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, 2022

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 ☐

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 ☐

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 34,305,039 as of July 31, 2022.

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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:

- the impact the COVID-19 pandemic and governmental actions taken to combat the COVID-19 pandemic will have on us, 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 our products, the ability and desire of patients and physicians to undergo and perform such procedures, the duration and any potential resurgence of the COVID-19 pandemic, and whether the COVID-19 pandemic will recur in the future;
- the impact the COVID-19 pandemic has on the global supply chain and our third-party manufacturers and suppliers, which could adversely impact the availability or cost of materials, which could disrupt our supply chain related to implants and instruments.
- 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 and commercialize 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;
- factors impacting the supply chains we rely on, including the availability of raw materials and skilled labor serving our suppliers, and the cost of these factors of production which may in turn impact the prices we pay for our devices;

- 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 ability to attract and retain employees, including those with specialized skills and experience;
- our expectations regarding acquisitions and strategic operations;
- our ability to access capital markets;
- 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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,319	$ 63,419
Short-term investments	90,095	83,560
Accounts receivable, net of allowance for doubtful accounts of $255 and $264, respectively	15,118	14,246
Inventory	16,484	11,498
Prepaid expenses and other current assets	2,325	3,143
Total current assets	148,341	175,866
Property and equipment, net	12,810	8,992
Operating lease right-of-use assets	4,611	5,248
Other non-current assets	385	400
TOTAL ASSETS	$ 166,147	$ 190,506
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,141	$ 3,198
Accrued liabilities and other	10,189	12,353
Current portion of long-term borrowings	—	—
Operating lease liabilities, current portion	1,342	1,339
Total current liabilities	16,672	16,890
Long-term borrowings	35,075	34,973
Operating lease liabilities, net of current portion	3,529	4,166
Other long-term liabilities	38	57
TOTAL LIABILITIES	55,314	56,086
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; 34,221,614 and 33,674,085 shares issued and outstanding, respectively	3	3
Additional paid-in capital	442,570	429,914
Accumulated other comprehensive income	32	352
Accumulated deficit	(331,772)	(295,849)
TOTAL STOCKHOLDERS' EQUITY	110,833	134,420
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 166,147	$ 190,506

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,	
	2022	2021	2022	2021
Revenue	$ 25,585	$ 22,194	$ 48,024	$ 42,636
Cost of goods sold	3,465	2,375	6,448	4,575
Gross profit	22,120	19,819	41,576	38,061
Operating expenses:				
Sales and marketing	28,843	23,084	54,448	44,006
Research and development	3,478	3,149	7,058	6,104
General and administrative	7,680	6,551	14,819	12,491
Total operating expenses	40,001	32,784	76,325	62,601
Loss from operations	(17,881)	(12,965)	(34,749)	(24,540)
Interest and other income (expense), net:				
Interest income	136	46	209	107
Interest expense	(622)	(1,075)	(1,183)	(2,139)
Other income (expense), net	(146)	13	(200)	349
Net loss	$ (18,513)	$ (13,981)	$ (35,923)	$ (26,223)
Other comprehensive income (loss):				
Changes in foreign currency translation	(14)	35	(14)	(80)
Unrealized gain (loss) on marketable securities	(58)	(5)	(306)	16
Comprehensive loss	$ (18,585)	$ (13,951)	$ (36,243)	$ (26,287)
Net loss per share, basic and diluted	$ (0.54)	$ (0.42)	$ (1.06)	$ (0.80)
Weighted-average number of common shares used to compute basic and diluted net loss per share	34,052,692	32,978,914	33,923,229	32,836,040

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, 2021	33,674,085	$ 3	$ 429,914	$ 352	$ (295,849)	$ 134,420
Issuance of common stock upon exercise of stock options, net of shares withheld	34,798	—	169	—	—	169
Issuance of common stock upon vesting of restricted stock units	163,480	—	—	—	—	—
Stock-based compensation	—	—	5,507	—	—	5,507
Net unrealized loss on marketable securities	—	—	—	(248)	—	(248)
Net loss	—	—	—	—	(17,410)	(17,410)
Balance as of March 31, 2022	**33,872,363**	**3**	**435,590**	**104**	**(313,259)**	**122,438**
Issuance of common stock upon exercise of stock options, net of shares withheld	4,469	—	30	—	—	30
Issuance of common stock related to employee stock purchase plan	112,773	—	1,199	—	—	1,199
Issuance of common stock upon vesting of restricted stock units	232,009	—	—	—	—	—
Stock-based compensation	—	—	5,751	—	—	5,751
Foreign currency translation	—	—	—	(14)	—	(14)
Net unrealized loss on marketable securities	—	—	—	(58)	—	(58)
Net loss	—	—	—	—	(18,513)	(18,513)
Balance as of June 30, 2022	**34,221,614**	**$ 3**	**$ 442,570**	**$ 32**	**$ (331,772)**	**$ 110,833**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	32,583,220	$ 3	$ 408,113	$ 524	$ (239,277)	$ 169,363
Issuance of common stock upon exercise of stock options, net of shares withheld	93,975	—	601	—	—	601
Issuance of common stock upon vesting of restricted stock units	131,339	—	—	—	—	—
Stock-based compensation	—	—	4,030	—	—	4,030
Vesting of early exercised stock options	—	—	9	—	—	9
Foreign currency translation	—	—	—	(115)	—	(115)
Net unrealized gain on marketable securities	—	—	—	21	—	21
Net loss	—	—	—	—	(12,242)	(12,242)
Balance as of March 31, 2021	**32,808,534**	**3**	**412,753**	**430**	**(251,519)**	**161,667**
Issuance of common stock upon exercise of stock options, net of shares withheld	140,917	—	650	—	—	650
Issuance of common stock related to employee stock purchase plan	104,861	—	1,566	—	—	1,566
Issuance of common stock upon vesting of restricted stock units	181,958	—	—	—	—	—
Stock-based compensation	—	—	4,257	—	—	4,257
Vesting of early exercised stock options	—	—	9	—	—	9
Foreign currency translation	—	—	—	35	—	35
Net unrealized loss on marketable securities	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(13,981)	(13,981)
Balance as of June 30, 2021	**33,236,270**	**$ 3**	**$ 419,235**	**$ 460**	**$ (265,500)**	**$ 154,198**

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,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (35,923)	$ (26,223)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	11,258	8,287
Depreciation and amortization	1,505	845
Accretion of discount on marketable securities	515	721
Amortization of debt issuance costs	101	175
Loss on sale and disposal of property and equipment	105	125
Changes in operating assets and liabilities:		
Accounts receivable	(720)	1,746
Inventory	(4,882)	(2,482)
Prepaid expenses and other assets	851	157
Accounts payable	936	554
Accrued liabilities and other	(2,099)	(1,415)
Net cash used in operating activities	(28,353)	(17,510)
Cash flows from investing activities		
Maturities of marketable securities	48,000	56,977
Purchases of marketable securities	(55,356)	(43,337)
Purchases of property and equipment	(4,275)	(4,191)
Net cash (used in) provided by investing activities	(11,631)	9,449
Cash flows from financing activities		
Proceeds from issuance of common stock under employee stock purchase plan	1,199	1,566
Proceeds from the exercise of stock options	199	1,251
Net cash provided by financing activities	1,398	2,817
Effect of exchange rate changes on cash and cash equivalents	(514)	(212)
Net decrease in cash and cash equivalents	(39,100)	(5,456)
Cash and cash equivalents at		
Beginning of period	63,419	53,581
End of period	$ 24,319	$ 48,125
Supplemental disclosure of non-cash information		
Vesting of early exercised stock options	$ —	$ 18
Unpaid purchases of property and equipment	1,593	106

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 musculoskeletal disorders of the sacropelvic anatomy. The Company introduced its first generation iFuse implant 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.

Risks and Uncertainties

The Company is subject to continuing risk and uncertainties as a result of the COVID-19 pandemic, and is closely monitoring the impact of the pandemic on all aspects of its business, including the impacts on its customers, patients that would benefit from procedures involving the Company's products, employees, suppliers, vendors, business partners and distribution channels. Economies worldwide continue to be negatively impacted by the COVID-19 pandemic, in particular with recurrent mutations of the virus, despite advances in vaccines, and the Company anticipates these disruptions will continue. While the Company has not experienced material disruptions to its supply chain to date, certain of its third-party suppliers have faced delays, product shortages and rising costs resulting from disruptions in the global supply chain, primarily related to the instruments. As a result, the Company is continuing to work closely with its manufacturing partners and suppliers, as well as determining alternative sourcing strategies to enable the Company to source key components and maintain appropriate inventory levels to meet customer demand. As such the Company's future results of operations and liquidity could be adversely impacted by a variety of factors related to the COVID-19 pandemic and global supply chain issues, including those discussed in the section entitled "Risk Factors" in this report. As of the date of issuance of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic and global supply chain issues may materially impact the Company's financial condition, liquidity, or results of operations remains uncertain.

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, 2021 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, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 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, 2021 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 1, 2022.

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 condensed consolidated financial statements primarily includes the fair value of performance-based restricted stock unit awards. 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, 2021. There have been no material changes to these accounting policies, except for the accounting policy related to performance-based restricted stock unit awards noted below that was added to the Company's significant accounting policies in the first quarter of 2022.

Performance-Based Restricted Stock Unit Awards

The Company grants restricted stock unit awards subject to market and service vesting conditions to certain executive officers. This type of grant consists of the right to receive shares of common stock, subject to achievement of time-based criteria and certain market-related performance goals over a specified period, as established by the Compensation Committee of the Company's Board of Directors. For these awards that are subject to market-related performance, the fair value is determined based on the number of shares granted and a Monte Carlo valuation model, which incorporates the probability of the achievement of the market-related performance goals as part of the grant date fair value. If such performance goals are not ultimately met, the expense is not reversed. Stock-based compensation expense is recognized ratably over the requisite service period.

Segments

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

The Company derives substantially all of its revenue from sales to customers in the U.S. Revenue by geography is based on billing address of the customer. International revenue accounted for less than 10% of the total revenue during the periods presented. Long-lived assets held outside the U.S. are immaterial. Following table summarizes the Company's revenue by geography:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
United States	$ 23,771	$ 20,230	$ 44,137	$ 39,000
International	1,814	1,964	3,887	3,636
	$ 25,585	$ 22,194	$ 48,024	$ 42,636

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (ASU 2016-02), which requires the lessee to recognize a lease right-of-use asset and a lease liability for operating leases, initially measured at the present value of lease payments, in its consolidated balance sheet. In the fourth quarter of 2021, the Company adopted ASU 2016-02 using the modified retrospective method with the effective date of January 1, 2021. As a result, the Company has retrospectively changed its previously issued condensed consolidated financial statements as of June 30, 2021 and for the three and six months ended June 30, 2021 as presented in its June 30, 2021 Quarterly Report on Form 10-Q to reflect the adoption of Topic 842 on January 1, 2021. The condensed consolidated financial statements for the three and six months ended June 30, 2021 presented herein differ from the Company's condensed consolidated financial statements included in its June 30, 2021 Quarterly Report on Form 10-Q, as those financial statements were prepared using the former accounting standard referred to as ASC Topic 840, Leases.

