionals, and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds; knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease, or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are also criminal penalties for making or presenting a false or fictitious or fraudulent claim to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third-party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which 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 applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, and 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, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our employees are found to have violated any of the above laws we may be subjected to administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties and damages, and damage to our reputation.

We have entered into consulting agreements and royalty agreements with surgeons, including some who are customers. We also engage in co-marketing arrangements with certain surgeons who use our products. In addition, a small number of our current customer surgeons own less than 1.0% of our stock, which they either purchased in an arm's length transaction on terms identical to those offered to others or received from us as fair market value consideration for consulting services performed. While all of these transactions were structured with the intention of complying with all applicable laws, including the federal Anti-Kickback Statute, state anti-kickback laws and other applicable laws, to the extent applicable, it is possible that regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to significant penalties. We would be materially and adversely affected if regulatory agencies interpret our financial relationships with surgeons who order our products to be in violation of applicable laws and we were unable to comply with such laws, which could subject us to, among other things, monetary penalties for non-compliance, the cost of which could be substantial.

In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved, or "off-label" uses of their products. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for "off-label" uses. We market our products and provide promotional materials and training programs to surgeons regarding the use of our products. If it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, criminal penalty, and damage to our reputation. Federal and state authorities also pursue actions for false claims based upon improper billing and coding advice or recommendations, as well as decisions related to the medical necessity of procedures, including the site-of-service where procedures are performed. Actions under the federal False Claims Act may also be brought by whistleblowers under its *qui tam* provisions.

To enforce compliance with the federal laws, the U.S. Department of Justice has increased its 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. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare company settles an investigation with the Department of Justice or other law enforcement agencies, it may need 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. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

The scope and enforcement of these laws is uncertain and subject to rapid change. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business.

In the ordinary course of our business, we collect and store sensitive data, including legally protected personally identifiable information. We collect this kind of information during the course of clinical trials and for post-marketing safety vigilance, helping enable surgeons and their patients to pursue claims for reimbursement for procedures using iFuse and servicing potential warranty claims.

There are a number of state, federal, and international laws protecting the privacy and security of health information and personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny of companies' data practices and escalating levels of enforcement and sanctions. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes certain requirements regarding the privacy, security, use, and disclosure of an individual's protected health information, or PHI, by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as "covered entities," and their "business associates," or subcontractors who provide services to covered entities that involve the creation, use, maintenance, or disclosure of PHI. ARRA included significant increases in the penalties for improper use or disclosure of an individual's PHI under HIPAA and extended enforcement authority to state attorneys general. The amendments also created notification requirements applicable to covered entities and business associates in certain cases when PHI in their control has been inappropriately accessed or disclosed. In the case of a breach of unsecured PHI, covered entities may be required to provide notification to individuals affected by the breach, federal regulators, and, in some cases, local and national media. In addition to HIPAA, most states have laws requiring notification of affected individuals and state regulators in the event of a breach of "personal information," which is a broader class of information than the PHI protected by HIPAA. Certain states also have data privacy requirements applicable to individually identifiable health information. Privacy laws in different states may contain different requirements, and such laws may not be pre-empted by HIPAA, which could complicate our efforts to comply.

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

Many foreign countries and governmental bodies, including the EU, Australia, and other relevant jurisdictions, have laws and regulations concerning the collection and use of personal or sensitive data obtained from their residents or by businesses operating within their jurisdiction. For example, the European Commission recently adopted the General Data Protection Regulation, or the GDPR, effective on May 25, 2018, that superseded current EU data protection legislation, imposed more stringent EU data protection requirements and provides for greater penalties for noncompliance. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use "personal data," or any information relating to an identified or identifiable natural person, in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, and substantial new obligations on services providers. Non-compliance with the GDPR can trigger steep fines of up to €20 million or 4% of total worldwide annual revenues, whichever is higher. Given the breadth and depth of changes in data protection obligations, achieving and maintaining GDPR compliance will require considerable time and resources.

