UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 No.)**

471 El Camino Real, Suite 101, Santa Clara, California 95050
(Address of principal executive offices including 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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☒	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the shares of common stock held by non-affiliates of the registrant as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1.1 billion, calculated based on the closing price of the registrant's common stock as reported by the Nasdaq Global Market. Shares of common stock held by each officer and director, and each entity affiliated with a director, have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of February 20, 2024 was 41,064,511 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Report.

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

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Item 1A. Risk Factors" below.

- 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, physicians, 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 triangular implants and choose to reimburse for procedures performed with competitive products, our market share and average selling prices could decline, adversely affecting our revenues;
- 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;
- Physicians 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, market dynamics, 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 does 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 United States. 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; and
- 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.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products/services, limit their use or adoption, and otherwise negatively affect our operating results and business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains 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 Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions, including those described under the sections in this Annual Report on Form 10-K entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements include, but are not limited to, statements about the following:

- our expectation that a significant portion of our revenues will be derived from sales of the iFuse Implant System, or iFuse;
- our ability to develop and commercialize additional revenue opportunities, including new indications for use and new products;
- our ability to retain and grow our sales team based on the demand for our products;
- our ability to identify, train, and retain physicians to perform procedures using our products;
- our ability to obtain and maintain favorable coverage and reimbursement determinations from third-party payors;
- our estimates of our market opportunity;
- our expectations regarding the scope of protection from intellectual property rights covering our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- timing of and results from clinical and other trials;
- marketing clearances and authorization from the FDA and regulators in other jurisdictions and CE Certificates of Conformity from Notified Bodies;

- 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;
- the impact of epidemics on our operations, financial results, liquidity, and capital resources, including the impact on our global supply chain, demand for and ability to obtain our products and procedures, and our ability to maintain a healthy workforce;
- our estimates regarding our costs and risks associated with our international operations and expansion;
- our expectations regarding our ability to retain and recruit key personnel;
- our ability to attract and retain employees, including those with specialized skills and experience;
- our expectations regarding acquisitions and strategic operations;
- our ability to access capital markets;
- our ability to fund our working capital requirements;
- our compliance with, and the cost of, federal, state, and foreign regulatory requirements;
- the factors that may impact our financial results; and
- anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements are based on management's current expectations, estimates, forecasts, and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this report may turn out to be inaccurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, 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

Item 1. Business.

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, as well as implantable bone products. Since launching our first generation iFuse in 2009, we have launched new titanium implant product lines, iFuse-3D in 2017, iFuse-TORQ in 2021 and iFuse Bedrock Granite in 2022. Within the United States, iFuse, iFuse-3D and iFuse-TORQ have clearances for applications across sacroiliac joint dysfunction and fusion, adult spinal 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 United States, and with a combination of a direct sales force, and sales agents and resellers in other countries. As of December 31, 2023, more than 95,000 procedures have been performed using our products by over 3,600 physicians 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 the 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 a selling stockholder, and we did not receive any proceeds from the sale by the selling stockholder.

Product and Applications

Our first-generation iFuse, a machined triangular titanium implant launched in 2009, has a triangular cross section that resists twisting or rotation of the implant. The triangular shape of this implant helps stabilize the joint, and the implant’s porous surface facilitates biologic fixation of the bone onto the implant, or bony on-growth and in-growth that results in fusion. The implant has at least three times the strength of a typical eight-millimeter cannulated surgical screw, and the large porous surface area of our implants allows for bony ingrowth. Our second generation iFuse product, the iFuse-3D implant, launched in 2017, is a patented titanium implant that combines the triangular cross-section of the first generation iFuse implant with a proprietary 3D-printed porous surface and fenestrated design. This design, with its open and porous structure, also allows the implant to self-harvest bone as it is impacted through the ilium. We hold patents on implants with cross-sections of many non-round shapes, including the triangular shape, as well as the fenestration configuration we use with our iFuse-3D implants. We also hold patents for the method of placing the implant across the sacroiliac joint, as well as other parts of the spine and pelvis.

In April 2019, we received clearance from the United States Food and Drug Administration, or FDA, to promote the use of our iFuse-3D implants for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint, which we call the Bedrock technique. We CE marked and began marketing iFuse for this indication and surgical technique in the European Union ("EU") in December 2019. In late-2019, 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. In March 2020, we received FDA 510(k) clearance for an expanded indication for our triangular titanium iFuse implants to support our trauma initiative.