The following table summarizes the effect of the adoption of Topic 842 on the condensed consolidated balance sheet as of January 1, 2021:

	As Previously Reported	Impact of Topic 842 Adoption	As Adjusted
		(in thousands)	
ASSETS			
Operating lease right-of-use assets	$ —	$ 3,507	$ 3,507
LIABILITIES AND STOCKHOLDERS' EQUITY			
Operating lease liabilities, current portion	—	852	852
Operating lease liabilities, net of current portion	—	2,933	2,933
Accrued liabilities and other	10,199	(345)	9,854
Accumulated deficit	(239,277)	68	(239,209)

The adoption of Topic 842 did not have any other material impact on the condensed consolidated financial statements as of June 30, 2021 and for the three and six months ended June 30, 2021.

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, Debt - Debt with Conversion and Other Options (ASC 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40). ASU 2020-06 simplifies the accounting for convertible instruments by removing the beneficial conversion and cash conversion accounting models for convertible instruments and removes certain settlement conditions that are required for contracts to qualify for equity classification. This new standard also simplifies the diluted earnings per share calculations by requiring that an entity use the if-converted method for convertible instruments and requires that the effect of potential share settlement be included in diluted earnings per share calculations when an instrument may be settled in cash or shares. The new standard requires entities to provide expanded disclosures about the terms and features of convertible instruments, how the instruments have been reported in the entity's financial statements, and information about events, conditions, and circumstances that can affect how to assess the amount or timing of an entity's future cash flows related to those instruments. The ASU is effective for public companies, excluding entities eligible to be smaller reporting companies, for fiscal years beginning after December 15, 2021. The new standard went effective on January 1, 2022, and it did not impact the Company's consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04 "Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options" ("ASU 2021-04") which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. An entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as follows: i) for a modification or an exchange that is a part of or directly related to a modification or an exchange of an existing debt instrument or line-of-credit or revolving-debt arrangements (hereinafter, referred to as a "debt" or "debt instrument"), as the difference between the fair value of the modified or exchanged written call option and the fair value of that written call option immediately before it is modified or exchanged; ii) for all other modifications or exchanges, as the excess, if any, of the fair value of the modified or exchanged written call option over the fair value of that written call option immediately before it is modified or exchanged. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The new standard went effective on January 1, 2022, and it did not impact the Company's consolidated financial statements and related disclosures.

Recently Accounting Standards Not Yet Effective

In March 2022, the FASB issued ASU 2022-02, Financial Instruments - Credit Losses (Topic 326), Troubled Debt Restructurings ("TDRs") and Vintage Disclosures. ASU 2022-02 eliminates the accounting guidance for TDRs in ASC 310-40, Receivables - Troubled Debt Restructurings by Creditors. In addition, ASU 2022-02 also requires that public business entities disclose current-period gross write-offs by year of origination for financing receivables and net investments in leases within the scope of Subtopic 326-20, Financial Instruments—Credit Losses—Measured at Amortized Cost. The ASU is effective for public companies, excluding entities eligible to be smaller reporting companies, for fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of applying this guidance on its consolidated financial statements and related disclosures.

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, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 18,084	$ —	$ —	$ 18,084
Cash equivalents	18,084	—	—	18,084
U.S. treasury securities	56,156	—	(257)	55,899
Corporate bonds	20,285	—	(84)	20,201
Commercial paper	13,995	—	—	13,995
Short-term investments	90,436	—	(341)	90,095
Total marketable securities	$ 108,520	$ —	$ (341)	$ 108,179

	December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 57,829	$ —	$ —	$ 57,829
Cash equivalents	57,829	—	—	57,829
U.S. treasury securities	28,064	—	(16)	28,048
Corporate bonds	31,558	4	(23)	31,539
Commercial paper	23,973	—	—	23,973
Short-term investments	83,595	4	(39)	83,560
Total marketable securities	$ 141,424	$ 4	$ (39)	$ 141,389

The amortized cost of the Company's available-for-sale securities approximates their fair value. Unrealized losses are generally due to interest rate fluctuations, as opposed to credit quality. However, the Company reviews individual securities that are in an unrealized loss position in order to evaluate whether or not they have experienced or are expected to experience credit losses. During the six months ended June 30, 2022 and 2021, unrealized gains and losses from the investments were not material and were not the result of a decline in credit quality. As a result, the Company did not recognize any credit losses related to its investments and that all unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive income (loss) on the condensed consolidated balance sheets as of June 30, 2022 and December 31, 2021.

The Company elected to present accrued interest receivable separately from short-term and long-term investments on its condensed consolidated balance sheets. Accrued interest receivable was $0.3 million as of June 30, 2022, and was recorded in prepaid expenses and other current assets. The Company also elected to exclude accrued interest receivable from the estimation of expected credit losses on its marketable securities and reverse accrued interest receivable through interest income (expense) when amounts are determined to be uncollectible. The Company did not write off any accrued interest receivable as of June 30, 2022 or December 31, 2021.

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 and liabilities that require 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, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 18,084	$ —	$ —	$ 18,084
U.S. treasury securities	55,899	—	—	55,899
Corporate bonds	—	20,201	—	20,201
Commercial paper	—	13,995	—	13,995
Total marketable securities	$ 73,983	$ 34,196	$ —	$ 108,179

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 57,829	$ —	$ —	$ 57,829
U.S. treasury securities	28,048	—	—	28,048
Corporate bonds	—	31,539	—	31,539
Commercial paper	—	23,973	—	23,973
Total marketable securities	$ 85,877	$ 55,512	$ —	$ 141,389

5. Balance Sheet Components

Inventory

As of June 30, 2022, inventory consisted of finished goods of $15.9 million and work-in-progress of $0.6 million. As of December 31, 2021, inventory consisted of finished goods.

Property and Equipment, net:

	June 30, 2022	December 31, 2021
	(in thousands)	
Machinery and equipment	$ 12,721	$ 10,573
Construction in progress	5,604	3,657
Computer and office equipment	909	916
Leasehold improvements	1,631	503
Furniture and fixtures	307	309
	21,172	15,958
Less: Accumulated depreciation and amortization	(8,362)	(6,966)
	$ 12,810	$ 8,992

As of June 30, 2022, construction in progress pertains to the cost of individual components of a custom instrument set used for surgical placement of the Company's products that have not yet been placed into service of $3.8 million and construction costs related to the new lease in Santa Clara of $1.8 million. Depreciation expense was $0.8 million and $0.5 million for the three months ended June 30, 2022 and 2021, respectively, and $1.5 million and $0.8 million for the six months ended June 30, 2022 and 2021, respectively.

Accrued Liabilities and Other:

	June 30, 2022	December 31, 2021
	(in thousands)	
Accrued compensation and related expenses	$ 7,927	$ 10,055
Accrued professional services	652	995
Others	1,610	1,303
	$ 10,189	$ 12,353

Accounts Receivable and Allowance for Credit Losses:

The movement in the allowance for credit losses was as follows:

	June 30, 2022	December 31, 2021
	(in thousands)	
Balance at beginning of year	$ 264	$ 263
Provision	—	14
Write-offs	(9)	(13)
Balance at end of year	$ 255	$ 264

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 and a building used for research and development and warehouse space in Santa Clara, California which expires in

October 2026. The Company also has non-cancelable operating leases for its office building spaces in Gallarate, Italy and Knaresborough, United Kingdom, which expire in August 2027 and December 2025, respectively.

The Company also leases vehicles under operating lease arrangements for certain of its personnel in Europe which expire at various times throughout 2022 to 2027.

Supplemental information related to lease expense and valuation of the lease assets and lease liabilities are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease expense	$ 397	$ 263	$ 806	$ 546
Variable lease expense	119	65	223	106
Total lease expense	$ 516	$ 328	$ 1,029	$ 652
Cash paid for amounts included in the measurement of operating lease liabilities	$ 396	$ 281	$ 804	$ 566
Leased assets obtained in exchange for new operating lease liabilities	$ 77	$ 240	$ 77	$ 277

	June 30, 2022	December 31, 2021
Weighted average remaining lease term (in years)	3.51	3.98
Weighted average discount rate	5.76%	5.75%

Future minimum lease payments under non-cancelable operating leases as of June 30, 2022 was as follows:

Year Ending December 31,	(in thousands)
Remainder of 2022	$ 800
2023	1,555
2024	1,498
2025	993
2026	529
Thereafter	8
Total operating lease payments	5,383
Less: imputed interest	(512)
Total operating lease liabilities	$ 4,871

As of June 30, 2022, the Company had no operating lease liabilities that had not commenced.

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 $0.6 million and $1.2 million as of June 30, 2022 and December 31, 2021, respectively.

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.

Legal Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of its business. The Company is not presently a party to any material legal proceedings that, if determined adversely to the Company, would have a material adverse effect on the Company.

7. Borrowings

Term Loan

The following table summarizes the outstanding borrowings from the term loan as of periods presented:

	June 30, 2022	December 31, 2021
	(in thousands)	
Principal outstanding and final fee	$ 35,700	$ 35,700
Less: Unamortized debt issuance costs	(85)	(100)
Unaccreted value of final fee	(540)	(627)
Outstanding debt, net of debt issuance costs and unaccreted value of final fee	$ 35,075	$ 34,973
Classified as:		
Long-term borrowings	$ 35,075	$ 34,973

In May 29, 2020, the Company entered into a term loan with Solar Capital Partners ("Solar"). Pursuant to the Loan and Security Agreement, Solar provided an aggregate principal amount of $40.0 million term loan (the "Solar Term Loan"). The Solar Term Loan bore interest at a rate per annum equal to 9.40% plus London Interbank Offered Rate ("LIBOR"), payable monthly in arrears. LIBOR means the greater of (i) 0.33% or (ii) 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 included an interest-only period of 36 months through June 2023, and then repaid in equal monthly principal payments plus interest through June 1, 2025. The Company was 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 Solar. With respect to the Solar Term Loan, this final fee was 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 Company paid in full and terminated the Solar Term Loan in August 2021. The effective interest rate related to the Solar Term Loan was 10.6% for three and six months ended June 30, 2021.

