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 June 30, 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	**26-2216351**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
471 El Camino Real, Suite 101, Santa Clara, California	**95050**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
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 x No o

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 x No o

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	☐	Accelerated filer	☒	Non-accelerated filer	☐
Smaller reporting company	☒	Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 x

The number of shares outstanding of the registrant's Common Stock was 28,629,991 as of July 31, 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, 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 products;
- 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,169	$ 10,435
Short-term investments	71,499	81,345
Accounts receivable, net of allowance for doubtful accounts of $263 and $238, respectively	10,260	11,720
Inventory	4,969	5,452
Prepaid expenses and other current assets	1,632	2,510
Total current assets	154,529	111,462
Long-term investments	—	1,278
Property and equipment, net	4,407	3,954
Other non-current assets	312	315
TOTAL ASSETS	$ 159,248	$ 117,009
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,455	$ 2,811
Accrued liabilities and other	9,272	11,605
Current portion of long-term borrowings	—	4,358
Total current liabilities	11,727	18,774
Long-term borrowings	39,264	34,865
Other long-term liabilities	389	362
TOTAL LIABILITIES	51,380	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; 28,612,451 and 25,163,803 shares issued and outstanding, respectively	3	3
Additional paid-in capital	328,079	258,121
Accumulated other comprehensive income	610	464
Accumulated deficit	(220,824)	(195,580)
TOTAL STOCKHOLDERS' EQUITY	107,868	63,008
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 159,248	$ 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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Revenue	$ 14,049	$ 16,317	$ 30,870	$ 31,308
Cost of goods sold	2,117	1,588	4,049	3,114
Gross profit	11,932	14,729	26,821	28,194
Operating expenses:				
Sales and marketing	15,755	16,727	35,036	32,542
Research and development	2,165	1,946	4,255	3,629
General and administrative	4,151	4,194	9,551	8,960
Total operating expenses	22,071	22,867	48,842	45,131
Loss from operations	(10,139)	(8,138)	(22,021)	(16,937)
Interest and other income (expense), net:				
Interest income	329	695	827	1,439
Interest expense	(2,683)	(1,233)	(3,914)	(2,463)
Other income (expense), net	21	22	(136)	(38)
Net loss	$ (12,472)	$ (8,654)	$ (25,244)	$ (17,999)
Other comprehensive income (loss):				
Changes in foreign currency translation	(2)	12	10	(7)
Unrealized gain (loss) on marketable securities	(85)	59	136	84
Comprehensive loss	$ (12,559)	$ (8,583)	$ (25,098)	$ (17,922)
Net loss per share, basic and diluted	$ (0.44)	$ (0.35)	$ (0.91)	$ (0.74)
Weighted-average number of common shares used to compute basic and diluted net loss per share	28,492,582	24,577,938	27,872,505	24,484,608

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
Net unrealized gain on marketable securities	—	—	—	221	—	221
Net loss	—	—	—	—	(12,772)	(12,772)
Balance as of March 31, 2020	28,406,128	3	323,922	697	(208,352)	116,270
Issuance of common stock upon exercise of stock options, net of shares withheld	46,608	—	185	—	—	185
Issuance of common stock related to employee stock purchase plan	74,685	—	991	—	—	991
Issuance of common stock upon vesting of restricted stock units	85,030	—	—	—	—	—
Stock-based compensation	—	—	2,955	—	—	2,955
Vesting of early exercised stock options	—	—	26	—	—	26
Foreign currency translation	—	—	—	(2)	—	(2)
Net unrealized loss on marketable securities	—	—	—	(85)	—	(85)
Net loss	—	—	—	—	(12,472)	(12,472)
Balance as of June 30, 2020	28,612,451	$ 3	$ 328,079	$ 610	$ (220,824)	$ 107,868

	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)
Net unrealized gain on marketable securities	—	—	—	25	—	25
Net loss	—	—	—	—	(9,345)	(9,345)
Balance as of March 31, 2019	24,497,566	3	248,829	445	(166,522)	82,755
Issuance of common stock upon exercise of stock options, net of shares withheld	137,185	—	442	—	—	442
Issuance of common stock related to employee stock purchase plan	99,086	—	1,263	—	—	1,263
Issuance of common stock upon vesting of restricted stock units	27,320	—	—	—	—	—
Stock-based compensation	—	—	1,814	—	—	1,814
Vesting of early exercised stock options	—	—	56	—	—	56
Foreign currency translation	—	—	—	12	—	12
Net unrealized gain on marketable securities	—	—	—	59	—	59
Net loss	—	—	—	—	(8,654)	(8,654)
Balance as of June 30, 2019	24,761,157	$ 3	$ 252,404	$ 516	$ (175,176)	$ 77,747

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)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (25,244)	$ (17,999)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,577	3,685
Depreciation and amortization	505	395
Bad debt expense	200	—
Accretion on marketable securities	(20)	(940)
Realized gain on marketable securities	(43)	—
Amortization of debt issuance costs	100	130
Loss on extinguishment of debt	1,534	—
Loss on sale and disposal of property and equipment	80	98
Changes in operating assets and liabilities:		
Accounts receivable	1,287	(916)
Inventory	500	(1,092)
Prepaid expenses and other assets	875	102
Accounts payable	(290)	338
Accrued liabilities and other	(2,289)	725
Net cash used in operating activities	(17,228)	(15,474)
Cash flows from investing activities		
Maturities of marketable securities	33,500	83,600
Sales of marketable securities	12,592	—
Purchases of marketable securities	(34,768)	(82,516)
Purchases of property and equipment	(1,264)	(893)
Net cash provided by investing activities	10,060	191
Cash flows from financing activities		
Proceeds from follow-on public offering, net of underwriting discounts, commissions and offering costs	62,978	—
Proceeds from debt financing	45,297	—
Principal repayments of debt financing	(45,297)	—
Payments of debt issuance costs	(589)	—
Payments of prepayment penalty and lender fees	(843)	—
Proceeds from issuance of common stock under employee stock purchase plan	991	1,263
Proceeds from the exercise of stock options	359	567
Payments of additional initial public offering related costs	—	(167)
Net cash provided by financing activities	62,896	1,663
Effect of exchange rate changes on cash and cash equivalents	6	(4)
Net increase (decrease) in cash and cash equivalents	55,734	(13,624)
Cash and cash equivalents at		
Beginning of period	10,435	25,120
End of period	$ 66,169	$ 11,496
Supplemental disclosure of non-cash information		
Vesting of early exercised stock options	$ 53	$ 122
Unpaid purchases of property and equipment	145	57
Unpaid debt issuance costs	161	—

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 first quarter of 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 and six months ended June 30, 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 and the information surrounding the pandemic is rapidly evolving. The Company's customers, which include hospitals and medical centers, diverted and may continue to divert resources to treat COVID-19 patients. As a result, the Company's customers deferred and may continue to defer elective surgical procedures. The actions of the Company's customers impacted and may continue to impact 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 has caused a global recession. Such economic disruption could have a continued 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.

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) the Company's total annual gross revenues are $1.07 billion or more; (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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
United States	$ 13,221	$ 15,019	$ 28,518	$ 28,469
International	828	1,298	2,352	2,839
	$ 14,049	$ 16,317	$ 30,870	$ 31,308

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 leases standard. Further, due to the impact of the COVID-19, in June 2020, the FASB issued ASU 2020-05 to further defer the effective date for one year for entities in the "all other" categories. For public companies, the new guidance became 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, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption is still permitted for any interim or annual financial statements not yet issued.

As an emerging growth company, the new leases standard is now effective for the Company for the fiscal year ending December 31, 2022 and interim periods within fiscal year ending December 31, 2023. The Company is currently evaluating the impact of this standard on its consolidated financial statements including the timing of its adoption. The Company anticipates electing 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 does 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.

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:

	June 30, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 56,750	$ —	$ —	$ 56,750
Cash equivalents	56,750	—	—	56,750
U.S. treasury securities	60,010	133	—	60,143
Corporate bonds	8,604	58	—	8,662
Commercial paper	2,694	—	—	2,694
Short-term investments	71,308	191	—	71,499
Total marketable securities	$ 128,058	$ 191	$ —	$ 128,249

	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 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 June 30, 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:

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 56,750	$ —	$ —	$ 56,750
U.S. treasury securities	60,143	—	—	60,143
Corporate bonds	—	8,662	—	8,662
Commercial paper	—	2,694	—	2,694
Total marketable securities	$ 116,893	$ 11,356	$ —	$ 128,249

	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 June 30, 2020 and December 31, 2019, inventory consisted entirely of finished goods.

Property and Equipment, net:

	June 30, 2020	December 31, 2019
	(in thousands)	
Machinery and equipment	$ 5,145	$ 4,613
Construction in progress	2,193	1,854
Computer and office equipment	615	598
Leasehold improvements	502	497
Furniture and fixtures	230	187
	8,685	7,749
Less: Accumulated depreciation and amortization	(4,278)	(3,795)
	$ 4,407	$ 3,954

Construction in progress pertains to cost of individual components of a custom instrument set used for surgical placement of iFuse implants that have not yet been placed into service. Depreciation expense was $0.3 million and $0.2 million for the three months ended June 30, 2020 and 2019, respectively, and $0.5 million and $0.4 million for the six months ended June 30, 2020 and 2019, respectively.

Accrued Liabilities and Other:

	June 30, 2020	December 31, 2019
	(in thousands)	
Accrued compensation and related expenses	$ 5,510	$ 7,274
Accrued litigation expense	2,605	3,200
Accrued professional services	277	392
Others	880	739
	$ 9,272	$ 11,605

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 2025. 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 June 30, 2020 and 2019, respectively, and $0.6 million and $0.6 million for the six months ended June 30, 2020 and 2019, respectively.

The table below summarizes aggregate future minimum lease payments under all leases as of June 30, 2020:

Year ending December 31,	(in thousands)
2020 (remaining six months)	$ 562
2021	1,030
2022	955
2023	867
2024	871
Thereafter	363
	$ 4,648

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 $0.3 million and $0.4 million as of June 30, 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 "California Action"). 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. Subsequently on December 20, 2019, Plaintiff the filed a putative class action captioned Eric B. Fromer Chiropractic, Inc. v. SI-BONE, Inc. (Case No. 1922-CC12323), in the Circuit Court of the City of St. Louis, State of Missouri (the "Missouri Action"). The Missouri Action alleges the same TCPA violations as the California Action. On December 23, 2019 the parties filed a joint stipulation of dismissal of the California Action 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.

The Company accrued litigation expense of $3.2 million during the year ended December 31, 2019 within general and administrative expenses in the condensed consolidated financial statements, which was the Company's estimated cost to resolve the matter pursuant to the Settlement Agreement and based on the estimated class members' claim submission rate. Following the notice and claims submission process, on June 22, 2020, the Circuit Court of the City of St. Louis, State of Missouri, approved a final order to pay the approved claims submitted by class members, fees, expenses and incentive awards totaling $2.6 million as final settlement. Accordingly, the Company recorded a reversal of accrued litigation expense of $0.6 million in the three and six months ended June 30, 2020 within general and administrative expenses in the condensed consolidated financial statements. The Company made the final settlement payment on July 1, 2020.

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

Term Loan

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

	June 30, 2020	December 31, 2019
	(in thousands)	
Principal and final fee payments	$ 41,000	$ 40,000
Less: Unamortized debt issuance costs	(736)	(777)
Unaccreted value of final fee	(1,000)	—
Outstanding debt, net of debt issuance costs and unaccreted value of final fee	$ 39,264	$ 39,223
Classified as:		
Current portion of long-term borrowings	$ —	$ 4,358
Long-term borrowings	$ 39,264	$ 34,865

The outstanding debt as of December 31, 2019 was related to a term loan entered by the Company with Biopharma Credit Investments IV Sub LP ("Pharmakon") in October 2017 for total loan proceeds of $40.0 million (the "Pharmakon Term Loan"). The Pharmakon Term Loan included an interest-only period for 35 months through September 2020 and then equal quarterly principal payments plus interest through December 2022. The Pharmakon Term Loan carried a fixed interest rate of 11.5% and allowed for early prepayment. The prepayment penalty fee was equal to the remaining interest due if prepaid within the first 30 months, a 2% penalty for months 31-48, and a 1% penalty for months 49-60.

On May 29, 2020, the Company entered into a Loan and Security Agreement with Solar Capital Partners ("Solar") providing for a term loan of an aggregate principal amount of $40.0 million to the Company (the "Solar Term Loan"). In accordance with the Loan and Security Agreement, the Company paid in full and terminated the Pharmakon Term Loan, which was accounted for as debt extinguishment in accordance with the accounting standards. The Company recognized the unamortized debt issuance costs of $0.7 million and the prepayment penalty and lender fees of $0.8 million related to Pharmakon Term Loan as a loss on debt extinguishment. The costs and fees are reflected as interest expense in the condensed consolidated statement of operations for the three and six months ended June 30, 2020. The total debt issuance costs of $0.8 million associated with the Solar Term Loan were recorded in the condensed consolidated balance sheet as a direct deduction from the carrying amount of the loan, and are amortized as a component of interest expense using straight-line method over the life of the term loan.

The Solar Term Loan bears interest at a rate per annum equal to 9.40% plus the greater of (i) London Interbank Offered Rate ("LIBOR") or (ii) 0.33%, payable monthly in arrears. LIBOR means the greater of one-month LIBOR (or a comparable replacement rate to be determined by the collateral agent if the LIBOR is no longer available), which rate shall reset monthly. The Solar Term Loan matures in 60 months on June 1, 2025 ("Maturity Date"), with an interest-only period of 36 months through June 2023, and then repaid in equal monthly principal payments plus interest through maturity date. Pursuant to the Loan and Security Agreement, the Company may voluntarily prepay the Solar Term Loan, in full or in part, but only in increments of $10.0 million, for a prepayment premium in an amount equal to 3.0% of the principal if prepaid in year one, 1.25% of the principal if prepaid in year two, and 0.50% of the principal if prepaid in year three or later. The prepayment premium will be waived if the Company voluntarily prepays and refinances the outstanding balance with Solar. The Solar Term Loan is secured by substantially all of the Company's assets.

The Company is also obligated to pay a final fee equal to $1.0 million or 2.5% of the aggregate principal amount of the Solar Term Loan, which was fully earned by Solar on the effective date of the Loan and Security Agreement. With respect to the Solar Term Loan, this final fee shall be due and payable on the earliest of (i) the maturity date, (ii) the acceleration of the loan balance or (iii) its full prepayment, refinancing, substitution or replacement. The final fee was included within the long-term borrowings and is accreted to interest expense using straight-line method over the life of the term loan.

The effective interest rate related to the Solar Term Loan and Pharmakon Term Loan (excluding the write-down of unamortized debt issuance costs and prepayment penalty related to the Pharmakon Term Loan) was 11.8% and 12.3% for the three months ended June 30, 2020 and 2019, respectively, and 12.0% and 12.2% for the six months ended June 30, 2020 and 2019, respectively.

The table below summarizes the future principal and final fee payments under the Solar Term Loan as of June 30, 2020:

Year ending December 31,	(in thousands)
2020 (remaining six months)	$ —
2021	—
2022	—
2023	11,667
2024	20,000
Thereafter	9,333
Total principal and final fee payments	$ 41,000

Subject to other customary covenants set forth in the Loan and Security Agreement with Solar, the Company is required to maintain unrestricted cash and cash equivalents based on the trailing 12-month net products revenues tested on a monthly basis as follows: (a) $15.0 million if net product revenue is less than $75.0 million; or (b) $7.5 million if net product revenue is greater than or equal to $75.0 million, but less than $100.0 million (the "minimum liquidity requirement"). The Company is not subject to minimum liquidity requirement when trailing twelve-month net product revenues exceeds $100.0 million. Upon the occurrence of an event of default of certain customary covenants, including the minimum liquidity requirements, as specified in the Loan and Security Agreement, subject to specified cure periods, all amounts owed by the Company would begin to bear interest at a rate that is 5.0% above the rate effective immediately before the event of default and may be declared immediately due and payable by Solar. As of June 30, 2020, the Company was in compliance with all debt covenants. Though there are uncertainties surrounding the impact of the COVID-19 pandemic that may impact our future revenue, the Company believes that it has sufficient cash and cash equivalents to meet the minimum liquidity requirements in the foreseeable succeeding periods.

PPP Loan

On March 27, 2020, the U.S. federal government enacted the "Coronavirus Aid, Relief and Economic Security (CARES) Act," and among other things, established the Paycheck Protection Program ("PPP"), administered by the Small Business Administration ("SBA"), whereby certain small businesses were eligible for a loan to fund payroll expenses, rent, and related costs. The loan may be forgiven if the funds are used for payroll and other qualified expenses. The Company met the requirements to apply for the PPP loan given that the Company has less than 500 employees and the business was negatively impacted by COVID-19. The Company submitted its application and was approved for the SBA program and received the proceeds from the PPP loan amounting to $5.3 million on April 21, 2020, pursuant to a Promissory Note with Silicon Valley Bank ("SVB"). In light of the subsequent clarifications from the U.S. government on the eligibility criteria, the Company determined it was appropriate to repay the entire amount of the PPP loan. Accordingly, on April 29, 2020, the Company repaid in full the PPP loan and correspondingly terminated the Promissory Note.

8. Stock-Based Incentive Compensation Plans

Stock Options

The table below summarizes the stock option activity for the six months ended June 30, 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	(89,942)	4.00
Canceled and forfeited	(2,582)	14.75
Outstanding as of June 30, 2020	2,652,683	8.24

As of June 30, 2020, the unrecognized compensation cost related to stock options was $4.3 million, which is expected to be recognized over a period of approximately 2.3 years.

There were no stock options granted during the three months ended June 30, 2020. The table below summarizes the weighted average grant date fair value per share and the assumptions used to estimate the grant date fair value using the Black-Scholes option-pricing model of the stock options granted during the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Weighted average grant date fair value per share	—	$8.00	$8.37	$9.79
Expected term (years)	—	5.0 to 7.0	5.5 to 7.0	5.0 to 7.0
Expected volatility	—	46.6% to 47.2%	46.7% to 47.2%	41.7% to 47.2%
Risk-free interest rate	—	1.83% to 2.41%	1.56% to 1.64%	1.83% to 2.59%
Dividend yield	—	—%	—%	—%

Early Exercise of Unvested Stock Options

Early exercises of stock options under the Company's 2008 Stock Option Plan 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 June 30, 2020 and December 31, 2019, the Company had a total of 9,732 shares and 21,404 shares of common stock, respectively, subject to repurchase under the Company's 2008 Stock Option Plan.