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. Relative to competitive trauma products, iFuse-TORQ is roughly four times as strong in bending and requires 10 times the rotational force, or torque, to insert due to its porosity and other design features. We believe that this rotational resistance gives physicians confidence in the strength of mechanical fixation that iFuse-TORQ provides, and that the technological advancements incorporated into iFuse-TORQ represent a significant improvement compared to conventional trauma screws. iFuse-TORQ has a larger surface area for bone in-growth and was specifically designed to allow for osteointegration, or incorporation of the bone in the implant's porous surface and structure. In 2022, the 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.

In May 2022, we launched our iFuse Bedrock Granite Implant System. The iFuse Bedrock Granite implant provides sacroiliac fusion and sacropelvic fixation as a foundational element for segmental spinal fusion. The iFuse Bedrock Granite implant has a machined titanium core surrounded by a fusion sleeve that is additively manufactured. The fusion sleeve offers greater surface area for both microporous and macroporous surface features as well as self-harvesting cutting flutes. The fusion sleeve provides numerous means for biological fixation (bony on-growth, in-growth and through-growth). The robust neck and the set screw design also provide more strength and reliability to the iFuse Bedrock Granite implant. Based on the implant's ability to drive fusion and fixation, iFuse

Bedrock Granite is designated by the FDA as a breakthrough device. In August 2022, the Centers for Medicare and Medicaid Services, or CMS, issued a final decision for a New Technology Add-on Payment, or NTAP, of up to $9,828 for eligible cases using iFuse Bedrock Granite. The Breakthrough Device Designation and NTAP award were based on the FDA's recognition of iFuse Bedrock Granite as a new technology that can provide substantial clinical improvement over already available therapies. The NTAP became effective October 1, 2022 and will be effective for a period of up to three years and is exclusive to iFuse Bedrock Granite. In December 2022, we received FDA clearance for promotion of the compatibility of iFuse Bedrock Granite with a broad class of commercially available rods.

In addition to our implants and instruments, we also provide enabling technologies that are cleared and compatible with Medtronic's surgical navigation systems and Medtronic Mazor surgical robots. We also market decortication and graft delivery systems that allow surgeons to remove intra-articular cartilage and deliver flowable bone graft materials to the sacroiliac joint.

Market Opportunity

As a sacropelvic solutions company, our products have applications across sacroiliac joint dysfunction and degeneration, spinopelvic fixation, and pelvic fractures. We estimate that our total addressable market in the United States exceeds $3.0 billion.

Sacroiliac Joint Dysfunction and Degeneration

Over 30 million American adults are estimated to have chronic lower back pain. Studies indicate that 15% to 30% of patients with chronic low back pain may have symptoms originating with the sacroiliac joint. Our experience in both clinical trials and commercial settings indicates that at least 30% of these patients may be candidates for surgical treatment with our implants. Based on our market experience and internal estimates, and the assumption that the average person suffering from sacroiliac joint dysfunction has been in pain for five years, we estimate that the potential annual market opportunity for sacroiliac joint fusion in the United States could be approximately 279,000 patients for a potential market in the United States of approximately $2.4 billion per year.

Sacroiliac joint patients may have experienced one or more events that have contributed to disruption and/or degeneration of the sacroiliac joint, such as pregnancy, falls, previous lumbar surgery, automobile accidents, and aging, which may cause degeneration of the cushioning in the joint much like other joints. Patients with sacroiliac joint dysfunction frequently experience significant pain simply from sitting, standing, or rolling over in bed. The pain can be exacerbated with activity - when a patient walks or runs. We believe that approximately 65% of people who suffer from sacroiliac pain are women. Although several non-surgical treatments exist for sacroiliac joint pain, including physical therapy, opiates and non-steroidal anti-inflammatory medications, intra-articular injection of steroid medications and radio frequency ablation, these treatments did not provide long-term pain or disability relief in our randomized controlled clinical trials.