We are at risk of enforcement actions taken by certain EU data protection authorities until such point in time that we may be able to ensure that all transfers of personal data to us from the European Economic Area are conducted in compliance with all applicable regulatory obligations, the guidance of data protection authorities and evolving best practices. We may find it necessary to establish systems to maintain personal data originating from the EU in the European Economic Area, which may involve substantial expense and may cause us to need to divert resources from other aspects of our business, all of which may adversely affect our business.

Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end-customers, and other affected individuals, and the imposition of integrity obligations and agency oversight, damage to our reputation, and loss of goodwill, any of which could harm our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the European Union, the United States, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products.

We are subject to risks associated with our non-U.S. operations.

The FCPA prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. Other anti-corruption or anti-bribery laws, such as the UKBA, prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business in foreign countries. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of slush funds from which such improper payments can be made. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, and result in a material adverse effect on our business, results of operations, and financial condition. We also could suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures, including further changes or enhancements to our procedures, policies, and controls, as well as potential personnel changes and disciplinary actions.

Furthermore, we are subject to anti-boycott laws, anti-money laundering laws, and the export controls and economic embargo rules and regulations of the United States, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute, or otherwise transfer our products or technology to prohibited countries or persons. A determination that we have failed to comply, whether knowingly or inadvertently, may result in substantial penalties, including fines and enforcement actions and civil and/or criminal sanctions, the disgorgement of profits, and the imposition of a court-appointed monitor, as well as the denial of export privileges, and may have an adverse effect on our reputation.

Even if our products are approved by regulatory authorities or CE marked, if we, our contractors, or our suppliers fail to comply with ongoing FDA or other foreign regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory clearance or approval, or a CE Certificate of Conformity, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA, our Notified Body and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain regulatory clearance or approval, or a CE Certificate of Conformity.

The failure by us or one of our suppliers to comply with applicable statutes and regulations, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance or premarket approval and conformity assessments of new products or modified products;
- limitations on the intended uses for which the product may be marketed;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- suspension or withdrawal of CE Certificates of Conformity;
- refusal to grant export approval for our products; and
- criminal prosecution.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace, or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation, or withdrawal of regulatory approvals or CE Certificates of Conformity, product seizures, injunctions, or the imposition of civil, administrative, or criminal penalties which would adversely affect our business, operating results, and prospects.

If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

The FDA inspected our facilities in May 2014. As a result, we received a Notice of Inspectional Observations, or Form 483, with three observations that have since been addressed with a corrective and preventative action, or CAPA, plan. We responded to the Agency in writing and the matter was closed as of October 2014 through the issuance of an Establishment Inspection Report. To date, the FDA has not taken any further action with respect to the May 2014 inspection or its findings. The FDA inspected our facilities again in December 2016 and no findings were noted.

Our employees, independent contractors, consultants, manufacturers, and third-party distributors may engage in misconduct or other improper activities, relating to regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, manufacturers, and third-party distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, disgorgement of profits, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

We may be subject to enforcement action, including fines, penalties or injunctions, if we are determined to be engaging in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. In the United States, the full indication for the iFuse Implant System is: "The iFuse Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life." Moreover, iFuse is one of the few devices regulated through the class II pathway that has claims for clinical improvements. iFuse-3D, which was FDA-cleared in 2017, has a very similar indication statement but does not have the statement regarding improvement in pain, function and quality of life. In the United States, our marketing strategies must adhere to the above statements. In all other countries, the indication statement for the iFuse Implant System (including iFuse-3D) more broadly indicates that the device is indicated for sacroiliac joint fusion. The above-described potential limitation in indication statements in the U.S. does not apply in other geographies.

We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, require us to stop promoting our products for those specific procedures until we obtain FDA clearance or approval for them, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines, and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government fund. In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

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.

Further, under the FDA's medical device reporting, regulations, we are required to report to the FDA any information that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products or repeated product malfunctions may result in a voluntary or involuntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations, and financial condition.

In the EEA, we must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the Member States of the EEA, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. 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. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products, whether in the United States or abroad 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 or another governmental authority, including foreign governmental authorities, or the discovery of serious safety issues or malfunctions with our products, can result in voluntary corrective actions or agency enforcement actions, which could have a significant adverse impact on us.

The FDA 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 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.

In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is an unreasonable risk of substantial public harm. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us or one of our third-party 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.