Restricted Stock Units

The table below summarizes restricted stock units activity for the six months ended June 30, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2019	543,041	$19.72
Granted	945,682	20.07
Vested	(148,968)	20.84
Canceled and forfeited	(6,254)	18.51
Outstanding as of June 30, 2020	1,333,501	19.85

As of June 30, 2020, the unrecognized compensation cost related to the restricted stock units was $22.9 million, which is expected to be recognized over a period of approximately 3.2 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 commences in May and November. On March 26, 2020, the Company's Compensation Committee approved the amendment of the terms of future offerings under the ESPP which, among other things, increased the maximum number of shares that may be purchased on any single purchase date, provided for automatic enrollment in a new offering, and provided that the offering which commenced in May 2020 be twelve months in duration and consist of two purchase periods. The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model, which is being amortized over the requisite service period. The Company issued 74,685 shares and 99,086 shares under the ESPP, representing approximately $1.0 million and $1.3 million in employee contributions for six months ended June 30, 2020 and June 30, 2019, respectively. As of June 30, 2020 and December 31, 2019, total accumulated ESPP related employee payroll deductions amounted to $0.2 million and $0.2 million, respectively, which were included within accrued compensation and related expenses in the condensed consolidated balance sheets.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Cost of goods sold	$ 85	$ 63	$ 156	$ 106
Sales and marketing	1,347	940	2,488	1,674
Research and development	288	124	528	220
General and administrative	1,235	687	2,405	1,685
	$ 2,955	$ 1,814	$ 5,577	$ 3,685

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands, except share and per share data)			
Net loss	$ (12,472)	$ (8,654)	$ (25,244)	$ (17,999)
Weighted-average shares used to compute basic and diluted net loss per share	28,492,582	24,577,938	27,872,505	24,484,608
Net loss per share, basic and diluted	$ (0.44)	$ (0.35)	$ (0.91)	$ (0.74)

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock options	2,652,683	3,024,743	2,652,683	3,024,743
Restricted stock units	1,333,501	564,638	1,333,501	564,638
Shares subject to repurchase	9,732	46,811	9,732	46,811
ESPP purchase rights	124,266	84,321	124,266	84,321
Common stock warrants	118,122	118,122	118,122	118,122
	4,238,304	3,838,635	4,238,304	3,838,635

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 and six months ended June 30, 2020, the Company expensed $22,000 and $44,000, respectively, 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 June 30, 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 and six months ended June 30, 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.

The CARES Act 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.

On June 29, 2020, Governor Gavin Newsom signed California Assembly Bill 85 (AB 85) into law. The legislation suspends the California net operating loss deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation of certain California Tax Credits for 2020, 2021, and 2022. The legislation disallows the use of California net operating loss deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $1.0 million. The carryover periods for net operating loss deductions disallowed by this provision will be extended. Additionally, any business credit will only offset a maximum of $5.0 million of California tax. Given the Company’s expected loss position in the current year, the new legislation will not impact the current year provision. The Company will continue to monitor the possible California net operating loss and credit limitations in future periods.

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 June 30, 2020, more than 48,000 procedures have been performed by over 2,100 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

The COVID-19 pandemic and the resulting economic downturn are affecting business conditions in our industry. The overall demand for our products decreased as a result of the pandemic, which impacted our operating results for the three and six months ended June 30, 2020. Many state and local governments in the U.S. and foreign governments issued orders that temporarily precluded elective procedures in order to conserve scarce health system resources in view of the pandemic. The decrease in hospital admission rates and elective surgeries decreases the demand for elective procedures using our iFuse implants. 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 a small portion of our worldwide sales. Beginning in mid-March 2020 through April 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. In May and June 2020, case volumes began to recover as hospitals and medical centers across the U.S. and Europe resumed performance of elective surgery procedures.

We have taken what we believe are all necessary precautions to safeguard our employees, patients, customers, and other stakeholders from COVID-19 pandemic. We are following the Centers for Disease Control and Prevention's guidance and local restrictions. We took actions to support patients, customers, and employees, while maintaining business continuity in response to the COVID-19 pandemic. The majority of our employees who are not related to manufacturing and order fulfillment are currently on a telecommunication work arrangement and have generally been able to successfully work remotely. We restricted non-essential travel to protect the health and safety of our employees, patients, and customers. We modified operations and clinical support starting in March 2020, maintaining streamlined assembly, distribution and related processes in order to continue providing products to our customers. Specific protocols were designed and implemented to minimize contact time among employees working on site. Where healthcare operations were impacted, we supported healthcare providers via telephone and online technologies. Starting in May 2020, we began to return to more normalized operations and clinical support as local restrictions were reduced. We also continue to focus on increasing surgeon activity by utilizing a virtual education series for surgeons and mid-level practitioners to continue our training activities.

During the quarter, our primary goal was to retain our employees and continue forward with major new product initiatives to protect the long-term prospects of our business. However, we curtailed operating expense in other areas due to limited visibility on the extent and duration of the impact from COVID-19. We took preemptive steps to manage spending, including implementing hiring restrictions, eliminating discretionary spending, reducing executive salaries, reducing capital expenditures, reducing non-essential marketing expenses, and delaying clinical research projects. We will continue to take a thoughtful approach to spending that will help align any return to investments in our business with a return to revenue growth, while managing our net loss and protecting our cash.

The extent to which the COVID-19 pandemic impacts our operations is dependent on future developments, which are still highly uncertain and cannot be fully predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the COVID-19 pandemic. In particular, the spread of the COVID-19 globally is adversely affecting global economies and financial markets which could materially and adversely impact our operations. The existence and further duration of the COVID-19 pandemic may also further exacerbate certain risks as described in "Item 1A - Risk Factors". Recently, certain U.S. states are experiencing increasing trends of COVID-19 infections and hospitalizations. This could result in governments reissuing orders that temporarily preclude elective procedures which may significantly reduce our future revenue and significantly impact our results of operations. We continue to monitor the rapidly evolving situation and guidance from authorities, including federal, state and local public health authorities and may take additional actions based on their recommendations. In these dynamic circumstances, there may be developments outside our control requiring us to adjust our operating plan. We intend to continue to execute on our strategic plans and operational initiatives during the COVID-19 outbreak. However, the uncertainties discussed above may result in delays or modifications to these plans and initiatives.

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 by, among other things, 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 have made significant investments in our sales force since our initial public offering in 2018. We have built a valuable sales team, and we believe they are the key to the recovery that follows the pandemic. As such, we have made it a top priority to support and retain our sales force through this challenging period. However, we have also limited new sales force hiring in the second quarter of 2020 given current uncertainties and are focusing on sales force productivity during this period. As of June 30, 2020, our U.S. sales force consisted of 62 territory sales managers and 54 clinical support specialists directly employed by us and 37 third-party distributors, compared to 50 territory sales managers and 37 clinical support specialists directly employed by us and 33 third-party distributors as of June 30, 2019. As of June 30, 2020, our international sales force consisted of 20 sales representatives directly employed by us and 31 third-party distributors, compared to 16 sales representatives directly employed by us and 28 third-party distributors as of June 30, 2019.

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 June 30, 2020 and 2019, in the U.S., more than 1,500 surgeons and 1,300 surgeons, respectively, have been trained on iFuse and have treated at least one patient. Outside the U.S., as of June 30, 2020 and 2019, more than 600 surgeons and 500 surgeons, respectively, 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., as well as international surgeons 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 implant placed in each sacroiliac joint (for a total of two implants per case) using a posterior approach, through the sacrum, across the sacroiliac joint, and into the ilium. The Bedrock technique is in contrast to placement with our traditional iFuse procedure, whereby three iFuse implants are placed into one sacroiliac joint via a lateral approach through the ilium and into the sacrum. 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 45 training courses at academic centers in the U.S., and more than 200 surgical residents and fellows have been trained. We 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 June 30, 2020, of the U.S. payors covering 297.8 million lives that reimburse for iFuse, 182.0 million lives are covered by private payors. This includes covered lives by Aetna, which adopted a new new coverage for minimally invasive arthrodesis of the sacroiliac joint for sacroiliac joint syndrome and sacroiliac joint pain, effective May 28, 2020. Aetna is the third largest commercial health plan in the U.S. with over 22 million members. Currently, the 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. As of June 30, 2019, U.S. payors covering 266.0 million lives reimbursed for iFuse, of which 131.0 million were covered by private payors. 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 June 30, 2020, 35 U.S. payors have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence, compared to 33 exclusive coverage policies as of June 30, 2019. These payors have based their exclusive coverage decisions on the quality of our data. Further, as of June 30, 2020 and 2019, there were 21 and 18, respectively, U.S. payors that 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 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. 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 and degeneration 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 and second quarters of 2020 due to local restrictions on elective surgeries. As the pandemic continued in the U.S. and Europe, it had a significant impact on our case volumes beginning mid-March 2020. The largest impact was felt in April 2020, where revenue declined by 84% from the prior year. Given the situation, a considerable number of cases were deferred from mid-March through the end of April 2020. In May 2020, case volumes began to recover as hospitals and medical centers across the U.S. and Europe resumed performance of elective surgery procedures, with revenue growth of 6% in May 2020 compared to the prior year. Case volumes continued to improve in June 2020 with revenue growth of 42% compared to the prior year. We believe a considerable number of cases performed in May 2020 and June 2020 were rescheduled surgeries cancelled in the second half of March through the end of April 2020. As rescheduled procedures diminish, in addition to the heightened risk of further shutdowns in elective procedures and geographic uncertainty, we do not view second quarter 2020 revenue performance as an indicator of future growth.

The COVID-19 pandemic significantly disrupted and may continue to disrupt capital markets as well as worldwide economies, leading to a prolonged global economic recession. This could pressure hospital spending, impacting our pricing. Further, the government restrictions to temporarily preclude elective procedures may continue to disrupt scheduled procedures. As a result of these factors, it has made it difficult for us to forecast future iFuse sales. Therefore, we believe that historical revenue 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 are 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.

Our operations ran at suboptimal capacity as a result of decreased iFuse demand from worldwide restrictions on elective procedures. Accordingly, certain labor and overhead costs were expensed as incurred which impacted our gross profit and gross margin in the second quarter of 2020. We may experience similar issues in future quarters due to the COVID-19 pandemic. As such, we cannot reliably estimate the extent to which the COVID-19 pandemic will impact our overall cost of goods sold, gross profit, and gross margin 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 are currently limiting hiring of staff at this time due to the COVID-19 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 reflected normal business activities into mid-March 2020. Due to the COVID-19 pandemic, we focused on protecting key investments in our field force while curtailing most other areas of sales and marketing spend during the second quarter of 2020. For example, we 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. In contrast, we reduced certain other spending during the COVID-19 pandemic, such as travel and related expenses, regional surgeon training, trade shows, and discretionary marketing. 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 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. Clinical study expenses declined during mid-March through April due to hospital postponement of trials as a result of the COVID-19 pandemic. However, most hospitals allowed the resumption of clinical trials starting in May and June 2020. As such, we anticipate that research and development expenses will continue to increase in the future.

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 COVID-19 pandemic recedes. General and administrative activities that sustain our business and support our operations as a public company, include but are 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, amortization of debt issuance costs and accretion of final fee on our Solar Term Loan. Following the refinancing of our term loan, interest expense also includes the loss on debt extinguishment.

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 June 30,				Six Months Ended June 30,			
	2020		2019		2020		2019	
	Amount	%	Amount	%	Amount	%	Amount	%
	(in thousands, except for percentages)							
Consolidated Statements of Operations Data:								
Revenue	$ 14,049	100 %	$ 16,317	100 %	$ 30,870	100 %	$ 31,308	100 %
Cost of goods sold	2,117	15 %	1,588	10 %	4,049	13 %	3,114	10 %
Gross profit	11,932	85 %	14,729	90 %	26,821	87 %	28,194	90 %
Operating expenses:								
Sales and marketing	15,755	112 %	16,727	103 %	35,036	113 %	32,542	104 %
Research and development	2,165	15 %	1,946	12 %	4,255	14 %	3,629	12 %
General and administrative	4,151	30 %	4,194	26 %	9,551	31 %	8,960	29 %
Total operating expenses	22,071	157 %	22,867	141 %	48,842	158 %	45,131	144 %
Loss from operations	(10,139)	(72)%	(8,138)	(51)%	(22,021)	(71)%	(16,937)	(54)%
Interest and other income (expense), net:								
Interest income	329	2 %	695	4 %	827	3 %	1,439	5 %
Interest expense	(2,683)	(19)%	(1,233)	(8)%	(3,914)	(13)%	(2,463)	(8)%
Other income (expense), net	21	— %	22	— %	(136)	— %	(38)	— %
Net loss	$ (12,472)	(89)%	$ (8,654)	(55)%	$ (25,244)	(81)%	$ (17,999)	(57)%

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 June 30,				Six Months Ended June 30,			
	2020		2019		2020		2019	
	Amount	%	Amount	%	Amount	%	Amount	%
	(in thousands except for percentages)							
United States	$ 13,221	94 %	$ 15,019	92 %	$ 28,518	92 %	$ 28,469	91 %
International	828	6 %	1,298	8 %	2,352	8 %	2,839	9 %
	$ 14,049	100 %	$ 16,317	100 %	$ 30,870	100 %	$ 31,308	100 %

Comparison of the Three Months Ended June 30, 2020 and June 30, 2019

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

	Three Months Ended June 30,			
	2020	2019	$ Change	% Change
	(in thousands, except for percentages)			
Revenue	$ 14,049	$ 16,317	$ (2,268)	(14)%
Cost of goods sold	2,117	1,588	529	33%
Gross profit	$ 11,932	$ 14,729	$ (2,797)	(19)%
Gross margin	85 %	90 %		

Revenue. The decrease in revenue for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 comprised a decrease of $1.8 million in our U.S. revenue and a decrease of $0.5 million in our international revenue. The decline in revenue is attributed to a reduction in U.S. and international case volumes due to restrictions on elective surgeries put in place by governments to address the COVID-19 pandemic.

Gross Profit and Gross Margin. Gross profit decreased $2.8 million for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019, driven both by lower revenue and higher cost of goods sold. The gross margin decreased to 85% for the three months ended June 30, 2020 as compared to 90% for the three months ended June 30, 2019 primarily due to certain period costs charged directly to cost of operations of $0.2 million and increases in inventory write-downs of $0.2 million. Certain period costs were expensed as incurred during the second quarter of 2020 because our operations ran at suboptimal capacity due to lower case volumes as a result of the COVID-19 pandemic.

Operating Expenses:

	Three Months Ended June 30,			
	2020	2019	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 15,755	$ 16,727	$ (972)	(6)%
Research and development	2,165	1,946	219	11%
General and administrative	4,151	4,194	(43)	(1)%
Total operating expenses	$ 22,071	$ 22,867	$ (796)	(3)%

Sales and Marketing Expenses. The decrease in sales and marketing expenses for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 was primarily due to decreases in travel and other sales and marketing related expenses of $2.7 million as a result of the actions taken to curtail discretionary spending in response to the COVID-19 pandemic. These decreases were partly offset by an increase of $1.8 million in employee related costs and stock-based compensation expense driven by increased headcount.

Research and Development Expenses. The increase in research and development expenses for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily due to an increase of $0.4 million in employee related costs and stock-based compensation expense driven by increased headcount. The increase was partly offset by a decrease of $0.2 million mainly due to the decline in clinical study activities while elective procedures were restricted.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2020 was relatively flat compared to the three months ended June 30, 2019. An increase of $0.8 million in employee related costs and stock-based compensation expense driven by increased headcount was offset by the reversal of accrued litigation expense of $0.6 million following the final settlement of the TCPA class action lawsuit as well as decreases in other general and administrative expenses of $0.2 million as a result of curtailment of discretionary spending in response to the COVID-19 pandemic.

Interest and Other Income (Expense), Net:

	Three Months Ended June 30,			
	2020	2019	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 329	$ 695	$ (366)	(53)%
Interest expense	(2,683)	(1,233)	(1,450)	118%
Other income, net	21	22	(1)	(5)%
Total interest and other expense, net	$ (2,333)	$ (516)	$ (1,817)	352%

Interest Income. The decrease in interest income for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 was mainly due to lower interest earned on our investments in marketable securities, primarily as a result of lower interest rates.

Interest Expense. The increase in interest expense for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 was mainly due to the loss on extinguishment of the Pharmakon Term Loan of $1.5 million, partly offset by lower interest associated with the Solar Term Loan.

Other Income, Net. Other income, net was relatively flat for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019.

Comparison of the Six Months Ended June 30, 2020 and June 30, 2019

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

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(in thousands, except for percentages)			
Revenue	$ 30,870	$ 31,308	$ (438)	(1)%
Cost of goods sold	4,049	3,114	935	30%
Gross profit	$ 26,821	$ 28,194	$ (1,373)	(5)%
Gross margin	87 %	90 %		

Revenue. The decrease in revenue for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was primarily due to a decrease of $0.5 million in our international sales due to the effects of COVID-19 pandemic. Our U.S. revenue was flat for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. The increasing growth trend of our U.S. case count prior to the impact of COVID-19 was offset by the decline in U.S. case volumes due to COVID-19. Prior to the impact of COVID-19, we experienced case growth trends consistent with those experienced in the fourth quarter of 2019. The case growth we experienced prior to impact of COVID-19 can be attributed to higher sales force productivity, higher numbers of sales personnel, and increased active surgeons due to improving U.S. reimbursement coverage.

Gross Profit and Gross Margin. Gross profit decreased $1.4 million for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 primarily driven by lower revenue and lower gross margin. The gross margin decreased to 87% for the six months ended June 30, 2020 as compared to 90% for the six months ended June 30, 2019 primarily due to certain period costs charged directly to cost of operations of $0.2 million and increases in inventory write-downs of $0.2 million. Certain period costs were expensed as incurred during the second quarter of 2020 because our operations ran at suboptimal capacity due to lower case volumes as a result of the COVID-19 pandemic.