Adult Deformity and Degeneration

To strengthen the base of spinal constructs, spine surgeons have been using longer and larger diameter pedicle screws in iliac and sacro-alar iliac trajectories. Third party data has shown that the use of pedicle screws to anchor to the pelvis has delivered sub-optimal patient outcomes resulting in revision surgeries. Acute set screw failure of sacro-alar iliac screws has been reported in approximately 5% of cases. Screw loosening within the sacrum/ilium is another common failure, occurring in 4-27% of cases and screw fracture has been reported in up to 20% of cases. Building on our experience with the Bedrock technique which we introduced in 2019, we introduced iFuse Bedrock Granite, a novel, patent-protected device designed for the specific demands of the sacro-pelvic anatomy at the end of spinal fusion constructs. We believe there are over 30,000 surgeries involving fixation of five or more spinal segments that involve fixation to the pelvis and an additional 100,000 surgeries involving two to four level spinal segment fixations to the sacrum, which we estimate to be an approximately $1.0 billion aggregate annual market opportunity.

Pelvic Trauma

Current treatment options for pelvic fragility fractures are sub-optimal. Sacroplasty has high rates of cement leakage and therefore lacks consistent coverage by payors. Traditional trauma screws do not integrate with bone and therefore loosen in more than 20% of the cases in which they are used. As a result, most patients are prescribed bed-rest, involving significant capacity and financial burdens on the health care system, and a one-year mortality rate range of 14%-27%. With the introduction of iFuse-TORQ in 2021, we are specifically targeting the pelvic trauma market, which we estimate to be an approximately $350 million market opportunity.

Clinical Evidence

Our triangular iFuse implants are the only minimally invasive products for sacroiliac joint fusion commercially available in the United States that, to our knowledge, are supported by substantial high-quality published evidence of safety, clinical effectiveness, durability, and economic utility. The safety, effectiveness and cost-effectiveness of our triangular iFuse implants are supported by more than 125 publications and several large prospective clinical studies, including two randomized trials, two large prospective multicenter trials and one long-term follow-up study. Additional long-term independent studies have reported follow-up data as far out as six years.

Table 1. Summary of SI-BONE sponsored trials.

Study Name	Implant	Geography	Condition*	Design**	Sample Size	Follow-up period	Status
iMIA	iFuse	EU	SIJD	MRCT	103	2 years	Complete
INSITE	iFuse	USA	SIJD	MRCT	148	2 years	Complete
SIFI	iFuse	USA	SIJD	PMSA	172	2 years	Complete
LOIS	iFuse	USA	SIJD	PMSA	103	5 years	Complete
SALLY	iFuse-3D	USA	SIJD	PMSA	51	5 years	Ongoing
SILVIA	iFuse-3D	USA, EU & AUS	ASD	MRCT	220	2 years	Ongoing
SAFFRON	iFuse-TORQ	USA	FFP	MRCT	120	1 year	Enrolling
STACI	iFuse-TORQ	USA	SIJD	PMSA	110	2 years	Enrolling

*MRCT = multicenter randomized controlled trial; PMSA = prospective, multicenter single-arm
**SIJD = sacroiliac joint dysfunction; ASD = adult spine deformity; FFP = fragility fracture of the pelvis

Table 1 summarizes clinical trials sponsored by SI-BONE. 4 studies of iFuse Implant System (INSITE, iMIA, SIFI and LOIS) have been completed. INSITE and iMIA were prospective multicenter, randomized controlled trials conducted in the US and Europe, respectively. In both trials, patients with chronic sacroiliac joint pain were assigned at random to either immediate sacroiliac joint fusion using iFuse implants or individually tailored non-surgical management. In both studies, subjects assigned to sacroiliac joint fusion reported large improvements in pain, disability related to pain and quality of life. In contrast, in subjects assigned to non-surgical management, only small, clinically unimportant improvements in these parameters were observed.

In ***INSITE*** (Investigation of Sacroiliac Fusion Treatment), more than 90% of subjects participating in the non-surgical group decided to cross over to sacroiliac joint fusion surgery, indicating that non-surgical treatment provided ineffective relief of pain and disability related to pain. After crossover sacroiliac joint fusion surgery, these subjects reported improvements in pain, disability and quality of life nearly identical to those subjects originally assigned to sacroiliac joint fusion. At two years, patients undergoing sacroiliac joint fusion had sustained improvements in pain, disability and quality of life. Two-year results from INSITE were published in August 2016. Further, an embedded cost-effectiveness analysis within INSITE, published in December 2015, showed the procedure to be highly cost-effective for the treatment of chronic sacroiliac joint pain.