The outstanding debt as of June 30, 2022 and December 31, 2021 is related to a term loan pursuant to the Loan and Security Agreement dated August 12, 2021 (the "Effective Date"), entered into by the Company with Silicon Valley Bank ("SVB"). Pursuant the agreement, SVB provided an aggregate principal amount of $35.0 million to the Company (the "SVB Term Loan"). The Company used the proceeds of the SVB Term Loan to repay in full and terminate the Solar Term Loan, which was accounted for as debt extinguishment in accordance with the accounting standards. The Company recognized the unamortized debt issuance costs and unaccreted value of final fee of $1.3 million and the prepayment penalty and lender fees of $0.5 million related to Solar Term Loan as a loss on debt extinguishment. The costs and fees are reflected as interest expense in the consolidated statement of operations for the year ended December 31, 2021. The total debt issuance costs of $0.1 million associated with the SVB 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 SVB Term Loan matures (the "Maturity Date") on either

(a) August 1, 2025 or (b) August 1, 2026 dependent on the Company's achievement of a certain financial performance milestone as of December 31, 2022, as set forth in the Loan Agreement. Interest on the SVB Term Loan is payable monthly at an annual rate set at the greater of (a) 5.75% and (b) prime rate as published in the Wall Street Journal plus 2.5%. Commencing on September 1, 2023, the Company will be required to make monthly principal amortization payments. The Company may elect to prepay the SVB Term Loan prior to the Maturity Date subject to a prepayment fee equal to 1% if the prepayment occurs prior to the second anniversary of the Effective Date and 0% if the prepayment occurs on or at any time after the second anniversary of the Effective Date. The SVB Term Loan is secured by substantially all the Company's assets other than the Company's intellectual property. The Company is also obligated to pay a final payment equal to $0.7 million or 2% of the aggregate principal amount of the SVB Term Loan, which is considered fully earned by SVB on the effective date of the Loan and Security Agreement with SVB. This final payment shall be due and payable on the earliest of (i) the Maturity Date, (ii) the full repayment of the loan, (iii) permitted prepayment and mandatory prepayment upon an acceleration as specified in the agreement or (iv) the termination of the agreement. The final payment is 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 SVB Term Loan for the three and six months ended June 30, 2022 was 6.9% and 6.6%, respectively.

The table below summarizes the future principal and final fee payments under the SVB Term Loan as of June 30, 2022:

Year ending December 31,	**(in thousands)**
Remainder of 2022	$ —
2023	7,292
2024	17,500
2025	10,908
2026	—
Total principal and final fee payments	$ 35,700

The Loan Agreement includes affirmative and negative covenants applicable to the Company and certain of its foreign subsidiaries. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental compliance, deliver certain financial reports, and maintain insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging the Company's intellectual property to other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions. As of June 30, 2022, the Company was in compliance with all debt covenants.

CARES Act

On March 27, 2020, the U.S. federal government enacted the "Coronavirus Aid, Relief and Economic Security (CARES) Act," which, among other things, allowed employers to defer the deposit and payment of an employer's share of social security taxes through December 31, 2020. The Company recorded a total liability of $0.5 million related to the deferral of the social security taxes that is included in the accrued liabilities and other in the condensed consolidated balance sheets as of June 30, 2022 and December 31, 2021.

8. Stock-Based Incentive Compensation Plans

Stock Options

The table below summarizes the stock option activity for the six months ended June 30, 2022:

	Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2021	2,009,513	$8.73
Exercised	(39,267)	5.09
Canceled and forfeited	(14,229)	12.36
Outstanding as of June 30, 2022	1,956,017	10.22

As of June 30, 2022, the unrecognized compensation cost related to stock options was $0.7 million, which is expected to be recognized over a period of approximately 0.5 years.

There were no stock options granted during the three and six months ended June 30, 2022 and 2021.

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, 2022 and December 31, 2021, the Company had no shares subject to repurchase.

Restricted Stock Units

Restricted stock units ("RSUs") are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. RSUs generally vest over two to four years based upon continued services and are settled at vesting in shares of the Company's common stock. The grant date fair value of the RSUs is equal to the closing price of the Company's common stock on the grant date.

In January 2022, the Company granted performance-based restricted stock unit awards subject to market and service vesting conditions to certain executive officers under SI-BONE's 2018 Equity Incentive Plan ("PSUs"). The shares subject to the PSUs vest over a three-year performance period beginning January 1, 2022 and ending December 31, 2024. The actual number of PSUs that will vest in each measurement period will be determined by the Compensation Committee based on the Company's total shareholder return ("TSR") relative to the TSR of the Median Peer Companies (as defined in the award agreement). The grant date fair value of each stock award with a market condition was determined using the Monte Carlo valuation model. The table below summarizes the assumptions used to estimate the grant date fair value of the PSUs granted:

	Six Months Ended June 30, 2022		
Expected volatility of common stock	48.9%	to	58.7%
Expected volatility of peer companies	24.2%	to	152.5%
Correlation coefficient of peer companies	(0.13)	to	1.00
Risk-free interest rate	0.4%	to	1.2%
Dividend yield	—%	to	1.0%

The table below summarizes RSU and PSU activity for the six months ended June 30, 2022:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2021	1,566,522	$25.17	—	$—
Granted	1,130,467	21.30	155,596	19.50
Vested	(395,489)	24.88	—	—
Canceled and forfeited	(129,123)	23.81	—	—
Outstanding as of June 30, 2022	2,172,377	23.29	155,596	19.50

As of June 30, 2022, the unrecognized compensation cost related to the RSUs was $42.2 million, which is expected to be recognized over a period of approximately 2.8 years. As of June 30, 2022, the unrecognized compensation cost related to the PSUs was $2.3 million, which is expected to be recognized over a period of approximately 2.5 years.

Employee Stock Purchase Plan

The Company's 2018 Employee Stock Purchase Plan (the "ESPP") allows eligible employees to purchase shares of the Company's common stock through payroll deductions at the price equal to 85% of the lesser of the fair market value of the stock as of the first date or the ending date of each six month offering period. The offering 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 112,773 and 104,861 shares under ESPP, representing approximately $1.6 million in employee contributions, for the six months ended June 30, 2022 and 2021. As of June 30, 2022 and December 31, 2021, total accumulated ESPP related employee payroll deductions amounted to $0.2 million and $0.3 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,	
	2022	2021	2022	2021
	(in thousands)			
Cost of goods sold	$ 117	$ 129	$ 238	$ 303
Sales and marketing	2,746	2,125	5,340	4,024
Research and development	664	404	1,297	823
General and administrative	2,224	1,599	4,383	3,137
	$ 5,751	$ 4,257	$ 11,258	$ 8,287

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,	
	2022	2021	2022	2021
	(in thousands, except share and per share data)			
Net loss	$ (18,513)	$ (13,981)	$ (35,923)	$ (26,223)
Weighted-average shares used to compute basic and diluted net loss per share	34,052,692	32,978,914	33,923,229	32,836,040
Net loss per share, basic and diluted	$ (0.54)	$ (0.42)	$ (1.06)	$ (0.80)

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,	
	2022	2021	2022	2021
Stock options	1,956,017	2,147,895	1,956,017	2,147,895
Restricted stock units	2,172,377	1,719,364	2,172,377	1,719,364
Shares subject to repurchase	—	1,945	—	1,945
ESPP purchase rights	59,688	34,070	59,688	34,070
Common stock warrants	118,122	118,122	118,122	118,122
	4,306,204	4,021,396	4,306,204	4,021,396

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. On April 27, 2021, Addendum No.1 to the Development Agreement was entered into by and between the Company and SeaSpine to extend certain obligations as described under the Development Agreement to a consultant of the Company.

Pursuant to the development plan, SeaSpine shall use reasonable efforts to assist in the development of the potential product offering, including licensing certain existing intellectual property to be incorporated into such product. Under the terms of the Development Agreement, the Company agreed to make monthly payments to SeaSpine to reimburse for full time resources employed by SeaSpine responsible to conduct the development activities. For the three months ended June 30, 2022 and 2021, the Company expensed $— and $13,854, respectively, of the reimbursement charges from SeaSpine. For the six months ended June 30, 2022 and 2021, the Company expensed $6,225 and $23,854, respectively, of the reimbursement charges from SeaSpine. The reimbursement charges were recorded within research and development expense in the condensed consolidated statements of operations.

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. The Company recorded an immaterial amount of royalty for the three and six months ended June 30, 2022. No royalties were recorded in fiscal year 2021.

The outstanding liability to SeaSpine as of June 30, 2022 was approximately $2,000 and was recorded within accrued liabilities and other in the condensed consolidated balance sheet. There was no outstanding liability to SeaSpine as of December 31, 2021

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, 2022 and 2021. The income taxes for the six months ended June 30, 2022, reflected the impact of a change in U.S. tax law effective January 1, 2022, which requires the capitalization and amortization of research and experimental expenditures incurred after December 31, 2021. Under the Tax Cuts and Jobs Act, for tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize certain research and experimental expenditures that are paid or incurred in connection with their trade or business. Due to the expected tax loss, the provision did not have tax impact to the quarter. 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 June 30, 2022 compared to December 31, 2021.

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 1, 2022. 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 dedicated to solving musculoskeletal disorders of the sacropelvic anatomy. We have pioneered a proprietary minimally invasive surgical implant system, which we call iFuse, to address sacroiliac joint dysfunction and degeneration, adult deformity, pelvic ring traumatic fractures. Since we introduced iFuse in 2009, as of June 30, 2022, more than 71,000 procedures have been performed by over 2,800 surgeons in the U.S. and 37 other countries.

Our iFuse Implant System includes a series of patented titanium implants and the instruments we have developed to enable surgeons to perform the procedure. Surgeons place our implants across the sacroiliac joint, either from a lateral approach through the iliac bones into the sacrum, or from a posterior approach through the sacrum and into the iliac bones. Surgeons typically use three iFuse implants to fuse a sacroiliac joint in the lateral procedure, and one iFuse implant in each sacroiliac joint, typically alongside another device crossing the joint and joining to the spinal construct.

Our first-generation iFuse implant has a triangular cross section that resists twisting or rotation of the implant within the bone within which it is implanted, regardless of the surgical approach and technique used to place the implants. The triangular shape of our implants helps stabilize the joint, and the implants' porous surface facilitates biologic fixation of the bone onto the implant, or bony ongrowth and ingrowth, that results in fusion. The implant has at least three times the strength of a typical eight-millimeter cannulated surgical screw, and the large porous surface area of our implants allows for bony ingrowth. We hold issued patents on implants with cross-sections of many non-round shapes, including the triangular shape of our first-generation iFuse implant. We also hold issued patents for the method of placing those implants across the sacroiliac joint, as well as other parts of the spine and pelvis.

