

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, 2020

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

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	The Nasdaq Global Market

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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>
Smaller reporting company <input checked="" type="checkbox"/>	Emerging growth company <input checked="" type="checkbox"/>	

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

The number of shares outstanding of the registrant's Common Stock was 28,427,133 as of April 30, 2020.

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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, sales force expansion, surgeon adoption, reimbursement determinations, clinical trial results, and U.S. Food and Drug Administration ("FDA") approvals, 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:

- impact the COVID-19 pandemic will have on our company, including our operations, financial results and liquidity and capital resources, the existence and duration of state and local orders temporarily prohibiting elective procedures including procedures using the iFuse Implant System, the ability and desire of patients and physicians to undergo and perform such procedures, the duration of the COVID-19 pandemic, and whether the COVID-19 pandemic will recur in the future;
- our ability to maintain a healthy workforce in light of the ongoing COVID-19 pandemic;
- our expectation that a significant portion of our revenues will be derived from sales of the iFuse Implant System, or iFuse;
- our ability to develop additional revenue opportunities, including new indications for use and new devices;
- our ability to retain and grow our sales team based on the demand for our products;
- our ability to identify, train, and retain surgeons to perform procedures using our products;
- our ability to obtain and maintain favorable coverage and reimbursement determinations from third-party payors;
- our estimates of our market opportunity;
- our expectations regarding the scope of protection from intellectual property rights covering our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- timing of and results from clinical and other trials;
- marketing clearances and authorization from the FDA and regulators in other jurisdictions;
- timing of regulatory filings and feedback;
- competition in the markets we serve;
- our expectations of the reliability and performance of our product;
- our expectations of the benefits to patients, providers, and payors of our products;
- our reliance on a limited number of suppliers, including sole source suppliers, which may impact the availability of instruments and materials;
- our ability to sustain or increase demand for our products;
- our estimates regarding our costs and risks associated with our international operations and expansion;
- our expectations regarding our ability to retain and recruit key personnel;
- 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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,568	\$ 10,435
Short-term investments	77,373	81,345
Accounts receivable, net of allowance for doubtful accounts of \$272 and \$238, respectively	9,361	11,720
Inventory	5,726	5,452
Prepaid expenses and other current assets	1,936	2,510
Total current assets	161,964	111,462
Long-term investments	1,274	1,278
Property and equipment, net	4,269	3,954
Other non-current assets	312	315
TOTAL ASSETS	\$ 167,819	\$ 117,009
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,577	\$ 2,811
Accrued liabilities and other	9,284	11,605
Current portion of long-term borrowings	8,731	4,358
Total current liabilities	20,592	18,774
Long-term borrowings	30,557	34,865
Other long-term liabilities	400	362
TOTAL LIABILITIES	51,549	54,001
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; 28,406,128 and 25,163,803 shares issued and outstanding, respectively	3	3
Additional paid-in capital	323,922	258,121
Accumulated other comprehensive income	697	464
Accumulated deficit	(208,352)	(195,580)
TOTAL STOCKHOLDERS' EQUITY	116,270	63,008
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 167,819	\$ 117,009

The accompanying notes are an integral part of these unaudited 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,	
	2020	2019
Revenue	\$ 16,821	\$ 14,991
Cost of goods sold	1,932	1,526
Gross profit	14,889	13,465
Operating expenses:		
Sales and marketing	19,281	15,815
Research and development	2,090	1,683
General and administrative	5,400	4,766
Total operating expenses	26,771	22,264
Loss from operations	(11,882)	(8,799)
Interest and other income (expense), net:		
Interest income	498	744
Interest expense	(1,231)	(1,230)
Other expense, net	(157)	(60)
Net loss	\$ (12,772)	\$ (9,345)
Other comprehensive income (loss):		
Changes in foreign currency translation	12	(19)
Unrealized gain on marketable securities	221	25
Comprehensive loss	\$ (12,539)	\$ (9,339)
Net loss per share, basic and diluted	\$ (0.47)	\$ (0.38)
Weighted-average number of common shares used to compute basic and diluted net loss per share	27,252,409	24,390,648

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

SI-BONE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	25,163,803	\$ 3	\$ 258,121	\$ 464	\$ (195,580)	\$ 63,008
Issuance of common stock from public offering, net of underwriting discounts, commissions and offering costs	3,135,053	—	62,978	—	—	62,978
Issuance of common stock upon exercise of stock options, net of shares withheld	43,334	—	174	—	—	174
Issuance of common stock upon vesting of restricted stock units	63,938	—	—	—	—	—
Stock-based compensation	—	—	2,622	—	—	2,622
Vesting of early exercised stock options	—	—	27	—	—	27
Foreign currency translation	—	—	—	12	—	12
Unrealized gain on marketable securities	—	—	—	221	—	221
Net loss	—	—	—	—	(12,772)	(12,772)
Balance as of March 31, 2020	<u>28,406,128</u>	<u>\$ 3</u>	<u>\$ 323,922</u>	<u>\$ 697</u>	<u>\$ (208,352)</u>	<u>\$ 116,270</u>

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of 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 costs	—	—	(160)	—	—	(160)
Foreign currency translation	—	—	—	(19)	—	(19)
Unrealized gain on marketable securities	—	—	—	25	—	25
Net loss	—	—	—	—	(9,345)	(9,345)
Balance as of March 31, 2019	<u>24,497,566</u>	<u>\$ 3</u>	<u>\$ 248,829</u>	<u>\$ 445</u>	<u>\$ (166,522)</u>	<u>\$ 82,755</u>

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

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

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (12,772)	\$ (9,345)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,622	1,871
Depreciation and amortization	249	193
Bad debts expense	192	—
Accretion on marketable securities	(25)	(479)
Amortization of debt issuance costs	65	65
Loss on sale and disposal of property and equipment	—	97
Changes in operating assets and liabilities:		
Accounts receivable	2,207	87
Inventory	(256)	(165)
Prepaid expenses and other assets	581	(167)
Accounts payable	76	451
Accrued liabilities and other	(2,294)	314
Net cash used in operating activities	<u>(9,355)</u>	<u>(7,078)</u>
Cash flows from investing activities		
Maturities of marketable securities	21,000	17,600
Purchases of marketable securities	(16,777)	(22,741)
Purchases of property and equipment	(884)	(412)
Net cash provided by (used in) investing activities	<u>3,339</u>	<u>(5,553)</u>
Cash flows from financing activities		
Proceeds from follow-on public offering, net of underwriting discounts, commissions and offering costs	62,978	—
Proceeds from the exercise of stock options	174	125
Net cash provided by financing activities	<u>63,152</u>	<u>125</u>
Effect of exchange rate changes on cash and cash equivalents	(3)	(53)
Net decrease in cash and cash equivalents	<u>57,133</u>	<u>(12,559)</u>
Cash and cash equivalents at		
Beginning of period	10,435	25,120
End of period	<u>\$ 67,568</u>	<u>\$ 12,561</u>
Supplemental disclosure of non-cash information		
Vesting of early exercised stock options	\$ 27	\$ 66
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 52	\$ 140
Public offering costs included in accounts payable	\$ —	\$ 167

The accompanying notes are an integral part of these unaudited 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 primary product, the iFuse Implant System, or iFuse, in 2009 in the U.S., in 2010 in certain countries in the European Union, and in 2015 in certain countries in the rest of the world.

In October 2018, the Company completed its initial public offering ("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 costs.

In January 2020, the Company received \$50.3 million of net proceeds, after deducting the underwriting discounts and commissions, from its public offering of 4,300,000 shares of the Company's common stock at a public offering price of \$21.50 per share, of which 2,490,053 shares were offered and sold by the Company. Further, in February 2020, the underwriters fully exercised their option to purchase 645,000 shares of the Company's common stock at a public offering price of \$21.50 per share for an additional net proceeds of \$13.0 million to the Company, after deducting underwriting discounts and commissions. The total public offering costs incurred in connection with the follow-on offering were allocated based on the gross proceeds received by the Company and the other selling shareholders on a pro-rated basis. Public offering cost of \$0.4 million allocated to selling of shares by the Company was charged against the gross proceeds received from the follow-on offering. Public offering costs of \$0.2 million allocated to selling of shares by the selling shareholders was recognized as transaction costs within general and administrative expenses on the unaudited condensed consolidated statements of operations in the three months ended March 31, 2020.

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 ("U.S. 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 U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2019 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, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 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, 2019 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2020.

Risks and Uncertainties

In late 2019, SARS-CoV-2, a novel strain of coronavirus which causes the disease COVID-19, was reported in China, and in March 2020 the World Health Organization declared it a pandemic. The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict, as the response to the pandemic is in its early stages and information is rapidly evolving. The Company's customers which include hospitals and medical centers are diverting resources to treat COVID-19 patients and deferring elective surgical procedures, both of which are likely to impact the Company's revenues as well as receivable collections and inventory obsolescence. Furthermore, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is likely that it could cause a local and/or global recession. Such economic disruption could have a material adverse effect on the Company's business. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remains uncertain.

SI-BONE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

The severity of the impact of the COVID-19 pandemic on the Company's business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company's customers, all of which are uncertain and cannot be predicted. The Company's future results of operations and liquidity could be adversely impacted by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions and uncertain demand, excess and obsolete inventory, and the impact of any initiatives and programs that the Company may undertake to address financial and operations challenges faced by its customers.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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; 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, 2019. 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 (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. Those standards apply to companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. The Company continues to be an emerging growth company until December 31, 2023, unless one of the following occurs: (i) if the Company's total annual gross revenues are \$1.07 billion or more; or (ii) the Company has issued more than \$1.0 billion in non-convertible debt in the past three years; or (iii) the Company becomes a "large accelerated filer," as defined in Rule 12b-2 of the Exchange Act.

