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, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from __________ to __________

Commission File Number: 001-38701

SI-BONE, INC.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SIBN	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

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

The number of shares outstanding of the registrant’s Common Stock was 40,197,135 as of August 2, 2023.

TABLE OF CONTENTS

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 titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements include, but are not limited to, statements about the following:

- our ability to continue to diversify our product mix, including identification of new opportunities and access the capital required to fund adequate new inventory of instruments and implants to address these opportunities;
- our expectation that a significant portion of our revenues will be derived from sales from a small family of products and a single family of procedures;
- 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 opportunities;
- 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 ability to successfully manage the supply chain and operational challenges, as well as governmental responses or mandates, associated with a disease outbreak, including epidemics, pandemics or similar widespread public health concerns;
- the continuing impact of COVID-19 or other disease outbreaks on the demand for, and timing of, our procedures;
- our ability to attract and retain a force of third party sales agents who sell our products in the U.S;
- 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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 110,815	$ 20,717
Short-term investments	58,615	76,573
Accounts receivable, net of allowance for credit losses of $500 and $400, respectively	20,422	20,674
Inventory	20,547	17,282
Prepaid expenses and other current assets	2,135	2,365
Total current assets	212,534	137,611
Property and equipment, net	17,579	15,564
Operating lease right-of-use assets	3,372	4,002
Other non-current assets	340	375
TOTAL ASSETS	$ 233,825	$ 157,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,157	$ 6,279
Accrued liabilities and other	10,642	13,511
Operating lease liabilities, current portion	1,403	1,388
Total current liabilities	18,202	21,178
Long-term borrowings	35,980	35,171
Operating lease liabilities, net of current portion	2,212	2,871
Other long-term liabilities	24	30
TOTAL LIABILITIES	56,418	59,250
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; 40,087,765 and 34,731,577 shares issued and outstanding, respectively	4	3
Additional paid-in capital	556,541	455,172
Accumulated other comprehensive income	298	232
Accumulated deficit	(379,436)	(357,105)
TOTAL STOCKHOLDERS' EQUITY	177,407	98,302
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 233,825	$ 157,552

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,	
	2023	2022	2023	2022
Revenue	$ 33,305	$ 25,585	$ 66,013	$ 48,024
Cost of goods sold	6,318	3,465	12,242	6,448
Gross profit	26,987	22,120	53,771	41,576
Operating expenses:				
Sales and marketing	27,492	28,843	54,805	54,448
Research and development	3,656	3,478	6,947	7,058
General and administrative	7,802	7,680	15,275	14,819
Total operating expenses	38,950	40,001	77,027	76,325
Loss from operations	(11,963)	(17,881)	(23,256)	(34,749)
Interest and other income (expense), net:				
Interest income	1,582	136	2,515	209
Interest expense	(850)	(622)	(1,689)	(1,183)
Other income (expense), net	25	(146)	99	(200)
Net loss	$ (11,206)	$ (18,513)	$ (22,331)	$ (35,923)
Other comprehensive income (loss):				
Changes in foreign currency translation	3	(14)	(19)	(14)
Unrealized gain (loss) on marketable securities	(5)	(58)	85	(306)
Comprehensive loss	$ (11,208)	$ (18,585)	$ (22,265)	$ (36,243)
Net loss per share, basic and diluted	$ (0.30)	$ (0.54)	$ (0.61)	$ (1.06)
Weighted-average number of common shares used to compute basic and diluted net loss per share	37,864,185	34,052,692	36,399,309	33,923,229

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, 2022	34,731,577	$ 3	$ 455,172	$ 232	$ (357,105)	$ 98,302
Issuance of common stock upon exercise of stock options, net of shares withheld	120,266	—	520	—	—	520
Issuance of common stock upon vesting of restricted stock units	254,320	—	—	—	—	—
Stock-based compensation	—	—	6,194	—	—	6,194
Foreign currency translation	—	—	—	(22)	—	(22)
Net unrealized gain on marketable securities	—	—	—	90	—	90
Net loss	—	—	—	—	(11,125)	(11,125)
Balance as of March 31, 2023	**35,106,163**	**3**	**461,886**	**300**	**(368,230)**	**93,959**
Issuance of common stock from public offerings, net of underwriting discounts, commissions and offering costs	4,068,497	1	83,671	—	—	83,672
Issuance of common stock upon exercise of stock options, net of shares withheld	497,926	—	3,515	—	—	3,515
Issuance of common stock related to employee stock purchase plan	130,867	—	1,471	—	—	1,471
Issuance of common stock upon vesting of restricted stock units	261,709	—	—	—	—	—
Issuance of common stock upon exercise of warrant, net of shares withheld	22,603	—	—	—	—	—
Stock-based compensation	—	—	5,998	—	—	5,998
Foreign currency translation	—	—	—	3	—	3
Net unrealized loss on marketable securities	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(11,206)	(11,206)
Balance as of June 30, 2023	**40,087,765**	**$ 4**	**$ 556,541**	**$ 298**	**$ (379,436)**	**$ 177,407**

	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**

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, 2023	Six Months Ended June 30, 2022
Cash flows from operating activities		
Net loss	$ (22,331)	$ (35,923)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	12,192	11,258
Depreciation and amortization	2,322	1,505
Accounts receivable credit losses	103	—
Accretion (amortization) of discount and premium on marketable securities	(1,249)	515
Amortization of debt issuance costs	123	101
Loss on disposal of property and equipment	340	105
Changes in operating assets and liabilities:		
Accounts receivable	88	(720)
Inventory	(3,293)	(4,882)
Prepaid expenses and other assets	262	851
Accounts payable	(7)	936
Accrued liabilities and other	(2,893)	(2,099)
Net cash used in operating activities	(14,343)	(28,353)
Cash flows from investing activities		
Maturities of marketable securities	69,000	48,000
Purchases of marketable securities	(49,723)	(55,356)
Purchases of property and equipment	(5,293)	(4,275)
Net cash provided by (used in) investing activities	13,984	(11,631)
Cash flows from financing activities		
Proceeds from public offering, net of discounts and commissions	84,137	—
Proceeds from debt financing	36,000	—
Repayments of debt financing	(35,275)	—
Payments of debt issuance costs	(40)	—
Proceeds from issuance of common stock under employee stock purchase plan	1,471	1,199
Proceeds from the exercise of stock options	4,035	199
Net cash provided by financing activities	90,328	1,398
Effect of exchange rate changes on cash and cash equivalents	129	(514)
Net increase (decrease) in cash and cash equivalents	90,098	(39,100)
Cash and cash equivalents at		
Beginning of period	20,717	63,419
End of period	$ 110,815	$ 24,319
Supplemental disclosure of non-cash information		
Unpaid purchases of property and equipment	510	1,593
Unpaid public offering costs	465	—

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. The second generation iFuse implant, iFuse-3D, was introduced in 2017 followed by iFuse-TORQ in 2021 and iFuse Bedrock Granite in 2022.

In May 2023, the Company received a total of $83.7 million of net proceeds after deducting the underwriting discounts and commissions from the offering of 3,775,000 shares of the Company's common stock and the exercise of underwriter's option to purchase from the Company an additional 566,250 shares of the Company's common stock, at a public offering price of $22.00 per share. Of these shares, 272,753 shares were offered by a selling stockholder, and the Company did not receive any proceeds from the sale by the selling stockholder.

Risks and Uncertainties

The Company is subject to uncertainties related to liquidity, the ability to meet covenants and access to funding for its capital needs as the financial service industry has experienced disruptions characterized by the bankruptcy, failure, collapse or sale of various financial institutions. The Company's cash and cash equivalents are primarily invested in deposits and money market accounts with two major financial institutions in the U.S. Deposits in these banks may exceed the federally insured limits or any other insurance provided on such deposits, if any. The Company had accounts with Silicon Valley Bank ("SVB"). On March 10, 2023, California regulators shut down SVB and the FDIC was appointed as SVB's receiver. On March 26, 2023, the FDIC announced that it had entered into a purchase and assumption agreement with First-Citizens Bank & Trust Company ("First-Citizens") under which all deposits of the former Silicon Valley Bank were assumed by First-Citizens. First-Citizens acquired the rights as lender under the Company's Loan and Security Agreement as amended. To date, the Company has not experienced any losses on its deposits of cash, cash equivalents and marketable securities and continues to have access to these funds.

The Company is subject to continuing risk and uncertainties resulting from COVID-19. The COVID-19 pandemic impacted the Company's supply chain and also caused delays or cancellations of the Company's procedures. Future outbreaks of COVID-19 or other public health concerns could contribute to health systems diverting resources to respond to COVID-19 which could lead to scheduling delays or cancellations of the Company's procedures. Future outbreaks could also cause or exacerbate supply chain shortages.

As such the Company's future results of operations and liquidity could be adversely impacted by a variety of factors related to uncertainties in the financial services industry and new or ongoing impacts of the COVID-19 pandemic, including those discussed in the section titled "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, economic disruption that has resulted from the pandemic and measures taken to stabilize economies during the pandemic, global supply chain issues and uncertainties of the financial services industry 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, 2022 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, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 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, 2022 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2023.

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, 2022. The Company updated the accounting policies related to the property and equipment and revenue recognition, as follows:

Property and Equipment
Construction in progress includes assets that have not yet been placed into service including the cost of individual components of an instrument tray. Once an instrument tray is placed into service, the Company transfers its carrying value into machinery and equipment and begins depreciating the cost of the instrument tray over its useful life. Leasehold improvements are amortized over the lesser of their useful lives or the life of the lease. Upon the sale or retirement of these assets, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is recognized in the consolidated statement of operations. Maintenance and repairs are charged to operations as incurred.