Operating Expenses:

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 35,036	$ 32,542	$ 2,494	8%
Research and development	4,255	3,629	626	17%
General and administrative	9,551	8,960	591	7%
Total operating expenses	$ 48,842	$ 45,131	$ 3,711	8%

Sales and Marketing Expenses. The increase in sales and marketing expenses for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was primarily due to an increase of $5.0 million in employee related costs and stock-based compensation expense driven by increased headcount. The increase was partly offset by decreases in travel and other sales and marketing related expenses of $2.5 million as a result of the actions taken to curtail discretionary spending in response to the COVID-19 pandemic.

Research and Development Expenses. The increase in research and development expenses for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was primarily due to increases in employee related costs and stock-based compensation expense of $0.8 million driven by increased headcount. The increase was partly offset by a decrease of $0.2 million mainly due to the decline in clinical study activities while elective procedures were restricted.

General and Administrative Expenses. The increase in general and administrative expenses for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was primarily due to an increase of $1.1 million in employee related costs and stock-based compensation expense driven by increased headcount and $0.2 million public offering costs allocated to sale of common stock by selling shareholders. The increase was partly offset by the reversal of accrued litigation expense of $0.6 million in the second quarter of 2020 following the final settlement of the TCPA class action lawsuit, and a decrease of $0.1 million in other general and administrative expenses as a result of curtailed discretionary spending in response to the COVID-19 pandemic.

Interest and Other Income (Expense), Net:

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 827	$ 1,439	$ (612)	(43)%
Interest expense	(3,914)	(2,463)	(1,451)	59%
Other expense, net	(136)	(38)	(98)	258%
Total interest and other expense, net	$ (3,223)	$ (1,062)	$ (2,161)	203%

Interest Income. The decrease in interest income for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was mainly due to lower interest earned on our investments in marketable securities, primarily as a result of lower interest rates.

Interest Expense. The increase in interest expense for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was mainly due to the loss on extinguishment of Pharmakon Term Loan of $1.5 million, partly offset by lower interest associated with the Solar Term Loan.

Other Expense, Net. The increase in other expense, net, for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was mainly due to higher foreign exchange losses.

Liquidity and Capital Resources

As of June 30, 2020, we had cash and marketable securities of $137.7 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 June 30, 2020 and December 31, 2019, we had $39.3 million and $39.2 million outstanding debt, respectively.

As of June 30, 2020, we had an accumulated deficit of $220.8 million. During the six months ended June 30, 2020, we incurred a net loss of $25.2 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.

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.

Term Loan

The outstanding debt as of June 30, 2020 is related to a term loan pursuant to the Loan and Security Agreement dated May 29, 2020, entered into by us with Solar Capital Partners (“Solar”). Pursuant to the Loan and Security Agreement, Solar provided an aggregate principal amount of $40.0 million term loan to us (the “Solar Term Loan”). Prior to Solar Term Loan, our outstanding debt was related to a $40.0 million Term Loan with Biopharma Credit Investments IV Sub LP (“Pharmakon”) entered in October 2017 (the “Pharmakon Term Loan”). In accordance with the Loan and Security Agreement, we paid in full and terminated the Pharmakon Term Loan, which we accounted for as debt extinguishment in accordance with the accounting standards. As of June 30, 2020 and December 31, 2019, there was no amount available that could be borrowed under the credit facilities.

The Pharmakon Term Loan included an interest-only period for 35 months through September 2020 and equal quarterly principal payments plus interest through December 2022. The Pharmakon Term Loan carried a fixed interest rate of 11.5% and allowed for early prepayment. The prepayment penalty was equal to the remaining interest due if prepaid within the first 30 months, a 2% penalty for months 31-48, and a 1% penalty for months 49-60.

The Solar Term Loan bears interest at a rate per annum equal to 9.40% plus the greater of (i) the London Interbank Offered Rate (“LIBOR”) or (ii) 0.33%, payable monthly in arrears. LIBOR means the greater of one-month LIBOR (or a comparable replacement rate to be determined by the collateral agent if the LIBOR is no longer available), which rate shall reset monthly. The Solar Term Loan matures in 60 months on June 1, 2025 (“Maturity Date”), with an interest-only period of 36 months through June 2023, and then repaid in equal monthly principal payments plus interest through maturity date. Pursuant to the Loan and Security Agreement, we may voluntarily prepay the Solar Term Loan, in full or in part, in increments of $10.0 million, for a prepayment premium in an amount equal to 3.0% of the principal if prepaid in year one, 1.25% of the principal if prepaid in year two, and 0.50% of the principal if prepaid if prepaid in year three or later. The prepayment premium will be waived if we voluntarily prepay and refinance the outstanding balance with Solar. The Solar Term Loan is secured by substantially all of our assets. We are also obligated to pay a final fee equal to $1.0 million or 2.5% of the aggregate principal amount of the Solar Term Loan. This final fee shall be due and payable on the earliest of (i) the maturity date, (ii) the acceleration of the loan balance, or (iii) the full prepayment, refinancing, substitution or replacement of Solar Term Loan. The final fee was included within the long-term borrowings and is accreted to interest expense using straight-line method over the life of the term loan.

In July 2017, the head of the United Kingdom Financial Conduct Authority announced the desire to phase out the use of LIBOR by the end of 2021. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee composed of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate (“SOFR”), a new index calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been a few issuances utilizing SOFR or the Sterling Over Night Index Average, an alternative reference rate that is based on transactions, it is unknown whether these alternative reference rates will attain market acceptance as replacements for LIBOR. There is currently no definitive information regarding the future utilization of LIBOR or of any particular replacement rate. As such, the potential effect of any replacement of the LIBOR could have on our business and financial condition cannot yet be determined.

Subject to other customary covenants set forth in the Loan and Security Agreement, we are required to maintain unrestricted cash and cash equivalents based on the trailing 12-month net products revenues tested on a monthly basis as follows: (a) $15.0 million if net product revenue is less than $75.0 million; or (b) $7.5 million if net product revenue is greater than or equal to $75.0 million, but less than $100.0 million (the "minimum liquidity requirement"). We are not subject to minimum liquidity requirement when trailing twelve-month net product revenues exceed $100.0 million. Upon the occurrence of an event of default of certain customary covenants, including the minimum liquidity requirement, as specified in the Loan and Security Agreement, subject to specified cure periods, all amounts owed by us would begin to bear interest at a rate that is 5.0% above the rate effective immediately before the event of default and may be declared immediately due and payable by Solar. As of June 30, 2020, we were in compliance with all debt covenants. Though there are uncertainties surrounding the impact of the COVID-19 pandemic that may impact our future revenue, we believe that we have sufficient cash and cash equivalents to meet the minimum liquidity requirements in the foreseeable succeeding periods.

Contractual Obligations

The following table summarizes our contractual obligations as of June 30, 2020:

		Payments Due By Period			
	Total	**Less than 1 year**	**1-3 years**	**4-5 years**	**More than 5 years**
			(in thousands)		
Principal obligations and final fee on long-term debt (1)	$ 41,000	$ —	$ —	$ 31,667	$ 9,333
Interest obligations (2)	15,990	2,346	7,892	5,550	202
Operating lease obligations	4,648	562	1,985	1,738	363
Purchase obligations	288	288	—	—	—
Total	$ 61,926	$ 3,196	$ 9,877	$ 38,955	$ 9,898

(1) Represents the principal obligations and the final fee at maturities of our Solar Term Loan.
(2) Represents the future interest obligations on our Solar Term Loan estimated using the fixed interest rate of 9.40% plus LIBOR held constant as of June 30, 2020.

This compared to $54.9 million of contractual obligations as of December 31, 2019.

Cash Flows

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

	Six Months Ended June 30,		
	2020	2019	$ Change
Net cash provided by (used in):	(in thousands)		
Operating activities	$ (17,228)	$ (15,474)	$ (1,754)
Investing activities	10,060	191	9,869
Financing activities	62,896	1,663	61,233
Effects of exchange rate changes on cash and cash equivalents	6	(4)	10
Net increase (decrease) in cash and cash equivalents	$ 55,734	$ (13,624)	$ 69,358

Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2020 of $17.2 million resulted from cash outflows due to a net loss of $25.2 million, adjusted for $7.9 million of non-cash items, partly offset by cash inflows from changes in operating assets and liabilities of $0.1 million. Net cash used in operating activities for the six months ended June 30, 2019 of $15.5 million resulted from cash outflows due to a net loss of $18.0 million, adjusted for $3.4 million of non-cash items, and cash outflows from changes in operating assets and liabilities of $0.8 million. The increase in net loss, net of non-cash items for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was mainly due to lower revenue due to the effects of COVID-19 and higher operating expenses from the growth of the business, partly offset by reduction of certain expenses as a result of the actions taken to curtail discretionary spending in response to COVID-19. Cash inflows from changes in operating assets and liabilities for the six months ended June 30, 2020 were primarily due to lower accounts receivable balance resulting from lower revenue and timing of collections and lower inventory mainly due to the timing of inventory build-up, partly offset by cash outflows due to decreases in operating liabilities resulting from timing of payments. Cash outflows from changes in operating assets and liabilities for the six months ended June 30, 2019 were primarily due to increases in inventory and accounts receivable from increased case volumes, partly offset by increased operating liabilities due to timing of payments.

Cash Provided by Investing Activities

Net cash provided by investing activities in the six months ended June 30, 2020 was $10.1 million compared to $0.2 million in the six months ended June 30, 2019. Net cash provided by investing activities for the six months ended June 30, 2020 consisted of maturities and sales of our marketable securities, net of purchases of $11.3 million, partially offset by purchases of property and equipment of $1.3 million. Net cash provided by investing activities for the six months ended June 30, 2019 consisted of maturities of our marketable securities, net of purchases of $1.1 million, partially offset by purchases of property and equipment of $0.9 million.

Cash Provided by Financing Activities

Cash provided by financing activities in the six months ended June 30, 2020 was $62.9 million compared to $1.7 million in the six months ended June 30, 2019. The difference was primarily due to the receipt of the proceeds, net of underwriting discounts, commissions and offering costs of $63.0 million from our follow-on public offering during the first quarter of 2020. Cash provided by financing activities in the six months ended June 30, 2020 also include proceeds from the issuance of common stock under our stock-based incentive compensation plans of $1.4 million, offset by payments associated with refinancing of our debt of $1.4 million. This compares to the cash provided by financing activities for the six months ended June 30, 2019 which consisted of proceeds from the issuance of common stock under our stock-based incentive compensation plans of $1.8 million, partly offset by payments of additional IPO related costs of $0.2 million.

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 June 30, 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 June 30, 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, certain of our employees still continued to work from home during the quarter. Management took measures to ensure that our internal control over financial reporting remained 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 six months ended June 30, 2020, we had a net loss of $25.2 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 June 30, 2020, we had an accumulated deficit of $220.8 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 infectious 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 an infectious 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, inability of our customers to meet their financial commitments due to strain on the healthcare system, 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 an infectious disease 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 hospital admission rates and the decision by patients to undergo elective surgery, each of which has decreased and may continue to impact 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 vaccines or one or more therapies that mitigate the effect of the virus will be developed, and, if so, when such vaccines and/or therapies 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 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, limit 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 revenue 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 surgery 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 for minimally invasive SI joint fusion 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 June 30, 2020, 35 of the largest 65 U.S. 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, in consultation with their patients, play the primary role in determining the course of treatment and, ultimately, any product that will be used in treatment. 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 their benefits. 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 can cause. 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 currently thought.

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 product. 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 and therefore choose to use competing products.

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. The 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 current or planned future 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 currently 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 family for some time. There can be no assurance that iFuse will maintain 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 June 30, 2020, our U.S. sales force consisted of 62 territory sales managers and 54 clinical support specialists directly employed by us, and 37 third-party distributors. As of June 30, 2020, our international sales force consisted of 20 sales representatives directly employed by us and 31 third-party distributors, which together have had sales in 35 countries through June 30, 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 temporarily or permanently take our approved product off the market 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 or field safety corrective action with respect to 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 manufacture and 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 currently 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 key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements;
- 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 impacts 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 some cases, following a successful product development effort, we may need to invest substantial resources in surgical instrumentation and implant inventory, prior to launch of the product, and before we understand the demand for such product. If we overestimate the demand for such products and invest too heavily in inventory to support the product line, the additional revenue and product margins may not produce a positive return on such investments, which could cause our financial results to suffer. 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 chosen for size based on 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, cost savings to patients, the healthcare system and the economy overall from its use, 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 changes in technology and the practice of medicine 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 uses;
- 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 in connection with marketing and selling our products, 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 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. Any of these actions would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue.

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 FDA 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 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 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. In these circumstances, we may be subject to significant enforcement actions, regulatory fines, or penalties, which could require us to redesign our products and harm our operating results.

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 to 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.

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 or significant clinical evidence to support regulatory approval and we may not successfully complete these clinical trials. 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. 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 devices manufacturers. Examples of the changes which will be introduced by these regulations include the following:

- additional scrutiny during the conformity assessment procedure for high risk medical devices;
- strengthening of the clinical data requirements related to medical devices;
- strengthening of the designation and monitoring processes governing notified bodies;
- the obligation for manufacturers and authorized representative to have a person responsible for regulatory compliance continuously at their disposal;
- authorized representatives would be held legally responsible and liable for defective products placed on the EU market;
- increased traceability of medical devices following the introduction of a Unique Device Identification (“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 augments the provisions of the Medical Device Directive governing clinical investigations of medical devices. Among other things, 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 places 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 may reduce reimbursement for procedures performed using 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. Surgeons may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. In addition, if longer-term patient results and experience indicate 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. 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. 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 the UK 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 nondisclosure agreements and other methods, to protect our proprietary technologies and know-how. As of June 30, 2020, we owned 40 issued U.S. patents and had 21 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. Competitors may market similar triangular shaped devices upon the expiration of the patents in 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.

As of June 30, 2020, we have 13 registered trademarks in the U.S. and have filed for 7 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 our 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 occur, 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 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 and state 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 NOLs carryforwards begin to expire in 2028 and 2020, respectively, subject to the recent California franchise tax law change affecting California state NOLs mentioned below. Portions of these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under legislation enacted in 2017, as modified by legislation enacted in 2020, unused U.S. federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. In the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. 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 NOLs and tax credit carryforwards are subject to limitation. We also updated our Section 382 ownership change analysis through June 30, 2019, considering the 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 period. 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 the first quarter of 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.

The California Assembly Bill 85 (AB 85) was signed into law by Governor Gavin Newsom on June 29, 2020. The legislation suspends the California NOL deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation of certain California Tax Credits for 2020, 2021, and 2022. The legislation disallows the use of California NOL deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $1.0 million. The carryover periods for NOL deductions disallowed by this provision will be extended. Given that we expect to be at a loss position in the current year, the new legislation will not impact our current year provision. We will continue to monitor the possible California NOLs and credit limitation in future periods.

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 term loan contains covenants that may restrict our business and financing activities.

On May 29, 2020, we entered into a Loan and Security Agreement with Solar Capital Ltd. ("Solar"), pursuant to which we borrowed $40.0 million pursuant to a term loan (the "Solar Term Loan"). We used the proceeds of the Solar Term Loan to repay in full and terminate our credit facility with BioPharma Credit Investments IV Sub LP.

The Loan and Security Agreement with Solar contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on the lenders' security interest over the collateral, a material adverse change, the occurrence of a default under certain other indebtedness of us or our subsidiaries, the rendering of certain types of judgments against us or our subsidiaries, the revocation of certain government approvals, violation of covenants, and incorrectness of representations and warranties in any material respect. Upon the occurrence of an event of default, subject to specified cure periods, all amounts owed by us would begin to bear interest at a rate that is 5.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by the Lenders. The Loan and Security Agreement with Solar also contains certain restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions, as well as financial reporting requirements.

The Solar Term Loan is secured by substantially all of our assets. The Loan and Security Agreement with Solar also contains a financial covenant related to our liquidity based on our trailing twelve-month net product revenues. We are required to hold at least $15.0 million in cash and cash equivalents so long as trailing twelve-month net product revenues are less than $75.0 million and at least $7.5 million in cash and cash equivalents so long as trailing twelve-month net product revenues are greater than or equal to $75.0 million but less than $100.0 million (collectively "Minimum Liquidity Requirements"). We are not subject to a Minimum Liquidity Requirement when trailing twelve-month net product revenues exceeds $100.0 million.

The covenants in the Solar Term Loan, 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 minimum trailing 12-month product revenue in future period. If not waived, future defaults could cause all of the outstanding indebtedness under our Loan and Security 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 June 30, 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 June 30, 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 June 30, 2020, approximately $58.0 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

None.

Item 6. Exhibits

Exhibit Number	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit/ Reference	Filing Date
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-Q	001-38701	4.3	5/5/2020
10.1*	Loan and Security Agreement, dated May 29, 2020, between SI-BONE, Inc. and Solar Capital Ltd., as collateral agent, and the lenders from time to time party thereto.				
10.2	SI-BONE, Inc. Severance Benefit Plan and Form of Participation Agreement	8-K	001-38701	10.1	7/17/2020
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.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* 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: August 4, 2020

By: /s/ Jeffrey W. Dunn

Jeffrey W. Dunn

President and Chief Executive Officer

(Duly Authorized Officer and Principal Executive Officer)

SI-BONE, Inc.

Date: August 4, 2020

By: /s/ Laura A. Francis

Laura A. Francis

Chief Operating Officer and Chief Financial Officer

(Duly Authorized Officer and Principal Financial and Accounting Officer)

EXHIBIT 10.1

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may be amended, restated, modified, or supplemented from time to time, this "**Agreement**") dated as of May 29, 2020 (the "**Effective Date**") among Solar Capital Ltd., a Maryland corporation, with an office located at 500 Park Avenue, 3rd Floor, New York, NY 10022 ("**Solar**"), as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), the lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), SI-BONE, Inc., a Delaware corporation, with offices located at 471 El Camino Real, Suite 101, Santa Clara, CA 95050, and other borrowers party hereto from time to time (individually and collectively, jointly and severally, "**Borrower**"), and the Guarantors party hereto from time to time, provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. DEFINITIONS AND OTHER TERMS

1.1 Terms. Capitalized terms used herein shall have the meanings set forth in Section 1.4 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules. Notwithstanding anything to the contrary contained herein, (a) all financial statements delivered hereunder shall be prepared, and all financial covenants contained herein shall be calculated, without giving effect to any election under the Statement of Financial Accounting Standards No. 159 (or any similar accounting principle) permitting a Person to value its financial liabilities or Indebtedness at the fair value thereof and (b) the financial statements delivered hereunder shall be prepared without giving effect to the implementation of Accounting Standards Codification 606: *Revenue from Contracts with Customers*. For the avoidance of doubt, and without limitation of the foregoing, Permitted Convertible Debt shall at all times be valued at the full stated principle amount thereof and shall not include any reduction or appreciation in value of the shares deliverable upon conversion thereof.