Segments

The Company manages and operates as one reportable segment. The Company derives substantially all of its revenue from sales to customers in the U.S. Revenue by geography is based on billing address of the customer. No single country outside the U.S. accounts for more than 10% of the total revenue during the periods presented. Long-lived assets held outside the U.S. are immaterial. The table below summarizes the Company's revenue by geography:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
United States	\$ 15,297	\$ 13,450
International	1,524	1,541
	<u>\$ 16,821</u>	<u>\$ 14,991</u>

Adoption of New Revenue Recognition Standard

The Company adopted the new revenue recognition standards ("ASC 606") using the modified retrospective method effective for the year ended December 31, 2019. This approach was applied to all contracts that were not completed as of January 1, 2019. As an emerging growth company that elected to take advantage of the JOBS Act accounting election, the Company was not required to adopt the new revenue standard in the interim reporting periods on the year of adoption and is not required, and intends not, to revise its 2019 interim periods which were reported under previous revenue recognition standards ("ASC 605"). The adoption of ASC 606 did not result in a material impact on the Company's condensed consolidated financial statements and no adjustment was made to the opening balance of accumulated deficit at January 1, 2019. ASC 606's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. As it relates to product sales where the Company's sales representative delivers the product at the point of implantation at hospital or medical facilities, which represents majority of the Company's revenue, the Company continues to recognize the revenue upon completion of the procedure and authorization by the customer, net of rebates and price discounts. As it relates to sale of products through distributors and hospitals where product is ordered in advance of the procedure, the Company continues to recognize the revenue upon shipments to the customers, net of rebates and price discounts. Additionally, ASC 606 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's sales commissions paid to its sales representatives is generally based on the surgeries performed. The Company applied the practical expedient that permits an entity to expense the cost to obtain a contract as incurred when the expected amortization is one year or less. As such, the Company recognize sales commission as expense when incurred.

The Company disaggregates revenues from contracts with customers into geographical regions. The Company determined that disaggregating revenue into these categories depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by regional economic factors. For information regarding revenue by geography, refer to Segments in "Note 2 - Summary of Significant Accounting Policies" in the accompanying Notes to Condensed Consolidated Financial Statements.

Recently Issued Accounting Standards Not Yet Effective

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. The new leases standard must be adopted using a modified retrospective transition method and allows for the application of the new guidance at the beginning of the earliest comparative period presented or at the adoption date. In November 2019, the FASB issued ASU 2019-10, which revised the mandatory effective dates of the new lease standard. For public companies, the new guidance remained effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the new guidance is now effective for fiscal years beginning after December 15, 2020 and interim periods within fiscal years beginning after December 15, 2021. Early adoption is still permitted for any interim or annual financial statements not yet issued.

SI-BONE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

As an emerging growth company, the new lease standard is now effective for the Company for the fiscal year ending December 31, 2021 and interim periods within fiscal year ending December 31, 2022. The Company is currently evaluating the impact of this standard on its consolidated financial statements including the timing of its adoption. The Company anticipates to elect several practical expedients that permit the Company not to reassess (1) whether a contract is or contains a lease, (2) the classification of existing leases, and (3) whether previously capitalized initial direct costs would qualify for capitalization under ASC 842. The Company expects that the adoption of this new standard will have a material impact on its balance sheet. The most significant impact would be the recognition of operating lease right-of-use assets and liability. The standard is not expected to have a material impact to the Company's consolidated statements of income and cash flows.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. FASB issued ASU 2019-05 in May 2019 and ASU 2019-08 in November 2019 for codification improvements of Topic 326. The new standard revises the accounting requirements related to the measurement of credit losses and will require organizations to measure all expected credit losses for financial assets based on historical experience, current conditions and reasonable and supportable forecasts about collectability. Assets must be presented in the financial statements at the net amount expected to be collected. In November 2019, the FASB issued ASU 2019-10, which defers the effective date of ASU 2016-13 for public companies that are eligible to be smaller reporting companies and all other companies, to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. In February 2020, the FASB issued ASU 2020-02, which provides guidance regarding methodologies, documentation, and internal controls related to expected credit losses. The Company is currently evaluating the impact of this standard on its consolidated financial statements, but do not expect the standard will have a 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 non-employees 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-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 assessing the impact of this new guidance but does not expect it to have a material impact on its 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 update 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 assessing the impact of this new guidance but does not expect it to have a material impact on its consolidated financial statements, and anticipates adopting the standard for the fiscal year ending December 31, 2020.

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3. Marketable Securities

All of the Company's marketable securities were available-for-sale and were classified based on their maturities. Marketable securities with remaining maturities at the date of purchase of three months or less are classified as cash equivalents. Short term investments are securities that original maturity or remaining maturity is greater than three months and not more than twelve months. Long-term investments are securities for which the original maturity or remaining maturity is greater than twelve months.

The table below summarizes the marketable securities:

March 31, 2020				
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
(in thousands)				
Money market funds	\$ 62,194	\$ —	\$ —	\$ 62,194
Cash equivalents	62,194	—	—	62,194
U.S. treasury securities	52,025	323	—	52,348
Corporate bonds	11,816	4	(47)	11,773
Commercial paper	13,252	—	—	13,252
Short-term investments	77,093	327	(47)	77,373
Corporate bonds	1,278	—	(4)	1,274
Long-term investments	1,278	—	(4)	1,274
Total marketable securities	\$ 140,565	\$ 327	\$ (51)	\$ 140,841

December 31, 2019				
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
(in thousands)				
Money market funds	\$ 3,068	\$ —	\$ —	\$ 3,068
Commercial paper	2,495	—	—	2,495
Cash equivalents	5,563	—	—	5,563
U.S. treasury securities	67,051	34	(2)	67,083
Corporate bonds	9,075	24	(2)	9,097
Commercial paper	5,165	—	—	5,165
Short-term investments	81,291	58	(4)	81,345
Corporate bonds	1,278	—	—	1,278
Long-term investments	1,278	—	—	1,278
Total marketable securities	\$ 88,132	\$ 58	\$ (4)	\$ 88,186

The long-term investments outstanding as of March 31, 2020 and December 31, 2019 mature in April 2021.

Unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive income (loss) on the condensed consolidated balance sheets. The Company evaluates its investments to assess whether those in unrealized loss positions are other-than-temporarily impaired. The Company considers impairments to be other-than-temporary if it is related to deterioration in credit risk or if it is likely the Company will sell the securities before the recovery of their cost basis. The Company did not identify any of its marketable securities as other-than-temporarily impaired as of March 31, 2020 and December 31, 2019.

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. There were no other financial assets or liabilities that required fair value hierarchy measurements and disclosures for the periods presented.

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:

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	\$ 62,194	\$ —	\$ —	\$ 62,194
U.S. treasury securities	52,348	—	—	52,348
Corporate bonds	—	13,047	—	13,047
Commercial paper	—	13,252	—	13,252
Total marketable securities	\$ 114,542	\$ 26,299	\$ —	\$ 140,841
December 31, 2019				
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	\$ 3,068	\$ —	\$ —	\$ 3,068
U.S. treasury securities	67,083	—	—	67,083
Corporate bonds	—	10,375	—	10,375
Commercial paper	—	7,660	—	7,660
Total marketable securities	\$ 70,151	\$ 18,035	\$ —	\$ 88,186

5. Balance Sheet Components

Inventory

As of March 31, 2020 and December 31, 2019, inventory consisted entirely of finished goods.

Property and Equipment, net:

	March 31, 2020	December 31, 2019
	(in thousands)	
Machinery and equipment	\$ 4,999	\$ 4,613
Construction in progress	1,994	1,854
Computer and office equipment	605	598
Leasehold improvements	502	497
Furniture and fixtures	189	187
	8,289	7,749
Less: Accumulated depreciation and amortization	(4,020)	(3,795)
	<u>\$ 4,269</u>	<u>\$ 3,954</u>

Depreciation expense was \$0.2 million and \$0.2 million for the three months ended March 31, 2020 and 2019, respectively.

Accrued Liabilities and Other:

	March 31, 2020	December 31, 2019
	(in thousands)	
Accrued compensation and related expenses	\$ 4,717	\$ 7,274
Accrued litigation expense	3,200	3,200
Accrued professional services	571	392
Others	796	739
	<u>\$ 9,284</u>	<u>\$ 11,605</u>

6. Commitments and Contingencies

Operating Leases

The Company has a non-cancelable operating lease for an office building space, located in Santa Clara, California which expires in May 2025. The Company also has non-cancelable operating leases for its office building spaces in Gallarate, Italy and Mannheim, Germany which both expire in November 2024, and in Knaresborough, United Kingdom, which expires in December 2026. Further, the Company also leases vehicles under operating lease arrangements for certain of its sales personnel in Europe which expire various times in 2020 to 2023.

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, 2020 and 2019, respectively.

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The table below summarizes aggregate future minimum lease payments under all leases as of March 31, 2020:

Year ending December 31,	(in thousands)
2020 (remaining nine months)	\$ 850
2021	1,024
2022	952
2023	866
2024	867
Thereafter	363
	<u>\$ 4,922</u>

Purchase Commitments and Obligations

The Company has certain purchase commitments related to its inventory management with certain manufacturing suppliers wherein the Company is required to purchase the amounts forecasted in a blanket purchase order. The contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude orders for goods and services entered into in the normal course of business that are not enforceable or legally binding. These outstanding commitments amounted to \$0.2 million and \$0.4 million as of March 31, 2020 and December 31, 2019, respectively.