Revenue Recognition
The Company's revenue is derived from the sale of its products to medical groups and hospitals through its direct sales force and third-party sales agents and resellers throughout the U.S. and Europe. The Company receives payment for its implants consumed during the surgery and does not receive additional or separate consideration for the use of the instrument tray furnished by the Company for the surgeon's use. The Company identifies the instrument trays as a lease component and the implants as a non-lease component in its arrangements with its customers. The Company determines that the non-lease component is qualitatively predominant, and as such, elected the practical expedient to not separate the lease and non-lease components. Therefore, the overall arrangement is accounted for under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606").

In accordance with ASC 606, the Company recognizes revenue when control is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for the goods or services. Under the revenue recognition standard, the Company applies the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied. As it relates to product sales where the Company's sales representative delivers the product at the point of implantation at the hospital or medical facilities, the Company continues to recognize the revenue upon completion of the procedure and authorization by the customer, net of rebates and price discounts. This represents the majority of the Company's consolidated revenue. The Company also generates a small portion of revenue from the sale of products through distributors and to certain hospital or medical facilities where the products are ordered in advance of a procedure. The performance obligation is the delivery of the products and therefore, revenue is recognized upon shipment to the customers, net of rebates and price discounts. The Company accounts for rebates and price discounts as a reduction to revenue, calculated based on the terms agreed to with the customer. Historically, there had been no significant price discounts. Sales prices are specified in either the customer contract or agreed price list, which is executed prior to the transfer of control to the customer. For certain hospitals and medical facilities, the Company has agreements in place consists of either a master services agreement or an agreed price list, which defines the terms and conditions of the arrangement, including the pricing information, payment terms and pertinent aspects of the relationship between the parties. The Company also has agreements in place with its distributors, which include standard terms that do not allow for payment contingent on resale of the product, obtaining financing, or other terms that could impact the distributor's payment obligation. The Company's standard payment terms are generally net 30 to 90 days.

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,	
	2023	**2022**	**2023**	**2022**
	(in thousands)			
United States	$ 31,215	$ 23,771	$ 61,665	$ 44,137
International	2,090	1,814	4,348	3,887
	$ 33,305	$ 25,585	$ 66,013	$ 48,024

Recent Accounting Pronouncements

No recently issued accounting standards are expected to have a material impact on the Company's consolidated financial statements.

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, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 93,052	$ —	$ —	$ 93,052
Cash equivalents	93,052	—	—	93,052
U.S. treasury securities	42,865	5	(11)	42,859
Corporate bonds	2,976	—	(4)	2,972
Commercial paper	6,910	—	—	6,910
U.S. agency bonds	5,880	2	(8)	5,874
Short-term investments	58,631	7	(23)	58,615
Total marketable securities	$ 151,683	$ 7	$ (23)	$ 151,667

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 8,002	$ —	$ —	$ 8,002
Cash equivalents	8,002	—	—	8,002
U.S. treasury securities	48,636	4	(105)	48,535
U.S. agency bonds	2,918	3	—	2,921
Corporate bonds	2,914	—	(3)	2,911
Commercial paper	22,206	—	—	22,206
Short-term investments	76,674	7	(108)	76,573
Total marketable securities	$ 84,676	$ 7	$ (108)	$ 84,575

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, 2023 and 2022, 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, 2023 and December 31, 2022.

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 $0.1 million as of June 30, 2023, 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, 2023 or December 31, 2022.

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, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 93,052	$ —	$ —	$ 93,052
U.S. treasury securities	42,859	—	—	42,859
Corporate bonds	—	2,972	—	2,972
U.S. agency bonds	—	5,874	—	5,874
Commercial paper	—	6,910	—	6,910
Total marketable securities	$ 135,911	$ 15,756	$ —	$ 151,667

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 8,002	$ —	$ —	$ 8,002
U.S. treasury securities	48,535	—	—	48,535
U.S. agency bonds	—	2,921	—	2,921
Corporate bonds	—	2,911	—	2,911
Commercial paper	—	22,206	—	22,206
Total marketable securities	$ 56,537	$ 28,038	$ —	$ 84,575

5. Balance Sheet Components

Inventory

As of June 30, 2023, inventory consisted of finished goods of $18.6 million and work-in-progress of $1.9 million. As of December 31, 2022, inventory consisted of finished goods of $15.6 million and work-in-progress and components of $1.7 million.

Property and Equipment, net:

	June 30, 2023	December 31, 2022
	(in thousands)	
Surgical equipment and instrument trays	$ 16,901	$ 13,092
Machinery and equipment	1,883	1,828
Construction in progress	8,008	7,854
Computer and office equipment	1,260	976
Leasehold improvements	1,625	1,631
Furniture and fixtures	391	390
	30,068	25,771
Less: Accumulated depreciation and amortization	(12,489)	(10,207)
	$ 17,579	$ 15,564

As of June 30, 2023, 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 $3.9 million and construction costs related to the Company's lease for research and development and warehouse space in Santa Clara and software costs of $4.1 million. Depreciation expense was $1.2 million and $0.8 million for the three months ended June 30, 2023 and 2022, respectively. Depreciation expense was $2.3 million and $1.5 million for the six months ended June 30, 2023 and 2022, respectively.

Accrued Liabilities and Other:

	June 30, 2023	December 31, 2022
	(in thousands)	
Accrued compensation and related expenses	$ 8,155	$ 11,365
Accrued royalty	1,087	818
Accrued professional services	517	355
Others	883	973
	$ 10,642	$ 13,511

Accounts Receivable and Allowance for Credit Losses:

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

	June 30, 2023	December 31, 2022
	(in thousands)	
Balance at beginning of period	$ 400	$ 264
Provision	103	150
Write-offs	(3)	(14)
Balance at end of period	$ 500	$ 400

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 a non-cancelable operating lease for its office building spaces in Gallarate, Italy which expires in August 2027.

The Company also leases vehicles under operating lease arrangements for certain of its personnel in Europe which expire at various times throughout 2023 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,	
	2023	2022	2023	2022
Operating lease expense	$ 390	$ 397	$ 783	$ 806
Variable lease expense	124	119	201	223
Total lease expense	$ 513	$ 516	$ 984	$ 1,029
Cash paid for amounts included in the measurement of operating lease liabilities	$ 439	$ 396	$ 836	$ 804
Leased assets obtained in exchange for new operating lease liabilities	$ 103	$ 77	$ 124	$ 77

	June 30, 2023	December 31, 2022
Weighted average remaining lease term (in years)	2.63	3.05
Weighted average discount rate	5.85%	5.77%

Future minimum lease payments under non-cancelable operating leases as of June 30, 2023 was as follows:

Year Ending December 31,	(in thousands)
Remainder of 2023	$ 796
2024	1,530
2025	1,018
2026	547
2027	9
Thereafter	—
Total operating lease payments	3,900
Less: imputed interest	(285)
Total operating lease liabilities	$ 3,615

As of June 30, 2023, 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 $0.4 million and $0.8 million as of June 30, 2023 and December 31, 2022, 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, 2023	December 31, 2022
	(in thousands)	
Principal outstanding and final fee	$ 36,720	$ 35,700
Less: Unamortized debt issuance costs	(93)	(73)
Unaccreted value of final fee	(647)	(456)
Outstanding debt, net of debt issuance costs and unaccreted value of final fee	$ 35,980	$ 35,171
Classified as:		
Long-term borrowings	$ 35,980	$ 35,171

The outstanding debt 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").

On January 6, 2023, the Company entered into a First Amendment to Loan and Security Agreement (the "Amendment") with SVB, which amended the Company's SVB Term Loan pursuant to which the Company had a term loan facility in an aggregate principal amount of $35.0 million (the "Original Loan Agreement" and with the Amendment, collectively the "Amended Loan Agreement"). Upon entry into the Amended Loan Agreement, the Company borrowed $36.0 million pursuant to a term loan (the "Term Loan"), which was substantially used to repay in full the $35.0 million term loan facility outstanding under the Original Loan Agreement and secured a revolving credit facility in an aggregate principal amount of up to $15.0 million (the "Revolver"). On March 14, 2023 all of SVB's assets and liabilities, including all of SVB's rights as the lender pursuant to the Amended Loan Agreement, were assigned to Silicon Valley Bridge Bank. On March 27, 2023, all of Silicon Valley Bridge Bank's assets and liabilities were assigned and assumed by First-Citizens Bank & Trust Company ("First-Citizens"). The Amended Loan Agreement also includes an uncommitted accordion term loan in an aggregate principal amount of up to $15.0 million, which accordion may be approved by First-Citizens solely in its discretion, upon the Company's request. The Term Loan matures on December 1, 2027 (the "Term Loan Maturity Date"). Interest on the Term Loan will be payable monthly at a floating annual rate set at the greater of the prime rate as published in the Wall Street Journal plus 0.5% or 6.75%. Commencing on July 1, 2025, the Company will be required to make monthly principal Term Loan amortization payments. A final fee payment of 2% of the original principal amount of the Term Loan is due upon the earlier of the Term Loan Maturity Date, termination, acceleration by First-Citizens following an event of default, or prepayment of the Term Loan. The Company may elect to prepay the Term Loan in whole prior to the Term Loan Maturity Date subject to a prepayment fee equal to 2% of the principal amount of the Term Loan prepaid at such time. No prepayment fee would be due if the Term Loan is refinanced by First-Citizens. Pursuant to the terms of the Amended Loan Agreement, revolving loans may be borrowed, repaid and reborrowed until the maturity date, which will be July 6, 2025 (the “Revolver Maturity Date”). Borrowings under the Revolver are based on 80% of eligible domestic accounts receivable borrowing base. Interest on the outstanding balance of the Revolver will be payable monthly at a floating annual rate set at the greater of the prime rate as published in the Wall Street Journal or 6.25%. Interest on borrowings is due monthly and any principal balance is due on the Revolver Maturity Date, provided that when Revolver Advances are outstanding, in the event the Company does not maintain an adjusted quick ratio of at least 1.5 to 1.0, then falling below such threshold will allow First-Citizens to apply accounts receivable collections to outstanding Revolver borrowings. The Company will pay a total commitment fee of $187,500 on account of the Revolver payable in installments, but fully earned at close. The Company will also be required to pay a fee of $150,000 if it terminates the Amended Loan Agreement or Revolver prior to Revolver Maturity Date. No termination fee would be due if the Revolver is replaced with a new facility with First-Citizens. No amounts were outstanding under the Revolver as of June 30, 2023.