1.2 Section References. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

1.3 Divisions. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person, and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its equity interests at such time.

1.4 Definitions. The following terms are defined in the Sections or subsections referenced opposite such terms:

"**Agreement**"	Preamble
"**Approved Lender**"	Section 12.1
"**Borrower**"	Preamble
"**Cash Excess Payment**"	Section 7.7
"**Claims**"	Section 12.2
"**Collateral Agent**"	Preamble
"**Collateral Agent Report"**	Exhibit B, Section 5
"**Connection Income Taxes**"	Exhibit C, Section 1
"**Default Rate**"	Section 2.3(b)
"**Effective Date**"	Preamble
"**Event of Default**"	Section 8
"**Excluded Taxes**"	Exhibit C, Section 1
"**FATCA**"	Exhibit C, Section 1
"**Foreign Lender**"	Exhibit C, Section 1
"**Indemnified Person**"	Section 12.2
"**Indemnified Taxes**"	Exhibit C, Section 1
"**Lender**" and "**Lenders**"	Preamble
"**Lender Transfer**"	Section 12.1
"**New Subsidiary**"	Section 6.10
"**Officer**"	Exhibit E, Preamble
"**Open Source Licenses**"	Section 5.2(f)
"**Other Connection Taxes**"	Exhibit C, Section 1
"**Other Taxes**"	Exhibit C, Section 1
"**Participant Register**"	Section 12.1
"**Perfection Certificate**" and "**Perfection Certificates**"	Section 5.1
"**Recipient**"	Exhibit C, Section 1
"**Refinancing Convertible Debt**"	Section 7.7
"**Register**"	Section 12.1
"**Solar**"	Preamble
"**Term Loan**"	Section 2.2(a)
"**Termination Date**"	Exhibit B, Section 8
"**Transfer**"	Section 7.1
"**U.S. Person**"	Exhibit C, Section 1
"**U.S. Tax Compliance Certificate**"	Exhibit C, Section 7(b)(ii)(C)
"**Withholding Agent**"	Exhibit C, Section 1

In addition to the terms defined elsewhere in this Agreement, the following terms have the following meanings:

"**Account**" is any "account" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes, without limitation, all accounts receivable and other sums owing to any Loan Party.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**ACH Letter**" is ACH debit authorization in the form of Exhibit G hereto.

"**Affiliate**" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Amortization Date**" is July 1, 2023.

"**Anti-Terrorism Laws**" are any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"**Approved Fund**" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

"**Bond Hedge Transaction**" has the meaning assigned to such term in the definition of "Permitted Call Spread Agreement".

"**Blocked Person**" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which commercial banks in New York, New York are required or authorized to be closed.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue, *provided* that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent, and (d) any money market or similar funds that exclusively hold any of the foregoing.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; *provided* that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; *provided further*, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of each Loan Party described on Exhibit A.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by any Loan Party or any Subsidiary (other than any Excluded Foreign Subsidiary) at any time.

"**Collateral Agent**" is Solar, not in its individual capacity, but solely in its capacity as collateral agent on behalf of and for the ratable benefit of the Secured Parties.

"**Commitment Percentage**" is set forth in Schedule 1.1, as amended from time to time.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Competitor**" means a direct competitor of Borrower, as reasonably determined by Collateral Agent.

"**Compliance Certificate**" is that certain certificate in substantially the form attached hereto as Exhibit E.

"**Consolidated EBITDA**" means, with respect to Borrower and its Subsidiaries on a consolidated basis for any period, an amount equal to Consolidated Net Income for such period, plus each of the following to the extent deducted in calculating such Consolidated Net Income, without duplication: (i) Consolidated Net Interest Expense for such period; (ii) the sum of federal, state, local and foreign income Taxes accrued or paid in cash during such period; (iii) the amount of depreciation expense deducted in determining Consolidated Net Income for such period; (iv) the amount of amortization expense deducted in determining Consolidated Net Income for such period; (v) any non-cash stock compensation expense recorded pursuant to FASB 123R for such period; (vi) to the extent actually paid during such period, fees and expenses related to the consummation of the transactions contemplated to be closed on the Effective Date; (vii) transaction costs related to Permitted Acquisitions, Permitted Investments, Permitted Convertible Debt or any offering by Borrower of its Equity Interests during such period; and (viii) litigation costs.

"**Consolidated Net Income**" means, with respect to Borrower and its Subsidiaries on a consolidated basis for any period, the net income (loss) of Borrower and its Subsidiaries for such period, determined on a consolidated basis and in accordance with GAAP, but excluding from the determination of Consolidated Net Income (without duplication): (a) any non-cash extraordinary or non-recurring gains or losses or non-cash gains or losses from Transfers for such period; (b) any restructuring charges; (c) effects of discontinued operations in such period; (d) any Tax refunds, net operating losses or other net Tax benefits received during such period on account of any prior period; and (e) the net income (or loss) of any Person accrued prior to the date (x) it becomes a Subsidiary of Borrower or (y) all or substantially all of the properties or assets of such Person are acquired by a Subsidiary of Borrower, in each case, determined on a consolidated basis and in accordance with GAAP.

"**Consolidated Net Interest Expense**" means, with respect to Borrower and its Subsidiaries on a consolidated basis for any period, total interest expense (including mark-to-market interest expense with respect to any warrants to purchase Equity Interests of Borrower), premium payments, debt discount, fees, charges and related expenses with respect to all outstanding Indebtedness (including Permitted Hedging Agreements) of Borrower and its Subsidiaries for such period, determined on a consolidated basis and in accordance with GAAP (including interest expense paid to Affiliates of Borrower), less interest income of Borrower and its Subsidiaries for such period, determined on a consolidated basis and in accordance with GAAP.

"**Consulting Royalties**" means, with respect to any health care professional or other Person who is a counterparty to a health care professional consulting agreement or similar contract with Borrower or any of its Subsidiaries, royalty payments due to, or obligations to make royalty payments to or enter into agreements to pay royalties to, such Person arising out of consulting services provided to Borrower or any of its Subsidiaries relating to product development; *provided* that in no event shall Consulting Royalties under any such agreement exceed more than ten percent (10%) of sales of the product identified in such agreement; *provided further*, that such agreements shall not provide for any transfer of Intellectual Property to such Person and such Person shall have no rights in any Intellectual Property other than non-exclusive licenses.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith in accordance with GAAP; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Call Spread Agreement shall not constitute a Contingent Obligation of the Borrower.

"**Control Agreement**" is any control agreement entered into among (a) the depository institution at which any Loan Party or any of its Subsidiaries (other than any Excluded Foreign Subsidiary) maintains a Deposit Account or the securities intermediary or commodity intermediary at which any Loan Party or any of its Subsidiaries (other than any Excluded Foreign Subsidiary) maintains a Securities Account or a Commodity Account, (b) such Loan Party or such Subsidiary, as applicable, and (c) Collateral Agent pursuant to which Collateral Agent, for the ratable benefit of the Secured Parties, obtains "control" (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Cross-Default Reference Obligation**" has the meaning assigned to such term in the definition of "Permitted Convertible Debt."

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Designated Deposit Account**" is Borrower's deposit account set forth on the ACH Letter.

"**Dollars**," "**dollars**" and "$" each mean lawful money of the United States.

"Domestic Subsidiary" means any Subsidiary organized under the laws of the United States of America, any State thereof or the District of Columbia.

"**Eligible Assignee**" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of One Billion Dollars ($1,000,000,000); *provided* that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) any Loan Party or any Loan Party's Affiliates or Subsidiaries, (ii) a Competitor or (iii) a Vulture Fund. Notwithstanding the foregoing, (x) in connection with any assignment by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; *provided* that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**Equity Interests**" means, with respect to any Person, any and all shares, interests, participations or other equivalents (however designated) of capital stock of a corporation, any and all equivalent ownership interests in such Person (other than a corporation), including partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire (by purchase, conversion, dividend, distribution or otherwise) any of the foregoing (including through convertible securities), and all other rights, powers, privileges, interests, claims and other property in any manner arising therefrom or relating thereto. Notwithstanding the foregoing, in no event shall any indebtedness convertible or exchangeable into Equity Interests constitute "Equity Interests" hereunder.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"**Excluded Accounts**" shall mean (a) any Collateral Account of any Loan Party or any Subsidiary that is used by such Person solely for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Loan Party's employees and as identified to Collateral Agent by Borrower as such in the Perfection Certificate; *provided* that the amount deposited therein shall not exceed the amount reasonably expected to be due and payable for the next two (2) succeeding pay periods (including, for the avoidance of doubt, any amounts deposited for customary seasonal bonuses), (b) accounts (including trust accounts) used exclusively for escrow, customs, insurance or fiduciary purposes, merchant accounts, accounts used exclusively for compliance with any Requirements of Law to the extent such Requirements of Law prohibits the granting of a Lien thereon, (c) zero balance accounts and (d) Collateral Accounts and securities accounts held in jurisdictions outside the United States.

"**Excluded Foreign Subsidiary**" means, with respect to any Loan Party, any Subsidiary of such Loan Party, at any date of determination, (a) that is a "controlled foreign corporation" as defined in Section 957(a) of the Internal Revenue Code, (b) that is a direct or indirect Subsidiary of a "controlled foreign corporation" as defined in Section 957(a) of the Internal Revenue Code, or (c) substantially all of the assets of which are (1) equity interests in one or more "controlled foreign corporations" as defined in Section 957(a) of the Internal Revenue Code, and/or (2) Indebtedness or accounts receivable owed by any CFC or other entity that is described in this definition.

"**Excluded Subsidiary**" shall mean (a) any subsidiary that is prohibited by any applicable law or, on the date such subsidiary is acquired (*provided*, that such prohibition is not be created in contemplation of such acquisition), its organizational documents, in each case, from guaranteeing the Obligations; (b) any subsidiary that is prohibited by any contractual obligation that existed on the date any such subsidiary is acquired (*provided*, that such prohibition is not created in contemplation of such acquisition) from guaranteeing the Obligations; (c) any subsidiary to the extent that the provision of any subsidiary guarantee of the Obligations would require the consent, approval, license or authorization of any governmental authority which has not been obtained, any subsidiary that is subject to such restrictions; (d) any Excluded Foreign Subsidiary; and (e) any subsidiary for which the provision of a subsidiary guarantee would result in a material adverse regulatory consequence to us or one of our subsidiaries, as applicable.

"**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of any Loan Party or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

"**FDA**" means the U.S. Food and Drug Administration or any successor thereto.

"**Fee Letter**" means that certain Fee Letter dated the Effective Date, between each Loan Party and Solar, as amended, amended and restated, supplemented or otherwise modified from time to time.

"**First-Tier Foreign Subsidiary**" means any Excluded Foreign Subsidiary, the capital stock of which is owned directly by any Loan Party.

"**Funding Date**" is any date on which a Term Loan is made to or on account of Borrower which shall be a Business Day.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any federal, state, municipal, national or other government, governmental department, commission, board, bureau, court, agency or instrumentality or political subdivision thereof (including the FDA) or any entity or officer exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to any government or any court, in each case whether associated with a state or locality of the United States, the United States, or a foreign government.

"**Guarantor**" is any other Person providing a Guaranty in favor of Collateral Agent for the benefit of the Secured Parties (including without limitation pursuant to Section 6.10) but excluding any Excluded Subsidiary.

"**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations up to the amount of the liability in respect thereof that would at that time be required to be capitalized on a balance sheet in accordance with GAAP as in effect on December 31, 2019, (d) non-contingent obligations of such Person to reimburse any bank or other Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, (e) equity securities of such Person subject to repurchase or redemption other than at the sole option of such Person, (f) obligations secured by a Lien on any asset of such Person, whether or not such obligation is otherwise an obligation of such Person, (g) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature of such Person arising out of purchase and sale contracts, (h) all Indebtedness of others guaranteed by such Person, (i) off-balance sheet liabilities and/or pension plan or multiemployer plan liabilities of such Person to the extent such liabilities could reasonably be expected to have a Material Adverse Change, and (j) Contingent Obligations. In no event shall obligations under any Permitted Call Spread Agreement constitute Indebtedness.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"**Intellectual Property**" means all of each Loan Party's or any of its Subsidiaries' right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to such Loan Party;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Intellectual Property Security Agreement**" means that certain Intellectual Property Security Agreement dated as of the Effective Date between the Loan Parties and Collateral Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Intercompany Subordination Agreement**" means that certain Intercompany Subordination Agreement, dated as of the date hereof among Borrower, each Subsidiary and Collateral Agent, as amended, amended and restated, supplemented or otherwise modified from time to time.

"**Internal Revenue Code**" means the Internal Revenue Code of 1986, as amended.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**IRS**" means the United States Internal Revenue Service.

"**Key Person**" is each of Borrower's (i) President and Chief Executive Officer, who is Jeffrey W. Dunn as of the Effective Date, and (ii) Chief Financial Officer, who is Laura A. Francis as of the Effective Date.

"**Knowledge**" means to the "best of" the applicable Loan Party's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

"**Lender**" is any one of the Lenders.

"**Lenders**" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"**Lenders' Expenses**" are (a) all reasonable audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses (whether generated in house or by outside counsel), as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating and administering the Loan Documents, and (b) all fees and expenses (including attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

"**LIBOR Rate**" means the greater of (a) 0.33% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (the "**Service**") (or on any successor or substitute page of such Service, or any successor to or substitute for such Service, as determined by Collateral Agent) for a term of one month, which determination by Collateral Agent shall be conclusive in the absence of manifest error; *provided* that if, at any time, Lenders notify Collateral Agent that Lenders have determined that (x) Lenders are unable to determine or ascertain such rate, (y) the applicable regulator has made public statements to the effect that the rate published by the Service is no longer used for determining interest rates for loans or (z) by reason of circumstances affecting the foreign exchange and interbank markets generally, deposits in eurodollars in the applicable amounts or for the relative maturities are not being offered for such period, then the LIBOR Rate shall be equal to an alternate benchmark rate and spread agreed between Collateral Agent and the Loan Parties (which may include SOFR, to the extent publicly available quotes of SOFR exist at the relevant time), giving due consideration to (i) market convention or (ii) selection, endorsement or recommendation by a Relevant Governmental Body. Such alternative benchmark rate and spread shall be binding unless the Required Lenders object within five (5) days following notification of such amendment.

"**Lien**" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement, the Fee Letter, each Control Agreement, the Pledge Agreement, the Intellectual Property Security Agreement, the Perfection Certificates, each Compliance Certificate, the ACH Letter, each Loan Payment Request Form, any Guarantees, the Intercompany Subordination Agreement and any other subordination agreements, any note, or notes or guaranties executed by any Loan Party or any other Person, any agreements creating or perfecting rights in the Collateral (including all insurance certificates and endorsements, landlord consents and bailee consents) and any other present or future agreement entered into by any Loan Party or any other Person for the benefit of the Lenders and Collateral Agent, as applicable, in connection with this Agreement; all as amended, restated, or otherwise modified.

"**Loan Party**" means, individually, Borrower and each Guarantor and "**Loan Parties**" means, collectively, Borrower and each Guarantor.

"**Loan Party's Books**" are, with respect to any Loan Party, such Loan Party's or any of its Subsidiaries' books and records including ledgers, federal, state, local and foreign tax returns, records regarding such Loan Party's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Loan Payment Request Form**" is that certain form attached hereto as Exhibit D.

"**Material Adverse Change**" is (a) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower and its Subsidiaries, when taken as a whole; (b) a material impairment of (i) the prospect of repayment of any portion of the Obligations, (ii) the legality, validity or enforceability of any Loan Document, (iii) the rights and remedies of Collateral Agent or Lenders under any Loan Document except as the result of the action or inaction of the Collateral Agent or Lenders, (iv) the validity, perfection or priority of any Lien in favor of Collateral Agent for the benefit of the Secured Parties on any of the Collateral except as the result of the action or inaction of the Collateral Agent or Lenders; or (c) a "Change in Control", "Fundamental Change" and/or "Make-Whole Fundamental Change" (each howsoever defined) under any indenture governing any Permitted Convertible Debt, in each case to the extent any repayment or payment obligation could result in connection with the occurrence of such event.

"**Material Agreement**" is any license, agreement or other contractual arrangement required to be disclosed (including amendments thereto) under regulations promulgated under the Securities Act of 1933 or Securities Exchange Act of 1934, as may be amended; provided, however, that "Material Agreements" shall exclude all real estate leases.

"**Maturity Date**" is June 1, 2025.

"**Measurement Date**" is the last day of each month.

"**Net Product Revenue**" means, with respect to the Loan Parties, product revenue (determined under GAAP) with respect to the sale of surgical devices and products of the Borrower and its Subsidiaries. For the avoidance of doubt, Net Product Revenue excludes any Consulting Royalties and any other royalties.

"**Obligations**" are all of each Loan Party's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Premium, all fees under the Fee Letter, and any other amounts such Loan Party owes the Collateral Agent or the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of any Loan Party assigned to the Lenders and/or Collateral Agent in connection with this Agreement and the other Loan Documents, and the performance of such Loan Party's duties under the Loan Documents.

"**OFAC**" is the U.S. Department of Treasury Office of Foreign Assets Control.

"**OFAC Lists**" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, re-examination certificates, utility models, extensions and continuations-in-part of the same.

"**Payment Date**" is the first (1st) calendar day of each calendar month, commencing on July 1, 2020.