Legal Proceedings

On February 6, 2019, a putative class action captioned Eric B. Fromer Chiropractic, Inc. ("Plaintiff") v. SI-BONE, Inc. (Civil Action No. 5:19-cv-633-SVK), was filed in the U.S. District Court, Northern District of California. The complaint alleges violations of the Telephone Consumer Protection Act (the "TCPA") on behalf of an individual and a putative class 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 plaintiff sought various forms of relief, including statutory damages of \$500 for each violation of the TCPA or, in the alternative, treble damages of up to \$1,500 for each knowing and willful violation of the TCPA and a permanent injunction prohibiting the Company from sending or having sent advertisements by way of facsimile transmission. On December 23, 2019 the parties filed a joint stipulation of dismissal of the case in the District Court in the Northern District of California and on January 14, 2020, the parties executed a definitive settlement agreement (the "Settlement Agreement") pursuant to which, the Company agreed to settle all disputes regarding the advertising faxes to the settlement class.

As this lawsuit is being resolved through a negotiated settlement and class resolution process, the Company believes that it will incur a loss associated with resolution of the claims against it. The Company has accrued litigation expense of \$3.2 million during the year ended December 31, 2019 within general and administrative expenses in the consolidated financial statements. The accrual reflects the estimable and probable costs that the Company may incur based on estimated claims submitted by members of the settlement class, as defined in the Settlement Agreement. As of March 31, 2020, the total accrued litigation expense remained the same as of December 31, 2019. The final disposition of the lawsuit may result in a loss in excess of the aggregate recorded amount.

Indemnification

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

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

The 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 following table summarizes the outstanding borrowings from the term loan described below, as of the dates presented:

	March 31, 2020	December 31, 2019
	(in thousands)	
Principal outstanding	\$ 40,000	\$ 40,000
Less: Unamortized debt issuance costs	(712)	(777)
Outstanding debt, net of debt issuance costs	<u>\$ 39,288</u>	<u>\$ 39,223</u>
Classified as:		
Current portion of long-term borrowings	<u>\$ 8,731</u>	<u>\$ 4,358</u>
Long-term borrowings	<u>\$ 30,557</u>	<u>\$ 34,865</u>

The outstanding debt is related to a term loan entered by the Company with Biopharma Credit Investments IV Sub LP, 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 in equal quarterly principal payments plus interest through December 2022 and carries a fixed interest rate of 11.5%. The term loan includes a pre-payment fee equal to the remaining 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 loan is a senior obligation secured with a blanket first lien on the assets of the Company. The effective interest rate for the three months ended March 31, 2020 and 2019 was 12.3% and 12.2%, respectively.

The table below summarizes annual future minimum principal payments under the loan agreement as of March 31, 2020:

Year ending December 31,	(in thousands)
2020 (remaining nine months)	\$ 4,444
2021	17,778
2022	17,778
Total future minimum payments	<u>40,000</u>
Less: Amount representing debt issuance costs	<u>(712)</u>
Long-term borrowings	<u>\$ 39,288</u>

The term loan requires the Company to maintain a minimum cash balance of \$5.0 million and to meet either minimum net sales or trailing 12-month consolidated earnings before interest, taxes, depreciation, and amortization targets. The Company was in compliance with all debt covenants as of March 31, 2020. Due to uncertainties surrounding the impact of the COVID-19 pandemic, there is a substantial risk that the Company may not meet the remaining minimum net sales or the trailing 12-month consolidated EBITDA targets in future quarters. If the Company is not in compliance with these requirements, the loan may become due immediately at Pharmakon's option.

8. Stock-Based Incentive Compensation Plans

Stock Options

The table below summarizes the stock option activity for the three months ended March 31, 2020:

	Number of Shares	Weighted- Average Exercise Price
Outstanding as of December 31, 2019	2,718,971	\$8.02
Granted	26,236	17.31
Exercised	(43,334)	4.03
Canceled and forfeited	(1,319)	12.87
Outstanding as of March 31, 2020	<u>2,700,554</u>	8.17

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As of March 31, 2020, there was \$5.0 million of unrecognized compensation cost related to stock options granted. These costs are expected to be recognized over a period of approximately 2.4 years.

The table below summarizes the weighted average grant date fair value per share and the assumptions used to estimate the grant date fair value of the stock options granted during the respective periods using the Black-Scholes option-pricing model:

	Three Months Ended March 31,					
	2020			2019		
Weighted average grant date fair value per share	\$8.37			\$10.40		
Expected term (years)	5.5	to	7.0	5.0	to	7.0
Expected volatility	46.74%	to	47.20%	42.00%	to	47.00%
Risk-free interest rate	1.56%	to	1.64%	2.52%	to	2.59%
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. As of March 31, 2020 and December 31, 2019, the Company had a total of 15,567 and 21,404 shares of common stock, respectively, subject to repurchase under the 2008 Stock Option Plan and \$0.1 million and \$0.1 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, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2019	543,041	\$19.72
Granted	868,683	20.43
Vested	(63,938)	21.00
Canceled and forfeited	(5,575)	18.43
Outstanding as of March 31, 2020	<u>1,342,211</u>	20.13

As of March 31, 2020, there was a total unrecognized compensation cost of \$23.4 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

The Company's 2018 Employee Stock Purchase Plan (the "ESPP") 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. The offer period generally commence in May and November. As of March 31, 2020 and December 31, 2019, total accumulated ESPP related employee payroll deductions amounted to \$0.9 million and \$0.2 million, respectively, which were included within accrued compensation and related expenses in the condensed consolidated balance sheets. On March 26, 2020, the Company's Board of Directors approved the amendment of the terms of future offerings under the ESPP, among other things, to provide that the offering set to commence in May 2020 be twelve months in duration and consist of two purchase periods, provide for automatic enrollment in a new offering, and increase the maximum number of shares that may be purchased on any single purchase date.

Stock-Based Compensation

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Cost of goods sold	\$ 71	\$ 42
Sales and marketing	1,141	670
Research and development	240	96
General and administrative	1,170	1,063
	<u>\$ 2,622</u>	<u>\$ 1,871</u>

9. Net Loss Per Share of Common Stock

The table below summarizes the computation of basic and diluted net loss per share:

	Three Months Ended March 31,	
	2020	2019
	(in thousands, except share and per share data)	
Net loss	\$ (12,772)	\$ (9,345)
Weighted-average shares used to compute basic and diluted net loss per share	<u>27,252,409</u>	<u>24,390,648</u>
Net loss per share, basic and diluted	<u>\$ (0.47)</u>	<u>\$ (0.38)</u>

Because the Company has reported a net loss in all periods presented, outstanding stock options, restricted stock units, shares subject to repurchase, ESPP purchase rights and common stock warrants are anti-dilutive and therefore diluted net loss per common share is the same as basic net loss per common share for the periods presented. The following anti-dilutive common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented:

	Three Months Ended March 31,	
	2020	2019
Stock options	2,700,554	3,047,130
Restricted stock units	1,342,211	531,669
Shares subject to repurchase	15,567	59,193
ESPP purchase rights	65,442	—
Common stock warrants	118,122	118,122
	<u>4,241,896</u>	<u>3,756,114</u>

10. Related Party Transaction

On February 24, 2020, the Company entered into a joint development agreement (the "Development Agreement") with SeaSpine Orthopedics Corporation ("SeaSpine") to develop a next generation device for sacropelvic fixation. Mr. Keith Valentine, who serves as the President, Chief Executive Officer and a member of the board of directors of SeaSpine, also serves as a member of the Company's Board of Directors since August 2015.

Pursuant to the development plan, SeaSpine shall use reasonable efforts to assist in the development of the potential product offering, including licensing certain existing intellectual property to be incorporated into such product. Under the terms of the Development Agreement, the Company agreed to make monthly payments to SeaSpine to reimburse for full time resources employed by SeaSpine responsible to conduct the development activities. For the three months ended March 31, 2020, the Company expensed \$22,000 of the reimbursement charges from SeaSpine, which was recorded within research and development expense in the condensed consolidated statement of operations. The outstanding liability to SeaSpine as of March 31, 2020 amounted to \$10,000, recorded within accrued liabilities and other in the condensed consolidated balance sheet.

Certain intellectual property developed pursuant to the project plan will be owned by the Company, certain intellectual property developed pursuant to the project plan will be owned by SeaSpine, and other intellectual property developed pursuant to the project plan will be jointly owned by SeaSpine and the Company. The Company also agreed to provide SeaSpine a royalty-free, worldwide, perpetual, non-exclusive license of certain of the Company's intellectual property incorporated into the product to be developed. The Company also agreed to pay SeaSpine a product royalty, in an amount specified in the Development Agreement, for each resulting product sold for a period of 10 years beginning on the initial market launch. The term of the Development Agreement shall continue until the expiration of all royalty terms, unless earlier terminated by either party, as provided for by the Development Agreement.

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, 2020 and 2019. 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, 2019.

On March 27, 2020, the U.S. federal government enacted the "Coronavirus Aid, Relief and Economic Security (CARES) Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company evaluated its impact of the CARES Act as part of ASC 740 consideration and does not expect the provisions of the CARES Act would result in a material impact to the consolidated financial statements. The Company continues to monitor the impact this CARES Act may have on its business.

12. Subsequent Events

Impact of COVID-19 Outbreak

As discussed in Note 2 - "Risk and Uncertainties" in the accompanying Notes to Condensed Consolidated Financial Statements, the extent of the impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict, as the response to the pandemic is in its incipient stages and information is rapidly evolving. As of the date of issuance of the unaudited condensed consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, judgments or revise the carrying value of its assets or liabilities. These estimates may change, as new events occur and additional information is obtained, and are recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's consolidated financial statements.