We introduced our second-generation implant, iFuse-3D, in 2017. This patented titanium implant combines the triangular cross-section of the iFuse implant with the proprietary 3D-printed porous surface and fenestrated design. This design also allows the surgeon to fill the implant with ground-up bone before implantation, which some surgeons believe accelerates bone through-growth and biological fixation. iFuse-3D implants have shown positive bony ingrowth, ongrowth and through-growth and in animal studies, whether or not ground-up bone is used. We hold issued patents on 3D-printed triangular implants with fenestrations, or holes, which allow bone to grow into and through the implants.

In April 2019, we received clearance from the United States Food and Drug Administration, or FDA, to promote the use of our iFuse-3D implants for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint. For this indication, surgeons typically use the posterior approach, through the sacrum and into the iliac bones, which we call the Bedrock technique. We received CE marking and began marketing iFuse for this indication and surgical technique in Europe in December 2019. In March 2020, we received FDA 510(k) clearance for an expanded indication for our triangular iFuse implants to support our trauma program.

In February 2021, we received clearance from the FDA for iFuse-TORQ, a 3D-printed portfolio of threaded implants designed to meet the needs of pelvic trauma and minimally invasive sacroiliac joint fusion applications. iFuse-TORQ is targeted to address an unmet clinical need for low energy pelvic ring fractures and chronic sacroiliac joint pain after high energy pelvic ring trauma. iFuse-TORQ also provides an opportunity for us to capture competitive screw business for minimally invasive sacroiliac joint fusions. In June 2022, the FDA provided clearance for an additional indication to include acute, non-acute and non-traumatic fractures. Fractures covered in this clearance include pelvic fragility fractures, which are fractures related to low-energy traumatic events, and pelvic insufficiency fractures.

In May 2022, we received clearance from the FDA for the iFuse-Bedrock Granite Implant System. The iFuse-Bedrock Granite implant provides sacroiliac fusion and sacropelvic fixation as a foundational element for segmental spinal fusion. The iFuse-Bedrock Granite is designated by the FDA as a breakthrough device and the Centers for Medicare and Medicaid Services has proposed a New Technology Add-on Payment for procedures that involve implanting this device.

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 expenses, from our first follow-on public offering of our common stock. In October 2020, we received a total of $71.6 million of net proceeds from our second follow-on offering of our common stock.

Impact of COVID-19 Pandemic

The global COVID-19 pandemic presents significant risks to us and has impacted, and continues to impact our business, operations, and financial results and condition, directly and indirectly, including, without limitation, impacts on the health of our management and employees; our manufacturing, distribution, marketing and sales operations; our research and development activities, including clinical activities; and customer and patient behaviors.

Access to many hospitals and other customer sites was impacted by prevalence of COVID-19, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and ambulatory surgery centers have in the past suspended and may suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers reside. Quarantines, shelter-in-place, elective procedure moratoria and similar government orders have also impacted, and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain. Periodic resurgence of the COVID-19 pandemic negatively impacted our revenues at various periods throughout 2021 and 2022 as evidenced by case deferrals attributed to COVID-19.

Throughout the pandemic, we have taken a variety of steps to address the impact of the COVID-19 , while attempting to minimize business disruption. We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate, and will take further actions that are considered prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products.

While we have not experienced material disruptions to our supply chain to date, certain of our third-party suppliers have faced delays, product shortages and rising costs resulting from disruptions in the global supply chain, primarily related to our instruments. As a result, we are continuing to work closely with our manufacturing partners and suppliers, as well as determining alternative sourcing strategies to enable us to source key components and maintain appropriate inventory levels to meet customer demand.

We cannot currently predict with certainty the full extent to which the COVID-19 pandemic will impact demand for our products in the future, or the impact of the COVID-19 pandemic on our supply chain or other aspects of our business. Accordingly, the COVID-19 pandemic could have a material adverse effect on our results of operations, financial condition and capital resources.

The existence and further duration of the COVID-19 pandemic may also further exacerbate certain risks as described in "Part II- Item 1A - Risk Factors" below.

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 and training, engage key opinion leaders, and leverage broad coverage.

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 expand the market and deliver revenue growth.

As of June 30, 2022, our U.S. sales force consisted of 85 territory sales managers and 76 clinical support specialists directly employed by us and 73 third-party distributors, compared to 74 territory sales managers and 59 clinical support specialists directly employed by us and 48 third-party distributors as of June 30, 2021. As of June 30, 2022, our international sales force consisted of 18 sales representatives directly employed by us and 30 exclusive third-party distributors, compared to 21 sales representatives directly employed by us and 30 exclusive third-party distributors as of June 30, 2021.

Increase surgeon activity and training

Our medical affairs team works closely with our sales team to increase surgeon activity and training. 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, 2022 and 2021, in the U.S., more than 1,900 surgeons and 1,700 surgeons, respectively, have been trained on iFuse and have treated at least one patient. Outside the U.S., as of each of June 30, 2022 and 2021, more than 800 surgeons and 700 surgeons, respectively, have been been trained on iFuse and have treated at least one patient. We will continue to pursue approximately 6,800 target surgeons in the U.S., as well as international surgeons to train or retrain in the future.

In addition to utilizing our traditional method of hands-on cadaveric and dry-lab training for surgeons and mid-level practitioners, we are using the SI-BONE SImulator - a portable, radiation-free, haptics and computer-based simulator for training purposes. Starting in July 2020 we began deploying the SImulators to cover all US regions and European subsidiaries and had 25 SImulators in our offices and the field as of the date of this report.

Launch new products

Our Bedrock technique is used in the treatment of adult spinal deformity. 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 utilizes our proprietary triangular iFuse Implants, with one implant placed across 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 differs from our traditional iFuse procedure, whereby three iFuse Implants are placed across one sacroiliac joint via a lateral transarticular approach through the ilium and into the sacrum. The Bedrock technique is performed to increase stability at the base of a long construct. Biomechanical testing has shown that iFuse Implants placed in this position reduce sacroiliac joint motion by approximately 30% in conjunction with a long construct. We received CE mark clearance for the promotion of the Bedrock technique in Europe in November 2019 and we launched the promotion of this technique in select European markets in December 2019.

In addition, we received FDA clearance for our trauma product, iFuse-TORQ, in the first quarter of 2021. iFuse-TORQ is a highly differentiated 3D-printed threaded implant for pelvic trauma and minimally invasive sacroiliac joint fusion applications. Relative to competitive trauma products, iFuse-TORQ is roughly two times stronger in bending and requires 10 times the rotational resistance, or torque, to insert due to its porosity and other design features. We believe that this rotational resistance gives surgeons confidence in the strength of mechanical fixation that iFuse-TORQ provides, and that the technological advancements incorporated into iFuse-TORQ represent a significant improvement compared to conventional trauma screws. Furthermore, iFuse-TORQ has a larger surface area for bone ingrowth than competitive trauma products and was specifically designed to allow for osteointegration. The addition of iFuse-TORQ to our product portfolio will allow us to serve a significant unmet need for patients with pelvic trauma, as well as sacroiliac joint dysfunction and degeneration. In June 2022, the FDA provided clearance for an additional indication to include acute, non-acute and non-traumatic fractures. Fractures covered in this clearance include pelvic fragility fractures, which are fractures related to low-energy traumatic events, and pelvic insufficiency fractures.

We received FDA 510(k) premarket clearance for the iFuse-Bedrock Granite in May 2022. The iFuse-Bedrock Granite implant is a unique device designed to address the specific demands of adult deformity surgery by providing both sacroiliac joint fusion and sacropelvic fixation as a foundational element for segmental spinal fusion. iFuse-Bedrock Granite offers a differentiated implant option comprising a machined screw shank and an additively manufactured fusion sleeve. It is designed for both strength and biologic fixation with a porous surface, fenestrations or wholes through which bone can grow, and features for bone self-harvesting, and a robust deformity-specific tulip and set screw. This 510(k) clearance follows the earlier designation by the FDA of iFuse-Bedrock Granite as a Breakthrough Device and, most recently, a proposal by the Centers for Medicare and Medicaid Services, or CMS, for a New Technology Add-on Payment, or NTAP, both awards recognizing iFuse-Bedrock Granite as a new technology that can provide substantial clinical improvement over already available therapies.

Engage key opinion leaders

We conduct training courses in several academic centers in the U.S. and engage key opinion leaders to support our development efforts. Interest in the Bedrock technique among deformity surgeons, including many key opinion leaders, has provided our sales representatives with access to important academic medical centers in the U.S. This enables our representatives to train a broader group of spine surgeons, including residents and fellows at these centers, on both the Bedrock technique and minimally invasive sacroiliac fusion. To date, we have trained residents and fellows in over 195 academic programs in the U.S., resulting in the training of approximately 1100 surgical residents and fellows since August 1, 2018.

Leverage broad coverage

We made significant progress in the number of covered lives for minimally invasive sacroiliac fusion in the U.S.

As of June 30, 2022, substantially all U.S. payors reimburse for sacroiliac joint fusion. As of June 30, 2022, a significant number of U.S. payors have issued positive coverage policies exclusive to our patented design of triangular titanium implants for sacroiliac joint fusion because of the clinical evidence.

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. With recent payor decisions, over 300 million people in the U.S. now have access to minimally invasive SI joint fusion, representing nearly universal coverage of the procedure.

Components of Results of Operations

Revenue

We generate most of our revenue from sales of iFuse triangular titanium implants. Our revenue from sales of implants fluctuate based on volume of cases (procedures performed), discounts, mix of international and U.S. sales, different implant pricing 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, seasonality, and the impact of COVID-19. In addition, our revenue is impacted by changes in average selling price as we respond to the competitive landscape and price differences at different medical facilities, such as hospitals and ambulatory surgical centers, or ASCs. 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.

Starting March 2020, the impact of COVID-19 pandemic on our revenue has varied by period and region based on various factors, including stage of containment, resurgence of variants, success of regional vaccination campaigns, and associated government and hospital actions around elective procedures.

Cost of Goods Sold, Gross Profit, and Gross Margin

We utilize third-party manufacturers for production of our implants and instrument sets. Cost of goods sold consists primarily of costs of the components of implants and instruments, instrument set depreciation, royalties, 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.

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 returned to more normalized spending levels starting in the fourth quarter of 2020. We intend to make investments to execute our strategic plans and operational initiatives. We anticipate certain operating expenses will continue to increase to support our growth.

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, as well as certain commission guarantees paid to our senior sales management, direct territory sales managers, clinical support specialists and third-party distributors.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, clinical and regulatory expenses (including clinical study expenses), 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. 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, insurance, compliance, and administrative matters.

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 fees on the Solar and SVB Term Loans.