The Company accounted for the Amended Loan Agreement as a debt modification. Accordingly, the remaining unamortized debt issuance costs related to the Original Loan Agreement together with any lender fees incurred in connection with the entry of the Amended Loan Agreement are amortized to interest expense using the straight-line method over the new term of the loan through December 2027.

The effective interest rate related to the First-Citizens Term Loan for the three and six months ended June 30, 2023 was 8.9% and 8.8%, respectively. 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 Fist-Citizens Term Loan as of June 30, 2023:

Year ending December 31,		**(in thousands)**
Remainder of 2023	$	—
2024		—
2025		8,400
2026		14,400
2027		13,920
Total principal and final fee payments	$	36,720

The Amended Loan Agreement contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on First-Citizens's security interest over the collateral, a material adverse change, the occurrence of a default under certain other indebtedness of the Company and its subsidiaries, the rendering of certain types of judgments against the Company and its subsidiaries, the revocation of certain government approvals, violation of covenants, and incorrectness of representations and warranties in any material respect. In addition, the Amended Loan Agreement contains a financial covenant which requires the Company to maintain, at all times when the Financial Covenant Measuring Period is in effect, certain net revenue levels as agreed upon by the Company and First-Citizens. If the Company does not comply with the various covenants under the Amended Loan Agreement and an event of default occurs under the Amended Loan Agreement, the interest rate on outstanding amounts can increase by 3% and First-Citizens may, subject to various customary cure rights, decline to provide additional advances under the Revolver, require the immediate payment of all amounts outstanding under the Amended Loan Agreement, and foreclose on all collateral.

On March 10, 2023, the Company violated one of the terms of the credit facility by opening bank accounts with another financial institution and transferring funds from SVB. The Company entered into a letter agreement with Silicon Valley Bridge Bank waiving enforcement of this covenant and providing the Company the right to hold a portion of its cash at other financial institutions. A future violation of any covenants could result in a default under the Amended Loan Agreement that would permit First-Citizens to restrict the Company's ability to further access the Revolving Line of Credit for loans and require the immediate repayment of any outstanding loans under the agreement. As of June 30, 2023, the Company was in compliance with all debt covenants, provided, however, that in order to access future credit advances under the Revolving Line of Credit, the Company will be required to transfer certain cash management accounts back to First-Citizens. As of June 30, 2023, the Company had cash management accounts with a financial institution other than First-Citizens and instructed its customers to direct payments to these separate operating accounts. Until such operating accounts are closed and the funds moved back to cash collateral accounts held at First-Citizens, the Company will be unable to obtain credit advances under the Revolver.

8. Stock-Based Incentive Compensation Plans

Stock Options

The table below summarizes the stock option activity for the six months ended June 30, 2023:

	Number of Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2022	1,903,341	$8.82
Exercised	(618,192)	6.53
Canceled and forfeited	(16,002)	21.23
Outstanding as of June 30, 2023	1,269,147	10.57

As of June 30, 2023, the unrecognized compensation cost related to stock options is insignificant and is expected to be recognized over a period of approximately 0.1 years.

There were no stock options granted during the three and six months ended June 30, 2023 and 2022.

Restricted Stock Units ("RSUs")

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. Certain RSUs vest based upon continued services and the achievement of financial milestones. The grant date fair value of the RSUs is equal to the closing price of the Company's common stock on the grant date. As of June 30, 2023, the unrecognized compensation cost related to the RSUs was $38.4 million, which is expected to be recognized over a period of approximately 2.6 years.

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 PSUs vest over a three-year performance period. 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,					
	2023			2022		
Expected volatility of common stock	58.0%	to	73.0%	48.9%	to	58.7%
Expected volatility of peer companies	33.0%	to	141.0%	24.2%	to	152.5%
Correlation coefficient of peer companies	(0.15)	to	1.00	(0.13)	to	1.00
Risk-free interest rate	3.9%	to	5.0%	0.4%	to	1.2%
Dividend yield	—%	to	1.3%	—%	to	1.0%

As of June 30, 2023, the unrecognized compensation cost related to the PSUs was $3.4 million, which is expected to be recognized over a period of approximately 2.2 years.

The table below summarizes RSU and PSU activity for the six months ended June 30, 2023:

	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, 2022	1,794,928	$22.72	155,596	$19.50
Granted	1,138,406	16.47	255,458	12.33
Vested	(490,097)	21.12	(25,932)	19.50
Canceled and forfeited	(122,487)	21.59	—	—
Outstanding as of June 30, 2023	2,320,750	20.05	385,122	14.74

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 130,867 and 112,773 shares under ESPP, representing approximately $1.5 million and $1.2 million in employee contributions for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023 and December 31, 2022, 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,	
	2023	2022	2023	2022
	(in thousands)			
Cost of goods sold	$ 161	$ 117	$ 298	$ 238
Sales and marketing	2,702	2,746	5,612	5,340
Research and development	748	664	1,500	1,297
General and administrative	2,387	2,224	4,782	4,383
	$ 5,998	$ 5,751	$ 12,192	$ 11,258

Warrants

During the three months ended June 30, 2023, a warrant holder exercised warrants, and the Company issued 22,603 net shares of common stock through a cashless exercise of the warrants in accordance with the conversion terms. The table below summarizes common stock warrants activity for the six months ended June 30, 2023:

Date		Outstanding Balance at December 31, 2022	Price per Share	Warrants Issued	Warrant Exercised	Warrant Expired	Outstanding Balance at June 30, 2023
Issuance	Expiration						
3/1/2017	3/1/2027	1,388	$ 5.94	—	—	—	1,388
7/22/2013	7/22/2023	32,983	$ 9.10	—	(32,983)	—	—
11/26/2014	11/26/2024	6,680	$ 16.47	—	—	—	6,680
10/20/2015	10/20/2025	41,650	$ 16.47	—	—	—	41,650
11/9/2015	11/9/2025	25,709	$ 16.47	—		—	25,709
12/22/2016	12/22/2026	9,712	$ 10.03	—	—	—	9,712
		118,122		—	(32,983)	—	85,139

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,	
	2023	2022	2023	2022
	(in thousands, except share and per share data)			
Net loss	$ (11,206)	$ (18,513)	$ (22,331)	$ (35,923)
Weighted-average shares used to compute basic and diluted net loss per share	37,864,185	34,052,692	36,399,309	33,923,229
Net loss per share, basic and diluted	$ (0.30)	$ (0.54)	$ (0.61)	$ (1.06)

Because the Company has reported a net loss in all periods presented, outstanding stock options, restricted stock units, 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,	
	2023	2022	2023	2022
Stock options	1,269,147	1,956,017	1,269,147	1,956,017
Restricted stock units	2,320,750	2,172,377	2,320,750	2,172,377
ESPP purchase rights	38,727	59,688	38,727	59,688
Common stock warrants	85,139	118,122	85,139	118,122
	3,713,763	4,306,204	3,713,763	4,306,204

10. Related Party Transaction

On February 24, 2020, the Company entered into a joint development agreement (the “Development Agreement”) with SeaSpine Orthopedics Corporation (“SeaSpine”), which merged with Orthofix Medical, Inc., 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 six months ended June 30, 2023, the Company did not incur any reimbursement charges from SeaSpine. For the six months ended June 30, 2022, the Company expensed approximately $6,000 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 $0.1 million of royalty for the three and six months ended June 30, 2023. The Company recorded an immaterial amount of royalty for the three and six months ended June 30, 2022.

The outstanding liability to SeaSpine as of June 30, 2023 and December 31, 2022 was both approximately $0.1 million, and was recorded within accrued liabilities and other in the condensed consolidated balance sheet.

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, 2023 and 2022. The Company continues to maintain a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding realization of such assets.

Under an Organization for Economic Co-operation and Development Inclusive Framework, countries that agreed to enact a two-pillar solution aim to address the challenges arising from the digitalization of the world economy (Pillar Two). Pillar Two sets out a global minimum Effective Tax Rate (ETR) rules to ensure that large multinational businesses with consolidated revenue over €750M are subject to a minimum ETR of 15% on income arising in low-tax jurisdictions. Rules under Pillar Two are expected to be enacted beginning January 1, 2024. The Company will continue to monitor the impact of Pillar Two; however, the Pillar Two is currently not applicable as the Company does not meet the threshold of having consolidated revenue over €750M.

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, 2023 compared to December 31, 2022.

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 2, 2023. 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. Leveraging our knowledge of pelvic anatomy and biomechanics, we have pioneered proprietary minimally invasive surgical implant systems to address sacroiliac joint dysfunction as well as address unmet clinical needs in pelvic fixation and management of pelvic fractures. Our products include a series of patented titanium implants and the instruments used to implant them. Since launching our first generation iFuse in 2009, we have launched three new implant product lines, iFuse-3D in 2017, iFuse-TORQ in 2021 and iFuse Bedrock Granite in 2022. Within the United States, our iFuse, iFuse-3D and iFuse-TORQ have clearances for applications across sacroiliac joint dysfunction and fusion, adult deformity and degeneration, and pelvic trauma.