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 condensed consolidated 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 11, 2020. 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 focused on the development of implantable devices used in the surgical treatment of the sacropelvic anatomy. We have pioneered a proprietary minimally invasive surgical implant system, which we call iFuse, to fuse the sacroiliac joint to treat sacroiliac joint dysfunction, which often causes severe lower back pain. Since we introduced iFuse in 2009, as of March 31, 2020, more than 46,000 procedures have been performed by over 2,000 surgeons in the U.S. and 35 other countries.

We introduced our second-generation implant, the iFuse-3D, in 2017. This patented titanium implant combines the triangular cross-section of our first-generation iFuse Implant with a proprietary 3D-printed porous surface and fenestrated design.

In April 2019, we received clearance from the U.S. Food and Drug Administration ("FDA"), to promote the use of our iFuse system with the iFuse Bedrock technique for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint. We received CE marking and began marketing our iFuse system for the same indication in Europe in December 2019. In March 2020, we received FDA 510(k) clearance for an expanded indication for the iFuse Implant System to support our trauma program.

We market our products primarily with a direct sales force as well as a number of distributors in the U.S., and with a combination of a direct sales force and distributors in other countries.

In October 2018, we completed our initial public offering ("IPO") resulting in net proceeds of \$113.4 million after deducting underwriting discounts and commissions and offering expenses. In January and February 2020, we received a total of \$63.0 million of net proceeds, after deducting the underwriting discounts, commissions and offering costs from our follow-on public offering of our common stock.

Impact of COVID-19 Pandemic

Prior to the spread of COVID-19, we experienced case growth trends consistent with those experienced in the fourth quarter of 2019. Beginning at the end of February 2020, we began to see an impact on case volumes in Northern Italy due to the spread of the virus in the Lombardy region, the location of our operation in Gallarate, Italy. Overall, the disruption was not significant through the middle of March 2020, as Italy represents approximately 1% of our worldwide sales. Beginning in mid-March 2020, we saw a substantial worldwide reduction in global case volumes due to deferral of elective surgeries as a result of the spread of COVID-19 in the U.S. and across Europe. Many state and local governments in the U.S. and foreign governments have issued orders that temporarily preclude elective procedures in order to conserve scarce health system resources in view of the pandemic. Our revenue declined due to decreases in hospital admission rates and elective surgeries, which decreased the demand for procedures using our iFuse implants.

We have been continually taking actions to support patients, our customers, and our employees, while maintaining business continuity in response to the COVID-19 pandemic including:

- **Protecting Employees and Others:** To reduce the risk to our employees and their families from potential exposure to COVID-19, all employees in the Santa Clara office and in other office locations have been required to work from home, with the exception of those related to manufacturing and order fulfillment, and select others, based on local restrictions and guidance. We also restricted non-essential business travel, and urged employees to restrict personal travel, to protect the health and safety of our employees, patients and customers.
- **Continuing Operations and Clinical Support:** Consistent with applicable exceptions, we are maintaining streamlined assembly, distribution and other related processes in order to continue providing products to our customers. Specific protocols have been designed and implemented in order to minimize contact time among employees working on site. Where healthcare operations have been impacted, the sales team is supporting healthcare providers via telephone and online technologies, until conditions permit resumption of healthcare operations.

- **Curtailing Operating Expenses:** Until we have more clarity on the extent and duration of the impact from the COVID-19, we have taken preemptive steps to curtail spending, including implementing hiring restrictions, eliminating discretionary spending, reducing executive salaries, reducing capital expenditures, reducing non-essential marketing expenses, and delaying clinical research projects.

Our immediate priority amidst this pandemic is the health and safety of our employees, customers and patients. We took actions and will continually assess whether it is prudent to take further actions to minimize business disruption, ensure we can continue supporting physicians, and reduce spending in areas not critical to patient care to ensure we have financial flexibility.

Factors Affecting Results of Operations and Key Performance Indicators

We monitor certain key performance indicators that we believe provide us and our investors indications of conditions that may affect results of our operations. Our revenue growth rate and commercial progress is impacted, among others, by our key performance indicators including our ability to leverage our sales force, increase surgeon activity, engage key opinion leaders and influence coverage and reimbursements.

Leverage our sales force

We made significant investments in our sales force in 2019 and made further progress in the first quarter of 2020. We continuously evaluate the need to expand our sales force in line with anticipated future demand for our products. As of March 31, 2020, our U.S. sales force consisted of 62 territory sales managers and 53 clinical support specialists directly employed by us and 37 third-party distributors, compared to 49 territory sales managers and 42 clinical support specialists directly employed by us and 34 third-party distributors as of March 31, 2019. As of March 31, 2020, our international sales force consisted of 19 sales representatives directly employed by us and 31 third-party distributors, compared to 17 sales representatives directly employed by us and 27 third-party distributors as of March 31, 2019. We have halted sales force hiring during the pandemic. We have built a valuable sales team, and we believe they will be important to the recovery that follows the pandemic.

Increase surgeon activity

We continue to focus on increasing surgeon activity. Surgeon activity includes both the number of surgeons performing iFuse procedures as well as the number of procedures performed per surgeon. As of March 31, 2020, more than 1,400 surgeons in the U.S. have been trained on iFuse and have treated at least one patient. We will continue to pursue the remainder of the approximately 7,500 target surgeons in the U.S. for training in the future. However, this process has been and will continue to be hampered during the duration of the COVID-19 outbreak. We are utilizing a virtual education series for surgeons and mid-level practitioners to continue our training activities. As restrictions are lifted, we will focus on increasing the number of procedures performed by our active surgeons, converting recently trained surgeons to first case, and converting inactive surgeons to active surgeons.

Engage key opinion leaders

We conduct training courses in several academic centers in the U.S. We are seeing interest from key opinion leaders at academic centers in our Bedrock technique. We introduced this technique in June 2019 for use in the fusion of the sacroiliac joints in conjunction with a multi-segment spinal fusion, or long construct, procedure. The Bedrock technique is based on our proprietary implants, with one implace placed a posterior approach, through the sacrum, across the sacroiliac joint, and into the ilium, in contrast to placement via of three iFuse implants placed via a lateral approach through the ilium and into the sacrum, as in our traditional iFuse procedure. The Bedrock technique is used to increase stability at the base of a long construct, and biomechanical testing has shown iFuse implants in this position reduce sacroiliac joint motion by approximately 30% in conjunction with a long construct. Interest in the Bedrock technique has enabled our field sales representatives to access leading spine surgeons at important academic medical centers in the U.S. Our representatives are often then able to train a broader group of spine surgeons, including residents and fellows in training at the centers, on both the Bedrock technique and minimally invasive sacroiliac fusion. Since the launch of Bedrock, we have conducted more than 40 training courses at academic centers in the U.S. We recently received CE mark clearance for the promotion of the Bedrock technique in Europe and we launched the promotion of this technique in select European markets. We believe that acceptance of the sacroiliac joint as a pain generator by leading spine surgeons may result in more widespread awareness of sacroiliac joint dysfunction and its role in causing certain types of chronic low back pain. Our ability to engage with key opinion leaders has been impeded by COVID-19. However, we are continuing our activities with key opinion leaders through our virtual education series.

Influence coverage and reimbursement

We made significant progress in both the number of covered lives and the Medicare physician fee for surgeons performing minimally invasive sacroiliac fusion in the U.S.

- ***Covered lives*** - As of March 31, 2020, of the U.S. payors covering 282.7 million lives that reimburse for iFuse, 147.9 million lives are covered by private payors. Currently, covered lives counts do not include Anthem, which announced in December 2019 that they would cover minimally invasive sacroiliac fusion procedures in the event of pelvic girdle trauma only. These figures compare to 266.0 million covered lives, of which 131.0 million were covered by private payors as of March 31, 2019. We track the number of U.S. covered lives, or individuals whose healthcare is paid for by a private commercial or governmental payor that routinely reimburses for minimally invasive sacroiliac fusion, as a proxy for availability of the procedure within the U.S. healthcare payment system. As of March 31, 2020, 33 private payors have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence, compared to 30 exclusive coverage policies as of March 31, 2019. These payors have based their exclusive coverage decisions on the quality of our data. Further, as of March 31, 2020 and 2019, 19 private payors are covering iFuse and other products for sacroiliac joint fusion. We believe that the full impact of each coverage decision grows over time as surgeons gain confidence that they will receive reimbursement for the majority of their diagnosed patients.
- ***Surgeon payment*** - The Center for Medicare & Medicaid Services ("CMS") announced in November 2019 that the U.S. national average physician fee reimbursement for minimally invasive sacroiliac joint fusion increased from \$720, effective January 1, 2019 to \$915, effective January 1, 2020. 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. Upon resumption of elective procedures, we believe that expanded coverage for minimally invasive sacroiliac fusion and the increase in physician reimbursement for the procedure may enable surgeons to treat more patients diagnosed with sacroiliac joint dysfunction with iFuse.

Components of Results of Operations

Revenue

We generate 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 and mix of our products either delivered at the point of implantation at the hospital or other medical facilities or delivered through distributors or to hospitals where the products were ordered in advance of the procedure. 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.

The COVID-19 pandemic reduced our expected number of cases in the first quarter of 2020. As the pandemic continues in the U.S. and Europe, it is having and will continue to have a more significant impact on case volumes, similar to how the pandemic impacted elective surgery cancellations we experienced in March 2020. The COVID-19 pandemic has also significantly disrupted capital markets as well as worldwide economies, which could lead to prolonged local and/or global economic recessions. This could pressure hospital spending, impacting our pricing. As a result of these factors, it has made it difficult for us to forecast future iFuse sales. Therefore, we believe that historical sales trends are not a good indicator of future growth.