"Permitted Acquisition" means an acquisition by Borrower or any Subsidiary of any Intellectual Property or all or substantially all of the assets of, all of the ownership interests in, or a business line, product line (including rights in respect of any medical device) or unit or division of another Person (including any foreign corporations) for cash consideration (including (x) any purchase price adjustments, indemnity payments and earn-out obligations in connection therewith and (y) any liability assumed in connection therewith, including without limitation any Indebtedness permitted under clause (p) of the definition of Permitted Indebtedness) up to Ten Million Dollars ($10,000,000) in any fiscal year (or such greater amount as may be agreed with the prior written consent of Lender); *provided* that (a) no Event of Default or event that with the passage of time would result in an Event of Default shall exist immediately before or immediately after the consummation of such acquisition, (b) such acquired Person or assets shall be in the same line of business as is conducted by Borrower as of the Effective Date (or a line of business reasonably related thereto), (c) such acquisition shall not cause the focus or locations of Borrower's and its Subsidiaries' operations (when taken as a whole) to be located outside of the United States, (d) such acquisition shall not constitute a hostile acquisition, (e) any Person acquired as a result of such acquisition shall become a secured Guarantor subject to the terms herein, (f) in connection with such acquisition, neither Borrower nor any of its Subsidiaries (including for this purpose, the target of the acquisition) shall acquire or be subject to any Indebtedness or Liens that are not otherwise permitted hereunder, (g) both immediately prior to and immediately upon giving effect to the consummation of such acquisition, Borrower is in compliance with Section 7.13, (h) to the extent the total consideration (including (x) any purchase price adjustments, indemnity payments and earn-out obligations in connection therewith and (y) any liability assumed in connection therewith, including without limitation any Indebtedness permitted under clause (p) of the definition of Permitted Indebtedness) in any fiscal year for acquisitions exceeds $5,000,000, the pro forma Consolidated EBITDA of Borrower immediately after consummation of such acquisition shall be greater than (and, for the avoidance of doubt, in the case of loss, less loss than) the Consolidated EBITDA of Borrower immediately prior to giving effect to such acquisition, (i) Borrower has notified the Lenders at least ten (10) Business Days in advance of entering into such transaction, which notice shall include a reasonably detailed description of such transaction and, to the extent the total consideration (including (x) any purchase price adjustments, indemnity payments and earn-out obligations in connection therewith and (y) any liability assumed in connection therewith, including without limitation any Indebtedness permitted under clause (p) of the definition of Permitted Indebtedness) in any fiscal year for acquisitions exceeds $5,000,000, updated pro forma projections for Borrower and its Subsidiaries evidencing the conditions set forth in the immediately preceding clauses (g) and (h), (j) all transactions related to such acquisition shall be consummated in all material respects in accordance with applicable law, and (k) Borrower shall provide to the Lenders as soon as available but in any event not later than five (5) Business Days after the execution thereof, a copy of the executed purchase agreement or similar agreement with respect to any such acquisition. Notwithstanding the foregoing and for the avoidance of doubt, in no event shall Borrower or any of its Subsidiaries assume any liabilities with respect to any acquisition, including without limitation, any Permitted Indebtedness, in excess of Five Million Dollars ($5,000,000) in any fiscal year.

"**Permitted Call Spread Agreements**" means (a) any call option transaction (including, but not limited to, any bond hedge transaction or capped call transaction) pursuant to which the Borrower acquires an option requiring the counterparty thereto to deliver to the Borrower shares of common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower), the cash value thereof or a combination thereof from time to time upon exercise of such option entered into by the Borrower in connection with the issuance of Permitted Convertible Debt (such transaction, a "Bond Hedge Transaction") and (b) any issued warrants to acquire common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower) (whether such warrant is settled in shares, cash or a combination thereof) issued by the Borrower in connection with the issuance of Permitted Convertible Debt (such transaction, a "Warrant Transaction"); *provided* that (i) the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined by the board of directors of Borrower (or a committee thereof) in good faith, (ii) the purchase price for such Bond Hedge Transaction, less the proceeds received by the Borrower from the sale of any related Warrant Transaction, does not exceed the net proceeds received by the Borrower from the issuance of the related Permitted Convertible Debt and (iii) in the case of clause (b) above, such warrants would be classified as an equity instrument in accordance with GAAP.

"**Permitted Convertible Debt**" means any unsecured notes issued by the Borrower that are convertible into a fixed number (subject to customary anti-dilution adjustments, "make-whole" increases and other customary changes thereto) of shares of common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower), cash or any combination thereof (with the amount of such cash or such combination determined by reference to the market price of such common stock or such other securities); *provided* that such Indebtedness must satisfy each of the following conditions: (i) both immediately prior to and after giving effect (including pro forma effect) to the issuance thereof, no Default or Event of Default shall exist or result therefrom, (ii) such Indebtedness matures after, and does not require any scheduled amortization or other scheduled or otherwise required payments of principal prior to, or have a scheduled maturity date earlier than, the date that is 180 calendar days after the Maturity Date (it being understood that none of (x) any provision requiring an offer to purchase such Indebtedness as a result of change of control or other fundamental change, which purchase is settled on a date no earlier than the date twenty (20) Business Days following the occurrence of such change of control or other fundamental change, (y) any conversion rights of the holders of any Permitted Convertible Debt and (z) any provisions providing for acceleration upon an event of default thereunder, in each case, shall violate the foregoing restriction), (iii) any cross-default or cross-acceleration event of default (each howsoever defined) provision contained therein that relates to indebtedness or other payment obligations of Borrower (or any of its Subsidiaries) (such indebtedness or other payment obligations, a "**Cross-Default Reference Obligation**") contains a cure period of at least thirty (30) calendar days (after written notice to the issuer of such Indebtedness by the trustee or to such issuer and such trustee by holders of at least 25% in aggregate principal amount of such Indebtedness then outstanding) before a default, event of default, acceleration or other event or condition under such Cross-Default Reference Obligation results in an event of default under such cross-default or cross-acceleration provision, (iv) the terms, conditions and covenants (other than pricing terms determined through a customary marketing process) of such Indebtedness must be customary for convertible Indebtedness of such type at the time of issuance (as determined by the board of directors of the Borrower, or a committee thereof, in good faith) and, (v) such Indebtedness is not guaranteed by any Subsidiary of the Borrower unless the Obligations are guaranteed by such Subsidiary on a secured basis.

"**Permitted Distributions**" are:

(a) [Reserved];

(b) The payment of dividends by Borrower solely in non-cash pay and non-redeemable capital stock (including, for the avoidance of doubt, dividends and distributions payable solely in Equity Interests);

(c) The (i) redemption or repurchase of Equity Interests or options or other equity or phantom equity in respect of its Equity Interests by Borrower from current or former officers, employees, directors and consultants of Borrower, so long as (A) an Event of Default does not exist at the time of such redemption or repurchase and would not exist after giving effect to such redemption or repurchase and (B) the amount paid for all such redemptions and repurchases shall not exceed Five Hundred Thousand Dollars ($500,000) in the aggregate, in any fiscal year of Borrower and (ii) purchase of unvested equity awards by Borrower from terminated employees, so long as such purchase is below the then-listed price of the Borrower's Equity Interests on a national exchange;

(d) The repurchase or other acquisition of Equity Interests deemed to occur (A) upon the exercise of stock options, warrants, restricted stock units or other rights to purchase Equity Interests if such Equity Interests represent a portion of the exercise price thereof or conversion price thereof and (B) in connection with any tax withholding imposed, levied, collected, withheld or assessed by any Governmental Authority upon the grant of or any exercise or vesting of any Equity Interests (or options in respect thereof) of current or former officers, employees, directors and consultants of Borrower;

(e) Cash payments in lieu of the issuance of fractional shares in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Equity Interests;

(f) In connection with any Permitted Acquisition by Borrower or any of its Subsidiaries, (A) the receipt or acceptance of the return to Borrower or any of its Subsidiaries of Equity Interests of Borrower constituting a portion of the purchase price consideration in settlement of indemnification claims, or as a result of a purchase price adjustment (including earn-outs or similar obligations) and (B) payments or distributions to equity holders pursuant to appraisal rights required under Requirements of Law; and

(g) The distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan.

Notwithstanding the foregoing, Subsidiaries shall be permitted to, directly or indirectly, pay dividends or make distributions to any Loan Party.

"**Permitted Hedging Agreement**" means any currency agreement, all rate swap transactions or other contract or arrangement designed solely to protect a Person against fluctuations in currency exchange rates and interest rate risk, and any confirmation executed in connection with any such agreement, contract, or arrangement, in each case, entered into by Borrower or any of its Subsidiaries solely to hedge or mitigate the risks of foreign exchange rate fluctuations and interest rate risk and not for any speculative or other purposes; *provided* that such agreement, contract or arrangement shall comply in all respects with the hedging policies or guidelines as are approved by the board of directors or as are approved by Lender (such approval not to be unreasonably withheld, delayed or conditioned); *provided further*, that all accrued and reasonably expected liabilities of Borrower or its Subsidiaries arising under Permitted Hedging Agreements shall not exceed Seven Hundred Fifty Thousand Dollars ($750,000) in the aggregate. For the avoidance of doubt, no Permitted Call Spread Agreement shall constitute a Permitted Hedging Agreement.

"**Permitted Indebtedness**" is:

(a) the Loan Parties' Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate;

(c) Subordinated Debt;

(d) secured and unsecured Indebtedness in connection with credit cards incurred in the ordinary course of business in an aggregate amount not to exceed One Million Dollars ($1,000,000);

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by any Loan Party or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets or software of such person; provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed One Million Dollars ($1,000,000) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of the Loan Parties' business;

(g) Unsecured intercompany Indebtedness subject to the Intercompany Subordination Agreement that constitutes a Permitted Investment under clause (l), (m) and (o) of the term "Permitted Investments";

(h) Indebtedness (without duplication of clause (k) of the definition of Permitted Liens) in respect of letters of credit, bank guarantees and similar instruments issued for the account of the Borrower or any Subsidiary in the ordinary course of business not to exceed Seven Hundred Fifty Thousand Dollars ($750,000);

(i) advances or deposits received in the ordinary course of business from customers or vendors;

(j) Indebtedness in respect of netting services, overdraft protections, payment processing, automatic clearinghouse arrangements, arrangements in respect of pooled deposit or sweep accounts, check endorsement guarantees, and otherwise in connection with deposit accounts or cash management services and Indebtedness arising in connection with automated clearing house transfer of funds or the use of other payment processing services;

(k) Indebtedness arising in connection with the financing of insurance premiums in the ordinary course of business;

(l) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business;

(m) other unsecured Indebtedness at any time not to exceed One Million Dollars ($1,000,000) in the aggregate;

(n) Indebtedness consisting of Contingent Obligations set forth in clause (a) of the definition of "Contingent Obligation" (i) of a Loan Party of Permitted Indebtedness of another Loan Party, (ii) of a Subsidiary of Borrower which is not a Loan Party of Permitted Indebtedness of another Subsidiary of Borrower which is not a Loan Party, (iii) of a Subsidiary of Borrower which is not a Loan Party of Permitted Indebtedness of a Loan Party and (iv) of a Loan Party of Permitted Indebtedness and non-debt obligations of a Subsidiary of Borrower which is not a Loan Party in an amount not to exceed Five Hundred Thousand ($500,000) in any fiscal year;

(o) Indebtedness consisting of Contingent Obligations (i) set forth in clause (b) of the definition of "Contingent Obligation" and (ii) set forth in clause (c) of the definition of "Contingent Obligation" in connection with any Permitted Acquisition;

(p) Indebtedness of any Person that becomes a Subsidiary (or of any Person not previously a Subsidiary that is merged or consolidated with or into a Subsidiary in a transaction permitted hereunder) of Borrower after the Effective Date, or Indebtedness of any Person that is assumed after the Effective Date by any Subsidiary in connection with an acquisition of assets by such Subsidiary, in either case, in a Permitted Acquisition; *provided* that (i) such Indebtedness exists at the time such Person becomes a Subsidiary (or such merger or consolidation) or such assets are acquired and is not created in contemplation of or in connection with such Person becoming a Subsidiary (or such merger or consolidation) or such assets being acquired or such Indebtedness arises as a result of an earn-out or similar arrangement, (ii) either: (A) no Subsidiary of Borrower (other than a Subsidiary without significant assets formed in order to effect such acquisition, including by way of a merger) or Borrower shall guarantee or otherwise become liable for the payment of such Indebtedness or (B) if any other Subsidiary of Borrower becomes liable for or guarantees such Indebtedness, its liability or guarantee with respect to such Indebtedness shall at all times be subordinated to its obligations hereunder, if any, pursuant to a subordination, intercreditor or other similar agreement in form and substance reasonably satisfactory to Lender and (iii) the creation, incurrence, assumption or guarantee of, or the liability with respect to, such Indebtedness would not otherwise result in an Event of Default;

(q) Indebtedness owed to (including obligations in respect of letters of credit or bank guarantees or similar instruments for the benefit of) any Person providing workers' compensation, health, disability or other employee benefits or property, casualty or liability insurance to Borrower or any of its Subsidiaries, pursuant to reimbursement or indemnification obligations to such Person, in each case, in the ordinary course of business;

(r) obligations in respect of Consulting Royalties;

(s) Indebtedness arising in connection with endorsement of instruments for deposit in the ordinary course of business;

(t) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (s) above, *provided* that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon the applicable Loan Party, or its Subsidiary, as the case may be;

(u) Permitted Convertible Debt in aggregate principal amount not to exceed Two Hundred Million Dollars ($200,000,000) in principal amount at any time outstanding;

(v) Indebtedness of Subsidiaries subject to the Intercompany Subordination Agreement owed to Loan Parties and their Subsidiaries in connection with the sale of Inventory in the ordinary course of business, and in each case, solely to the extent constituting a Permitted Investment;

(w) purchase price adjustments, indemnity payments and earn-out obligations in connection with any Permitted Acquisition (to the extent not in excess of the consideration limitations set forth in the definition thereof); and

(x) Permitted Hedging Agreements.

"**Permitted Investments**" are:

(a) Investments disclosed on the Perfection Certificate and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any Investments permitted by the Loan Parties' investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of the Loan Parties' business;

(d) Investments consisting of Collateral Accounts in which Collateral Agent has a perfected Lien (subject to the terms of this Agreement) for the ratable benefit of the Secured Parties except as permitted in Section 6.6 hereof;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's board of directors; not to exceed Five Hundred Thousand Dollars ($500,000) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of any Loan Party in any Subsidiary;

(i) Investments in joint ventures or strategic alliances in the ordinary course of the Loan Parties' business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support; provided that any cash investments by Borrower and its Subsidiaries do not exceed Five Hundred Thousand Dollars ($500,000) in the aggregate in any fiscal year;

(j) [Reserved];

(k) Investments consisting of acquisitions from third parties of Inventory, Equipment, office supplies, software and other similar assets in the ordinary course of business;

(l) Investments consisting of Permitted Licenses;

(m) Investments (including Investments arising out of Transfers of Inventory by Borrower to Subsidiaries that are not Loan Parties pursuant to those certain affiliate distribution, subdistribution and market logistic support agreements set forth as items 3-8 on Schedule 7.9 and attached to the Perfection Certificate (or as otherwise approved by the Lender in its reasonable discretion) in the ordinary course of business (and any related intercompany balances and any capitalization of such balance)) by (i) any Loan Party in or to any other Loan Party, (ii) any Subsidiary of Borrower which is not a Loan Party in or to another Subsidiary of Borrower which is not a Loan Party in an amount not to exceed Three Million Five Hundred Thousand Dollars ($3,500,000) per fiscal year, (iii) any Subsidiary of Borrower which is not a Loan Party in or to any Loan Party and (iv) any Loan Party to any Subsidiary of a Loan Party which is not a Loan Party in an amount not to exceed Five Million Dollars ($5,000,000) per fiscal year;

(n) Permitted Acquisitions; and

(o) Investments of any Person that (i) becomes a Subsidiary of Borrower (or of any Person not previously a Subsidiary of Borrower that is merged or consolidated with or into a Subsidiary of Borrower in a transaction permitted hereunder) after the Effective Date, or (ii) are assumed after the Effective Date by any Subsidiary of Borrower in connection with an acquisition of assets from such Person by such Subsidiary, in either case, in a Permitted Acquisition; *provided* that, in each case, any such Investment (x) exists at the time such Person becomes a Subsidiary of Borrower (or is merged or consolidated with or into a Subsidiary of Borrower) or such assets are acquired, (y) was not made in contemplation of or in connection with such Person becoming a Subsidiary of Borrower (or merging or consolidating with or into a Subsidiary of Borrower) or such acquisition of assets, and (z) such Investment would not otherwise result in a Default or an Event of Default;

(p) any Permitted Acquisitions and Investments required in connection with a Permitted Acquisition (including the formation of any Subsidiary for the purpose of effectuating such Permitted Acquisition, the capitalization of such Subsidiary whether by capital contribution or intercompany loans, in each case, to the extent permitted by the terms of this Agreement, related Investments in Subsidiaries necessary to consummate such Permitted Acquisition, and the receipt of any non-cash consideration in a Permitted Acquisition);

(q) Investments arising out of the receipt of non-cash consideration for any Transfer permitted hereunder;

(r) any Permitted Call Spread Agreements;

(s) other Investments not otherwise permitted under Section 7.8 in an aggregate amount (valued at the time of the making thereof) not to exceed One Million Dollars ($1,000,000) at any time; and

(t) Investments not to exceed Five Million Dollars ($5,000,000) at any time outstanding to fund the expansion of any Loan Party or any Subsidiary in Japan, China or any other jurisdiction as may be agreed by the Collateral Agent in its sole discretion.

"**Permitted Licenses**" are (a) licenses existing on the Effective Date and disclosed on the Perfection Certificate, (b) licenses of over-the-counter software that is commercially available to the public, (c) non-exclusive licenses for the use of the Intellectual Property of any Loan Party or any of its Subsidiaries entered into in the ordinary course of business; *provided*, that, with respect to each such license described in clause (c), the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property, (d) non-exclusive intercompany licenses or other similar arrangements among the Loan Parties and their Subsidiaries, *provided* that such licenses or arrangements shall not permit any transfer of assets, (e) non-exclusive licensing of (or granting of a covenant not to sue with respect to) technology or Intellectual Property, granting of development, manufacture, distribution, co-promotion or similar commercial rights, the development of technology or the providing of technical support, (f) a non-exclusive or an exclusive grant of manufacturing and distribution licenses to contract manufacturing organizations or contract research organizations in the ordinary course of business; *provided*, that such licenses shall be terminable upon the occurrence of a change of control, (g) inbound licensing of Intellectual Property in the ordinary course of business and consistent with past practice to the extent constituting a Permitted Acquisition (including without limitation subject to the limitations with respect to Permitted Acquisitions under this Agreement), and (h) exclusive licenses for the use of the Intellectual Property of any Loan Party or any of its Subsidiaries entered into in the ordinary course of business, *provided*, that, with respect to each such license described in this clause (h), (i) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of any Loan Party or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (ii) the license is limited in territory with respect to a specific geographic country or region (i.e. Japan, Germany, northern China) outside of the United States, and (iii) the applicable Loan Party uses commercially reasonable efforts to obtain the consent and acknowledgement of the counterparty to such license for the collateral assignment of such license to the Collateral Agent for the benefit of the Lenders.