We market our products primarily with a direct sales force as well as a number of third-party sales agents in the U.S., and with a combination of a direct sales force, and sales agents and resellers in other countries. As of June 30, 2023, more than 85,000 procedures have been performed by over 3,300 surgeons in the United States and 38 other countries since we introduced iFuse in 2009.

In May 2023, we received a total of $83.7 million of net proceeds from the offering of 3,775,000 shares of our common stock, and the exercise of underwriter's option to purchase an additional 566,250 shares of our common stock, at a public offering price of $22.00 per share. Of these shares, 272,753 shares were offered by the selling stockholder, and we did not receive any proceeds from the sale by the selling stockholder.

Impact of COVID-19

The global COVID-19 pandemic, and the healthcare and economic disruptions it caused, may continue to pose future risks with the emergence of new variants. Even with the public health actions that have been taken to reduce the spread of the virus, the market could experience disruptions with respect to demand for our procedures, or the ability of healthcare facilities to provide our elective procedures to patients.

Elevated infection rates and measures taken to reduce infection 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 2022 as evidenced by case deferrals attributed to COVID-19.

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 expand access to solutions, increase surgeon penetration, launch new products, address human capital needs and gain operational efficiencies.

Expand Access to Solutions

As we expand our portfolio, the experience, caliber, and strong clinician relationships of our sales force, including our network of third-party sales agents, will be crucial to drive adoption of our future products and procedures. Since our initial public offering in 2018, we have made significant investments in our commercial infrastructure to build a valuable sales team to expand the market, drive surgeon engagement and deliver revenue growth.

While we will continue to selectively expand our sales force, we are also focused on increasing our sales managers capacity and driving sales force productivity by adding more clinical support specialists and implementing hybrid models, including selectively adding third-party sales agents for case coverage and by consigning instrument trays and implants at selective sites of service. This expansion of our sales force is one aspect of increasing the overall number of procedures in a given period that we can support with products, which is what we call “surgical capacity.” Our surgical capacity is also limited by the volume of implant inventory and the number of instrument trays held ready for surgery, either at our headquarters facility, forward deployed with our sales force or consigned to customer facilities. As we grow, and as adoption of our solutions continues to mature, our overall surgical capacity may become an important driver of the amount of revenue that we can generate.

As of June 30, 2023, our U.S. sales force consisted of 85 territory sales managers and 66 clinical support specialists directly employed by us and 141 third-party sales agents, compared to 85 territory sales managers and 76 clinical support specialists directly employed by us and 73 third-party sales agents as of June 30, 2022. As of June 30, 2023, our international sales force consisted of 12 sales representatives directly employed by us and a total of 31 third-party sales agents and resellers, compared to 18 sales representatives directly employed by us and a total of 30 third-party sales agents and resellers as of June 30, 2022.

With the steady increase in the numbers of minimally invasive procedures, including sacroiliac joint fusion procedures, being performed at ASCs, we continue to actively engage the ASCs to educate them on our clinical evidence, exclusive commercial payor coverage and focus on driving improved education and pathways between pain physicians and surgeons. As of June 30, 2023, over 20 percent of procedures for sacroiliac joint dysfunction using our products were performed at ASCs.

We have been making targeted investments in digital marketing initiatives to drive patient awareness, to empower and educate patients as they manage their sacroiliac joint dysfunction and associated pain. These marketing programs are targeted at patients in chronic, severe sacroiliac joint pain who have been in conservative care for an extended period of time. We are focused on connecting patients with surgeons in their area who perform minimally invasive SI-Joint procedures through our Find-a-Doctor website tool. Through a variety of channels, including search, social and display, we have deployed a number of campaigns and are continually optimizing to maximize patient awareness and to connect patients with surgeons. Our data-driven approach enables us to focus our investment on the most cost-effective programs.

Surgeon Engagement

Engaging and educating surgeons and other healthcare professionals about the clinical merits and patient benefits of our solutions will be important to grow surgeon adoption. Our medical affairs team works closely with our sales team to increase surgeon engagement and activation. Surgeon activity includes both the number of surgeons performing our procedures as well as the number of procedures performed per surgeon. In addition to training new surgeons, we have several initiatives to re-engage inactive surgeons.

We utilize a combination of hands-on cadaveric and dry-lab training, as well as SI-BONE SImulator - a portable, radiation-free, haptics and computer-based simulator for training purposes, and optimize our programs to improve adoption rate, time to first case and ultimately surgeon productivity.

As of June 30, 2023 and 2022, in the U.S. more than 2,400 and 1,900 surgeons, respectively, have been trained on our solutions and have treated at least one patient. Outside the U.S., as of June 30, 2023 and 2022, more than 940 and 800 surgeons, respectively, have been trained on iFuse and have treated at least one patient. We will continue to pursue approximately 5,100 target surgeons in the U.S., as well as international surgeons to train and retrain in the future. Since launching our academic training program in August 2018, we have trained residents and fellows in over 220 academic programs in the U.S., resulting in the training of over 1,400 surgical residents and fellows.

Expand Addressable Markets

Expanding our platform of sacropelvic solutions to address sacroiliac joint dysfunction, pelvic fixation and pelvic trauma has been a key tenet of our strategy, and we have made substantial progress on this mission. With iFuse-3D, iFuse-TORQ and iFuse Bedrock Granite, we believe that the value of our innovative, versatile, and complementary product portfolio provides surgeons with a comprehensive set of alternatives, and positions us as the top choice for surgeons for sacropelvic solutions. We also offer an allograft bone implant called iFuse-Bone for surgeons who believe that this kind of implant can be important to obtaining fusion.

In June 2022, we completed enrollment in SILVIA, a two-year prospective international multi center randomized controlled trial of two different methods for pelvic fixation in adult patients undergoing long-construct spinal fusion. We anticipate the results for the primary endpoint in 2024. In September 2022 we enrolled the first of the targeted 120 patients in our SAFFRON study, a prospective randomized controlled trial of surgery using our iFuse-TORQ device vs. non-surgical management in patients with debilitating sacral fragility or insufficiency fractures. We anticipate results to be available in late 2024. We are working with a select group of physicians on STACI, a prospective study on the use of iFuse TORQ in patients with sacroiliac joint dysfunction. The purpose of STACI is to provide post-market information on the safety and effectiveness of minimally invasive sacroiliac joint fusion procedures performed with TORQ.

We continue to invest in R&D initiatives to bring new and differentiated solutions to the market that deliver on our vision of improving patient quality of life through differentiated solutions to target segments with a clear unmet clinical need. Robust clinical evidence is central to drive adoption and favorable reimbursement, and we remain focused on continuing to set the industry standard in delivering evidence-based care through best-in-class clinical trials that demonstrate the efficacy, safety, and economic benefit of our solutions. During six months ended June 30, 2023, we spent $6.9 million on R&D, equating to 11% of our revenue.

Enhance Employee Experience and Engagement

Our ability to recruit, develop and retain highly skilled talent is a significant determinant of our success. To facilitate talent attraction, retention, and development, we strive to make SI-BONE an inclusive, diverse, and safe workplace with opportunities for our employees to grow and develop in their careers, supported by strong compensation, benefits, and health and wellness programs, as well as by programs that build connections between our employees and the communities in which they live and work.

In addition to ensuring workforce diversity as well as fair and equitable pay to our employees, we remain focused on enhancing employee retention and job satisfaction. To that effect, we have created a feedback framework to monitor and respond to employee sentiment on an ongoing basis. Leveraging the insights from this feedback, we are focused on implementing strategies to enhance productivity and increase employee empowerment to drive quick decision making and prioritization across the organization. Additionally, we offer ongoing learning and leadership training opportunities that support growth and development. In 2022 we conducted a formal management training program and implemented a new career development program which includes a formalized framework that reflects how an employee can advance their career within the company. Through our engagement programs and voluntary and giving activities, we are also focused on building connections between our employees, their families, and our communities to create a more meaningful and fulfilling workplace. We experienced a decrease in voluntary employee attrition during 2022, which we believe was at least in part to due to our actions to improve employee experience.

Gain operational efficiency

To support our growing portfolio of solutions, we continue to evolve our business processes to identify, measure and improve operational efficiency. The information developed will allow us to optimize processes, increase sales force productivity and improve asset utilization.

We are focused on increasing our sales managers and sales representatives capacity, efficiency and productivity. We may do this by adding more clinical support specialists and third-party sales agents as part of hybrid arrangements for case coverage, and by consigning instrument trays and implants at selective sites of service. At the end of June 30, 2023, our trailing twelve-month average revenue per territory in the U.S. was approximately $1.4 million dollars.

We have made significant investments in instrument sets used to perform surgeries. Our goal is to deploy instrument sets to the market where the demand exists to increase our asset utilization rates over time and use capital more effectively by having our instrument sets used in more surgeries in any given time period. Given supply chain disruptions impacting the industry, we are working closely with our suppliers to reduce lead time for our implants to ensure we can support our expanding surgeon footprint and over time build the resilience in our supply chain to reduce our cash investment in inventory. Additionally, we are partnering with our suppliers around design for manufacturing, specifically for newer products, to reduce the overall cost of the implants as we scale, and reduce waste and rework. Lastly, we are integrating our demand planning and manufacturing systems, to ensure we leverage actual usage trends as we build surgical capacity to support our growth.