The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Modifications to our products may require new 510(k) clearances or premarket approvals and new conformity assessment by our Notified Body, or may require us to cease marketing or recall the modified products until clearances, approvals, or CE Certificates of Conformity are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer make and document this determination in the first instance. A manufacturer may determine that a modification could not significantly affect safety or effectiveness and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. FDA may review any manufacturer's decision and may not agree with our decisions regarding whether new clearances or approvals are necessary. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified until clearance or approvals can be obtained, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances new 510(k) clearances or PMAs are not required. If the FDA disagrees with our determination and requires us to submit new 510(k) clearances or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant enforcement action, regulatory fines, or penalties.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions.

In the EEA, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial changes to our quality system or changes to our devices which could affect compliance with the essential requirements or the devices' intended use. The Notified Body will then assess the changes and verify whether they affect the products' conformity. There can be no assurances that the assessment will be favorable and that the Notified Body will attest our compliance with the essential requirements, which will prevent us from selling our products in the EEA.

Obtaining regulatory clearances or approvals and CE Certificates of Conformity can be a time-consuming process, and delays in obtaining required future regulatory clearances or approvals, and CE Certificates of Conformity would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

There is no guarantee that the FDA will grant 510(k) clearance or premarket approval of our future products or that our Notified Body will issue the required CE Certificate of Conformity, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

We are in the process of developing our regulatory strategies for obtaining clearance or approval for future products. Some of them may require 510(k) clearance by the FDA or a new CE Certificate of Conformity. Other future products may require premarket approval. In addition, some of our new products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products or our Notified Body may not issue CE Certificate of Conformity for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products, new intended uses, or modifications to existing products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.

We currently market our products internationally and intend to expand our international marketing. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. For example, we intend to continue to seek domestic and international regulatory clearance to market our primary products Asia, Latin America, and the Middle East and other key markets. The approval procedures vary among countries and may involve requirements for substantial additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain FDA clearance or approval or to obtain CE Certificates of Conformity.

Clearance or approval by the FDA or obtaining a CE Certificate of Conformity does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA, and the CE marking of our products in the EEA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval, or a CE Certificate of Conformity for a medical device in the EEA in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA clearance or approval, or a CE Certificate of Conformity in the EEA and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations, and financial condition could be adversely affected.

Clinical trials necessary to support a 510(k) or PMA application or a conformity assessment procedure will be expensive and may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support a PMA application for our future products and additional safety and effectiveness data beyond that typically required for a 510(k) clearance for iFuse, as well as other possible future product candidates, and to support a conformity assessment procedure would be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the inclusion and exclusion criteria for participation in the clinical trial and patient compliance. Development of sufficient and appropriate clinical protocols to demonstrate safety and effectiveness are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA or our Notified Body may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA or our Notified Body may not consider our data adequate to demonstrate safety and effectiveness. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Our facility and our clinical investigational sites operate under procedures that govern the conduct and management of FDA-regulated clinical studies under 21 CFR Parts 50 and 812, and Good Clinical Practices. The FDA may conduct Bioresearch Monitoring inspections of us and/or our clinical sites to assess compliance with 21 CFR Parts 50 and 812, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action, as well as refusal to accept all or part of our data in support of our 510(k) or PMA, or we may need to conduct additional studies.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA, foreign authorities, or our Notified Body will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenue. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

U.S. legislative or FDA or foreign regulatory reforms may make it more difficult and costly for us to obtain regulatory clearances or approvals, or CE Certificates of Conformity for our product candidates and to manufacture, market, and distribute our products after approval is obtained.

From time to time, Congress introduces legislation that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

In December 2016, the 21st Century Cures Act was enacted, with a number of provisions impacting medical device regulation. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market, and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

The policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. Moreover, leadership, personnel and structural changes within the FDA as well as recent and future federal election outcomes could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Another example can be found in the European Economic Area, or EEA. On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the EEA. These proposals are intended to strengthen the medical devices rules in the EEA. On May 25, 2017, the new Medical Devices Regulation (2017/745 or "MDR") entered into force. Following its entry into application on May 26, 2020, the MDR will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EEA. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the EU MDR repeals and replaces the EU 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 regulation of medical devices among EEA Member States. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices to ensure a high level of safety and health while supporting innovation. The MDR will only become applicable in May 2020, three years after its first publication. The In Vitro Diagnostic Medical Devices Regulation (IVDR) also was adopted by the Parliament and the Council and will be applicable in May 2022. These regulations will substantially impact medical devices manufacturers. Examples of the changes which will be introduced by these regulations include the following:

- additional scrutiny during the conformity assessment procedure for high risk medical devices;
- strengthening of the clinical data requirements related to medical devices;
- strengthening of the designation and monitoring processes governing notified bodies;
- the obligation for manufacturers and authorized representative to have a person responsible for regulatory compliance continuously at their disposal;
- authorized representatives would be held legally responsible and liable for defective products placed on the EU market;
- increased traceability of medical devices following the introduction of a Unique Device Identification, or UDI, system;
- new rules governing the reprocessing of medical devices; and
- increased transparency with the establishment of EUDAMED III as information from several databases concerning economic operators, CE Certificates of Conformity, conformity assessment, clinical investigations, the UDI system, adverse event reporting and market surveillance would be available to the public.

Transition from the regulation of our products under the current EU Medical Device Directive, and implementing legislation in each EU member state, to regulation under the EU MDR may require a substantial transition effort by us. In addition, detail as to how certain aspects of the MDR will be implemented remains unclear. Failure to update our quality system and regulatory documentation could delay our transition to compliance with the MDR and delay or prevent us from obtaining new CE Certificates of Conformity under the MDR. Transition from compliance with the MDD to the MDR could result in disruption to our business in the EEA which could adversely affect our business, results of operation and financial condition. In addition, any changes to the membership of the European Union, such as the departure of the United Kingdom from the EU, may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations, and other healthcare-related organizations. Recent political, economic, and regulatory influences are subjecting the healthcare industry to fundamental changes that can impact coverage and reimbursement from third-party payors. For example, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, among other things, reduced and/or limited Medicare reimbursement to certain providers. Legislative changes to the Patient Protection and Affordable Care Act remain possible in the 116th United States Congress and under the Trump Administration. We expect that the Patient Protection and Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products. Other federal laws further reduce Medicare's payments to providers by two percent through 2024. These reductions reduce reimbursement for our products, which could potentially negatively impact our revenue, and may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, imposes, among other things, an annual excise tax on any entity that manufactures or imports medical devices offered for sale in the United States.

Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to \$20.0 billion over the next decade. A two-year moratorium currently applies to this tax through December 2019. After that time, the tax may be repealed or modified, or the moratorium may be lifted, in which case sales of our iFuse would be subject to this excise tax.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture, and sale of medical devices for sacroiliac joint surgery procedures. Sacroiliac joint surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis, and even death. In addition, if longer-term patient results and experience indicates that our products or any component of a product cause tissue damage, motor impairment, or other adverse effects, we could be subject to significant liability. Surgeons may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects, or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts, or product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation, our ability to attract and retain customers and our results of operations or financial condition.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial retentions or deductibles that we are responsible for. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, results of operations, and financial condition.

In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities.

The manufacture of certain of our products, including our implants and products, and the handling of materials used in the product testing process, including in our cadaveric laboratory, involve the use of biological, hazardous and/or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state, and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling, and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations, and financial condition.

The comprehensive tax reform bill adopted in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses arising after 2017 to 80% of current year taxable income and elimination of carrybacks of such net operating losses, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modification or repeal of many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

The UK's pending withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

Brexit has created significant uncertainty concerning the terms of the UK withdrawal from the EU and the future relationship between the UK and the EU. On April 11, 2019, the European Council agreed at its Special Meeting to extend the UK's departure date to October 31, 2019. It is possible the UK could withdraw from the EU prior to October 31, 2019 pursuant to agreed terms for a

transition period; however, both the EU and the UK are preparing for a “no deal” scenario in which the UK will leave the EU as a “third country” without the benefit of any transition arrangements.

The “no deal” scenario has been recognized by the policy makers in the UK and the EU as likely to cause significant market and economic disruption. The effects of Brexit will depend on whether the UK retains access to EU markets either during a transitional period or more permanently. Brexit could disrupt the single internal market principle, which ensures the free movement of goods, services and people between the UK and the EU, undermine bilateral cooperation in key policy areas and significantly disturb trade relationships between the UK and the EU. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace, amend or adopt.