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,			
	2022		2021		2022		2021	
	Amount	%	Amount	%	Amount	%	Amount	%
	(in thousands, except for percentages)							
Consolidated Statements of Operations Data:								
Revenue	$ 25,585	100 %	$ 22,194	100 %	$ 48,024	100 %	$ 42,636	100 %
Cost of goods sold	3,465	14 %	2,375	11 %	6,448	13 %	4,575	11 %
Gross profit	22,120	86 %	19,819	89 %	41,576	87 %	38,061	89 %
Operating expenses:								
Sales and marketing	28,843	113 %	23,084	104 %	54,448	113 %	44,006	103 %
Research and development	3,478	14 %	3,149	14 %	7,058	15 %	6,104	14 %
General and administrative	7,680	30 %	6,551	30 %	14,819	31 %	12,491	29 %
Total operating expenses	40,001	157 %	32,784	148 %	76,325	159 %	62,601	147 %
Loss from operations	(17,881)	(71)%	(12,965)	(59)%	(34,749)	(72)%	(24,540)	(58)%
Interest and other income (expense), net:								
Interest income	136	1 %	46	— %	209	— %	107	— %
Interest expense	(622)	(2)%	(1,075)	(5)%	(1,183)	(2)%	(2,139)	(5)%
Other income (expense), net	(146)	(1)%	13	— %	(200)	— %	349	1 %
Net loss	$ (18,513)	(73)%	$ (13,981)	(64)%	$ (35,923)	(74)%	$ (26,223)	(62)%

We derive the majority of our revenue from sales to customers in the U.S. Revenue by geography is based on billing address of the customer. The table below summarizes our revenue by geography:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022		2021		2022		2021	
	Amount	%	Amount	%	Amount	%	Amount	%
	(in thousands except for percentages)							
United States	$ 23,771	93 %	$ 20,230	91 %	$ 44,137	92 %	$ 39,000	91
International	1,814	7 %	1,964	9 %	3,887	8 %	3,636	9
	$ 25,585	100 %	$ 22,194	100 %	$ 48,024	100 %	$ 42,636	100

Comparison of the Three Months Ended June 30, 2022 and 2021

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

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except for percentages)			
Revenue	$ 25,585	$ 22,194	$ 3,391	15%
Cost of goods sold	3,465	2,375	1,090	46%
Gross profit	$ 22,120	$ 19,819	$ 2,301	12%
Gross margin	86 %	89 %		

Revenue. The increase in revenue for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 comprised a $3.5 million increase in our U.S. revenue and a decrease of $0.1 million in our international revenue. The increase in revenue is due to the increase in domestic and international case volumes, higher number of sales personnel as we continue to invest in our sales organization and increased active surgeons. This increase was partially offset by lower average selling prices and impact of foreign exchange on our international revenue.

Gross Profit and Gross Margin. Gross profit increased $2.3 million for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021, mainly driven by higher revenue. The gross margin was 86% for the three months ended June 30, 2022 as compared to 89% for the three months ended June 30, 2021. Gross margin decreased in the second quarter 2022 due to an increase in cost of operations to support the growth of the business.

Operating Expenses:

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 28,843	$ 23,084	$ 5,759	25 %
Research and development	3,478	3,149	329	10 %
General and administrative	7,680	6,551	1,129	17 %
Total operating expenses	$ 40,001	$ 32,784	$ 7,217	22 %

Sales and Marketing Expenses. The increase in sales and marketing expenses for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was primarily due to (a) increases in employee related costs, commissions and stock-based compensation of $3.5 million driven by increased headcount and higher revenues, (b) as COVID-19 pandemic restrictions eased, we experienced higher levels of travel, marketing, training activities, facilities and other related costs resulting in an increase of $1.9 million and (c) higher consulting fees of $0.4 million associated with more surgeon training programs.

Research and Development Expenses. The increase in research and development expenses for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was primarily due to an increase of $0.2 million in employee related costs and stock-based compensation driven by increased headcount and an increase of $0.1 million due to increased consulting, clinical study, research and development activities and facilities costs.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was primarily due to an increase of $0.8 million in employee related costs and stock-based compensation driven by increased headcount and an increase of $0.3 million in consulting associated with SOX compliance requirements and employee training.

Interest and Other Income (Expense), Net:

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 136	$ 46	$ 90	196 %
Interest expense	(622)	(1,075)	453	(42)%
Other income (expense), net	(146)	13	(159)	(1223)%
Total interest and other expense, net	$ (632)	$ (1,016)	$ 384	(38)%

Interest Income. The increase in interest income for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was mainly due to higher interest earned on our investments in marketable securities, primarily as a result of higher interest rates.

Interest Expense. The decrease in interest expense for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was primarily due to lower interest associated with the SVB Term Loan compared to the Solar Term Loan.

Other Income (Expense), Net. Other income, net decreased for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 due to foreign currency fluctuations.

Comparison of the Six Months Ended June 30, 2022 and 2021

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

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except for percentages)			
Revenue	$ 48,024	$ 42,636	$ 5,388	13 %
Cost of goods sold	6,448	4,575	1,873	41 %
Gross profit	$ 41,576	$ 38,061	$ 3,515	9 %
Gross margin	87 %	89 %		

Revenue. The increase in revenue for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 comprised a $5.1 million increase in our U.S. revenue and an increase of $0.3 million in our international revenue. The increase in revenue is due to the increase in domestic and international case volumes, higher number of sales personnel as we continue to invest in our sales organization and increased active surgeons. This increase was partially offset by lower average selling prices and the impact of foreign exchange on our international revenue.

Gross Profit and Gross Margin. Gross profit increased $3.5 million for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021, mainly driven by higher revenue. The gross margin was 87% for the six months ended June 30, 2022 as compared to 89% for the six months ended June 30, 2021. Gross margin decreased in the second quarter 2022 due to an increase in cost of operations to support the growth of the business.

Operating Expenses:

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 54,448	$ 44,006	$ 10,442	24 %
Research and development	7,058	6,104	954	16 %
General and administrative	14,819	12,491	2,328	19 %
Total operating expenses	$ 76,325	$ 62,601	$ 13,724	22 %

Sales and Marketing Expenses. The increase in sales and marketing expenses for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 was primarily due to (a) increases in employee related costs, commissions and stock-

based compensation of $6.5 million driven by increased headcount and higher revenues, (b) as COVID-19 pandemic restrictions eased, we experienced higher levels of travel, marketing, training activities, facilities and other related costs resulting in an increase of $3.4 million and (c) higher consulting fees of $0.5 million associated with more surgeon training programs and surgeon consulting fees.

Research and Development Expenses. The increase in research and development expenses for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was primarily due to an increase of $0.6 million in employee related costs and stock-based compensation driven by increased headcount and an increase of $0.3 million due to increased clinical study, research and development activities and facilities costs.

General and Administrative Expenses. The increase in general and administrative expenses for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was primarily due to an increase of $1.7 million in employee related costs and stock-based compensation driven by increased headcount and an increase of $0.6 million in consulting, employee training, legal, accounting and audit fees associated with SOX compliance requirements.

Interest and Other Income (Expense), Net:

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 209	$ 107	$ 102	95 %
Interest expense	(1,183)	(2,139)	956	(45)%
Other income (expense), net	(200)	349	(549)	(157)%
Total interest and other expense, net	$ (1,174)	$ (1,683)	$ 509	(30)%

Interest Income. The increase in interest income for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 was mainly due to higher interest earned on our investments in marketable securities, primarily as a result of higher interest rates.

Interest Expense. The decrease in interest expense for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 was primarily due to lower interest associated with the SVB Term Loan compared to the Solar Term Loan.

Other Income (Expense), Net. Other income, net decreased for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 due to foreign currency fluctuations.

Liquidity and Capital Resources

As of June 30, 2022, we had cash and marketable securities of $114.4 million compared to $147.0 million as of December 31, 2021. We have financed our operations primarily through our public offerings and debt financing arrangements. As of June 30, 2022, we had $35.1 million in outstanding debt, compared to $35.0 million as of December 31, 2021 .

As of June 30, 2022, we had an accumulated deficit of $331.8 million, compared to $295.8 million as of December 31, 2021. During the six months ended June 30, 2022, we incurred a net loss of $35.9 million. During the years ended December 31, 2021 and 2020, we incurred a net loss of $56.6 million and $43.7 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 over the next 12 months and beyond. 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 risks and uncertainties in our future available capital resources. Further, we may face challenges and uncertainties and, as a result, may need to raise additional capital as 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

In May 29, 2020, we entered into a term loan with Solar Capital Partners ("Solar"). Pursuant to the Loan and Security Agreement, Solar provided an aggregate principal amount of $40.0 million term loan (the "Solar Term Loan"). We paid in full and terminated the Solar Term Loan in August 2021.

The outstanding debt as of June 30, 2022 and December 31, 2021 is related to a term loan pursuant to the Loan and Security Agreement dated August 12, 2021 (the "Effective Date"), entered into by us with Silicon Valley Bank ("SVB"). Pursuant the agreement, SVB provided an aggregate principal amount of $35.0 million to us (the "SVB Term Loan"). We used the proceeds of the SVB Term Loan to repay in full and terminate the Solar Term Loan, which was accounted for as debt extinguishment in accordance with the accounting standards. We recognized the unamortized debt issuance costs and unaccreted value of final fee of $1.3 million and the prepayment penalty and lender fees of $0.5 million related to Solar 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 year ended December 31, 2021. The total debt issuance costs of $0.1 million associated with the SVB 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 SVB Term Loan matures (the "Maturity Date") on either (a) August 1, 2025 or (b) August 1, 2026 dependent on our achievement of a certain financial performance milestone as of December 31, 2022, as set forth in the Loan Agreement. Interest on the SVB Term Loan is payable monthly at an annual rate set at the greater of (a) 5.75% and (b) prime rate as published in the Wall Street Journal plus 2.5%. Commencing on September 1, 2023, we will be required to make monthly principal amortization payments. We may elect to prepay the SVB Term Loan prior to the Maturity Date subject to a prepayment fee equal to 1% if the prepayment occurs prior to the second anniversary of the Effective Date and 0% if the prepayment occurs on or at any time after the second anniversary of the Effective Date. The SVB Term Loan is secured by substantially all our assets other than our intellectual property. We are also obligated to pay a final payment equal to $0.7 million or 2% of the aggregate principal amount of the SVB Term Loan, which is considered fully earned by SVB on the effective date of the Loan and Security Agreement with SVB. This final payment shall be due and payable on the earliest of (i) the maturity date, (ii) the full repayment of the loan, (iii) permitted prepayment and mandatory prepayment upon an acceleration as specified in the agreement or (iv) the termination of the agreement. The final payment is included within the long-term borrowings and is accreted to interest expense using straight-line method over the life of the term loan.

The Loan Agreement includes affirmative and negative covenants applicable to us and certain of its foreign subsidiaries. The affirmative covenants include, among others, covenants requiring us to maintain its legal existence and governmental compliance, deliver certain financial reports, and maintain insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging our intellectual property to other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions. As of June 30, 2022, we were in compliance with all debt covenants.