Components of Results of Operations

Revenue

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 mix of our products used, and the sales channel through which each procedure is supported. 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.

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 as patients have more time in the winter months to have the procedure completed or want to take advantage of their annual insurance coverage limits. However, taken as a whole, seasonality does not have a material impact on our financial results from year to year.

Starting March 2020, the impact of COVID-19 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, and the direct and indirect impacts of economic and financial measures taken to mitigate the economic impacts of the pandemic.

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.

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 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 sales agents.

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 First-Citizens Term Loan.

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,			
	2023		2022		2023		2022	
	Amount	%	Amount	%	Amount	%	Amount	%
	(in thousands, except for percentages)							
Consolidated Statements of Operations Data:								
Revenue	$ 33,305	100 %	$ 25,585	100 %	$ 66,013	100 %	$ 48,024	100 %
Cost of goods sold	6,318	19 %	3,465	14 %	12,242	19 %	6,448	13 %
Gross profit	26,987	81 %	22,120	86 %	53,771	81 %	41,576	87 %
Operating expenses:								
Sales and marketing	27,492	83 %	28,843	113 %	54,805	83 %	54,448	113 %
Research and development	3,656	11 %	3,478	14 %	6,947	11 %	7,058	15 %
General and administrative	7,802	23 %	7,680	30 %	15,275	23 %	14,819	31 %
Total operating expenses	38,950	117 %	40,001	157 %	77,027	117 %	76,325	159 %
Loss from operations	(11,963)	(36)%	(17,881)	(71)%	(23,256)	(36)%	(34,749)	(72)%
Interest and other income (expense), net:								
Interest income	1,582	5 %	136	1 %	2,515	4 %	209	— %
Interest expense	(850)	(3)%	(622)	(2)%	(1,689)	(3)%	(1,183)	(2)%
Other income (expense), net	25	— %	(146)	(1)%	99	— %	(200)	— %
Net loss	$ (11,206)	(34)%	$ (18,513)	(73)%	$ (22,331)	(35)%	$ (35,923)	(74)%

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,			
	2023		2022		2023		2022	
	Amount	%	Amount	%	Amount	%	Amount	%
	(in thousands except for percentages)							
United States	$ 31,215	94 %	$ 23,771	93 %	$ 61,665	93 %	$ 44,137	92
International	2,090	6 %	1,814	7 %	4,348	7 %	3,887	8
	$ 33,305	100 %	$ 25,585	100 %	$ 66,013	100 %	$ 48,024	100

Comparison of the Three Months Ended June 30, 2023 and 2022

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

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	$ Change	% Change
	(in thousands, except for percentages)			
Revenue	$ 33,305	$ 25,585	$ 7,720	30%
Cost of goods sold	6,318	3,465	2,853	82%
Gross profit	$ 26,987	$ 22,120	$ 4,867	22%
Gross margin	81 %	86 %		

Revenue. The increase in revenue for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 comprised a $7.4 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 case volumes and higher domestic average selling prices.

Gross Profit and Gross Margin. Gross profit increased $4.9 million for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022, mainly driven by higher revenue. The gross margin was 81% for the three months ended June 30, 2023 as compared to 86% for the three months ended June 30, 2022. Gross margin decreased in the second quarter 2023 due to procedure and product mix given the higher total costs of iFuse-TORQ and iFuse Bedrock Granite implants and the increase in depreciation costs to support the growth of the business.

Operating Expenses:

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 27,492	$ 28,843	$ (1,351)	(5)%
Research and development	3,656	3,478	178	5 %
General and administrative	7,802	7,680	122	2 %
Total operating expenses	$ 38,950	$ 40,001	$ (1,051)	(3)%

Sales and Marketing Expenses. The decrease in sales and marketing expenses for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 was primarily due to timing of commercial activities resulting in a decrease of $1.4 million.

Research and Development Expenses. The increase in research and development expenses for the three months ended June 30, 2023 compared to the three months ended June 30, 2022 was primarily due to an increase of $0.1 million in employee related costs and stock-based compensation.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended June 30, 2023 compared to the three months ended June 30, 2022 was primarily due to an increase of $0.3 million in employee related costs and stock-based compensation driven by higher headcount, partially offset by a decrease of $0.2 million in consulting, legal fees and insurance costs.

Interest and Other Income (Expense), Net:

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 1,582	$ 136	$ 1,446	1063 %
Interest expense	(850)	(622)	(228)	(37)%
Other income (expense), net	25	(146)	171	117 %
Total interest and other expense, net	$ 757	$ (632)	$ 1,389	220 %

Interest Income. The increase in interest income for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 was mainly due to higher interest earned, primarily as a result of higher interest rates and higher cash and investments balance resulting from the net proceeds received from the offering of our common stock in May 2023.

Interest Expense. The increase in interest expense for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022 was primarily due to higher interest rates associated with the First-Citizens Term Loan.

Other Income (Expense), Net. The change in other income (expense), net for the three months ended June 30, 2023 compared to the three months ended June 30, 2022 was due to foreign currency fluctuations.

Comparison of the Six Months Ended June 30, 2023 and 2022

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

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	$ Change	% Change
	(in thousands, except for percentages)			
Revenue	$ 66,013	$ 48,024	$ 17,989	37 %
Cost of goods sold	12,242	6,448	5,794	90 %
Gross profit	$ 53,771	$ 41,576	$ 12,195	29 %
Gross margin	81 %	87 %		

Revenue. The increase in revenue for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022 comprised a $17.5 increase in our U.S. revenue and an increase of 0.5 million in our international revenue. The increase in revenue is due to the increase in case volumes and higher domestic average selling prices.

Gross Profit and Gross Margin. Gross profit increased $12.2 million for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022, mainly driven by higher revenue. The gross margin was 81% for the six months ended June 30, 2023 as compared to 87% for the six months ended June 30, 2022. Gross margin decreased due to procedure and product mix given the higher total costs of iFuse-TORQ and iFuse Bedrock Granite implants and the increase in depreciation and freight costs to support the growth of the business.

Operating Expenses:

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 54,805	$ 54,448	$ 357	1 %
Research and development	6,947	7,058	(111)	(2)%
General and administrative	15,275	14,819	456	3 %
Total operating expenses	$ 77,027	$ 76,325	$ 702	1 %

Sales and Marketing Expenses. The increase in sales and marketing expenses for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022 was primarily due to (a) an increase of $1.7 million in employee related costs, commissions and stock-based compensation driven by higher revenues, partially offset by (b) timing of certain commercial activity resulting in a decrease of $1.3 million.

Research and Development Expenses. The decrease in research and development expenses for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 was primarily due to a decrease of $0.4 million in consulting and research and development activities related to the timing of new product development, partially offset by an increase of $0.3 million in employee related costs and stock-based compensation.

General and Administrative Expenses. The increase in general and administrative expenses for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 was primarily due to an increase of $0.8 million in employee related costs and stock-based compensation driven by higher headcount, partially offset by a decrease of $0.3 million in consulting and insurance costs.

	Six Months Ended June 30, 2023			
	2023	**2022**	**$ Change**	**% Change**
	(in thousands, except for percentages)			
Interest income	$ 2,515	$ 209	$ 2,306	1103
Interest expense	(1,689)	(1,183)	(506)	(43
Other income (expense), net	99	(200)	299	(150
Total interest and other expense, net	$ 925	$ (1,174)	$ 2,099	179

Interest Income. The increase in interest income for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022 was mainly due to higher interest earned, primarily as a result of higher interest rates and higher cash and investments balance resulting from the net proceeds received from the offering of our common stock in May 2023.

Interest Expense. The increase in interest expense for the six months ended June 30, 2023 as compared to the six months ended June 30, 2022 was primarily due to higher interest rates associated with the First-Citizens Term Loan.

Other Income (Expense), Net. The change in other income (expense), net for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 was due to foreign currency fluctuations.

Liquidity and Capital Resources

As of June 30, 2023, we had cash and marketable securities of $169.4 million compared to $97.3 million as of December 31, 2022. We have financed our operations primarily through our public offerings and debt financing arrangements. As of June 30, 2023, we had $36.0 million in outstanding debt, compared to $35.2 million as of December 31, 2022 .

As of June 30, 2023, we had an accumulated deficit of $379.4 million, compared to $357.1 million as of December 31, 2022. During the six months ended June 30, 2023, we incurred a net loss of $22.3 million. During the years ended December 31, 2022 and 2021, we incurred a net loss of $61.3 million and $56.6 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date.

In May 2023, we received a total of $83.7 million of net proceeds after deducting the underwriting discounts and commissions from the public offering of our common stock.

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 potential resurgence of the COVID-19 pandemic and uncertainties affecting the economic and capital markets environment and the financial services industry 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 and reimbursement 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. In addition, as we seek to deploy new product offerings, the need for additional capital to fund the purchase of inventories of implants and instrument sets may become more acute and may limit the number of revenue opportunities that we pursue. Each new product family introduced typically requires the purchase of consumable implant inventory as well as investment in a fleet of instrument sets required to support procedures nationwide.

Term Loan

The outstanding debt is related to a term loan pursuant to the Loan and Security Agreement dated August 12, 2021 (the “Effective Date”), entered into by us and Silicon Valley Bank (“SVB”). Pursuant the agreement, SVB provided an aggregate principal amount of $35.0 million to us (the “SVB Term Loan”).