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificate or arising under this Agreement and the other Loan Documents;

(b) Liens for Taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith by appropriate proceedings diligently conducted and for which the applicable Loan Party maintains adequate reserves on such Loan Party's Books in accordance with GAAP, *provided* that no notice of any such Lien has been filed or recorded under the Internal Revenue Code and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clauses (d), (e), (h), (j), (k), (l), (o)(i), (p), (q), (s) and (t) of the definition of "Permitted Indebtedness," *provided* that in the case of Liens secured Indebtedness under clause (e), (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within ninety (90) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of any Loan Party other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, landlords, suppliers, mechanics or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Five Hundred Thousand Dollars ($500,000) and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) (i) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA) and (ii) deposits in respect of letters of credit, bank guarantees or similar instruments issued for the account of Borrower or any Subsidiary in the ordinary course of business supporting obligations of the type set forth in clause (i) above;

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of the Loan Parties' business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of the Loan Parties' business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with any Loan Party's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(a) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) Permitted Licenses;

(k) without duplication of clause (h) of the definition of Permitted Indebtedness, security deposits under real property leases that are made in the ordinary course of business not to exceed Seven Hundred Fifty Thousand Dollars ($750,000) at any time;

(l) easements, zoning restrictions, rights of way and similar encumbrances on real property imposed by law or arising in the ordinary course of business, and other minor title imperfections with respect to real property that do not secure any monetary obligations and do not materially impair the value of the affected property or interfere with the ordinary conduct of business of Borrower or any Subsidiary;

(m) Liens on earnest money deposits in connection with any Permitted Acquisition or other acquisition of properties or assets not provided hereunder;

(n) other Liens not exceeding One Hundred Thousand Dollars ($100,000) in the aggregate outstanding at any time; *provided* that such liens be limited to specific assets and not all assets or substantially all assets of any Loan Party; and

(o) Liens on cash and Cash Equivalents securing obligations under Permitted Hedging Agreements.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Pledge Agreement**" means that certain Pledge Agreement dated as of the Effective Date, between the Loan Parties and Collateral Agent, as amended, amended and restated, supplemented or otherwise modified from time to time.

"**Prepayment Premium**" is, with respect to any Term Loan subject to prepayment, refinancing, substitution or replacement prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise (including, but not limited to, upon the occurrence of a bankruptcy or insolvency event (including the acceleration of claims by operation of law)), an additional fee payable to the Lenders in amount equal to:

(a) for a prepayment, refinancing, substitution or replacement made on or after the Effective Date through and including the first anniversary of the Effective Date, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(b) for a prepayment, refinancing, substitution or replacement made after the date which is after the first anniversary of the Effective Date through and including the second anniversary of the Effective Date, one and a quarter percent (1.25%) of the principal amount of the Term Loans prepaid; and

(c) for a prepayment, refinancing, substitution or replacement made after the date which is after the second anniversary of the Effective Date and prior to the Maturity Date, one half percent (0.50%) of the principal amount of the Term Loans prepaid.

Notwithstanding the foregoing, Solar agrees to waive the Prepayment Premium if Solar or any Affiliate of Solar (in their sole and absolute discretion) agree in writing to refinance the Term Loan prior to the Maturity Date.

"**Property**" means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"**Qualified Cash**" means the amount of the Loan Parties' cash and Cash Equivalents held in accounts subject to a Control Agreement in favor of Collateral Agent; *provided* that prior to the requirement to deliver Control Agreements pursuant to Section 3.5, "Qualified Cash" shall include all of the Loan Parties' cash and Cash Equivalents, regardless of whether it is held in accounts subject to Control Agreements.

"**Qualified Cash A/P Amount**" means the amount of any Loan Party's accounts payable that have not been paid within one hundred twenty (120) days from the invoice date of the relevant account payable (other than accounts that are subject to good faith disputes as permitted herein and for which such Loan Party maintains adequate reserves in accordance with GAAP).

"**Redemption Conditions**" means, with respect to any redemption by the Borrower of any Permitted Convertible Debt, satisfaction of each of the following events: (a) no Default or Event of Default shall exist or result therefrom, and (b) both immediately before and after such redemption, Borrower's Qualified Cash shall be no less than the outstanding principal balance of the Term Loans at the time of such redemption.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Registration**" means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, abbreviated new drug applications, biologics license applications, investigational new drug applications, over-the-counter drug monograph, device pre-market approval applications, device pre-market notifications, investigational device exemptions, product recertifications, manufacturing approvals, registrations and authorizations, CE Marks, pricing and reimbursement approvals, labeling approvals or their foreign equivalent, controlled substance registrations, and wholesale distributor permits).

"**Regulatory Action**" means an administrative, regulatory, or judicial enforcement action, proceeding, investigation or inspection, FDA Form 483 notice of inspectional observation, warning letter, untitled letter, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, injunction or consent decree, issued by the FDA or a federal or state court.

"**Related Persons**" means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

"**Relevant Governmental Body**" means the Federal Reserve Board, the Federal Reserve Bank of New York, and/or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York, or any successor thereto.

"**Required Lenders**" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "**Original Lender**") have not assigned or transferred any of their interests in their Term Loan other than to an Affiliate of such Lender, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; *provided, however*, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officer**" is any of the President, Chief Executive Officer, or Chief Financial Officer of any Loan Party acting alone.

"**Secured Parties**" means the Collateral Agent and the Lenders.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**SOFR**" means the daily Secured Overnight Financing Rate provided by the Federal Reserve Bank of New York as the administrator of the benchmark (or a successor administrator) on the Federal Reserve Bank of New York's Website.

"**Solvent**" means, with respect to any Person, that (a) the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities, (b) such Person is not left with unreasonably small capital giving effect to the transactions contemplated by this Agreement and the other Loan Documents, and (c) such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

"**Subordinated Debt**" is indebtedness incurred by any Loan Party or any of its Subsidiaries subordinated to all Indebtedness of such Loan Party and/or its Subsidiaries to the Lenders (pursuant to a "deep" subordination, intercreditor, or other similar agreement (including full payment, lien and enforcement subordination) in form and substance reasonably satisfactory to Collateral Agent and the Required Lenders entered into between Collateral Agent, any Loan Party, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Required Lenders in their reasonable discretion. For the avoidance of doubt, Permitted Convertible Debt shall not constitute Subordinated Debt.

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"**Taxes**" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1.

"**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of each Loan Party and each of its Subsidiaries connected with and symbolized by such trademarks.

"**Unqualified Opinion**" means an opinion on financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion which opinion shall not include any qualifications, other than a qualification as to "going concern" (x) related to negative profits solely for the audited financial statements delivered for the fiscal year ended December 31, 2020 or (y) as a result of debt maturities within one year of applicable maturity date with respect to the opinion given for any fiscal year.

"**Vulture Fund**" means, as determined by Collateral Agent, any hedge fund or private equity fund that exclusively buys distressed securities of commercial companies or sovereign nations and then uses various methods to gain a larger amount than the purchase price of such securities.

"**Warrant Transaction**" has the meaning assigned to such term in the definition of "Permitted Call Spread Agreement".

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate principal amount of Forty Million Dollars ($40,000,000) according to each Lender's Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term Loan**", and collectively as the "**Term Loans**"). After repayment, no Term Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall (i) make monthly payments of interest, to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon the effective rate of interest applicable to the Term Loan, as determined in Section 2.3(a) plus (ii) make consecutive equal monthly payments of principal to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (A) the respective principal amounts of such Lender's Term Loans outstanding, and (B) a repayment schedule equal to the number of months remaining from the Amortization Date until the Maturity Date. All unpaid principal and accrued and unpaid interest with respect to each such Term Loan is due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated (including, but not limited to, upon the occurrence of a bankruptcy or insolvency event (including the acceleration of claims by operation of law)) or if any prepayments are to be made pursuant to Section 7.1(k), Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal (or that portion of the principal required to be prepaid pursuant to Section 7.1(k), as applicable) of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) any fees payable under the Fee Letter by reason of such prepayment, (iii) the Prepayment Premium, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if any fees payable under the Fee Letter by reason of such prepayments had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to each Lender in accordance with the terms of the Fee Letter. The Prepayment Premium shall also be payable in the event the Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other means. EACH LOAN PARTY EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE FOREGOING PREPAYMENT PREMIUM IN CONNECTION WITH ANY SUCH ACCELERATION.

(d) Permitted Prepayment of Term Loans. Borrower shall have the option to prepay all, or any portion in minimum increments of Ten Million Dollars ($10,000,000) (or such lesser amount solely to the extent such lesser amount constitutes the entire outstanding principal amount of the Term Loans), of the outstanding principal balance of the Term Loans advanced by the Lenders under this Agreement, *provided* Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least five (5) Business Days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the outstanding principal of the Term Loans, or portion(s) thereof being prepaid, plus accrued and unpaid interest thereon through the prepayment date, (B) any fees payable under the Fee Letter by reason of such prepayment, (C) the Prepayment Premium, plus (D) all other Obligations that are due and payable on such prepayment date, including any Lenders' Expenses and interest at the Default Rate (if any) with respect to any past due amounts. Prepayments of the Term Loan shall be applied to the Term Loan in inverse order of maturity.

2.3 Payment of Interest on the Term Loans.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the LIBOR Rate in effect from time to time *plus* 9.40%, which aggregate interest rate shall be determined by Collateral Agent on the third Business Day prior to the Funding Date of the applicable Term Loan and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Except as set forth in Section 2.2(b), such interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full (or any payment is made hereunder).

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, all Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year for the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower, including the Designated Deposit Account, for principal and interest payments or any other amounts any Loan Party owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by any Loan Party under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Person's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by any Loan Party hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds. Collateral Agent may at its discretion and with prior notice of at least one (1) Business Day, initiate debit entries to such Loan Party's account as authorized on the ACH Letter (i) on each payment date of all Obligations then due and owing, (ii) at any time any payment due and owing with respect to Lender Expenses, and (iii) upon an Event of Default, any other Obligations outstanding.

2.4 Fees. The Loan Parties shall pay to Collateral Agent and/or Lenders (as applicable) the following fees, which shall be deemed fully earned and non-refundable upon payment:

(a) Fee Letter. When due and payable under the terms of the Fee Letter, to Collateral Agent and each Lender, as applicable, the fees set forth in the Fee Letter.

(b) Prepayment Premium. The Prepayment Premium, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares. Each Loan Party expressly agrees (to the fullest extent that each may lawfully do so) that: (i) the Prepayment Premium is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (ii) the Prepayment Premium shall be payable notwithstanding the then prevailing market rates at the time payment is made; (iii) there has been a course of conduct between Collateral Agent, Lenders and each Loan Party giving specific consideration in this transaction for such agreement to pay the Prepayment Premium and (iv) each Loan Party shall be estopped hereafter from claiming differently than as agreed to in this paragraph. Each Loan Party expressly acknowledges that its agreement to pay the Prepayment Premium to Lenders as herein described is a material inducement to Lenders to provide the Term Loan Commitments and make the Term Loans.

(c) Lenders' Expenses. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

2.5 Taxes; Increased Costs. Each Loan Party, Collateral Agent and the Lenders each hereby agree to the terms and conditions set forth on Exhibit C attached hereto.

2.6 Original Issue Discount Legend. For purposes of Sections 1272, 1273 and 1275 of the Internal Revenue Code, the Term Loans are being issued with original issue discount; please contact the Chief Financial Officer of SI-BONE, Inc., 471 El Camino Real, Suite 1010, Santa Clara, CA 95050, telephone: +1 (669) 206-2462 to obtain information regarding the issue price, the amount of original issue discount and the yield to maturity.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Term Loan. Subject to Section 3.5, each Lender's obligation to make a Term Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by each Loan Party;

(b) a completed Perfection Certificate for each Loan Party;

(c) [reserved];

(d) a duly executed Fee Letter;

(e) the Operating Documents and good standing certificates of each Loan Party certified by the Secretary of State (or equivalent agency) of each Loan Party's jurisdiction of organization or formation, each as of a date no earlier than thirty (30) days prior to the Effective Date**;**

(f) a certificate of each Loan Party in substantially the form of Exhibit F hereto executed by the Secretary of each Loan Party with appropriate insertions and attachments, including with respect to (i) the Operating Documents of each Loan Party (which Certificate of Incorporation or its equivalent document, as applicable, of each Loan Party shall be certified by the Secretary of State of the State, or its equivalent authority, as applicable, of such entity's jurisdiction of formation) and (ii) the resolutions adopted by each Loan Party's board of directors (or similar governing body) for the purpose of approving the transactions contemplated by the Loan Documents;

(g) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan, will be terminated or released;

(h) a duly executed legal opinion of counsel to the Loan Parties dated as of the Effective Date;

(i) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Secured Parties;

(j) a payoff letter in form and substance satisfactory to Collateral Agent and the Lenders evidencing the repayment in full and release of liens with respect to the Loan Parties' existing Indebtedness; and

(k) payment of the fees payable under the terms of the Fee Letter and Lenders' Expenses then due as specified in Section 2.4 hereof.

3.2 Conditions Precedent to all Term Loans. The obligation of each Lender to extend each Term Loan, including the initial Term Loan, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Loan Payment Request Form in the form of Exhibit D attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the Funding Date of each Term Loan; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and *provided further*, that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the funding of such Term Loan;

(c) in such Lender's reasonable discretion, there has not been any Material Adverse Change;

(d) No Event of Default or an event that with the passage of time could result in an Event of Default, shall exist; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.4 hereof.

3.3 Covenant to Deliver. Each Loan Party agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Term Loan. Each Loan Party expressly agrees that a Term Loan made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of any Loan Party's obligation to deliver such item, and any such Term Loan in the absence of a required item shall be made in each Lender's sole discretion

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain the Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon New York City time three (3) Business Days prior to the date the Term Loan is to be made (or such earlier date as the Lenders may agree in their sole discretion). Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to Collateral Agent by electronic mail or facsimile a completed Loan Payment Request Form executed by a Responsible Officer or his or her designee. The Collateral Agent may rely on any telephone notice given by a person whom Collateral Agent reasonably believes is a Responsible Officer or designee.

3.5 Post-Closing Obligations. Notwithstanding any provision herein or in any other Loan Document to the contrary, to the extent not actually delivered on or prior to the Effective Date, each Loan Party shall, no later than three (3) Business Days (or such later date as the Collateral Agent may agree in its sole discretion) after the Effective Date, deliver duly executed Control Agreements with respect to any Collateral Accounts (other than Excluded Accounts) maintained by such Loan Party.

4. CREATION OF SECURITY INTEREST

4. Grant of Security Interest. Each Loan Party hereby grants Collateral Agent, for the ratable benefit of the Secured Parties, to secure the payment and performance in full of all of the Obligations, a continuing first priority security interest in, and pledges to Collateral Agent, for the ratable benefit of the Secured Parties, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products and supporting obligations (as defined in the Code) in respect thereof. If any Loan Party shall acquire any commercial tort claim (as defined in the Code), such Loan Party shall grant to Collateral Agent, for the ratable benefit of the Secured Parties, a first priority security interest therein and in the proceeds and products and supporting obligations (as defined in the Code) thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to extend Term Loans has terminated, Collateral Agent shall, at the sole cost and expense of the Loan Parties, release its Liens in the Collateral and all rights therein shall revert to the Loan Parties.

d2 Authorization to File Financing Statements

. Each Loan Party hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral (held for the ratable benefit of the Secured Parties), without notice to such Loan Party, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents.

5. REPRESENTATIONS AND WARRANTIES

Each Loan Party represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Each Loan Party and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and such Loan Party and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be so qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, each Loan Party and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate on or prior to the Effective Date (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Each Loan Party represents and warrants that all the information set forth on the Perfection Certificates pertaining to such Loan Party and each of its Subsidiaries is accurate and complete.

The execution, delivery and performance by each Loan Party and each of its Subsidiaries of the Loan Documents to which it is, or they are, a party have been duly authorized, and do not (i) conflict with any of such Loan Party's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which such Loan Party or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which such Loan Party, any of its Subsidiaries or any of their respective properties, is bound. Neither any Loan Party nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Each Loan Party and each its Subsidiaries have good title to, has rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and none of the Loan Parties or any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith in respect of which such Loan Party or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein to the extent required under this Agreement. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to involuntary Permitted Liens that, under applicable law, have priority over Collateral Agent's Lien.

(c) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee, and (ii) no such third party bailee possesses components of the Collateral in excess of One Million Dollars ($1,000,000).

(d) All Inventory and Equipment is in all material respects of good and marketable quality, free from material defects.

(e) Each Loan Party and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens and over the counter software that is commercially available to the public. Except as noted on the Perfection Certificate (which, upon the consummation of a transaction not prohibited by this Agreement, may be updated to reflect such transaction), none of the Loan Parties or any of its Subsidiaries is a party to, nor is bound by, any material license or other Material Agreement.

(f) None of the Loan Parties or any Subsidiary has used any software or other materials that are subject to an open-source or similar license (including the General Public License, Lesser General Public License, Mozilla Public License, or Affero License) (collectively, "**Open Source Licenses**") in a manner that would cause any software or other materials owned by any Loan Party or used in any Loan Party products to have to be (i) distributed to third parties at no charge or a minimal charge, (ii) licensed to third parties for the purpose of creating modifications or derivative works, or (iii) subject to the terms of such Open Source License.

5.3 Litigation. Except as disclosed on the Perfection Certificate or with respect to which Borrower has provided notice as required hereunder, there are no actions, suits, investigations, or proceedings pending or, to the Knowledge of the Responsible Officers, threatened in writing by or against any Loan Party or any of its Subsidiaries involving more than One Million Dollars ($1,000,000).