Our material cash requirements include various contractual and other obligations consisting of long-term debt obligations with SVB, operating lease obligations and purchase obligations with some of our suppliers and have not changed materially since the 2021 Form 10-K filed with the SEC on March 1, 2022. As of June 30, 2022, expected timing of those payments are as follows:

		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)	$ 35,700	$ —	$ 24,792	$ 10,908	$ —
Interest obligations (2)	5,477	1,297	3,933	248	—
Operating lease obligations	5,383	800	3,054	1,522	8
Purchase obligations	611	611	—	—	—
Total	$ 47,171	$ 2,707	$ 31,779	$ 12,678	$ 8

(1) Represents the principal obligations and the final fee at maturities of our SVB Term Loan.
(2) Represents the future interest obligations on our SVB Term Loan estimated using an interest rate of 7.25% as of June 30, 2022.

This compared to $48.4 million of contractual obligations as of December 31, 2021 .

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,		
	2022	2021	$ Change
Net cash provided by (used in):	(in thousands)		
Operating activities	$ (28,353)	$ (17,510)	$ (10,843)
Investing activities	(11,631)	9,449	(21,080)
Financing activities	1,398	2,817	(1,419)
Effects of exchange rate changes on cash and cash equivalents	(514)	(212)	(302)
Net decrease in cash and cash equivalents	$ (39,100)	$ (5,456)	$ (33,644)

Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2022 of $28.4 million resulted from cash outflows due to a net loss of $35.9 million, adjusted for $13.5 million of non-cash items, and cash outflows from net changes in operating assets and liabilities of $5.9 million. Net cash used in operating activities for the six months ended June 30, 2021 of $17.5 million resulted from cash outflows due to a net loss of $26.2 million, adjusted for $10.2 million of non-cash items, and cash outflows from changes in operating assets and liabilities of $1.5 million. The increase in net loss, net of non-cash items for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was mainly due to higher operating expenses from the growth of the business. Net cash outflows from changes in operating assets and liabilities for the six months ended June 30, 2022 were primarily due to higher inventory due to the timing of inventory build-up related to our iFuse-TORQ and iFuse-Bedrock Granite implants, higher accounts receivable due to timing of collections and higher accrued liabilities and others driven by the timing of other third-party payments and higher compensation and benefits accruals, partly offset primarily by lower accounts payable and prepaid expenses and other assets attributable primarily to the normal course timing of expenses. Net cash outflows from changes in operating assets and liabilities for the six months ended June 30, 2021 were primarily due to higher inventory due to the timing of inventory build-up related to our iFuse-TORQ and iFuse-Bedrock Granite implants, timing of vendor payments, partly offsets by timing of collections of account receivables.

Cash Flows From Investing Activities

Net cash used in investing activities in the six months ended June 30, 2022 was $11.6 million compared to cash provided by investing activities of $9.4 million in the six months ended June 30, 2021. Net cash used in investing activities for the six months ended June 30, 2022 consisted of purchases of our marketable securities, net of maturities of $7.3 million, and purchases of property and equipment of $4.3 million primarily related to individual components in instrument sets to support revenue growth, as well as leasehold improvements made to the building used for research and development and warehouse space in Santa Clara. Net cash provided by investing activities for the six months ended June 30, 2021 consisted of maturities of our marketable securities, net of purchases of $13.6 million and purchase of property and equipment of $4.2 million primarily related to individual components in instrument sets as we anticipated increased case volumes.

Cash Provided by Financing Activities

Cash provided by financing activities in the six months ended June 30, 2022 was $1.4 million compared to $2.8 million in the six months ended June 30, 2021. For both periods, the cash provided was from the proceeds from the issuance of common stock under our stock-based incentive compensation plans.

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 1, 2022. There had been no material changes to the descriptions of these accounting policies, judgments and estimates. See Note 2 of Notes to Condensed Consolidated Financial Statements (Unaudited) for related discussions on updates on recently issued accounting pronouncements.

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.

Recent Accounting Pronouncements

See Note 2 of Notes to Condensed Consolidated Financial Statements (Unaudited) for related discussions on updates on recently issued accounting pronouncements not yet effective.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks, including changes to foreign currency exchange rates and interest rates.

Foreign Currency Exchange Risk

We have foreign currency risks related to our revenue and operating expenses denominated in currencies other than the U.S. dollar, primarily the Euro. Accordingly, changes in exchange rates, and in particular a strengthening of the U.S. dollar, have in the past, and may in the future, negatively affect our revenue and other operating results as expressed in U.S. dollars.

We have experienced and will continue to experience fluctuations in net loss as a result of transaction gains or losses related to remeasuring certain current asset and current liability balances denominated in currencies other than the functional currency of the entities in which they are recorded. At this time, we have not entered into, but in the future we may enter into, derivatives or other financial instruments in an attempt to hedge our foreign currency exchange risk. It is difficult to predict the effect hedging activities would have on our results of operations. Foreign currency gains or losses, net recognized in the six months ended June 30, 2022 and 2021 were not material.

Interest Rate Risk

Our exposure to changes in interest rates relates to interest earned and market value on our cash and cash equivalents and short-term investments. Our cash and cash equivalents and short-term investments consist of cash, money market funds, U.S. government securities, commercial paper and investment grade corporate debt securities. The market value of our marketable securities may decline if current market interest rates rise. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements. We do not make investments for trading or speculative purposes.

Interest rate risk also reflects our exposure to movements in interest rates associated with our long-term debt that bears interest at an annual rate set at the greater of (a) 5.75% and (b) prime rate as published in the Wall Street Journal plus 2.5%. Rising interest rates will increase the amount of interest paid on this debt.

A hypothetical 100 basis point increase in interest rates would decrease the fair market value of our investment portfolio by $0.3 million for the six months ended June 30, 2022. Such losses would only be realized if we sold the investments prior to maturity.

A hypothetical 100 basis point increase in interest rates would increase the interest owed on our debt by $0.2 million for the six months ended months ended June 30, 2022.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

As of June 30, 2022, our management, with the participation of our Chief Executive Officer ("CEO") and our Chief Financial Officer ("CFO"), have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Based on that evaluation, our CEO and our CFO have concluded that, as of June 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

During the quarter ended June 30, 2022, there were no changes in our internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are involved in various claims, complaints, investigations and legal actions that arise from time to time in the normal course of business, including commercial and employment matters. There are no matters pending that we currently believe are material. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, financial condition or results of operations.

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.

Risk Factor Summary

- 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;
- Epidemic diseases, or the perception of their effects, may have (or, in the case of the COVID-19 pandemic, will continue to have during its duration) an adverse effect on our business, financial condition, results of operations, or cash flows;
- Prolonged inflation and supply chain disruptions could result in delayed product launches, lost revenue, higher costs and decreased profit margins;
- Disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products by third-party suppliers could adversely affect our business, financial condition and results of operations;
- If hospitals, surgeons, and other healthcare providers are unable to obtain and maintain adequate or any coverage and reimbursement from third-party payors for procedures performed using our products, further adoption of our products may be delayed, and it is unlikely that they will gain further acceptance, and the prices paid for our implants may decline;
- 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;
- 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 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;
- Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the presence of "physician-owned distributorships" may impact our ability to sell our product at prices necessary to support our current business strategies;
- Practice trends or other factors, including the COVID-19 pandemic, may cause procedures to shift from the hospital environment to ambulatory surgical centers, or ASCs, where pressure on the prices of our products is generally more acute;
- 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;
- We are highly dependent on revenue from the sale of a single family of products focused on procedures, the goal of which is to stabilize and fuse the sacroiliac joint. Reliance on a single family of products and single family of procedures could negatively affect our results of operations and financial condition;
- If clinical experience with our iFuse Bedrock technique or iFuse Bedrock Granite does not result in positive outcomes for patients, or if clinical trials involving the use of iFuse Bedrock and/or iFuse Bedrock Granite fail to show meaningful patient benefit, sales of our iFuse and/or iFuse Bedrock Granite implants could be adversely impacted;

- 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;
- Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel;
- If use of our products results in adverse events, this may require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- Various factors outside our direct control may adversely affect manufacturing, sterilization, and distribution of our products;
- 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, 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;
- We and our sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to healthcare provider kickbacks and false claims for reimbursement, and other applicable federal and state healthcare laws, as well as equivalent foreign laws, and failure to comply could negatively affect our business;
- 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;

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, 2022, we had a net loss of $35.9 million. For the years ended December 31, 2021 and 2020, we had net losses of $56.6 million and $43.7 million, respectively. As of June 30, 2022, we had an accumulated deficit of $331.8 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. 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, investment in implants and instruments, and the timing and extent of spending on the development of our technology to increase our product offerings, and potential investment in additional product and service offerings through the acquisition of other businesses. We may need additional funding for 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. In the past six months, capital markets have deteriorated substantially, especially with respect to securities issued by companies in the medical device and technology sectors. Equity and debt capital have become substantially more expensive and difficult to raise on attractive terms. 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, may have (or, in the case of the COVID-19 pandemic, will continue to have during its duration) an 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 COVID-19 pandemic could also negatively affect hospital admission rates and the decision by patients to undergo elective surgery, which could decrease demand for procedures using our 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, 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 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 measures, we have experienced and expect to continue to experience significant and unpredictable reductions in the demand for our products, negative impact on hospital admission rates and delay in the decision by patients to undergo elective surgery, each of which has decreased and may continue to impact the demand for procedures using our implants. There are numerous uncertainties associated with the COVID-19 pandemic, including the number of individuals who will become infected, the effectiveness of vaccines or one or more therapies that mitigate the effect of the virus, the availability of vaccines and the vaccination rates in the U.S. and worldwide, the emergence of variants of the COVID-19 virus such as the delta and omicron variants, 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, 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 pandemic. However, these uncertainties may result in delays or modifications to these plans and initiatives.

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 providing education and support.

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 increase 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 long-term impacts on our operations and financial results.

The existence and further duration of the COVID-19 pandemic may also further exacerbate certain of the risks as described in this “Item 1A - Risk Factors” of this Quarterly Report on Form 10-Q.”

Prolonged inflation and supply chain disruptions could result in delayed product launches, lost revenue, higher costs and decreased profit margins.

A majority of our products are manufactured and sold inside of the United States, which increases our exposure to domestic inflation and fuel price increases. Recent inflationary pressures have resulted in increased fuel, raw materials and other costs which, if they continue for a prolonged period, may adversely affect our results of operations. We have experienced shortages in certain raw materials and component inputs of our products, primarily surgical instruments, as suppliers have been unable to meet delivery schedules due to excess demand and labor shortages, and lead times have lengthened throughout our supply chain. Our efforts to mitigate supply chain weaknesses may not be successful or may have unfavorable effects. For example, efforts to purchase raw materials in advance for product manufacturing may result in increased storage costs or excess supply. If our costs rise due to continuing significant inflationary pressures or supply chain disruptions, we may not be able to fully offset such higher costs through price increases. In addition, delays in obtaining materials, components or instruments from our suppliers could delay product launches or result in lost opportunities to sell our products due to their availability. Increased costs and decreased product availability due to supply chain issues could adversely impact our revenue and/or gross margin, and could thereby harm our business, financial condition, and results of operation.

Disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products by third-party suppliers could adversely affect our business, financial condition and results of operations.

Our suppliers purchase many of the materials and components used in the manufacture of our products from third-party suppliers. Certain of these materials and components can only be obtained from a single source or a limited number of sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. In certain cases, our suppliers may not be able to establish additional or replacement suppliers for such materials or components or outsourced activities in a timely or cost effective manner. A reduction or interruption in the supply of materials or components used in manufacturing our products, such as due to one or more suppliers experiencing reductions in operations and/or worker absences due to the COVID-19 pandemic or other health epidemics, an inability to timely develop and validate alternative sources if required, or a significant increase in the price of such materials or components could adversely affect our business, financial condition and results of operations. For example, certain of our products require titanium, which is sourced from third-party suppliers. While the titanium required for such products is not directly sourced from Russia, the current geopolitical events involving Russia and Ukraine are negatively impacting the wider titanium supply chain and such geopolitical events and factors relating thereto or resulting therefrom, including related sanctions, may negatively impact the ability of our suppliers' third-party supply sources to timely supply titanium to our suppliers and may increase or result in additional costs to us.

In addition, many of our products require sterilization prior to sale, and our suppliers use contract sterilizers to perform this service. To the extent that these contract sterilizers are unable to sterilize our products, whether due to capacity, availability of materials for sterilization, regulatory or other constraints, including reductions in operations and/or worker absences due to the COVID-19 pandemic or other health epidemics, we may be unable to transition to other contract sterilizers, sterilizer locations or sterilization methods in a timely or cost effective manner or at all, which could have a material impact on our results of operations and financial condition.

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

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. When a procedure using our implants is performed, both the surgeon and the healthcare facility, either a hospital or ambulatory surgical center, submit claims for reimbursement to the healthcare payor. 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 by healthcare facilities or to compensate surgeons for their time spent diagnosing patients and performing procedures using our products.

While all Medicare Administrative Contractors are regularly reimbursing for minimally invasive sacroiliac joint fusion, some private payors still have policies that treat the procedure as experimental or investigational and do not regularly reimburse for the procedure. Future action by the Centers for Medicare & Medicaid Services ("CMS") or third-party payors may further reduce the availability of payments to physicians, outpatient surgery centers, and/or hospitals for procedures using our products.

The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they chose to cover. 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.

Effective January 1, 2022, the Medicare physician fee reimbursement for minimally invasive fusion with our iFuse implants, described as CPT Code 27279, is $860. Commercial payors generally set their physician fee reimbursement with reference to Medicare reimbursement rates. 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. 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.

The American Medical Association (AMA) develops and maintains Current Procedural Terminology (CPT) codes that are used by third-party payors to determine the amount of reimbursement that a healthcare provider and facility will receive for a particular

service. CPT codes are divided into three categories: Category I codes represent existing services or procedures that are widely used. Category II codes are supplemental tracking codes, and Category III codes are temporary codes that represent new technologies, services, and procedures. A Category III code does not have a payment rate established and reimbursement is at the payor's discretion. CPT Code 27279, which describes minimally-invasive surgical fusion of the sacroiliac joint performed with our iFuse implants, is a Category I CPT code. As the number of products and surgical procedures to address sacroiliac joint dysfunction has expanded and diversified, we are aware that certain medical societies have requested that the AMA create a Category III CPT code representing some of these unproven technologies. If either the current or future procedures performed with our products are determined to be best described by a Category III CPT code, or if the levels of reimbursement for, and consistency of coverage associated with, procedures performed with our medical devices, either under the existing Category I CPT Code or under any newly created Category I or III CPT Code, could decrease which could make the procedures we support less attractive to healthcare professionals using our products.

Recent political, economic, and regulatory influences are subjecting the healthcare industry to fundamental changes that can impact coverage and reimbursement from third-party payors. We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, 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. CMS budget neutrality requirements may impose cuts to the Medicare physician fee schedule, which may be mitigated by acts of Congress or other changes to regulations. Other federal laws, known as budget sequestration, further reduce Medicare's payments to providers by two percent through 2030. However, COVID-19 relief support legislation suspended the 2% Medicare reductions from May 1, 2020 through April 1, 2022, and reduced the Medicare reductions to 1% from April 1 to June 30, 2022. 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, which could adversely affect our business, results of operations and financial condition.

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 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, 2022, a significant number of the largest U.S. payors that we track and target have issued positive coverage policies covering the patented design of our triangular 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 triangular titanium implants and the lack of clinical evidence supporting the use of other products. 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. 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, our triangular iFuse implants. Payors could also abandon their decisions to cover triangular implants exclusively for other reasons.

Healthcare payors which have adopted sacroiliac joint fusion coverage policies exclusive to titanium triangles could reverse the exclusive nature of their policies and allow surgeons to use other types of products when performing sacroiliac fusion procedures. For example, on April 1, 2022, AIM, a clinical evidence evaluation organization which influences Anthem, among other payors, promulgated such a policy that is no longer exclusive to titanium triangles and which will become effective September 1, 2022. If healthcare payors covering a significant number of covered lives reverse their policies of covering minimally invasive sacroiliac joint fusion exclusively when performed with triangular titanium implants, sales of our triangular 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 demonstrate to 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 demonstrating the merits of iFuse to surgeons, 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. 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, allografts, 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 because they feel these interventions are superior or because they have a financial interest in offering additional treatments to these patients. If we are unable to demonstrate to potential referring health care providers 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 United States have either received premarket clearance under Section 510(k) of the United States. 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. 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.

Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the presence 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 and revenue down and harm our ability to market and sell our products.

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.

Practice trends or other factors, including the COVID-19 pandemic, may cause procedures to shift 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. We anticipate that this trend will nevertheless continue as a cost control measure with the healthcare system. 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. In addition, ASC are generally more economically favorable site of service, and surgeons performing the procedures sometimes have ownership interests in the ASC. Because ASC facility fee reimbursement is typically less than facility fee reimbursement for hospitals and due to surgeons' economic interest in ASCs, 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. In addition, some surgeons may choose to use fewer implants due to their interest in the profitability of the ASC. 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 United States 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 addition, if these competitors use technology, contracts, or intellectual property measures to limit or eliminate the compatibility of their surgical imaging, navigation and robotic systems with our products, sales of our products could decline or fail to grow, which could adversely affect our business and results of operations.

In the United States, we believe that our primary competitors marketing implantable devices currently are Medtronic plc and Globus Medical, Inc. In addition, a number of smaller companies selling allograft implants to a variety of physicians have collectively become a larger presence in our market. Our primary competitors in Europe are Globus Medical, Inc. and SIGNUS Medizintechnik GmbH. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of the sacroiliac joint that compete directly or indirectly with our products. They may also develop and patent processes or products earlier than we can, or obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for competing products in the European Economic Area ("EEA"), more rapidly than we can, which could impair our ability to develop

and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products and our results of operations could be negatively affected.

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 are highly dependent on revenue from the sale of a single family of products focused on procedures, the goal of which is to stabilize and fuse the sacroiliac joint. Reliance on a single family of products and single family of procedures could negatively affect our results of operations and financial condition.

Substantially all of our revenue comes from the sale of iFuse, iFuse-3D and iFuse-TORQ implants, and related tools and instruments. Therefore, we are 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 or iFuse Bedrock Granite does not result in positive outcomes for patients, or if clinical trials involving the use of iFuse Bedrock and/or iFuse Bedrock Granite fail to show meaningful patient benefit, sales of our iFuse and/or iFuse Bedrock Granite implants could be adversely impacted.

In November 2018, we introduced our iFuse Bedrock technique, in which spine surgeons place iFuse triangular 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. In May 2022, we introduced iFuse Bedrock Granite, an implant which fuses the sacroiliac joint and attaches to the rods placed in a multi-segment spinal fusion construct, and which is used in substantially similar procedures to the iFuse Bedrock Technique. To date, clinical experience with the iFuse Bedrock technique and with iFuse Bedrock Granite is limited and we have yet to complete a clinical trial to evaluate the iFuse Bedrock technique or the iFuse Bedrock Granite implant. Surgeons do not know if the addition of sacroiliac fusion devices to the implants used to fuse multiple levels of the lumbar spine will result in patient benefit. If surgeons' clinical experience with our implants in these procedures 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, 2022, our U.S. sales force consisted of 85 territory sales managers and 76 clinical support specialists directly employed by us, and 73 third-party distributors. As of June 30, 2022, our international sales force consisted of 18 sales representatives directly employed by us and 30 third-party distributors, which together have had sales in 38 countries through June 30, 2022. 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. 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 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.

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. 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 business is highly reliant on a base of skilled employees, including those serving in engineering, information technology, operational, strategic marketing and sales functions. Many of these employees have developed specialized skills which are valuable within the medical device and life sciences industry, and, in some cases, in a broader variety of industries. Competition for skilled employees is significant, and some of the labor markets we compete in have experienced tightening in the past year. In addition, rates of employee turnover have increased among our employees, consistent with the rates experienced by other companies in these industries. If these conditions persist, we could experience further turnover among our employees which could become difficult and more costly to manage, adversely impacting our results of operation. Sustained pressure in these labor markets could also cause prevailing wages to rise, which could adversely impact our business and results of operation and financial condition.

If use of our products results in adverse events, this 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.

Unfavorable media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our products.

We introduced iFuse Bone, an implantable bone product manufactured from sterilized recovered cadaveric bone tissue, to meet the demand of some of our surgeon customers to use implantable bone products to support and augment the patient's own bone tissue in orthopedic procedures. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to the transmission of disease, may affect the rate of future tissue donation and market acceptance of technologies incorporating human tissue. In addition, negative publicity could cause the families of potential donors to become reluctant to donate tissue to for-profit tissue processors. These reports could have a negative effect on sales of iFuse Bone.

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 depend on for quality control and release of products;
- large-scale epidemics of communicable diseases such as COVID-19;
- supply chain disruptions, including those caused by material and labor supply shortages in the wake of 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, including our implants, 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 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 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, raw materials and components, or experience significant delays in obtaining them, resulting in an interruption in the manufacture, assembly and shipment of our systems;

- we or our third-party manufacturers could experience plant closures due to 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 and to launch new 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 and 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. A local outbreak of COVID-19 cases, 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 products 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 and related markets, we must enhance and broaden our product offerings in response to 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 addition, as we introduce new implants and instruments with the same intended uses as existing products, the older products may fall out of favor with our customers, causing them to become obsolete. 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. 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 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;
- inability of the local healthcare system to absorb prices for our product that would enable our business to become profitable in those markets;
- 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;
- insufficient numbers of patients requiring procedures that use our products;
- 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.