On January 6, 2023, we entered into a First Amendment to Loan and Security Agreement (the “Amendment”) with SVB, which amends our SVB Term Loan pursuant to which we had a term loan facility in an aggregate principal amount of $35.0 million (the “Original Loan Agreement” and with the Amendment, collectively the “Amended Loan Agreement”). Upon entry into the Amended Loan Agreement, we borrowed $36.0 million pursuant to a term loan (the “Term Loan”), which was substantially used to repay in full the $35.0 million term loan facility outstanding under the Original Loan Agreement and secured a revolving credit facility in an aggregate principal amount of up to $15.0 million (the “Revolver"). On March 14, 2023 all of SVB’s assets and liabilities, including all of SVB’s rights as the lender pursuant to the Amended Loan Agreement, were assigned to Silicon Valley Bridge Bank. On March 27, 2023, all of Silicon Valley Bridge Bank’s assets and liabilities were assigned and assumed by First-Citizens Bank & Trust Company (“First-Citizens”). The Amended Loan Agreement also includes an uncommitted accordion term loan in an aggregate principal amount of up to $15.0 million, which accordion may be approved by First-Citizens, solely in its discretion, upon our request. The Term Loan matures on December 1, 2027 (the “Term Loan Maturity Date”). Interest on the Term Loan will be payable monthly at a floating annual rate set at the greater of the prime rate as published in the Wall Street Journal plus 0.5% or 6.75%. Commencing on July 1, 2025, we will be required to make monthly principal Term Loan amortization payments. A final fee payment of 2% of the original principal amount of the Term Loan is due upon the earlier of the Term Loan Maturity Date, termination, acceleration by First-Citizens following an event of default, or prepayment of the Term Loan. We may elect to prepay the Term Loan in whole prior to the Term Loan Maturity Date subject to a prepayment fee equal to 2% of the principal amount of the Term Loan prepaid at such time. No prepayment fee would be due if the Term Loan is refinanced by First-Citizens. Pursuant to the terms of the Amended Loan Agreement, revolving loans may be borrowed, repaid and reborrowed until the maturity date, which will be July 6, 2025 (the “Revolver Maturity Date”). Borrowings under the Revolver are based on 80% of eligible domestic accounts receivable borrowing base. Interest on the outstanding balance of the Revolver will be payable monthly at a floating annual rate set at the greater of the prime rate as published in the Wall Street Journal or 6.25%. Interest on borrowings is due monthly and any principal balance is due on the Revolver Maturity Date, provided that when Revolver Advances are outstanding, in the event we do not maintain an adjusted quick ratio of at least 1.5 to 1.0, then falling below such threshold will allow First-Citizens to apply accounts receivable collections to outstanding Revolver borrowings. We will pay a total commitment fee of $187,500 on account of the Revolver payable in installments, but fully earned at close. We will also be required to pay a fee of $150,000 if it terminates the Amended Loan Agreement or Revolver prior to Revolver Maturity Date. No termination fee would be due if the Revolver is replaced with a new facility with First-Citizens. No amounts were outstanding under the Revolver as of June 30, 2023.

On March 10, 2023, we violated one of the terms of the credit facility by opening bank accounts with another financial institution and transferring funds from SVB. We entered into a letter agreement with Silicon Valley Bridge Bank waiving enforcement of this covenant and providing us the right to hold a portion of our cash at other financial institutions. A future violation of any covenants could result in a default under the Amended Loan Agreement that would permit First-Citizens to restrict our ability to further access the Revolving Line of Credit for loans and require the immediate repayment of any outstanding loans under the agreement. As of June 30, 2023, we were in compliance with all debt covenants, provided, however, that in order to access future credit advances under the Revolving Line of Credit, we will be required to transfer certain cash management accounts back to First-Citizens. As of June 30, 2023, we had cash management accounts with a financial institution other than First-Citizens and instructed our customers to direct payments to us to these separate operating accounts. Until such operating accounts are closed and the funds moved back to cash collateral accounts held at First-Citizens, we will be unable to obtain credit advances under the Revolver.

The Amended Loan Agreement contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on First-Citizens's security interest over the collateral, a material adverse change, the occurrence of a default under certain other indebtedness of our company and 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. In addition, the Amended Loan Agreement contains a financial covenant which requires us to maintain, at all times when the Financial Covenant Measuring Period is in effect, certain net revenue levels as agreed upon by us and First-Citizens. If we do not comply with the various covenants under the Amended Loan Agreement and an event of default occurs under the Amended Loan Agreement, the interest rate on outstanding amounts can increase by 3% and First-Citizens may, subject to various customary cure rights, decline to provide additional advances under the Revolver, require the immediate payment of all amounts outstanding under the Amended Loan Agreement, and foreclose on all collateral.

Our material cash requirements include various contractual and other obligations consisting of long-term debt obligations with First-Citizens, operating lease obligations and purchase obligations with some of our suppliers and have not changed materially since the Form 10-K filed with the SEC on March 2, 2023. As of June 30, 2023, 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 debt (1)	$ 36,720	$ —	$ 8,400	$ 28,320	$ —
Interest obligations (2)	10,262	1,610	6,209	2,443	—
Operating lease obligations	3,900	796	2,548	556	—
Purchase obligations	390	390	—	—	—
Total	$ 51,272	$ 2,796	$ 17,157	$ 31,319	$ —

(1) Represents the principal obligations and the final fee at maturities of our First-Citizens Term Loan.
(2) Represents the future interest obligations on our First-Citizens Term Loan estimated using an interest rate of 8.75% as of June 30, 2023.

This compared to $48.7 million of contractual obligations as of December 31, 2022.

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,		
	2023	2022	$ Change
Net cash provided by (used in):		(in thousands)	
Operating activities	$ (14,343)	$ (28,353)	$ 14,010
Investing activities	13,984	(11,631)	25,615
Financing activities	90,328	1,398	88,930
Effects of exchange rate changes on cash and cash equivalents	129	(514)	643
Net increase (decrease) in cash and cash equivalents	$ 90,098	$ (39,100)	$ 129,198

Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 of $14.3 million resulted from cash outflows due to a net loss of $22.3 million, adjusted for $13.8 million of non-cash items, and cash outflows from net changes in operating assets and liabilities of $5.8 million. 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 changes in operating assets and liabilities of $5.9 million. The decrease in net loss, net of non-cash items for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 was mainly due to increased revenues. Net cash outflows from changes in operating assets and liabilities for the six months ended June 30, 2023 was primarily due to higher inventory due to the inventory build-up related to our implants, and lower accrued liabilities attributable to the normal course timing of expenses. 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 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.

Cash Flows From Investing Activities

Net cash provided by investing activities in the six months ended June 30, 2023 was $14.0 million compared to cash used in investing activities of $11.6 million in the six months ended June 30, 2022. Net cash provided by investing activities for the six months ended June 30, 2023 consisted of maturities of our marketable securities net of purchases of $19.3 million, partially offset by purchases of property and equipment of $5.3 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 used by investing activities for the six months ended June 30, 2022 consisted of maturities of marketable securities, net of purchases 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.

Cash Provided by Financing Activities

Cash provided by financing activities in the six months ended June 30, 2023 was $90.3 million resulting from net proceeds of $0.7 million from the refinancing of our term loan with First-Citizens, proceeds of $4.0 million from the issuance of common stock under our stock-based incentive compensation plans, and proceeds of $84.1 million, excluding the payment of $0.5 million in offering costs, from the issuance of common stock under our follow-on public offering. This compares to $1.4 million provided by financing activities in the six months ended June 30, 2022, which consisted solely of 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, Significant Judgments, and Use of Estimates” in our Annual Report on Form 10-K filed with the SEC on March 2, 2023. There had been no material changes to the descriptions of these accounting policies, judgments and estimates.

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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

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, 2023, 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, 2023, 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, 2023, 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;
- 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;
- Epidemic diseases, or the perception of their effects, may continue to adversely affect our business, financial condition, results of operations, or cash flows;
- We may not be able to convince physicians that our products are attractive alternatives to our competitors' products and that our procedures are attractive alternatives to existing surgical and non-surgical treatments for their respective indications;
- Surgeons and payors may not find the clinical evidence supporting our more recent products 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, the presence of physician-owned distributorships, and payor consolidation 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, have caused and may continue to 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, iFuse Bedrock Granite product, or iFuse-TORQ product do not result in positive outcomes for patients, or if clinical trials involving the use of iFuse Bedrock, iFuse Bedrock Granite, and/or

iFuse-TORQ fail to show meaningful patient benefit, sales of our iFuse, iFuse-3D, iFuse-TORQ, and/or iFuse Bedrock Granite implants could be adversely impacted;

- If we are unable to maintain our network of direct sales representatives, third-party sales agents, and resellers, 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;
- Adverse developments affecting the banking industry or the broader financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity; and
- Our ability to access credit on favorable terms, if necessary, for the funding of our operations and capital projects may be limited due to changes in credit markets.

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, 2023, we had a net loss of $22.3 million. For the years ended December 31, 2022 and 2021, we had net losses of $61.3 million and $56.6 million, respectively. As of June 30, 2023, we had an accumulated deficit of $379.4 million. We have financed our operations primarily through the net proceeds of our public offerings of our common stock, private placements of equity securities, certain debt-related financing arrangements, and from sales of our products. We have devoted substantially all of our resources to research and development of our products, sales and marketing activities, investments in training and educating surgeons and other healthcare providers, and clinical and regulatory matters for our products. There can be no assurances that we will be able to generate sufficient revenue from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flows, and even if we are able to do so, our ability to do so has been delayed by the COVID-19 pandemic. 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 depend on many factors including expanding our surgeon base, the expansion of our sales force, investment in implants and instruments, 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. The capital markets have deteriorated substantially since the beginning of 2022, 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.

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 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, such as that caused by inflation and rising interest rates, 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. These geopolitical events and related factors and results, 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 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 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 utilizing laterally placed transfixing devices, a small number of 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 and 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. Volatility in the payment rates that physicians and hospitals receive from CMS may have a material impact on their willingness to perform procedures including our products, as well as place additional pressure on pricing of our implants.