5.4 No Material Adverse Change; Financial Statements. All consolidated financial statements for the Loan Parties and its consolidated Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, and in all material respects the consolidated financial condition of the Loan Parties and its consolidated Subsidiaries, and the consolidated results of operations of the Loan Parties and its consolidated Subsidiaries. Since December 31, 2019, there has not been a Material Adverse Change; *provided*, *however*, that current financial and market conditions engendered by the COVID-19 pandemic solely as of and up to and including the Effective Date (but not after such date) shall not be given effect in determining whether a Material Adverse Change has occurred with respect to Borrower and its Subsidiaries.

5.5 Solvency. Each Loan Party is Solvent. Each Loan Party and each of its Subsidiaries, when taken as a whole, is Solvent.

5.6 Regulatory Compliance. No Loan Party or any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. None of the Loan Parties or any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Each Loan Party and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. None of the Loan Parties or any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. None of the Loan Parties or any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. None of the Loan Parties' or any of its Subsidiaries' properties or assets has been used by such Loan Party or such Subsidiary or, to such Loan Party's Knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Each Loan Party and each of its Subsidiaries has obtained all material consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of the Loan Parties, any of its Subsidiaries, or any Loan Party's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of the Loan Parties, any of its Subsidiaries, or to the Knowledge of such Loan Party and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. None of the Loan Parties or any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Each Loan Party and each of its Subsidiaries have filed all required income and other material tax returns and reports (or extensions thereof), and each Loan Party and each of its Subsidiaries have timely paid all material foreign, federal, state, and local Taxes, assessments, deposits and contributions owed by such Loan Party and such Subsidiaries in all jurisdictions in which any such Loan Party or any such Subsidiary is subject to Taxes, including the United States, unless such Taxes are being contested in accordance with the next sentence. Each Loan Party and each of its Subsidiaries may defer payment of any contested Taxes, *provided* that such Loan Party or such Subsidiary, (a) in good faith contests its obligation to pay the Taxes by appropriate proceedings promptly and diligently instituted and conducted; and (b) maintains adequate reserves or other appropriate provisions on its books in accordance with GAAP. There are no Liens for any Taxes (other than Permitted Liens) upon any of the Collateral. Each of the Loan Parties and its Subsidiaries has paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and none of the Loan Parties or any of its Subsidiaries has withdrawn from participation in, has permitted partial or complete termination of, or has permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of such Loan Party or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. The Loan Parties shall use the proceeds of the Term Loans to repay all outstanding obligations under Borrower's existing debt facility with BioPharma Credit Investments IV Sub LP, as working capital and to fund its general business requirements, and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of any Loan Party or any of its Subsidiaries in any certificate or written statement, when taken as a whole, given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that projections and forecasts provided by the Loan Parties in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

6. AFFIRMATIVE COVENANTS

Each Loan Party shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Other than specifically permitted hereunder, maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which any Loan Party or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by any Loan Party and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Secured Parties, in all of the Collateral.

6.2 Financial Statements, Reports, Certificates; Notices.

(a) Deliver to Collateral Agent:

(i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and, if prepared by any Loan Party or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of the Loan Parties and its consolidated Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to the Collateral Agent;

(ii) as soon as available, but no later than forty-five (45) days after the last day of each of Borrower's first three fiscal quarters, a company prepared consolidated and, if prepared by the Loan Parties or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of the Loan Parties and its consolidated Subsidiaries for such fiscal quarter certified by a Responsible Officer and in a form reasonably acceptable to the Collateral Agent;

(iii) as soon as available, but no later than ninety (90) days after the last day of Borrower's fiscal year or within five (5) days of filing of the same with the SEC, audited consolidated financial statements covering the consolidated operations of the Loan Parties and its consolidated Subsidiaries for such fiscal year, prepared under GAAP, consistently applied, together with an Unqualified Opinion on the financial statements;

(iv) as soon as available after approval thereof by each Loan Party's board of directors (or similar governing body), but no later than the earlier of (x) ten (10) days' after such approval and (y) February 28 of such year, Borrower's annual financial projections for the entire current fiscal year as approved by each Loan Party's board of directors (or similar governing body); *provided* that, any revisions to such projections approved by any Loan Party's board of directors (or similar governing body) shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval;

(v) within five (5) days of delivery, copies of all non-ministerial statements, reports and notices made available to any Loan Party's security holders or holders of Subordinated Debt (other than materials provided to members of any Loan Party's board of directors (or similar governing body) solely in their capacities as security holder or holders of Subordinated Debt), *provided*, *however*, the foregoing may be subject to such exclusions and redactions as Borrower deems reasonably necessary, in the exercise of its good faith judgment, in order to (i) preserve the confidentiality of highly sensitive information, (ii) prevent impairment of the attorney-client privilege or (iii) conflict of interest with Lenders for new financings;

(vi) within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission;

(vii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by each Loan Party or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by each Loan Party or directly from the applicable institution(s);

(viii) prompt delivery of (and in any event within five (5) days after the same are sent or received) copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to any Loan Party's business or that otherwise could reasonably be expected to have a Material Adverse Change;

(ix) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the value of the Intellectual Property or (B) could reasonably be expected to result in a Material Adverse Change;

(x) written notice delivered at least (10) days' prior to any Loan Party's creation of a New Subsidiary in accordance with the terms of Section 6.10;

(xi) written notice delivered at least (30) days' prior to any Loan Party's (A) adding any new offices or business locations, including warehouses (unless such new offices or business locations contain less than One Million Dollars ($1,000,000) in assets or property of any Loan Party or any of its Subsidiaries), (B) changing its respective jurisdiction of organization, (C) changing its organizational structure or type, (D) changing its respective legal name, or (E) changing any organizational number(s) (if any) assigned by its respective jurisdiction of organization;

(xii) upon any Loan Party becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, and such Loan Party's proposal regarding how to cure such Event of Default or event;

(xiii) immediate notice if any Loan Party or its Subsidiary has Knowledge that any Loan Party, or any Subsidiary or Affiliate of any Loan Party, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering;

(xiv) notice of any commercial tort claim (as defined in the Code) or letter of credit rights (as defined in the Code) held by any Loan Party or any Guarantor, in each case in an amount greater than Two Hundred Fifty Thousand Dollars ($250,000) and of the general details thereof;

(xv) prompt notice of the execution any Material Agreement or any amendment to, modification of, termination of or waiver under any Material Agreement; and

(xvi) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, the financial statements required to be delivered pursuant to clauses (ii) and (iii) above may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender:

(i) a duly completed Compliance Certificate signed by a Responsible Officer;

(ii) with respect the delivery of financial statements pursuant to Section 6.2(a)(ii) and within ninety (90) days after the last day of each of Borrower's last fiscal quarter of each year, an updated Perfection Certificate to reflect any amendments, modifications and updates, if any, to certain information in the Perfection Certificate after the Effective Date to the extent such amendments, modifications and updates are permitted by one or more specific provisions in this agreement;

(iii) copies of any material Governmental Approvals obtained by any Loan Party or any of its Subsidiaries not otherwise filed with the Securities and Exchange Commission;

(iv) written notice of the commencement of, and any material development in, the proceedings contemplated by Section 5.8 hereof;

(v) prompt written notice of any litigation or governmental proceedings pending or threatened (in writing) against any Loan Party or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to such Loan Party or any of its Subsidiaries of One Million Dollars ($1,000,000), in the aggregate; and

(vi) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Five Hundred Thousand Dollars ($500,000), individually, or One Million Dollars ($1,000,000), in the aggregate, in any calendar year.

(c) Keep proper, complete and true books of record and account in accordance with GAAP in all material respects. Each Loan Party shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of such Loan Party, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (*provided* that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between any Loan Party, or any of its Subsidiaries, as applicable, and their respective Account Debtors shall follow such Loan Party's, or such Subsidiary's, customary practices as they exist as of the Effective Date.

6.4 Taxes; Pensions. Timely file, and require each of its Subsidiaries to timely file, all required tax returns and reports, and timely pay, and require each of its Subsidiaries to pay, all foreign, federal, state, and local income and other material Taxes owed by any Loan Party or its Subsidiaries, except (a) to the extent that the failure to do so could not reasonably expected to have a material adverse effect or (b) as otherwise permitted pursuant to the terms of Section 5.8 hereof; deliver to each Lender, on demand, appropriate certificates attesting to such payments; and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep each Loan Party's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in each Loan Party's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and shall waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent (for the ratable benefit of the Secured Parties), as additional insured. Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Collateral Agent, that it will give Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, the Loan Parties shall deliver to Collateral Agent certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Secured Parties, on account of the then-outstanding Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy within one hundred eighty (180) days of receipt thereof up to Five Hundred Thousand Dollars ($500,000) with respect to any loss, but not exceeding One Million Dollars ($1,000,000), in the aggregate for all losses under all casualty policies in any one year, toward the replacement promptly or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If any Loan Party or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make (but has no obligation to do so), at such Loan Party's expense, all or part of such

payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

Operating Accounts.

(a) Maintain each Loan Party's and Guarantors' Collateral Accounts with depositary institutions that have agreed to execute Control Agreements in favor of Collateral Agent with respect to such Collateral Accounts. The provisions of the previous sentence shall not apply to Excluded Accounts.

(b) Each Loan Party shall provide Collateral Agent ten (10) days' prior written notice before such Loan Party establishes any Collateral Account. In addition, for each Collateral Account that any Loan Party at any time maintains, such Loan Party shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account (held for the ratable benefit of the Secured Parties) in accordance with the terms hereunder prior to the establishment of such Collateral Account. The provisions of the previous sentence shall not apply to Excluded Accounts.

(c) None of the Loan Parties nor any Guarantor shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with this Section 6.6.

6.7 Protection of Intellectual Property Rights. Each Loan Party and its Subsidiaries shall: (a) protect, defend and maintain the validity and enforceability of its respective Intellectual Property that is material to its business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its respective Intellectual Property; and (c) not allow any of its respective Intellectual Property material to its respective business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, each Loan Party and such Loan Party's officers, employees and agents and each Loan Party's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to such Loan Party.

6.9 Landlord Waivers; Bailee Waivers. In the event that any Loan Party or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then, in the event that the Collateral at any new location is valued (based on book value) in excess of One Million Dollars ($1,000,000) in the aggregate, at Collateral Agent's election, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.10 Creation/Acquisition of Subsidiaries. In the event any Loan Party or any Subsidiary of any Loan Party creates or acquires any Subsidiary after the Effective Date (other than any Excluded Subsidiary), such Loan Party or such Subsidiary shall promptly notify Collateral Agent and the Lenders of such creation or acquisition, and such Loan Party or such Subsidiary shall take all actions reasonably requested by Collateral Agent or the Lenders to achieve any of the following with respect to such "**New Subsidiary**" (defined as a Subsidiary formed or acquired after the date hereof during the term of this Agreement): (i) to cause such New Subsidiary, if such New Subsidiary is not an Excluded Foreign Subsidiary, to become either a co-Borrower hereunder, or a secured Guarantor with respect to the Obligations; and (ii) to grant and pledge to Collateral Agent a perfected security interest in (x) one hundred percent (100%) of the stock, units or other evidence of ownership held by any Loan Party or its Subsidiaries of any such New Subsidiary which is not an Excluded Foreign Subsidiary, and (y) 65% of the Equity Interests, membership units, or other securities of any New Subsidiary that is a First-Tier Foreign Subsidiary which shares entitle the holder thereof to vote for directors or any other matter and one hundred percent (100%) of the issued and outstanding non-voting Equity Interests of such First-Tier Foreign Subsidiary.

6. Further Assurances. Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

7. NEGATIVE COVENANTS

No Loan Party shall, and no Loan Party shall permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, dispose of, license (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) cash or Cash Equivalents in the ordinary course of business and pursuant to transactions not prohibited by this Agreement; (e) Transfers to Borrower or any of its Subsidiaries that are co-Borrowers or Guarantors from Borrower or any of its Subsidiaries that are co-Borrowers or Guarantors; (f) the sale or discount without recourse of accounts receivable arising in the ordinary course of business in connection with the compromise or collection thereof; (g) any abandonment, cancellation, non-renewal or discontinuance of use or maintenance of immaterial Intellectual Property (or rights relating thereto) of Borrower and its Subsidiaries that Borrower reasonably determines in good faith is no longer economically practicable to maintain or useful in the ordinary course of business and that is not adverse to the rights, remedies and benefits available to, or conferred upon, Lender under any Loan Document in any material respect or otherwise does not materially diminish the value of the Collateral securing the Obligations; (h) the granting of Consulting Royalties; (i) the sale or issuance of Equity Interests of any Subsidiary of Borrower to any Loan Party or to any other Subsidiary of Borrower permitted in Section 7.2; (j) other Transfers not involving any material Intellectual Property (or rights relating thereto) and not otherwise permitted under this Section 7.1 in an aggregate amount not to exceed Five Hundred Thousand Dollars ($500,000) in any fiscal year; and (k) other Transfers in which such Loan Party will receive cash proceeds in an amount equal to no less than seventy-five percent (75%) of all Transfer consideration (fixed or contingent) paid or payable to such Loan Party or Subsidiary, but only so long as, unless otherwise waived by Collateral Agent in its sole discretion, the net cash proceeds of such Transfer are utilized to repay or prepay, in whole or in part, Indebtedness to Lender under and in accordance with this Agreement and the other Loan Documents.

For the avoidance of doubt, none of (a) the sale of any Permitted Convertible Indebtedness, (b) the sale of any Warrant Transaction, (c) the purchase of any Bond Hedge Transaction or (d) the performance by Borrower of its obligations under any Permitted Convertible Indebtedness, any Warrant Transaction or any Bond Hedge Transaction (including the settlement or termination of any Bond Hedge Transaction or Warrant Transaction) shall constitute a Transfer.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by such Loan Party or such Subsidiary, as applicable, as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) permit any Key Person to cease being actively engaged in the management of each Loan Party unless written notice thereof is provided to each Lender within ten (10) days of such cessation, or (ii) enter into any transaction or series of related transactions in which (A) the stockholders of any Loan Party who were not stockholders immediately prior to the first such transaction own more than forty percent (40%) of the voting stock of such Loan Party immediately after giving effect to such transaction or related series of such transactions and (B) except as permitted by Section 7.3, any Loan Party ceases to own, directly or indirectly, 100% of the ownership interests in each Subsidiary of such Loan Party. No Loan Party shall, and no Loan Party shall permit any of its Subsidiaries to, without at least thirty (30) days' prior written notice to Collateral Agent: (A) change its respective jurisdiction of organization, (B) except as permitted by Section 7.3, change its respective organizational structure or type, (C) change its respective legal name, or (D) change any organizational number(s) (if any) assigned by its respective jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or shares or any property of another Person, in each case including for the avoidance of doubt through a merger, purchase, in-licensing arrangement or any similar transaction. Notwithstanding the foregoing, (a) a Subsidiary may merge or consolidate into another Subsidiary (provided that such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder in accordance with Section 6.10) or with (or into) any Loan Party provided such Loan Party is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom, (b) a Subsidiary that is not a Loan Party may merge or consolidate with another Subsidiary that is not a Loan Party so long as such merger or consolidation results in no material and adverse impact on the Collateral and (c) any Subsidiary may be dissolved or liquidated; *provided* that any and all of the properties and assets of such Subsidiary are distributed to one or more Loan Parties.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Secured Parties) with any Person which directly or indirectly prohibits or has the effect of prohibiting any Loan Party, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of such Loan Party's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" (including Permitted Licenses).

7.6 Maintenance of Collateral Accounts. With respect to any Loan Party, maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Restricted Payments. (a) Declare or pay any dividends (other than dividends payable solely in capital stock) or make any other distribution or payment in respect of or redeem, retire or purchase any capital stock other than Permitted Distributions, and (b) be a party to or bound by an agreement that restricts a Subsidiary from paying dividends or otherwise distributing property to any Loan Party.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit (i) the conversion by holders of (including any cash payment upon conversion), or required payment of any principal or premium on, or required payment of any interest with respect to, any Permitted Convertible Debt, in each case, in accordance with the terms of the indenture governing such Permitted Convertible Debt; *provided* that the preceding sentence shall only allow principal payments with respect to any repurchase in connection with the redemption of Permitted Convertible Debt upon satisfaction of a condition related to the stock price of the Borrower's common stock if the Redemption Conditions are satisfied in respect of such redemption; *provided further* that, to the extent both (a) the aggregate amount of cash payable upon conversion or redemption of any Permitted Convertible Debt (excluding any required payment of interest with respect to such Permitted Convertible Debt and excluding any payment of cash in lieu of a fractional share due upon conversion thereof) exceeds the aggregate principal amount thereof and (b) such conversion or redemption does not trigger or correspond to an exercise or early unwind or settlement of a corresponding portion of the Bond Hedge Transactions constituting Permitted Call Spread Agreements relating to such Permitted Convertible Debt (including, for the avoidance of doubt, the case where there is no Bond Hedge Transaction constituting a Permitted Call Spread Agreement relating to such Permitted Convertible Debt), the payment of such excess cash (any such payment, a "**Cash Excess Payment**") shall not be permitted by this clause (i); and (ii) any required payment with respect to (including, for the avoidance of doubt, the payment of the relevant premium for the purchase thereof), or required early unwind or settlement of, any Permitted Call Spread Agreement, in each case, in accordance with the terms of the agreement governing such Permitted Call Spread Agreement; *provided* that, to the extent cash is required to be paid under a Warrant Transaction as a result of the election of "cash settlement" (or substantially equivalent term) as the "settlement method" (or substantially equivalent term) thereunder by the Borrower (or its Affiliate) (including in connection with the exercise and/or early unwind or settlement thereof), the payment of such cash shall not be permitted by this clause (ii).

Notwithstanding the foregoing, the Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Debt by delivery of shares of the Borrower's common stock and/or a different series of Permitted Convertible Debt (which series matures after, and does not require any scheduled amortization or other scheduled payments of principal prior to, the analogous date under the indenture governing the Permitted Convertible Debt that are so repurchased, exchanged or converted) (any such series of Permitted Convertible Debt, "**Refinancing Convertible Debt**") and/or by payment of cash (x) in lieu of any fractional shares, (y) in respect of accrued and unpaid interest of such Permitted Convertible Debt and (z) additional cash in an amount that does not exceed the proceeds received by the Borrower from the substantially concurrent issuance of shares of the Borrower's common stock and/or a Refinancing Convertible Debt plus the net cash proceeds, if any, received by the Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Call Spread Agreements pursuant to the immediately following proviso; *provided* that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Debt that is so repurchased, exchanged or converted, the Borrower shall (and, for the avoidance of doubt, shall be permitted under this Section 7.7 to) exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Call Spread Agreements, if any, corresponding to such Permitted Convertible Debt that is so repurchased, exchanged or converted.