The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations, and the pending withdrawal of the UK from the EU may also adversely affect European and global economic and market conditions, which may cause third-party payers, including governmental organizations, to closely monitor their costs and reduce their spending budgets, and which could contribute to instability in the global financial and foreign exchange markets. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us.

Risks Related to Our Intellectual Property

We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements and other methods, to protect our proprietary technologies and know-how. As of March 31, 2019, we owned 37 issued U.S. patents and had 15 pending U.S. patent applications, and we owned 9 issued foreign patents and had 5 pending foreign patent applications. As of March 31, 2019, we have 12 registered trademarks in the United States and have filed for 2 more. We have sought protection for at least 2 of these trademarks in 60 countries including the 28 European member countries of the Madrid Protocol.

We have applied for patent protection relating to certain existing and proposed products and processes. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. Furthermore, we cannot assure investors that any of our patent applications will be approved. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested, or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available. Since most of our issued patents are for the United States only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our products.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. We cannot assure investors that our trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure investors that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We also rely on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality and intellectual property assignment agreements with parties that develop intellectual property for us and/or have access to it, such as our officers, employees, consultants, and advisors. However, in the event of unauthorized use or disclosure or other breaches of such agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. If any of our trade secrets, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition, and results of operations could be materially adversely affected.

In the future, we may enter into licensing agreements to maintain our competitive position. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek damages or to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

If a competitor infringes upon one of our patents, trademarks, or other intellectual property rights, enforcing those patents, trademarks, and other rights may be difficult and time consuming. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources to defend our patents or trademarks against challenges or to enforce our intellectual property rights. In addition, if third parties infringe any intellectual property that is not material to the products that we make, have made, use, or sell, it may be impractical for us to enforce this intellectual property against those third parties.

We may be subject to damages resulting from claims that we, our employees, or our third-party distributors 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.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. Some of our third-party distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees, or our third-party distributors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and 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. Even if we are successful in defending against these claims, litigation could result in substantial costs, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations, and financial condition.

The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, and/or prevent us from developing or marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in 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 and sell our products. We have conducted a limited review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and the uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. 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 medical device industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, including treble, or triple, damages if an infringement is found to be willful, and/or royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, 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. If passed into law, patent reform legislation currently pending in the U.S. Congress could significantly change the risks associated with bringing or defending a patent infringement lawsuit. For example, fee shifting legislation could require a non-prevailing party to pay the attorney fees of the prevailing party in some circumstances.

In addition, we generally indemnify our customers and third-party distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or third-party distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or third-party 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 or third-party distributors or may be required to obtain licenses to intellectual property owned by such third parties. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers and third-party distributors may be forced to stop using or selling our products.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile, and the value of an investment in our common stock could decline.

Prior to October 17, 2018, there was no public market for our common stock. Medical device stocks have historically experienced volatility, and the trading price of our common stock may fluctuate substantially. These fluctuations could cause our stockholders to lose all or part of their investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following:

- actual or anticipated changes or fluctuations in our results of operations;
- results of our clinical trials and that of our competitors' products;
- regulatory actions with respect to our products or our competitor's products;
- announcements of new offerings, products, services or technologies, commercial relationships, acquisitions, or other events by us or our competitors;
- price and volume fluctuations in the overall stock market from time to time;
- significant volatility in the market price and trading volume of healthcare companies, in general, and of companies in the medical device industry in particular;
- fluctuations in the trading volume of our shares or the size of our public float;
- negative publicity;
- whether our results of operations meet the expectations of securities analysts or investors or those expectations change;
- litigation involving us, our industry, or both;
- regulatory developments in the United States, foreign countries, or both;
- lock-up releases and sales of large blocks of our common stock;
- additions or departures of key employees or scientific personnel; and
- general economic conditions and trends.

In addition, if the market for healthcare stocks or the stock market, in general, experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations, and financial condition.