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, instrument set depreciation, scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs. Our cost of goods sold has historically increased 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. Due to an expected decrease in overall demand in the second quarter of 2020 from COVID-19, we anticipate that our operations will run at less than normal capacity. Accordingly, certain labor and overhead costs will be expensed as incurred, which could significantly reduce our gross profit and gross margin. We cannot reliably estimate the extent to which the COVID-19 pandemic will impact our overall demand in the near-term.

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 anticipate operating expenses will continue to increase to support our employees. However, we have paused on hiring of staff at this time due to the pandemic. In addition, we have taken steps to reduce variable expenses that are ineffective due to the COVID-19 pandemic.

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 senior sales management, direct territory sales managers, territory associate representatives and third-party distributors.

Our sales and marketing spending in the first quarter 2020 reflected normal business activities into March and then a curtailment of certain costs associated with the impact of the COVID-19 pandemic. And while certain spending will decrease in the near-term as a result of a reduction in revenue and activities limited by the COVID-19 pandemic, much of our spending will continue to increase to support our customers and the continuity of our business. For example, we have guaranteed certain levels of incentive compensation to members of our field sales organization for the second quarter 2020 in order to retain these employees and partially mitigate the impact of the pandemic to their compensation. We have, however, eliminated certain other spending during the COVID-19 pandemic, such as travel and related expenses, regional surgeon training, trade shows, and discretionary marketing, and we expect these expenditures will resume as the acuity of the pandemic recedes.

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.

Research and development expenses for engineering projects fluctuate with project timing. Based upon our broader set of product development initiatives and the stage of the underlying projects, we expect to continue to make investments in research and development. As such, we anticipate that research and development expenses will continue to increase in the future. The increase in engineering expenditures will be partially offset in the near term by a decline in clinical study expenses due to postponement of these activities due to COVID-19 pandemic.

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 have taken measures to control discretionary items classified as general and administrative expenses, but expect our general and administrative expenses to return to normal levels as the acuity of the pandemic recedes, and thereafter increase to sustain our business and support our operations 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 primarily related to our investments of excess cash in money market funds and marketable securities.

Interest Expense

Interest expense is primarily related to borrowings and amortization of debt issuance costs.

Other Income (Expense), Net

Other income (expense), net consists primarily of net foreign exchange gains and losses on foreign transactions.

Results of Operations

We manage and operate as one reportable segment. The table below summarizes our results of operations for the periods presented (percentages are amounts as a percentage of revenue), which we derived from the accompanying condensed consolidated financial statements:

	Three Months Ended March 31,			
	2020		2019	
	Amount	%	Amount	%
	(in thousands, except for percentages)			
Consolidated Statements of Operations Data:				
Revenue	\$ 16,821	100 %	\$ 14,991	100 %
Cost of goods sold	1,932	11 %	1,526	10 %
Gross profit	14,889	89 %	13,465	90 %
Operating expenses:				
Sales and marketing	19,281	115 %	15,815	106 %
Research and development	2,090	12 %	1,683	11 %
General and administrative	5,400	32 %	4,766	32 %
Total operating expenses	26,771	159 %	22,264	149 %
Loss from operations	(11,882)	(70)%	(8,799)	(59)%
Interest and other income (expense), net:				
Interest income	498	3 %	744	5 %
Interest expense	(1,231)	(7)%	(1,230)	(8)%
Other income (expense), net	(157)	(1)%	(60)	— %
Net loss	\$ (12,772)	(75)%	\$ (9,345)	(62)%

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

	Three Months Ended March 31,			
	2020		2019	
	Amount	%	Amount	%
	(in thousands except for percentages)			
United States	\$ 15,297	91 %	\$ 13,450	90 %
International	1,524	9 %	1,541	10 %
	\$ 16,821	100 %	\$ 14,991	100 %

Comparison of the Three Months Ended March 31, 2020 and March 31, 2019

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

	Three Months Ended March 31,			
	2020	2019	\$ Change	% Change
	(in thousands, except for percentages)			
Revenue	\$ 16,821	\$ 14,991	\$ 1,830	12%
Cost of goods sold	1,932	1,526	406	27%
Gross profit	\$ 14,889	\$ 13,465	\$ 1,424	11%
Gross margin	88.5 %	89.8 %		

Revenue. Revenue increased \$1.8 million or 12%, for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The increase was primarily due to an increase of \$1.8 million as a result of growth in domestic case volumes. Our international sales were relatively flat. Our U.S. case volumes increased due to higher sales force productivity, higher numbers of sales personnel, and increased active surgeons due to improving U.S. reimbursement coverage. Though our total revenue increased as discussed above, it was partly impacted by lower than anticipated case volumes in the second half of March 2020 due to the effects of the COVID-19 pandemic.

Cost of Goods Sold, Gross Profit, and Gross Margin. Total cost of goods sold increased \$0.4 million, or 27%, for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The increase in cost of goods sold was primarily due to higher sales volume and implant costs. Higher net revenue, partly offset by a write-down of inventory, resulted in increased gross profit of \$1.4 million, or 11%. The gross margin decreased to 88.5% for the three months ended March 31, 2020 as compared to 89.8% for the three months ended March 31, 2019 due to higher cost of operations to support the growth of the business and the increases in the write-down of inventory.

Operating Expenses:

	Three Months Ended March 31,		\$ Change	% Change
	2020	2019		
	(in thousands, except for percentages)			
Sales and marketing	\$ 19,281	\$ 15,815	\$ 3,466	22%
Research and development	2,090	1,683	407	24%
General and administrative	5,400	4,766	634	13%
Total operating expenses	\$ 26,771	\$ 22,264	\$ 4,507	20%

Sales and Marketing Expenses. Sales and marketing expenses increased \$3.5 million, or 22%, for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The increase was primarily due to an increase of \$1.8 million in employee related costs and stock-based compensation expense driven by increased headcount, \$1.4 million in commissions due to increased sales and \$0.3 million in facilities and other related expenses due to the overall growth of our sales and marketing department.

Research and Development Expenses. Research and development expenses increased \$0.4 million, or 24%, for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The increase was primarily due to increase in employee related costs and stock-based compensation expense due to increase in headcount.

General and Administrative Expenses. General and administrative expenses increased \$0.6 million, or 13%, for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The increase was primarily due to an increase of \$0.3 million in employee related costs and stock-based compensation expense driven by increased headcount, \$0.2 million public offering costs allocated to sale of common stock by selling shareholders, and \$0.1 million in facilities and other related expenses from expansion of our general and administrative department.

Interest and Other Income (Expense), Net:

	Three Months Ended March 31,		\$ Change	% Change
	2020	2019		
	(in thousands, except for percentages)			
Interest income	\$ 498	\$ 744	\$ (246)	-33%
Interest expense	(1,231)	(1,230)	(1)	0%
Other expense, net	(157)	(60)	(97)	162%
Total interest and other expense, net	\$ (890)	\$ (546)	\$ (344)	63%

Interest Income. Interest income decreased by \$0.2 million for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019, mainly due to lower interest on our investments in marketable securities.

Interest Expense. Interest expense, which mainly relates to our outstanding debt, remained relatively unchanged for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019.

Other Expense, Net. Other expense, net increased by \$0.1 million for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 mainly due to higher foreign exchange losses.

Liquidity and Capital Resources

As of March 31, 2020, we had cash and marketable securities of \$146.2 million compared to \$93.1 million as of December 31, 2019. We have financed our operations through our public offerings, debt financing arrangements, and the sale of our products. As of March 31, 2020 and December 31, 2019, we had \$39.3 million and \$39.2 million principal amount of outstanding debt, net of debt issuance costs, respectively.

As of March 31, 2020, we had an accumulated deficit of \$208.4 million. During the three months ended March 31, 2020, we incurred a net loss of \$12.8 million. During the years ended December 31, 2019 and 2018, we incurred a net loss of \$38.4 million and \$17.5 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 earnings before interest, taxes, depreciation, and amortization ("EBITDA") targets as discussed in detail below. If we do not comply with these covenants, the debt could immediately become due.

Based upon our current operating plan, we believe that our existing cash and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. However, the economic impact of the duration and severity of the COVID-19 pandemic, and our responses thereto (including such actions we have taken or may take in the future as disclosed elsewhere in this Report) pose risk and uncertainties in our future available capital resources. Further, we may face challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to, but not limited to, the following as a result of the COVID-19 pandemic or otherwise: (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.

Borrowings

The outstanding debt is related to a term loan we entered with Biopharma Credit Investments IV Sub LP, or Pharmakon, in October 2017 for total loan proceeds of \$40.0 million (our "term loan"). The term loan includes an interest-only period for 35 months through September 2020 and is then repaid in equal principal payments plus interest through December 2022 and carries a fixed interest rate of 11.5% and a closing fee of 1.5%. 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 is collateralized by all of our assets, including intellectual property. The term loan requires us to maintain a minimum cash balance of \$5.0 million.

We are also required to meet either the 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 remaining minimum net sales and trailing 12-month consolidated EBITDA targets are as follows:

Twelve Months Ending	Minimum Net Sales	Trailing 12-Month Consolidated EBITDA
(in thousands)		
June 30, 2020	\$58,500	or \$2,000
thereafter, as applicable	\$60,000	or \$3,000

As of March 31, 2020 and December 31, 2019, we were in compliance with all of our debt obligations and covenants. Due to uncertainties surrounding the impact of the COVID-19 pandemic, there is a substantial risk that we may not meet the remaining minimum net sales or the trailing 12-month consolidated EBITDA targets in future quarters. If we are not in compliance with these requirements, the loan may become due immediately at Pharmakon's option.