7.8 Investments. Directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so other than Permitted Investments.

7.9 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of any Loan Party or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of such Loan Party's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to such Loan Party or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by such Loan Party's investors in such Loan Party or its Subsidiaries, (c) intercompany transactions expressly permitted by Sections 7.1, 7.3, 7.4, 7.7 or 7.8, (d) normal and reasonable compensation and reimbursement of expenses of officers and directors in the ordinary course of business approved by such Loan Party's or such Subsidiary's board of directors, (e) employment arrangements with executive officers approved by Borrower's Board of Directors and entered into in the ordinary course of business, (f) equity financings of the Parent that are permitted by the terms of this Agreement and (g) transactions set forth on Schedule 7.9.

7.10 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.11 Compliance. (a) Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Term Loan for that purpose; (b) fail to meet the minimum funding requirements of ERISA; (c) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; (d) fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; or (e) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of any Loan Party or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.12 Compliance with Anti-Terrorism Laws. Directly or indirectly, knowingly permit any Affiliate to enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Directly or indirectly, knowingly permit any Affiliate to, (a) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (b) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (c) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

7.13 Financial Covenant.

(a) Minimum Liquidity. Permit, at any time, Qualified Cash to be less than the sum of the Qualified Cash A/P Amount plus the following amount:

(i) at all times Net Product Revenue, determined as of the most recent Measurement Date and measured on a trailing twelve-month basis, is less than Seventy-Five Million Dollars ($75,000,000), Fifteen Million Dollars ($15,000,000);

(ii) at all times Net Product Revenue, determined as of the most recent Measurement Date and measured on a trailing twelve-month basis, is greater than or equal to Seventy-Five Million Dollars ($75,000,000) and less than One Hundred Million Dollars ($100,000,000), Seven Million Five Hundred Thousand Dollars ($7,500,000); or

(iii) if Net Product Revenue, determined as of the most recent Measurement Date and measured monthly on a trailing twelve-month basis, is greater than One Hundred Million Dollars ($100,000,000), Zero Dollars ($0).

7.14 Material Agreements. Without the consent of Collateral Agent, amend a Material Agreement in a manner adverse to Collateral Agent and the Lenders.

7.15 Redemption of Permitted Convertible Debt. Exercise any redemption right with respect to any Permitted Convertible Debt upon satisfaction of a condition related to the stock price of the Borrower's common stock, unless the Redemption Conditions are satisfied in respect of such redemption.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Any Loan Party fails to (a) make any payment of principal or interest on any Term Loan on its due date, or (b) pay any other Obligation within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof);

8.2 Covenant Default.

(a) Any Loan Party or any of its Subsidiaries fails or neglects to perform any obligation in Sections 3.5 (Post-Closing Obligations), 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers), 6.10 (Creation/Acquisition of Subsidiaries) or any Loan Party violates any provision in Section 7; or

Any Loan Party, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document to which such person is a party, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within twenty (20) days after the occurrence thereof; *provided*, *however*, that if the default cannot by its nature be cured within the twenty (20) day period or cannot after diligent attempts by such Loan Party or such Subsidiary, as applicable, be cured within such twenty (20) day period, and such default is likely to be cured within a reasonable time, then such Loan Party shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Term Loans shall be made during such cure period);

8.3 Material Adverse Change. A Material Adverse Change has occurred;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Loan Party or any of its Subsidiaries or of any entity under control of any Loan Party or its Subsidiaries on deposit with any institution at which any Loan Party or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against any Loan Party or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) of this clause (a) are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of any Loan Party's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents any Loan Party or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) any Loan Party or any of its Subsidiaries is or becomes Insolvent; (b) any Loan Party or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against any Loan Party or any of its Subsidiaries and not dismissed or stayed within sixty (60) days (but no Term Loans shall be extended while any Loan Party or any of its Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is any default and such default continues (after the applicable grace, cure or notice period) in any debt agreement to which any Loan Party or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of One Million Dollars ($1,000,000); for the avoidance of doubt, (x), the exchange, repurchase, conversion or settlement with respect to any Permitted Convertible Debt, or satisfaction of any condition giving rise to or permitting the foregoing, pursuant to their terms that does not result from a default thereunder or an event of the type that constitutes an Event of Default or (y) any early payment requirement or unwinding or termination with respect to any Permitted Call Spread Agreement, or satisfaction of any condition giving rise to or permitting the foregoing, in accordance with the terms thereof where neither the Borrower nor any of its Affiliates is the "defaulting party" (or substantially equivalent term) under the terms of such Permitted Call Spread Agreement, in each case, shall not constitute an Event of Default under this Section 8.6;

8.7 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars ($500,000) (not covered by independent third-party insurance as to which (a) any Loan Party reasonably believes such insurance carrier will accept liability, (b) any Loan Party or the applicable Subsidiary has submitted such claim to such insurance carrier and (c) liability has not been rejected by such insurance carrier) shall be rendered against any Loan Party or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of twenty (20) days after the entry thereof;

8.8 Misrepresentations. Any Loan Party or any of its Subsidiaries or any Person acting for any Loan Party or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or the Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made;

8.9 Subordinated Debt. A default or breach occurs under any subordination agreement, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect other than as a result of a transaction permitted under this Agreement; (b) any Guarantor does not perform any obligation or covenant under any Guaranty, after any applicable grace or cure period; or (c) any circumstance described in Section 8 occurs with respect to any Guarantor, beyond any applicable grace or cure period;

8.11 Governmental Approvals; FDA Action. (a) Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or (b) (i) the FDA, DOJ or other Governmental Authority initiates a Regulatory Action or any other enforcement action against any Loan Party or any of its Subsidiaries or any supplier of any Loan Party or any of its Subsidiaries that causes any Loan Party or any of its Subsidiaries to recall, withdraw, remove or discontinue manufacturing, distributing, and/or marketing any of its products, even if such action is based on previously disclosed conduct that, as to any single or related series of transactions, incidents or conditions, could reasonably be expected to result in a Material Adverse Change; (ii) the FDA or any other comparable Governmental Authority issues a warning letter to any Loan Party or any of its Subsidiaries with respect to any of its activities or products which could reasonably be expected to result in a Material Adverse Change; (iii) any Loan Party or any of its Subsidiaries conducts a mandatory or voluntary recall which could reasonably be expected to result in liability and expense to any Loan Party or any of its Subsidiaries of One Million Dollars ($1,000,000) or more; (iv) any Loan Party or any of its Subsidiaries enters into a settlement agreement with the FDA, DOJ or other Governmental Authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions, of One Million Dollars ($1,000,000) or more, or that could reasonably be expected to result in a Material Adverse Change, even if such settlement agreement is based on previously disclosed conduct; or (v) the FDA or any other comparable Governmental Authority revokes any authorization or permission granted under any Registration, or any Loan Party or any of its Subsidiaries withdraws any Registration, that could reasonably be expected to result in a Material Adverse Change; and

8. Lien Priority. Except as the result of the action or inaction of Collateral Agent or the Lenders, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens, subject to the terms of the Loan Documents.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to any Loan Party, (ii) by notice to any Loan Party declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to any Loan Party suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for any Loan Party's benefit under this Agreement or under any other agreement between any Loan Party and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for any Loan Party's benefit under this Agreement or under any other agreement between any Loan Party and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right and at the written direction of the Required Lenders shall, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) make a demand for payment upon any Guarantor pursuant to the Guaranty delivered by such Guarantor;

(iii) apply to the Obligations any (A) balances and deposits of the Loan Parties that Collateral Agent or any Lender holds or controls, (B) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of any Loan Party, or (C) amounts received from any Guarantor in accordance with the respective Guaranty delivered by such Guarantor; and/or

(iv) commence and prosecute an Insolvency Proceeding or consent to any Loan Party commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing any Loan Party money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its Liens in the Collateral (held for the ratable benefit of the Secured Parties). The Loan Parties shall assemble the Collateral if Collateral Agent requests and make it available at such location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Each Loan Party grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, any of the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, each Loan Party's labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, each Loan Party's rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any Collateral Account maintained with Collateral Agent or any Lender or otherwise in respect of which a Control Agreement has been delivered in favor of Collateral Agent (for the ratable benefit of the Secured Parties) and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of any Loan Party's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of any Loan Party; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance.

9.2 Power of Attorney. Each Loan Party hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse any Loan Party's name on any checks or other forms of payment or security; (b) sign any Loan Party's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts of any Loan Party directly with the applicable Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under any Loan Party's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Each Loan Party hereby appoints Collateral Agent as its lawful attorney-in-fact to sign any Loan Party's name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make extend Term Loans hereunder. Collateral Agent's foregoing appointment as any Loan Party's attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Term Loans terminates.

9.3 Protective Payments. If any Loan Party fails to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which any Loan Party is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide any Loan Party with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) each Loan Party irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of any Loan Party or any of its Subsidiaries of all or any part of the Obligations, and, as between each Loan Party on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other Obligations owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to the Lenders' Pro Rata Shares unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's Pro Rata Share of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by any Loan Party. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; *provided*, *however*, if it is later determined that a Lender received more than its Pro Rata Share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other the Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its Pro Rata Share, then the portion of such payment or distribution in excess of such Lender's Pro Rata Share shall be received and held by such Lender in trust for and shall be promptly paid over to the other Lenders (in accordance with their respective Pro Rata Shares) for application to the payments of amounts due on such other Lenders' claims. To the extent any payment for the account of any Loan Party is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for the Secured Parties for purposes of perfecting Collateral Agent's security interest therein (held for the ratable benefit of the Secured Parties).

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. The Loan Parties bear all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by any Loan Party of any provision of this Agreement or by any Loan Party or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Each Loan Party waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which any Loan Party or any Subsidiary is liable.

10. NOTICES

Other than as specifically provided herein, all notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or the Loan Parties may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to the Loan Parties:	SI-BONE, Inc. 471 El Camino Real, Suite 101, Santa Clara, CA 95050 Attn: Michael Pisetsky; Laura Francis Fax: (408) 557-8312 Email: mpisetsky@si-bone.com; lfrancis@si-bone.com
with a copy (which shall not constitute notice) to:	COOLEY LLP 55 Hudson Yards New York, NY 10001 Attn: Patrick Flanagan Email: pflanagan@cooley.com
If to Collateral Agent:	SOLAR CAPITAL LTD. 500 Park Avenue, 3rd Floor New York, NY 10022 Attention: Anthony Storino Fax: (212) 993-1698 Email: storino@Solarcapltd.com
with a copy (which shall not constitute notice) to:	LATHAM & WATKINS LLP 505 Montgomery Street, Suite 2000 San Francisco, CA 94111 Attention: Haim Zaltzman Facsimile: (415) 395-8095 Email: haim.zaltzman@lw.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

11.1 Waiver of Jury Trial. EACH LOAN PARTY, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG EACH LOAN PARTY, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG EACH LOAN PARTY, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

11.2 Governing Law and Jurisdiction. THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL; PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

11.3 Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the State of New York located in the City of New York, Borough of Manhattan, or of the United States of America for the Southern District of New York and, by execution and delivery of this Agreement, each Loan Party hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against any Loan Party (or any property of any Loan Party) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of *forum non conveniens*, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

11.4 Service of Process. Each Loan Party irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of the Loan Parties specified herein (and shall be effective when such mailing shall be effective, as provided therein). Each Loan Party agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

11.5 Non-exclusive Jurisdiction. Nothing contained in this Article 11 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against any Loan Party in any other jurisdiction.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. No Loan Party may transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to any Loan Party, to sell, transfer, assign, pledge, negotiate, or grant participation in **(any** such sale, transfer, assignment, negotiation**,** or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided*, *however*, that (x) any such Lender Transfer (other than (i) any Transfer at any time that an Event of Default has occurred and is continuing, or (ii) a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of Collateral Agent (such approved assignee, an "**Approved Lender**") and (y) participations shall not require notice to or consent from any Loan Party. Each Loan Party and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of any Loan Party, a then-current direct competitor of any Loan Party, as reasonably determined by Collateral Agent at the time of such assignment. Collateral Agent, acting solely for this purpose as an agent of Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of the Lenders, and the Term Loan Commitments of, and principal amounts (and stated interest) of the Term Loans owing to each Lender pursuant to the terms hereof from time to time (the "**Register**"). The entries in the Register shall be conclusive absent manifest error, and Borrower, Collateral Agent and Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by Borrower and any Lender at any reasonable time and from time to time upon reasonable prior notice. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Term Loans or other obligations under the Loan Documents (the "**Participant Register**"); *provided* that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, Collateral Agent (in its capacity as Collateral Agent)

shall have no responsibility for maintaining a Participant Register. Each Loan Party agrees that each participant shall be entitled to the benefits of the provisions in Exhibit C attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Exhibit C attached hereto (it being understood that the documentation required under Section 7 of Exhibit C attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to this Section 12.1; *provided* that such participant shall not be entitled to receive any greater payment under Exhibit C attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation.

12.2 Indemnification. Each Loan Party agrees to indemnify, defend and hold each Secured Party and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing such Secured Party (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses and Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents (including reasonable attorneys' fees and expenses), except, in each case, for Claims and/or losses directly caused by such Indemnified Person's bad faith, gross negligence or willful misconduct. Each Loan Party hereby further agrees to indemnify, defend and hold each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of the Loan Parties, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct. This Section 12.2 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim.

12.3 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.4 Correction of Loan Documents. Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties**.**

12.5 Amendments in Writing; Integration. No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by any Loan Party or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by the Loan Parties, Collateral Agent and the Required Lenders, *provided* that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize any Loan Party to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its Guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in

this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by any Loan Party of any of its rights and obligations under any Loan Document or release any Loan Party of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations or (I) amend any of the provisions of Section 12.8. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(a) Other than as expressly provided for in Section 12.5(a)(i)–(iii), Collateral Agent may, at its discretion, or if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of the Loan Parties.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

12.7 Survival. Except as otherwise provided in this Agreement, all covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of the Loan Parties in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.8 Confidentiality. In handling any confidential information of the Loan Parties, each of the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loans (*provided*, *however*, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, rule, regulation, regulatory or self-regulatory authority, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and/or Collateral Agent, as applicable, with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent through no breach of this provision by the Lenders or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

12.9 Right of Set Off. Each Loan Party hereby grants to Collateral Agent and to each Lender, a Lien, security interest and right of set off as security for all Obligations to Secured Parties hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of any Secured Party or any entity under the control of such Security Party (including a Collateral Agent Affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, any Secured Party may set off the same or any part thereof and apply the same to any liability or obligation of the Loan Parties even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF ANY LOAN PARTY ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY SUCH LOAN PARTY.

12.10 Cooperation of the Loan Parties. If necessary, each Loan Party agrees to (i) execute any documents reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment (or portion thereof) or Term Loan (or portion thereof) to an assignee in accordance with Section 12.1, (ii) make each Loan Party's management personnel available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments, the Term Loans or portions thereof (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent and the Lenders in the preparation of information relating to the financial affairs of each Loan Party as any prospective participant or assignee of a Term Loan Commitment (or portions thereof) or Term Loan (or portions thereof) reasonably may request. Subject to the provisions of Section 12.8, each Loan Party authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment (or portions thereof), any and all information in such Lender's possession concerning each Loan Party and its financial affairs which has been delivered to such Lender by or on behalf of any Loan Party pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of any Loan Party in connection with such Lender's credit evaluation of the Loan Parties prior to entering into this Agreement.

12.11 Public Announcement. Each Loan Party hereby agrees that Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use any Loan Party's name, tradenames and logos. Collateral Agent and the Lenders may also make disclosures to the Securities and Exchange Commission or other governmental agency and any other public disclosure with investors, other governmental agencies or other related persons.

12.12 Collateral Agent and Lender Agreement. Collateral Agent and the Lenders hereby agree to the terms and conditions set forth on Exhibit B attached hereto. Each Loan Party acknowledges and agrees to the terms and conditions set forth on Exhibit B attached hereto.

12.13 Time of Essence. Time is of the essence for the performance of Obligations under this Agreement.

12.14 Termination Prior to Maturity Date; Survival. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms and all Obligations have been satisfied. So long as each Loan Party has satisfied the Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made) in accordance with the terms of this Agreement, this Agreement may be terminated prior to the Maturity Date by any Loan Party, effective five (5) Business Days after written notice of termination is given to Collateral Agent and the Lenders.

12.15 Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Collateral Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

SI-BONE, INC.

By: /s/ Laura Francis
Name: Laura Francis
Title: Chief Financial Officer

[Signature Continues on the Next Page]

AGENT:

SOLAR CAPITAL LTD.

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

LENDERS:

SOLAR CAPITAL LTD.

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SUNS SPV LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND L.P.

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME BDC LLC

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CORPORATE LENDING FUND L.P.

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP SF DEBT FUND L.P.

By: /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCHEDULE 1.1

Lenders and Commitments

Lender	Term Loan Commitment	Commitment Percentage
SOLAR CAPITAL LTD.	$17,843,354.85	44.61%
SUNS SPV LLC	$2,742,296.93	6.86%
SCP PRIVATE CREDIT INCOME FUND L.P.	$4,681,186.56	11.70%
SCP PRIVATE CREDIT INCOME BDC LLC	$3,492,143.75	8.73%
SCP PRIVATE CORPORATE LENDING FUND L.P.	$9,055,750.04	22.64%
SCP SF DEBT FUND L.P.	$2,185,267.87	5.46%
TOTAL	$40,000,000.00	**100.00%**

Exhibit 31.1

CERTIFICATION OF PRINCIPAL 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) 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

   d) 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 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.

/s/ Jeffrey W. Dunn

Date: August 4, 2020

Jeffrey W. Dunn
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) 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

   d) 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.

/s/ Laura A. Francis

Date: August 4, 2020

Laura A. Francis
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL 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 June 30, 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.

/s/ Jeffrey W. Dunn

Date: August 4, 2020

Jeffrey W. Dunn
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Laura A. Francis

Date: August 4, 2020

Laura A. Francis
Chief Operating Officer and Chief Financial Officer
(Principal 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.