Sales of substantial amounts of our common stock in the public markets, including when the “lock-up” or “market standoff” period from our IPO ends, or the perception that sales might occur, could reduce the price of our common stock and may dilute our stockholders’ voting power and ownership interest in us.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, could adversely affect the market price of our common stock, and may make it more difficult for our stockholders to sell our common stock at a time and price that they deem appropriate. All of the shares of common stock sold in our IPO are freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any shares held by our “affiliates” as defined in Rule 144 under the Securities Act. However, subject to certain exceptions, we, our directors and officers and the holders of substantially all of our capital stock, warrants and stock options prior to the IPO have agreed not to offer, sell or agree to sell, directly or indirectly, any shares of common stock without the permission of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated until April 14, 2019. When the lock-up period expires, our security holders will be able to sell shares in the public market subject to any restrictions under the securities laws. In addition, Morgan Stanley and Merrill Lynch may, in their discretion, release all or some portion of the shares subject to lock-up agreements prior to the expiration of the lock-up period. Sales of a substantial number of such shares upon expiration or early release of the lock-up, or the perception that such sales may occur, could cause our share price to fall, or make it more difficult for our stockholders to sell our common stock at a time and price that they deem appropriate.

The holders of approximately 12 million shares, or approximately 55.4%, of our common stock, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

We may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Insiders have substantial control over us, which could limit our other stockholders’ ability to influence the outcome of key transactions, including a change of control.

Our directors, executive officers, and each of our stockholders that own greater than 5% of our outstanding common stock, in the aggregate, beneficially own approximately 51.3% of the outstanding shares of our common stock as of March 31, 2019. As a result, these stockholders will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from our other stockholders’ interests and may vote in a manner that is adverse to our other stockholders’ interests. This concentration of ownership may have the effect of deterring, delaying, or preventing a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

We may be unable to utilize our federal net operating loss carryforwards to reduce our income taxes.

As of December 31, 2018, we had net operating loss, or NOL, carryforwards of \$135.5 million and \$109.9 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in 2029 and 2019, respectively. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which generally occurs if the percentage of the corporation’s stock owned by 5% stockholders increases by more than 50% over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have determined that we have experienced Section 382 ownership changes in 2010 and \$1.4 million of our NOL and tax credit carryforwards are subject to limitation. In addition, we are still analyzing the effect that our IPO may have had on our NOLs, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result of our IPO, or if a future ownership change occurs, our ability to use our NOL tax credit carryforwards may be materially limited, which would harm our future operating results by effectively increasing our future tax obligations.

The requirements of being a public company may strain our resources, divert our management's attention, and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming, or costly and increase demand on our systems and resources. Among other things, the Exchange Act requires that we file annual, quarterly, and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal controls over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and results of operations. Although we have already hired additional employees to comply with these requirements, we may need to hire even more employees in the future, which will increase our costs and expenses.

As a public company, these new rules and regulations have made it more expensive for us to obtain director and officer liability insurance. In the future, we may be required to accept reduced coverage. These factors could make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Failure to establish and maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq Global Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing with the year ending December 31, 2019, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K for that year, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. As a result, we may experience difficulty in producing accurate financial statements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. In addition, in connection with the future attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, our stockholders could lose confidence in our reporting, and the market price of our stock could decline. In addition, we could be subject to sanctions or investigations by the Nasdaq Global Market, the Securities and Exchange Commission, or SEC, or other regulatory authorities.

We are an "emerging growth company," and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;

- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements, and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from complying with new or revised financial accounting standards until such time as such standards are applicable to private companies.

If some investors find our common stock less attractive because we will rely on these exemptions, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) in 2023, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

If securities or industry analysts do not publish research or reports about our business, or publish unfavorable research reports about our business, our share price and trading volume could decline.

The trading market for our common stock depends, to some extent, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us publishes unfavorable commentary about us or changes their opinion of our business prospects, our share price would likely decline. If one or more of these analysts ceases coverage of or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

We have never declared or paid any dividends on our common stock. We intend to retain any earnings to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the future. As a result, our stockholders may only receive a return on an investment in our common stock if the market price of our common stock increases. In addition, our loan and security agreements contain restrictions on our ability to pay dividends.

Our credit facility contains covenants that may restrict our business and financing activities.