Contractual Obligations

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business as of March 31, 2020 compared to our contractual obligations and commitments as of December 31, 2019 as reported in tabular format in our Annual Report on Form 10-K for the year ended December 31, 2019.

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
	2020	2019		
Net cash provided by (used in):	(in thousands, except for percentages)			
Operating activities	\$ (9,355)	\$ (7,078)	\$ (2,277)	32%
Investing activities	3,339	(5,553)	8,892	(160)%
Financing activities	63,152	125	63,027	50,422%
Effects of exchange rate changes on cash and cash equivalents	(3)	(53)	50	(94)%
Net increase (decrease) in cash and cash equivalents	\$ 57,133	\$ (12,559)	\$ 69,692	

Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2020 of \$9.4 million resulted from cash outflows due to a net loss of \$12.8 million, adjusted for \$3.1 million of non-cash items, partially offset by cash inflows from changes in operating assets and liabilities of \$0.3 million. Net cash used in operating activities for the three months ended March 31, 2019 of \$7.1 million resulted from cash outflows due to a net loss of \$9.3 million, adjusted for \$1.7 million of non-cash items, and cash inflows from changes in operating assets and liabilities of \$0.5 million. The increase in net loss, net of non-cash items for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 was mainly due to higher operating expenses from expansion of the business, partially offset by higher revenue. Cash inflows from changes in operating assets and liabilities for the three months ended March 31, 2020 was primarily due to a decrease in accounts receivable due to the timing of collections and cases performed, partly offset by decreases in accrued expenses and other liabilities due to timing of payments. Cash inflows from changes in operating assets and liabilities for the three months ended March 31, 2019 was primarily due to the timing of payments of our accounts payable, accrued expenses and other liabilities.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities in the three months ended March 31, 2020 was \$3.3 million compared to net cash used in investing activities of \$5.6 million in the three months ended March 31, 2019. Net cash provided by investing activities for the three months ended March 31, 2020 consisted of maturities of our marketable securities of \$21.0 million, partially offset by purchases of marketable securities of \$16.8 million and purchases of property and equipment of \$0.9 million. Net cash used in investing activities for the three months ended March 31, 2019 consisted of purchases of marketable securities of \$22.7 million and purchases of property and equipment of \$0.4 million, partially offset by maturities of marketable securities of 17.6 million.

Cash Provided by Financing Activities

Cash provided by financing activities in the three months ended March 31, 2020 was \$63.2 million compared to \$0.1 million in the three months ended March 31, 2019. Cash provided by financing activities for the three months ended March 31, 2020 consisted of proceeds from the follow-on public offering, net of underwriting discounts, commissions and offering costs of \$63.0 million and proceeds received from exercises of stock options of \$0.2 million. Cash provided by financing activities for the three months ended March 31, 2019 consisted of proceeds from 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 11, 2020. There had been no material changes to these accounting policies. See Note 2 of Notes to Condensed Consolidated Financial Statements (Unaudited) for related discussions on updates on recently issued accounting pronouncements.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

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, are 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 Condensed Consolidated Financial Statements (Unaudited) for related discussions on updates on recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a "smaller reporting company," we are not required to provide the information required by this Item.

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 ("CEO") and Chief Operating Officer and Chief Financial Officer ("COO/CFO"), 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 CEO and COO/CFO, 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 CEO and COO/CFO have concluded that, as of March 31, 2020, our disclosure controls and procedures were effective at the reasonable assurances level.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. In response to the COVID-19 pandemic, our employees have begun working from home beginning on March 17, 2020. Management has taken measures to ensure that our internal control over financial reporting are unchanged during this period.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, refer to *Legal Proceedings* in “Note 6 - Commitments and Contingencies” in the accompanying Notes to Condensed Consolidated Financial Statements (Unaudited), which information is incorporated by reference here.

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 condensed 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, 2020, we had net loss of \$12.8 million. For the years ended December 31, 2019 and 2018, we had net losses of \$38.4 million and \$17.5 million, respectively. As of March 31, 2020, we had an accumulated deficit of \$208.4 million. We have financed our operations primarily through the net proceeds of our public offerings of our common stock, 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, and even if we are able to do so, our ability to do so has been delayed by the COVID-19 pandemic. Once restrictive measures put in place to deal with the COVID-19 outbreak are lifted and we determine that we are able to resume normal operations, 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. 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.

Epidemic diseases, or the perception of their effects, have had and could have (or, in the case of the COVID-19 pandemic, will continue to have during its duration) a material adverse effect on our business, financial condition, results of operations, or cash flows.

Outbreaks of epidemic, pandemic, or contagious diseases, such as COVID-19, and historically, the Ebola virus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome, or the H1N1 influenza virus, could divert medical resources and priorities towards the treatment of that disease. An outbreak of a contagious disease, or continued escalation of the outbreak of COVID-19 could also negatively affect hospital admission rates and the decision by patients to undergo elective surgery, which could decrease demand for procedures using our iFuse implants and cause other disruptions to our business. Business disruptions could include disruptions or restrictions on our ability to travel or to distribute our products, government orders suspending the performance of elective surgical procedures such as the iFuse procedure, as well as temporary closures of our facilities or the facilities of our suppliers and their contract manufacturers, and a reduction in the business hours of hospitals and ambulatory surgery centers. Any disruption of our suppliers and their contract manufacturers or our customers would likely impact our sales and operating results. In addition, a significant outbreak of epidemic, pandemic, or contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products. Any of these events could negatively impact the number of procedures using our iFuse implants that are performed and have a material adverse effect on our business, financial condition, results of operations, or cash flows.

To date, COVID-19 has had, and we expect will continue to have, an adverse impact on our operations as a result of preventive and precautionary measures that we, other businesses, health systems and governments are taking. Due to these impacts and measures, we have experienced and expect to continue to experience significant and unpredictable reductions in the demand for our products, negatively impacted by hospital admission rates and the decision by patients to undergo elective surgery, which decreased the demand for procedures using our iFuse implants. These developments and effects are expected to continue and may also significantly affect our business across the U.S. and other countries where COVID-19 has spread and may continue to spread. There are numerous uncertainties associated with this COVID-19 outbreak, including the number of individuals who will become infected, whether a vaccine or cure that mitigates the effect of the virus will be synthesized, and, if so, when such vaccine or cure will be ready to be used, the extent of the protective and preventative measures that have been put in place by both governmental entities and other businesses and those that may be put in place in the future, whether the virus's impact will be seasonal, the effect that testing for COVID-19 and antibodies, once available, will enable relaxation of protective measures for a subset of the population, and numerous other uncertainties. We intend to continue to execute on our strategic plans and operational initiatives during the COVID-19 outbreak. However, the aforementioned uncertainties may result in delays or modifications to these plans and initiatives.

Existing travel restrictions, and the risk that countries may continue to close borders, impose prolonged quarantines, and further restrict travel, limits our ability to reach surgeons with our goal of increasing surgeon activity by educating them to include the sacroiliac joint in their differential diagnosis of lower back pain and to regularly perform the iFuse procedure for patients for whom the procedure is indicated.

In addition, the COVID-19 pandemic has adversely affected, and may continue to adversely affect, the economies and financial markets of many countries, which may result in a period of regional, national, and global economic slowdown or regional, national, or global recessions that could curtail or delay spending by hospitals and affect demand for our products as well as increased risk of customer defaults or delays in payments. These market disruptions could impair our ability to raise capital, should our business experience a prolonged period of reduced revenue requiring additional capital to sustain the business. COVID-19 and the current financial, economic, and capital markets environment, and future developments in these and other areas present material uncertainty and risk with respect to our performance, financial condition, results of operations, and cash flows. Due to the uncertain scope and duration of the pandemic and uncertain timing of global recovery and economic normalization, we are unable to estimate the impacts on our operations and financial results. As a result, we have withdrawn our full year 2020 financial and procedure guidance.

The existence and further duration of the COVID-19 pandemic may also further exacerbate certain of the risks described below.

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 or reduce their current levels of payment, or if reimbursement levels are insufficient to support use of our products or compensate surgeons for their time spent diagnosing patients and performing procedures using our products. For example, our sales decreased significantly after minimally invasive sacroiliac joint fusion was assigned to a Category III Current Procedural Terminology ("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 ("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 U.S. 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 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.

Effective January 1, 2020, the national average Medicare payment to hospital outpatient departments is \$15,944 and the Medicare payment to an ambulatory surgical center for a sacroiliac joint fusion is \$12,981. 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 U.S. Effective January 1, 2020, the average Medicare payment for the Category I CPT code is \$915. 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 may continue to view the Medicare and commercial reimbursement amounts 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 adversely affect our revenues.

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, 2020, 33 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. If healthcare payors covering a significant number of covered lives reverse their policies of covering minimally invasive sacroiliac joint fusion exclusively when performed with the iFuse system, sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

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 system 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, their use of our products may decline, adversely affecting our revenues and profitability.

Historically, most spine surgeons did not include an evaluation of the sacroiliac joint in their diagnostic work-up because they did not have an adequate surgical procedure to perform for patients diagnosed with sacroiliac joint dysfunction. As a result, some patients with lower back pain resulting from sacroiliac joint dysfunction have been misdiagnosed. We believe that educating surgeons and other healthcare professionals about the clinical merits and patient benefits of iFuse is an important element of building our business. 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 surgical procedures 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. 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 and other products intended to treat the sacroiliac joint or the pain it causes. 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 U.S. have either received premarket clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act ("FDCA"), or are exempt from premarket review. Those marketed in the European Union ("EU"), have been the subject of a CE Certificate of Conformity. The 510(k) clearance process of the U.S. Food and Drug Administration ("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, ("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 U.S. 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 U.S. 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 maintain and grow our market share. 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 ("POD"), 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 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.