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 choose 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, 2023, the Medicare physician fee reimbursement for minimally invasive fusion with our laterally placed transfixing iFuse implants, described as Current Procedural Terminology ("CPT") Code 27279, is $827. 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 fusion procedures utilizing laterally placed transfixing devices 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 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 laterally placed transfixing 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, certain medical societies requested that the AMA create additional codes representing some of these newer, and different procedures utilizing non-transfixing technologies. In May 2022, the AMA CPT Editorial Panel adopted a proposal for a new Category III code to become effective January 1, 2023, describing a different sacroiliac joint procedure to place interpositional, intra-articular and non-transfixing implants typically using a dorsal, or posterior, approach. In September 2022, the AMA CPT Editorial Panel subsequently voted to convert the Category III Code to describe procedures to implant the newer, non-transfixing (dorsally placed) implants to a Category I Code effective January 1, 2024. If the levels of reimbursement for, and consistency of coverage associated with, procedures performed with our medical devices under the existing Category I CPT Code decrease as a result of or in connection with these coding changes, it could make the procedures in which our implants are used less attractive to healthcare professionals, decreasing the number of devices we are able to sell and adversely affecting our business, results of operations and financial condition.

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. Under current legislation, the reduction in Medicare payments will vary from 2% under the Budget Control Act of 2011 (as extended through a series of amendments and currently set to expire in 2032) to 4% if budget sequestration is triggered under the Statutory Pay-As-You-Go Act of 2010. 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, 2023, 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 triangular implants could reverse the exclusive nature of their policies and allow surgeons to use other types of products when performing sacroiliac fusion procedures. Some payor have removed such exclusivity in the past and others could do so in the future. For example, AIM, a clinical evidence evaluation organization which influences Anthem, among other payors, promulgated such a policy, effective September 11, 2022, that is no longer exclusive to titanium triangles. 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.

Epidemic diseases, or the perception of their effects, may continue to adversely affect our business, financial condition, results of operations, or cash flows.

As the COVID-19 global pandemic enters its fourth year, the impact of COVID-19 on our business remains highly dependent on future developments, which are uncertain and unpredictable. Although the U.S. public health emergency ended on May 11, 2023, an outbreak of an infectious disease, or a re-escalation of COVID-19 infection rates could divert medical resources toward the treatment of that disease, and 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 have included, and could continue to 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 regional or global economic downturns that could affect demand for our products, as well as increase risk of customer defaults or delays in payments. 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, cash flows, or ability to raise capital.

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 described herein.

We may not be able to convince physicians that our products are attractive alternatives to our competitors' products and that our procedures are attractive alternatives to existing surgical and non-surgical treatments for their respective indications.

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 products 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 our products 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 our products and procedures;
- costs associated with the purchase of our products; and
- time commitment that may be required for training.

Furthermore, we believe surgeons will not widely use our products 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.

Patients with sacroiliac joint dysfunction are cared for by a variety of health care providers, including spine surgeons and pain physicians and other interventionalists, who are generally trained as anesthesiologists, interventional radiologists, or physical medicine and rehabilitation specialists. These 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, fusion devices and other products intended to treat the sacroiliac joint or the pain it can cause. Our professional education program seeks to teach these physicians, and other health care providers, about the benefits of our iFuse products, with the intent of either having them adopt and perform our procedures or refer their patients with sacroiliac joint dysfunction to physicians who have been trained to perform our procedures. Providers who have not adopted our procedures may, however, prefer to continue to treat these patients with the interventions they offer because they feel that 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 physicians 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 the clinical evidence supporting our more recent products 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, iFuse-TORQ and iFuse Bedrock Granite have been launched prior to gathering substantial prospective clinical trial evidence, and our post-market 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, the presence of physician-owned distributorships, and payor consolidation 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 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, have caused and may continue to 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 anticipate that more outpatient eligible procedures will be performed in ASCs as a cost control measure within the healthcare system. This shift accelerated during the COVID-19 pandemic, and we expect it to continue because ASCs are generally a 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 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 is 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 viewed as 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, other companies have dedicated, and likely will continue to 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 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 Globus Medical, Inc. and Medtronic plc. 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.

In addition, a number of companies selling allograft implants for use by a variety of physicians have collectively become a much larger presence in our market. If customers view allograft implants and our products as interchangeable, we risk increased pricing pressure on our products. It is unclear how the creation of the Category III code for these procedures effective January 1, 2023, and the conversion of the Category III Code to a Category I Code effective January 1, 2024, will impact the market for these products and procedures.

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, iFuse-TORQ and iFuse Bedrock Granite 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, iFuse Bedrock Granite product, or iFuse-TORQ product do not result in positive outcomes for patients, or if clinical trials involving the use of iFuse Bedrock, iFuse Bedrock Granite, and/or iFuse-TORQ fail to show meaningful patient benefit, sales of our iFuse, iFuse-3D, iFuse-TORQ, 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 as 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.

In February 2021, we launched iFuse-TORQ, a line of 3D-printed threaded implants designed for use in pelvic trauma, as well as applications in sacroiliac joint dysfunction and degeneration. In 2022, FDA provided clearance for an expanded indication for iFuse-TORQ to include acute, non-acute and non-traumatic fractures as well as for placement across the sacroiliac joint using our Bedrock technique. Clinical experience with iFuse-TORQ is limited and we have yet to complete a clinical trial to evaluate the use of iFuse-TORQ in patients with sacral fragility or insufficiency fractures. Surgeons do not yet know if pelvic fracture fixation and SI joint fusion using iFuse-TORQ is superior to nonsurgical management in this class of patients. 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, third-party sales agents, and resellers, we may not be able to generate anticipated sales.

As of June 30, 2023, our U.S. sales force consisted of 85 territory sales managers and 66 clinical support specialists directly employed by us, and 141 third-party sales agents. As of June 30, 2023, our international sales force consisted of 12 sales representatives directly employed by us and a total of 31 third-party sales agents and resellers, which together have had sales in 39 countries through June 30, 2023. Our operating results are directly dependent upon the sales and marketing efforts of both our direct sales force and of our third-party sales agents and resellers.

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 sales agents and resellers with significant technical knowledge in various areas, such as spine and pelvic 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 sales agent or reseller departs and is 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. The launch of new products or entrance into new markets could distract our sales representatives from existing customers and markets and redirect resources from existing to novel markets. Furthermore, any such change affects our ability to hire, contract with and retain members of our direct sales force and third-party sales agents and resellers. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified third-party sales agents and resellers 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 sales agents and resellers would prevent us from expanding our business and generating sales. If our direct sales representatives or third-party sales agents and resellers 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, 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, and prolonged inflation;
- 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.

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;
- create sufficient product differentiation to expand overall market share and minimize cannibalization of existing product markets;
- obtain and maintain adequate coverage from third-party payors for new products or procedures;
- mitigate downward pricing pressure on new and existing products;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and effectiveness of new products;
- provide sufficient infrastructure needed for product commercialization;
- 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 minimally invasive sacroiliac fusion performed with a lateral approach, such as the iFuse procedure, 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 minimally invasive sacroiliac fusion performed using a lateral approach or cost savings as a result of the 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;
- lower average selling prices of our implants in most foreign markets;
- reliance on a more concentrated surgeon base in international markets due to the surgeon acquisition costs relative to the selling price of our implants;
- 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;
- customer relationship management;
- inventory management;
- compliance and regulatory reporting requirements;
- 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 internal or external breaches of our cybersecurity;
- power losses; and
- computer systems, 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 in the future, could be 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 third-party sales agents and resellers. 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.

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 medical device or make a significant modification to an existing product in the U.S., with 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 expect, 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, third-party sales agents and resellers 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 sales agents and resellers 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 coding of claims for reimbursement for medical procedures submitted to private and governmental payors and reporting of other 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 third-party sales agents and resellers' 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 2, 2023.

Certain states and countries also have enacted analogous state and foreign law equivalents of each of the above federal laws and 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 and foreign 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 2, 2023.

The California Consumer Privacy Act, which became effective on January 1, 2020, as amended by the California Privacy Rights Act ("CCPA"), 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, receive detailed information about how their personal information is used and shared, correct inaccurate personal information, and limit the use and disclosure of certain sensitive personal information. 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 initiatives regarding protection of personal information, such as Virginia, Colorado, Utah, Connecticut, and Washington. 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 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 sales agents and resellers 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, third-party sales agents and resellers may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates applicable laws and regulations, such as FDA reporting requirements, 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.

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 sales agents or resellers 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 have in the past, and may in the future, 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, COVID-19 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. Physicians 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.

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, 2023, we owned 57 issued U.S. patents and had 30 pending U.S. patent applications, and we owned 17 issued foreign patents and had 20 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 December 2025. Competitors may market similar triangular shaped devices upon the expiration of the patents in late 2025. 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 September 2035.

As of June 30, 2023, we have 20 registered trademarks in the U.S. 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, our third-party sales agents or resellers 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 sales agents or resellers sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees, our third-party sales agents or resellers 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 sales agents and resellers 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 sales agents and resellers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or third-party sales agents and resellers, 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 sales agents and resellers 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 sales agents and resellers 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:

- 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;
- the impact of infectious diseases, and measures taken to combat them, on our business;
- 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:

- 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;
- the impact of COVID-19 or other infectious disease outbreaks on our business;
- 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, 2022, we had net operating loss ("NOL") carryforwards of $298.6 million and $238.7 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. California NOL suspension and tax credit utilization limitation did not impact the Company due to taxable loss positions for 2020, 2021, and 2022.