Like other public companies, we have in the past, and could be in the future, subject to instances of phishing attacks on our email systems, other cyber-attacks, industrial espionage, insider threats, computer denial-of-service attacks, computer viruses, ransomware and other malware, wire fraud or other cyber incidents. The techniques used to obtain unauthorized access, or to sabotage systems, are becoming more sophisticated, frequent and adaptive, and therefore we may be unable to anticipate these techniques or to implement adequate preventative measures. Any security breach could result in: the unauthorized publication of our confidential business or proprietary information; the unauthorized release of employee, customer or vendor data and payment information; a loss of confidence by our customers; damage to our reputation; a disruption to our business; litigation and legal liability; and a negative impact on our future sales. In addition, the cost and operational consequences of implementing further data protection or data restoration measures could be significant.

In addition, we accept payments for many of our sales through credit card transactions, which are handled through third-party payment processors. 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 processors are breached. We and our third-party credit card payment processors 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 processors 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 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.

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

On August 12, 2021, we entered into a Loan and Security Agreement with Silicon Valley Bank (“SVB”), pursuant to which we borrowed $35.0 million pursuant to a term loan (the “SVB Term Loan”). The Loan and Security Agreement with SVB contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on SVB's security interest over the collateral, a material adverse change, the occurrence of a default under certain other indebtedness incurred by us or our subsidiaries, the rendering of certain types of judgments against us and our subsidiaries, the revocation of certain government approvals, violation of covenants, and incorrectness of representations and warranties in any material respect.

The SVB Term Loan is secured by substantially all our assets other than our intellectual property. The Loan and Security Agreement with SVB includes affirmative and negative covenants applicable to us and certain of our foreign subsidiaries. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental compliance, deliver certain financial reports, and maintain insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging our intellectual property to other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions.

The covenants in the SVB 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. If not waived, future defaults could cause all of the outstanding indebtedness under our Loan and Security Agreement with SVB 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.

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., a single regulatory approval process exists, and conformity with its requirements is required to affix a CE mark to our medical devices, without which they cannot be marketed or sold in the EEA. To obtain a CE mark, defined products must meet minimum standards of performance, safety, and quality, and then, according to their classification, undergo a conformity assessment procedure. Except for low risk medical devices, a conformity assessment procedure requires the intervention of a third-party organization designated by the competent authorities of a EEA country, known as a Notified Body. The competent authorities of the E.U. countries separately regulate the clinical research for medical devices and the market surveillance of products once they are placed on the market. A new Medical Device Regulation was published by the E.U. in 2017 and became effective on May 26, 2021. Medical devices marketed in the EEA will require certification according to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directives before May 2020, can be placed on the market until May 2024. The new EU MDR includes significant additional premarket and post-market requirements. Penalties for regulatory non-compliance could be severe, including fines and revocation or suspension of a company's business license, mandatory price reductions and criminal sanctions.

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 healthcare provider kickbacks and false claims for reimbursement, and other applicable federal and state healthcare laws, as well as equivalent foreign laws, and failure to comply could negatively affect our business.

Healthcare providers, distributors 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. 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 comply 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 1, 2022.

Certain states also have enacted analogous state and foreign law equivalents of each of the above federal laws and certain states may 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. Many of these state laws 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 significant 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 physicians and healthcare executives, including some who are customers. We also engage in co-marketing arrangements with certain surgeons who use our products. In addition, prior to our IPO, a small number of our current customer surgeons 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 to comply with 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.

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. To enforce compliance with the federal laws, the U.S. Department of Justice has continued 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 for billing, reimbursement support, marketing purposes, post-marketing safety vigilance, servicing potential warranty claims and during the course of clinical trials. 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 1, 2022.

The California Consumer Privacy Act ("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. 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. Our compliance costs and potential liability with respect to personal information may also increase in response to other states adopting and considering initiative regarding protection of personal

information. In March 2021, Virginia passed the Consumer Data Protection Act ("CDPA") which will take effect on January 1, 2023. Virginia is the second state to pass comprehensive privacy litigation. Colorado passed the Colorado Privacy Act ("CPA") on July 7, 2021 with enforcement to begin on July 1, 2023. In 2022, both Utah and Connecticut also enacted comprehensive data privacy legislation. While these laws are similar in certain respects, the laws differ and compliance with one law does not equate to compliance with the other laws. Several other states (including Washington, New York, and Minnesota) also are considering comprehensive privacy legislation that could further complicate and increase the cost of complying with various state privacy laws. If states pass a patchwork of privacy laws, this also could increase pressure on the U.S. Congress to harmonize privacy laws through federal legislation.

We have in the past, and could be in the future, subject to data breaches. 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.

For any product for which we obtain regulatory clearance or approval, or a CE Certificate of Conformity, 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 ("ISO") 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.

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 which could result in regulatory sanctions and serious harm to our reputation. 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. In the EEA, we must report serious incidents and field safety corrective actions through the Commission's electronic system on vigilance and post-market surveillance, which reports are transmitted to the competent authority of the Member State in which the incident occurred.

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.

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, 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. 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 De Novo 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 De Novo 510(k) or PMA application for our possible future products or to support a conformity assessment procedure for 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 and support staff, the proximity of patients to clinical sites, and the ability 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 occurrence of adverse events.

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 events 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 entered 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. 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.

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

Another example can be found in the EEA. The Medical Devices Regulation ("MDR") entered into application on May 26, 2021. MDR introduced substantial changes to the obligations with which medical device manufacturers must comply in the EEA. 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 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 also substantially impacts 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 Medical Device Directive, and implementing legislation in each EU Member State, to regulation under the Medical Devices Regulation has required and will continue to 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. For example, pursuant to guidance issued by the UK Government as a result of the UK formally withdrawing from the European Union, the Medicines and Healthcare products Regulatory Agency ("MHRA") became the standalone medicines and medical devices regulator for the UK as of January 1, 2021. A new mark referred to as "UKCA" (UK Conformity Assessed) has also been introduced and will replace the CE conformity mark. Although CE conformity marketing and certificates issued by Notified Bodies will continue to be recognized in the UK through June 2023, all medical devices must be registered with the MHRA as of January 1, 2021. Complying with this new regulatory framework will require us to invest in additional resources and could be expensive, time-consuming and disruptive to our existing operations in the UK.

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 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. We own and operate certain x-ray equipment at our facilities which requires adoption of a radiation safety plan. Our failure to follow such safety plan or otherwise use this equipment properly could be hazardous to our employees and expose us to liability as the employer. 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.

Certain of our products are derived from human tissue and are or could be subject to additional regulations and requirements.

Our iFuse Bone product is derived from human bone tissue, and as a result is subject to FDA and certain state regulations regarding human cells, tissues and cellular or tissue-based products, or HCT/Ps. To date, iFuse Bone is our only HCT/P product, and as a product regulated under Section 361 of the Public Health Service Act, we have not been required to file a 510(k) with respect to iFuse Bone. However, the FDA could require us to obtain a 510(k) clearance for future tissue products not regulated as 361 HCT/Ps. The process of obtaining a 510(k) clearance could take time and consume resources, and failing to receive such a clearance would render us unable to market and sell such products, which could have a material and adverse effect on our business.

In addition, procurement of certain human organs and tissue for transplantation is subject to the National Organ Transplant Act, or NOTA, which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment for costs associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses and costs associated with development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses we can recover in our pricing for our products, thereby reducing our future revenue and profitability. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.

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, 2022, we owned 48 issued U.S. patents and had 38 pending U.S. patent applications, and we owned 15 issued foreign patents and had 19 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 November 2024. Competitors may market similar triangular shaped devices upon the expiration of the patents in late 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, 2022, we have 18 registered trademarks in the U.S. and have filed for 10 more. We have sought protection for at least two of these trademarks in 60 countries including the 27 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.

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;
- changes in interest rates, investor risk appetite and other macroeconomic factors impacting the market for securities issued by medical device companies;
- the risk of inflation, interest rate increases and other macroeconomic factors impacting patients' economic ability and likelihood of undergoing elective procedures, whether real or as perceived by investors;

- 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, 2021, we had net operating loss ("NOL") carryforwards of $255.5 million and $203.2 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in 2029 and 2022, 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. At 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 updated our Section 382 ownership change analysis through December 31, 2020. The analysis determined that we have experienced Section 382 ownership changes in 2010 and 2020. A total of $1.4 million of our NOLs and tax credit carryforwards are subject to limitation as a result of the ownership change.

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. On February 9, 2022, California Senate Bill 133 (SB 133) was signed into law. The new bill lifted the limitation for California NOL and credit utilization disallowed by AB 85. We will continue to monitor the possible California NOLs and credit limitation in future periods

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

Nothing to report.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

On June 16, 2022, we held our 2022 Annual Meeting of Stockholders, at which our stockholders voted, on an advisory basis, that the stockholders be able to cast an advisory vote on the description of the compensation paid to our named executive officers each year. We have determined, in light of and consistent with the advisory vote of our stockholders as to the preferred frequency of stockholder advisory votes on executive compensation, to include a stockholder advisory vote on executive compensation in our annual meeting proxy materials in each of the next six years. Under Section 14A(a)(2) of the Securities Exchange Act of 1934, as amended, we will hold the next non-binding advisory vote on the frequency of future stockholder advisory votes to approve our executive compensation no later than our 2028 Annual Meeting of Stockholders.

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.				
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 Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Santa Clara, California, on August 9, 2022.

SI-BONE, Inc.

Date: August 9, 2022

By: /s/ Laura A. Francis

Laura A. Francis

Chief Executive Officer

(Duly Authorized Officer and Principal Executive Officer)

SI-BONE, Inc.

Date: August 9, 2022

By: /s/ Anshul Maheshwari

Anshul Maheshwari

Chief Financial Officer

(Duly Authorized Officer and Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE 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 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 9, 2022

Laura A. Francis
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, Anshul Maheshwari, 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/ Anshul Maheshwari

Date: August 9, 2022

Anshul Maheshwari
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), Laura A. Francis, Chief Executive Officer of SI-BONE, Inc. (the "Company"), and Anshul Maheshwari, Chief Financial Officer of the Company, each hereby certify that, to the best of her or his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022, 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/ Laura A. Francis

Date: August 9, 2022

Laura A. Francis
Chief Executive Officer
(Principal Executive Officer)

/s/ Anshul Maheshwari

Date: August 9, 2022

Anshul Maheshwari
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.