Borrowings under our credit facility are secured by substantially all of our assets. Our credit facility also restricts our ability to, among other things:

- dispose of or sell assets;
- make material changes in our business or management;
- consolidate or merge with or acquire other entities;
- incur additional indebtedness;
- incur liens on our assets;
- pay dividends or make distributions on our capital stock;
- make certain investments;
- enter into transactions with our affiliates;
- make any payment in respect of any subordinated indebtedness; and
- waive or amend any of our current intellectual property agreements or material contracts.

These restrictions are subject to certain exceptions. In addition, our loan and security agreement requires us to maintain a minimum cash balance and revenue targets. Beginning with the three months ended March 31, 2019, we are required to meet either revenue or earnings targets

The covenants in our credit facility, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in, expand, or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under our credit facility agreements. If not waived, future defaults could cause all of the outstanding indebtedness under our credit facility agreement to become immediately due and payable and terminate all commitments to extend further credit.

If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate our business.

Our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions include:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue 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 exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our 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;
- 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 a majority vote of our entire board of directors, the chairman of our board of directors, or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply 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, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time.

A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of, and do not currently intend to opt out of, this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which restricts our stockholders' ability to bring a lawsuit against us or our directors, officers, or employees in jurisdictions other than Delaware and federal district courts.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for these types of disputes with us or our directors, officers, or other employees.

Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, in light of a Delaware Chancery Court opinion issued in December 2018, we announced that we currently do not intend to enforce this aspect of our forum selection clause.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from our Public Offering of Common Stock

On October 16, 2018, our registration statement on Form S-1 (File No. 333-227445) relating to our IPO of common stock became effective. The IPO closed on October 16, 2018 at which time we issued 8,280,000 shares of our common stock at an initial offering price of \$15.00 per share for gross proceeds of \$124.2 million. We received net proceeds from the IPO of approximately \$113.4 million, after deducting the underwriting discount of \$8.7 million and other estimated offering-related expenses of \$2.1 million. None of the expenses associated with the IPO or private placement were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Morgan Stanley & Co. LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Canaccord Genuity Inc. and JMP Securities LLC acted as underwriters for the offering.

Shares of our common stock began trading on the Nasdaq Global Market on October 17, 2018. The shares were registered under the Securities Act on registration statement on Form S-1 (Registration No. 333-227445).

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 16, 2018.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description	Incorporation By Reference			Filing Date
		Form	SEC File No.	Exhibit/Reference	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38701	3.1	10/19/2018
3.2	Amended and Restated Bylaws.	S-1/A	333-227445	3.4	10/5/2018
4.1	Form of Common Stock Certificate of the Company.	S-1/A	333-227445	4.1	10/5/2018
4.2	Reference is made to Exhibits 3.1 and 3.2 .				
10.1	2019 US Bonus Plan	8-K	001-38701	Item 5.02	1/22/2019
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

** Furnished herewith. Exhibit 32.1 is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

SIGNATURES

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

SI-BONE, Inc.

Date: May 9, 2019

By: /s/ Jeffrey W. Dunn

Jeffrey W. Dunn

President and Chief Executive Officer

(Duly Authorized Officer and Principal Executive Officer)

SI-BONE, Inc.

Date: May 9, 2019

By: /s/ Laura A. Francis

Laura A. Francis

Chief Financial Officer

(Duly Authorized Officer and Principal Financial and Accounting Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeffrey W. Dunn, certify that:

1. I have reviewed this Form 10-Q of SI-Bone, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Jeffrey W. Dunn

Jeffrey W. Dunn
President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Laura A. Francis, certify that:

1. I have reviewed this Form 10-Q of SI-Bone, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Laura A. Francis

Laura A. Francis
Chief Financial Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jeffrey W. Dunn, President and Chief Executive Officer of SI-Bone, Inc. (the “Company”), and Laura A. Francis, Chief Financial Officer of the Company, each hereby certify that, to the best of his or her knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2019, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2019

/s/ Jeffrey W. Dunn
Jeffrey W. Dunn
President and Chief Executive Officer

Date: May 9, 2019

/s/ Laura A. Francis
Laura A. Francis
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of SI-Bone, Inc. 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.