The COVID-19 pandemic will likely cause procedures to be shifted from the hospital environment to ambulatory surgical centers, or ASCs, where pressure on the prices of our products is generally more acute.

To protect health care professionals involved in surgical care and their patients, we anticipate that more outpatient eligible procedures will be performed in ASCs during the COVID-19 pandemic, and as its acuity declines and the healthcare system returns to a more normalized state. Since patients do not stay overnight in ASCs and COVID-19 patients would not otherwise be treated in ASCs, it is likely that the ASC will be viewed as a safer site of service for patients and health care providers, where the risk of transmission of the novel coronavirus can be more effectively controlled. Because ASC facility fee reimbursement is typically less than facility fee reimbursement for hospitals, we typically experience more pressure on the pricing of our products by ASCs than by hospitals, and the average price for which we sell our products to ASCs is less than the average prices we charge to hospitals. An accelerated shift of procedures using our products to ASCs as a result of the COVID-19 pandemic could adversely impact the average selling prices of our products and our revenues could suffer as a result.

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 adversely affected.

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 U.S. has grown from zero to more than 20 since 2008. Some 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 U.S., we believe that our primary competitors currently are Medtronic plc and Globus Medical, Inc. Our primary competitors in Europe are Globus Medical, Inc. and SIGNUS Medizintechnik GmbH. 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 ("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 competitors are considerably larger than us, or are subsidiaries of larger 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 market share or product margins could decrease, thereby harming our business.

We currently manufacture and sell a single family of products focused on procedures, the goal of which is to stabilize and fuse the sacroiliac joint, 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 grow the market for iFuse and increase our share within that market or any other event impeding our ability to sell iFuse, could adversely affect our results of operations, financial condition and continuing operations.

If clinical experience with our iFuse Bedrock technique does not result in positive outcomes for patients or if clinical trials involving the use of iFuse Bedrock fail to show meaningful patient benefit, sales of our iFuse implants could be adversely impacted.

In November 2018, we introduced our iFuse Bedrock technique, in which spine surgeons place iFuse implants across the sacroiliac joint using a different surgical approach to treat sacroiliac joint dysfunction at the same time they are fusing multiple levels of the spine above and affixing those spinal fusion devices to the pelvis. In April 2019, the FDA cleared promotion of iFuse Bedrock for a broader and more general purpose, to provide additional stability and immobilization of the sacroiliac joint in connection with a thoracolumbar fusion procedure. To date, clinical experience with the iFuse Bedrock technique is limited and we have yet to complete a clinical trial to evaluate the iFuse Bedrock technique. Surgeons do not know if the addition of iFuse implants to the implants used to fuse multiple levels of the lumbar spine will result in patient benefit. If surgeons' clinical experience with iFuse Bedrock is not positive, or if our clinical trials do not show meaningful benefits to the patients undergoing this procedure, sale of our iFuse implants for this indication could be adversely impacted, which could negatively affect our operations and financial condition.

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

As of March 31, 2020, our U.S. sales force consisted of 62 territory sales managers and 53 clinical support specialists directly employed by us, and 37 third-party distributors. As of March 31, 2020, our international sales force consisted of 19 sales representatives directly employed by us and 31 third-party distributors, which together have had sales in 35 countries through March 31, 2020. 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.

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.

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.

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;
- large-scale epidemics of communicable diseases such as COVID-19;
- 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 could 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 future 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 RMS for iFuse 3D implants and Orchid for iFuse 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 or our third-party manufacturers could experience plant closures do local epidemics of communicable diseases, such as COVID-19, or local outbreaks of such diseases among their workforce, thereby shuttering a plant in which our products are manufactured;
- 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.

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.

After the most acute effects of the COVID-19 pandemic subside, 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 system 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 business could be adversely affected. 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, we estimate cost savings to the economy and healthcare system as a result of the iFuse procedure based on our market research. If our estimates and projections overestimate the size of this market or these benefits and 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 potential for 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 international business 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 ("FCPA"), and the United Kingdom Bribery Act ("UKBA"), anti-boycott laws, anti-money laundering laws, and regulations relating to economic sanctions imposed by the U.S., including the Office of Foreign Asset Control of the U.S. Treasury. Any failure to comply with applicable legal and regulatory obligations in the U.S. 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 successful conduct of our international business 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 or breach of our cybersecurity;
- 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. 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 U.S. 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 U.S., with only limited exceptions, we must obtain either clearance under Section 510(k) of the FDCA for Class II devices or approval of a 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 U.S., 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 U.S.

In the EEA, our medical devices must currently 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 including the clinical evaluation, 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.

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.

In May 2017, the EU Medical Device Regulation, (Regulation 2017/745) was adopted as described in "Item 1. Business - Regulation - International Regulation of Our Products" in our Annual Report on Form 10-K filed with the SEC on March 11, 2020. On April 24, 2020, the European Parliament adopted legislation deferring effectiveness of the EU Medical Device Regulation until May 2021.

The FDA and other regulatory authorities, including foreign 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, variation, 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. For example, we are subject to the federal health care Anti-Kickback Statute, the federal civil False Claims Act, the Health Insurance Portability and Accountability Act ("HIPAA") and the federal Physician Payment Sunshine Act, each of which is described in detail in "Item 1. Business - "Healthcare Fraud and Abuse" and "Data Privacy and Security Laws" in our Annual Report on Form 10-K filed with the SEC on March 11, 2020.

Certain states also mandate implementation of corporate compliance programs, require compliance with the industry's voluntary compliance guidelines, impose restrictions on device manufacturer marketing practices, and/or require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities. 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 and patients; 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 subject to administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare, Medicaid, and equivalent foreign programs, significant fines, monetary penalties and damages, imposition of compliance obligations and monitoring, the curtailment or restructuring of our operations, 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 have previously acquired from us less than 1.0% of our current outstanding common 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, 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 and criminal, civil and administrative liability. 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, state and foreign 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, state and foreign 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.

Various state and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. The Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal Anti-Kickback Statute. 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, deferred or non-prosecution agreement, 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 and processes 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. In doing so, we are subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, in the U.S. and regulations in the European Union (“EU”), which are described in detail in Item 1 Business - Data Privacy and Security Laws” in our Annual Report on Form 10-K filed with the SEC on March 11, 2020.

In June 2018, California enacted the California Consumer Privacy Act (“CCPA”). The CCPA, which became effective on January 1, 2020, requires a broad range of businesses to honor the requests of California residents to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used and shared. The CCPA provides for civil penalties of up to \$7,500 for intentional violations, and a private right of action for data breaches that allows private plaintiffs to seek the greater of actual damages or statutory damages of up to \$750 per consumer per data breach. These remedies are expected to increase data breach litigation. The California Attorney General, who is charged with interpreting and enforcing the law, has not yet promulgated final implementing regulations, and considerable uncertainty as to how the law will be implemented and enforced remains. Although the CCPA includes exemptions for certain clinical trials data, and protected health information governed by HIPAA, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and 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 on our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the European Union, the U.S., 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 U.S. 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 U.S., 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 ("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, variation or withdrawal of CE Certificates of Conformity;
- refusal to grant export approval for our products; and
- criminal prosecution.

In addition, we are 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 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, state and foreign healthcare laws and regulations, data privacy laws 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 national and foreign laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA and equivalent third country authorities do not restrict or regulate a physician's choice of treatment within the practice of medicine. In the U.S., the full indication for the iFuse Implant System is: "The iFuse Implant System is intended for sacroiliac fusion for the following conditions: (i) 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 6 months. (ii) To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. (iii) Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint." In the U.S., 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 and our notified body. However, if the FDA or an equivalent third country authority 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 or third country authority 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.

Under the FDA's medical device reporting, regulations, and equivalent rules of other countries we are required to report to the FDA or a similar authority in such other country, 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 or applicable authority in another country within the required timeframes, or at all, FDA, or the applicable authority in the other country 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 ("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. The entry into application in May 2021 of the Medical Device Regulation will increase the obligation that we must fulfill in relation to vigilance and post-market surveillance obligations.

Any adverse event involving our products, whether in the U.S. 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. Equivalent procedures and penalties have been established in other countries including EU Member States.

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 to 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, manufacturing process, 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 with Essential Requirements and related applicable laws. 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. Moreover, any substantial changes that take place in the coming years may impact the continuing effectiveness of our CE Certificates of Conformity that were issued on the basis of the Medical Device Directive.

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 adversely affect our business prospects.

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 business prospects.

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 and our Notified Body may refuse to issue new CE Certificates of Conformity. Failure to receive clearance, approval, or Certificates of Conformity 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, or new indications for use for existing 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 to support a new CE Certificate of Conformity 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, or new indication for use, 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. For example, the COVID-19 pandemic has caused substantial delays in site initiation and patient enrollment in our SILVIA trial designed to assess the safety and efficacy of our Bedrock technique. 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, or on a delayed basis, 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. Moreover, the new Medical Device Regulation will enter into application on May 26, 2021. 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.

Leadership, personnel and structural changes within the FDA as well as recent and impending federal election outcomes, including the 2020 presidential election, 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 EEA. The Medical Devices Regulation became effective on May 25, 2017. Following its entry into application on May 26, 2020, the Medical Devices Regulation 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 Medical Devices Regulation repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA Member States, regulations are directly applicable, i.e., without the need for adoption of national legislation in EEA Member States implementing them. The purpose of regulations is to eliminate current differences in regulation of medical devices among EEA Member States. The Medical Devices Regulation, 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. These regulations will substantially impact medical device 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 ("UDI"), system;
- new rules governing the reprocessing of medical devices; and
- increased transparency with the establishment of European database on medical devices ("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.