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.

Adverse developments affecting the banking industry or the broader financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver.

Although a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure and we and other depositors with SVB received such access on March 13, 2023, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

In addition, if any parties with whom we conduct business are unable to access funds held in uninsured deposit accounts or pursuant to lending arrangements with a financial institution that is placed in receivership by the FDIC, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

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

Our Loan and Security Agreement (as amended, the "Amended Loan Agreement") with First-Citizens Bank & Trust Company ("First-Citizens") contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on First-Citizens 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 Amended Loan Agreement is secured by substantially all our assets other than our intellectual property. The Amended Loan Agreement 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 Amended Loan Agreement, 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 the Amended Loan Agreement to become immediately due and payable.

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

Our ability to access credit on favorable terms, if necessary, for the funding of our operations and capital projects may be limited due to changes in credit markets.

Our Amended Loan Agreement with First-Citizens provides for a secured revolving credit facility, or Revolver, in an aggregate principal amount of up to $15.0 million. The Revolver matures on July 6, 2025. As of June 30, 2023, we had not drawn on this credit facility. On March 10, 2023, we violated one of the terms of the Amended Loan Agreement by opening bank accounts with another financial institution and transferring funds from SVB. We entered into a letter agreement with Silicon Valley Bridge Bank waiving enforcement of this covenant and providing us the right to hold a portion of our cash at other financial institutions. Any future violation of any of the covenants could result in a default under the Amended Loan Agreement that would permit First-Citizens to restrict our ability to further access the Revolver for loans and require the immediate repayment of any outstanding loans under the agreement. In addition, certain provisions in the these covenants are subject to renegotiation at the beginning of each fiscal year, which further reduces our ability to anticipate whether this source of capital will continue to be available in the near term. As of June 30, 2023, we had cash management accounts with a financial institution other than First-Citizens and instructed our customers to direct payments to us to these separate operating accounts. Until such operating accounts are closed and the funds moved back to cash collateral accounts held at First-Citizens, we will be unable to obtain credit advances under the Revolver. See “Note 7. Borrowings” to the “Notes to Condensed Consolidated Financial Statements” included in this report.

Additionally, in the past, the credit markets and the financial services industry have experienced disruption characterized by the bankruptcy, failure, collapse or sale of various financial institutions, increased volatility in securities prices, diminished liquidity and credit availability and intervention from the U.S. and other governments. Continued concerns about the systemic impact of potential long-term or widespread downturn, energy costs, geopolitical issues, the availability and cost of credit, the global commercial and residential real estate markets and related mortgage markets and reduced consumer confidence have contributed to increased market volatility. The cost and availability of credit has been and may continue to be adversely affected by these conditions. We cannot be certain that funding for our capital needs will be available from our existing financial institutions and the credit markets if needed, and if available, to the extent required and on acceptable terms. The Amended Loan Agreement terminates on December 1, 2027 and if we cannot renew or refinance this facility or obtain funding when needed, in each case on acceptable terms, such conditions may have an adverse effect on our ability to operate our business.

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

None.

Item 6. Exhibits

Exhibit Number	Description	Incorporation By Reference: Form	SEC File No.	Exhibit/ Reference	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38701	3.1	10/19/2018
3.2	Amended and Restated Bylaws.	S-1/A	333-227445	3.4	10/5/2018
4.1	Form of Common Stock Certificate of the Company.	S-1/A	333-227445	4.1	10/5/2018
4.2	Reference is made to Exhibits 3.1 and 3.2.				
10.1*	2023 Non-Employee Directors' Compensation Policy				
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 8, 2023.

		SI-BONE, Inc.	
Date:	August 8, 2023	By:	/s/ Laura A. Francis
			Laura A. Francis
			Chief Executive Officer
			(Duly Authorized Officer and Principal Executive Officer)
		SI-BONE, Inc.	
Date:	August 8, 2023	By:	/s/ Anshul Maheshwari
			Anshul Maheshwari
			Chief Financial Officer
			(Duly Authorized Officer and Principal Financial and Accounting Officer)

SI-BONE, Inc.
2023 Non-Employee Directors' Compensation Policy
Approved by the Board of Directors
June 9, 2023

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of SI-BONE, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Directors' Compensation Policy (the "***Director Compensation Policy***") for his or her Board service. The Director Compensation Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

Each Eligible Director shall receive the cash compensation described below. The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board ("***Committee***") at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash retainer fees are vested upon payment.

1. Annual Board Service Retainer: $45,000 payable in cash ("***Annual Retainer***")

2. Annual Committee Member / Chair Service Retainer:
    a. Member / Chairperson of the Audit Committee: $10,000 / $20,000
    b. Member / Chairperson of the Compensation Committee: $7,000 / $15,000
    c. Member / Chairperson of the N&CG Committee: $5,000 / $10,000
    d. Chair of the Board: $45,000

3. Annual Lead Independent Director Service Retainer:
    a. Lead Independent Director: $5,000

Equity Compensation

The equity compensation set forth below will be granted under the SI-BONE, Inc. 2018 Equity Incentive Plan (the "***Plan***") and will be documented on the applicable form of equity award agreement most recently approved for use by the Board (or a duly authorized committee thereof) for Eligible Directors. Any stock options granted under the Director Compensation Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan). Any RSU grant provided for by this Director Compensation Policy that vests quarterly shall have quarterly vesting dates of March 15, June 15, September 15 and December 15 (the "***Quarterly Vesting Dates***"), and any RSU Grant that vests annually shall vest on the earlier to occur of the one-year anniversary of the date of grant or the Company's next Annual General Meeting of its stockholders.

1. Initial Share Grant: Upon first election to the Board, each Eligible Director will be granted, upon approval by the Board or Compensation Committee of the Board, restricted stock units having a value of $250,000 based on the 30-day trailing average of the Company's closing stock price (the "***Initial RSU Grant***"). The Initial RSU Grant will vest quarterly over three years beginning on the Quarterly Vesting Date that follows the date of grant, such that the Initial RSU Grant will be fully vested on the next Quarterly Vesting Date that follows the third anniversary of the Eligible Director's first election to the Board, subject to the Eligible Director's Continuous Service on each applicable vesting date. In addition, in the event of a Change in Control or a Corporate Transaction, any unvested portion of the Initial RSU Grant will fully vest and become exercisable as of immediately prior to the effective time of such Change

in Control or Corporate Transaction, subject to the Eligible Director's Continuous Service on the effective date of such transaction.

2. Additional RSU Grants: The Compensation Committee may review and approve additional equity grants to Eligible Directors on the date of each subsequent annual meeting. At the first Board meeting held following the Company's annual stockholder meeting, each incumbent Eligible Director shall receive an annual RSU grant having an approximate value of $120,000 based on the 30-day trailing average of the Company's closing stock price, which will vest approximately one year from the grant date (the "***Additional Annual RSU Grant***"), subject to the Eligible Director's Continuous Service on each applicable vesting date. In addition, in the event of a Change in Control or a Corporate Transaction, any unvested portion of the Additional Annual RSU Grant will fully vest and become exercisable as of immediately prior to the effective time of such Change in Control or Corporate Transaction, subject to the Eligible Director's Continuous Service on the effective date of such transaction. With respect to any person who first becomes an Eligible Director after the annual stockholder meeting of the preceding year, the Additional Annual RSU Grant shall be prorated based on the portion of the 12-month period prior to the annual stockholder meeting that such person served as an Eligible Director. By way of example, if an Eligible Director joins the Board on March 15 and the annual stockholder meeting is held June 15, s/he would receive an Additional Annual RSU Grant having an approximate value of $30,000 based on the 30-day trailing average of the Company's closing stock price.

Annual Pay Limit

The aggregate value of all compensation granted or paid, as applicable, to any individual for service as an Eligible Director with respect to any calendar year, including equity compensation awards granted and cash fees paid by the Company to such Eligible Director, will not exceed (i) $750,000 in total value or (ii) in the event such Eligible Director is first appointed or elected to the Board during such calendar year, $1,000,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes.

Philosophy

The Director Compensation Policy is designed to attract and retain experienced, talented individuals to serve on the Board. The Board anticipates that the Board, or a duly authorized committee thereof, will generally review Eligible Director compensation on an annual basis on or about the date of the Company's Annual General Meeting of its stockholders. The Director Compensation Policy, as amended from time to time, may take into account the time commitment expected of Eligible Directors, best practices and market rates in director compensation, the economic position of the Company, broader economic conditions, historical compensation structure, the advice of the compensation consultant that the Compensation Committee or the Board may retain from time to time, and the potential dilutive effect of equity awards on our stockholders.

Under the Director Compensation Policy, Eligible Directors receive cash compensation in the form of retainers to recognize their level of responsibility as well as the necessary time commitment involved in serving in a leadership role and/or on Committees. Eligible Directors also receive equity compensation because we believe that stock ownership provides an incentive to act in ways that maximize long-term stockholder value. Further, we believe that stock-based awards are essential to attracting and retaining talented Board members. When stock options are granted, these stock options will have an exercise price at least equal to the Fair Market Value of Common Stock on the date of grant, so that stock options provide a return only if the Fair Market Value appreciates over the period in which the stock option vests and remains exercisable. We believe that the vesting acceleration provided in the case of a Change in Control or other Corporate Transaction is consistent with market practices and is critical to attracting and retaining high quality directors.

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 8, 2023

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.

Date: August 8, 2023	/s/ Anshul Maheshwari 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, 2023, 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 8, 2023	Laura A. Francis Chief Executive Officer (Principal Executive Officer)
	/s/ Anshul Maheshwari
Date: August 8, 2023	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.