The Medical Device Regulation substantially amplifies the provisions of the Medical Device Directive governing clinical investigations of medical devices. Among others, it imposes specific obligations concerning incapacitated subjects, minors, pregnant or breastfeeding women and clinical investigations in emergency situations. In addition to detailed provisions concerning the authorization and conduct of clinical investigations, the Regulation imposes on non-EU sponsors a responsibility to appoint a legal representative established in the EU and an obligation on EU Member States to ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place and on sponsors and investigators the obligation to ensure they make use of these systems.

Transition from the regulation of our products under the current Medical Device Directive, and implementing legislation in each EU Member State, to regulation under the Medical Devices Regulation may require a substantial transition effort by us. In addition, detail as to how certain aspects of the Medical Devices Regulation will be applied remains unclear. Failure to update our quality system and regulatory documentation could delay our transition to compliance with the Medical Devices Regulation and delay or prevent us from obtaining new CE Certificates of Conformity under the Regulation. Transition from compliance with the Medical Device Directive to the Medical Devices Regulation 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 U.S. 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 U.S. 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.

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 surgical devices. Sacroiliac joint and other orthopedic spine surgeries involve 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 withdrawal from the EU and uncertainty regarding tariffs affecting U.S. imports and exports may have a negative effect on global economic conditions, financial markets and our business.

On January 31, 2020, the UK withdrew from the EU. Brexit has created significant uncertainty concerning the future relationship between the UK and the EU. In light of the fact that a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product in the UK or the EU. Any changes in our manufacturing or commercialization activities as a result of Brexit, could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the euro with respect to each other and to the U.S. dollar have already been, and may continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

We do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to membership in the EU will impact our business, particularly our ability to conduct international business from a base of operations in the UK. The UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, possibly resulting in increased trade barriers, which could make doing business in Europe more difficult and/or costly. Moreover, in the U.S., tariffs on certain U.S. imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, these tariffs and other trade restrictions, whether resulting from the UK's withdrawal from the EU or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

Risks Related to Our Intellectual Property

If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired.

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, 2020, we owned 40 issued U.S. patents and had 20 pending U.S. patent applications, and we owned 11 issued foreign patents and had 6 pending foreign patent applications. We have focused the majority of our foreign patent efforts in China, Europe, and Japan. Our current U.S. patents on iFuse, including the triangular shape, expire in August 2024. Our current U.S. patents on iFuse 3D, including the fenestrated design, expire in September 2035. Our foreign patents will expire between August 2025 and October 2031. Competitors may market similar triangular shaped devices upon the expiration of the patents in 2024. We will continue to have patent protection of our 3D-printed fenestrated implants through 2035.

As of March 31, 2020, we have 13 registered trademarks in the U.S. and have filed for 4 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 U.S. Even if patents are granted outside the U.S., effective enforcement in those countries may not be available. Since most of our issued patents are for the U.S. 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 U.S. 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.

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:

- the impact that the COVID-19 pandemic has on our business;
- 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 U.S., 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 further 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.

Our sales volumes and our operating results may fluctuate over the course of the year, which could affect the price of our common stock.

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:

- the impact that the COVID-19 pandemic has on our business;
- 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 U.S., and commercialization of such products outside of the U.S. 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.

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

As of December 31, 2019, we had net operating loss ("NOL") carryforwards of \$164.4 million and \$129.6 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 2028 and 2020, 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. We also updated our Section 382 ownership change analysis through June 30, 2019, considering the recent changes in ownership following our IPO in October 2018. Based on the result of the analysis, we concluded that we did not undergo ownership change that would require for any additional limitations on our NOL carryforwards. We further concluded that the equity shift between June 30, 2019 to December 31, 2019 was not material, considering the changes in the outstanding number of shares at each respective periods. We will continually assess the need to update our Section 382 ownership change analysis, including the impact of the completion of our follow-on public offering in January and February 2020, as we may experience ownership changes that could materially limit our ability to use our NOL carryforwards, which may harm our future operating results by effectively increasing our future tax obligations.

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. Due to uncertainties surrounding the impact of COVID-19 pandemic, there is a substantial risk that we may not meet the remaining minimum net sales or the trailing 12-month consolidated EBITDA targets in future quarters. If not waived, future defaults could cause all of the outstanding indebtedness under our credit facility agreement to become immediately due and payable.

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 U.S. federal district courts 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 U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

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

Recent Sales of Unregistered Securities

There were no sales of unregistered equity securities during the three months ended March 31, 2020.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of shares or equity securities during the three months ended March 31, 2020.

Use of Proceeds from our Initial Public Offering of Common Stock

On October 16, 2018, our registration statement on Form S-1 (File No. 333-227445) relating to our Initial Public Offering ("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 offering-related expenses of \$2.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

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. As of March 31, 2020, approximately \$49.7 million of the net proceeds had been used for general corporate purposes including cash used in operations and capital expenditures.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

In the description of our common stock, as described in Exhibit 4.3 of our Form 10-K filed with the Securities and Exchange Commission on March 11, 2020, we stated that as a result of the recent decision by the Delaware Chancery Court in the *Sciabacucchi* case, we did not currently intend to enforce the federal forum selection provision of our Certificate of Incorporation unless the *Sciabacucchi* decision described therein is appealed and the Delaware Supreme Court reverses the decision. That appeal occurred and the Delaware Supreme Court reversed the decision, upholding the validity of the federal forum selection clause in that case. As a result, we may assert the federal forum selection provision of our Certificate of Incorporation in any future proceeding in which it applies. Accordingly, we are refiling the description of our common stock as Exhibit 4.3 to this report to include this update.

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 .				
4.3	Description of SI-BONE, Inc. Common Stock				
10.1	January 2020 changes to Chief Executive Officer, Chief Operating Officer & Chief Financial Officer, and Chief Commercial Officer Compensation	8-K	001-38701	Item 5.02	1/3/2020
10.2	March 2020 changes to Chief Executive Officer, Chief Operating Officer & Chief Financial Officer, and Chief Commercial Officer Compensation	8-K	001-38701	Item 5.02	3/30/2020
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*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline 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 5, 5020

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 5, 5020

By: /s/ Laura A. Francis

Laura A. Francis

Chief Operating Officer and Chief Financial Officer

(Duly Authorized Officer and Principal Financial and Accounting Officer)

DESCRIPTION OF SI-BONE, INC. COMMON STOCK

Our authorized capital stock consists of 100,000,000 shares of common stock, \$0.0001 par value per share, and 5,000,000 shares of preferred stock, \$0.0001 par value per share. A description of our common stock and the material terms and provisions of our certificate of incorporation and bylaws affecting the rights of holders of our common stock is set forth below. The description is intended as a summary, and is qualified in its entirety by reference to our certificate of incorporation and the bylaws.

Common Stock

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption, or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders are distributable ratably among the holders of our common stock, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Anti-takeover Effects of Provisions of our Certificate of Incorporation and Bylaws and Delaware Law

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. This section prevents some Delaware corporations from engaging, under some circumstances, in a business combination, which includes a merger or sale of at least 10% of the corporation's assets with any interested stockholder, meaning a stockholder who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of the corporation's outstanding voting stock, unless:

- the transaction is approved by the board of directors prior to the time that the interested stockholder became an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- subsequent to such time that the stockholder became an interested stockholder the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or amended and restated bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Certificate of Incorporation and Bylaws Provisions

Our amended and restated certificate of incorporation and our amended and restated bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control of our management team, including the following:

- *Board of Directors Vacancies.* Our amended and restated certificate of incorporation and amended and restated bylaws authorize our board of directors to fill vacant directorships, including newly-created seats. In addition, the number of directors constituting our board of directors is set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.
- *Classified Board.* Our amended and restated certificate of incorporation and amended and restated bylaws provide that our board of directors is classified into three classes of directors, each of whom will hold office for a three-year term. In addition, directors may only be removed from the board of directors for cause and only by the approval of a majority of our then-outstanding shares of our common stock. The existence of a classified board could delay a successful tender offeror from obtaining majority control of our board of directors, and the prospect of that delay might deter a potential offeror.
- *Stockholder Action; Special Meeting of Stockholders.* Our amended and restated certificate of incorporation provides that stockholders are not able to take action by written consent, and are only be able to take action at annual or special meetings of our stockholders. Stockholders are not permitted to cumulate their votes for the election of directors. Our amended and restated bylaws further provide that special meetings of our 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.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations.* Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at any meeting of stockholders. Our amended and restated bylaws also specify certain requirements regarding the form and content of a stockholder’s notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.
- *Issuance of Undesignated Preferred Stock.* Our board of directors have the authority, without further action by the holders of common stock, to issue up to 5,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by the board of directors. The existence of authorized but unissued shares of preferred stock enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise.

Choice of Forum

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 fiduciary duty by any director, officer, or other employee to us or our stockholders; 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 or any director or officer or other employee that is governed by the internal affairs doctrine. The provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. The enforceability of similar choice of forum provisions in other companies’ certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The Delaware Supreme Court has held that this type of clause is enforceable, and we may therefore assert it in any future proceeding in which it applies.

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 5, 2020

/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 5, 2020

/s/ Laura A. Francis

Laura A. Francis

Chief Operating Officer and 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 Operating Officer and 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, 2020, 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 5, 2020

/s/ Jeffrey W. Dunn

Jeffrey W. Dunn
President and Chief Executive Officer

Date: May 5, 2020

/s/ Laura A. Francis

Laura A. Francis
Chief Operating Officer and 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.