In ***iMIA*** (iFuse Implant System Minimally Invasive Arthrodesis), similar large differences were observed between subjects undergoing sacroiliac joint fusion vs. those undergoing non-surgical management. Similarly, subjects crossing over from non-surgical to surgical treatment showed marked improvements in all parameters assessed. Improvements in pain, disability and quality of life after sacroiliac joint fusion were sustained at two years. Two-year results were published in March 2019.

In ***SIFI*** (Sacroiliac Joint Fusion with iFuse Implant System), patients with chronic sacroiliac joint pain seen at 26 US centers underwent sacroiliac joint fusion using iFuse Implant System. Eligibility criteria were identical to those of INSITE and very similar to those of iMIA. Similar improvement in pain, disability and quality of life were observed throughout study follow-up. Two-year results were published in April 2016.

In INSITE, iMIA and SIFI, the rate of procedure-related adverse events was low.

In ***LOIS*** (Long term Outcomes of INSITE and SIFI), subjects participating in INSITE and SIFI were enrolled in a long-term follow-up study. Five-year results, published in April 2018, showed sustained improvements in pain, disability and quality of life as well as a high satisfaction rate at 5 years. Moreover, independent radiographic analysis showed a high rate of bony apposition to implants on both the sacral and iliac sides (98%) as well as a high rate of sacroiliac joint fusion (88% bridging bone) at five years. There were no reported adverse events related to the study device or procedure at five years.

Ongoing studies are as follows.

SALLY (Study of Bone Growth in the Sacroiliac Joint After Minimally Invasive Surgery with Titanium Implants) is a prospective, multicenter single-arm clinical study of the same patient population (i.e., sacroiliac joint dysfunction) who underwent sacroiliac joint fusion using iFuse-3D. The purpose of the study was to show that the 3D printed version of the device produces results

similar to prior studies of iFuse. Two-year results, published in June 2021, showed similar improvements in pain, disability and quality of life compared to prior studies of iFuse as well as CT evidence of earlier fusion of the sacroiliac joint. The study also showed marked reduction in opioid use and improvement in objective functional tests. Five year follow-up is starting and expected to be completed in late 2024.

SILVIA (sacroiliac joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial) is an ongoing prospective randomized trial of iFuse-3D placement during multilevel spine fusion with fixation to the pelvis. The target patient population of this trial is patients undergoing multilevel spine fusion surgery primarily for degenerative scoliosis of the spine. All participants undergo pelvic fixation. At random, approximately 50% of participants are assigned to additional placement of iFuse-3D in the sacro-alar-iliac trajectory using the Bedrock technique. The primary endpoint of the study is the incidence of sacroiliac joint pain and/or distal junctional failures. The study aims to show that placement of iFuse-3D in the Bedrock configuration reduces the rate of these outcomes. Early study results, which focused on device placement feasibility and 90-day safety events, have been accepted for publication. They demonstrate the feasibility and safety of pelvic fixation utilizing a sacral-alar-iliac screw combined with iFuse-3D in the bedrock configuration. Additionally, the study reveals that sacroiliac joint pain is common among patients undergoing surgery for adult spine deformity, with a baseline prevalence of 16%. Enrollment in this trial was completed in 2022 and follow-up is ongoing. Long-term results are expected to be completed in 2025.

SAFFRON (Sacral Fracture Fusion/Fixation for Rapid Rehabilitation) is a prospective randomized controlled trial comparing pelvic fracture fixation and sacroiliac joint fusion using iFuse-TORQ with non-surgical management in patients with debilitating fragility fractures of the sacrum. We anticipate initial results to be available in late 2024.

STACI (iFuse-TORQ for the treatment of Sacroiliac Joint Dysfunction) is an ongoing prospective, multi-center, single-arm study. This study will enroll 110 subjects with diagnosed sacroiliac joint dysfunction at 15 U.S. sites. All patients undergo sacroiliac joint fusion using iFuse-TORQ and are followed for two years. The study's eligibility criteria are similar to those of prior U.S. studies (INSITE, SIFI and SALLY). Like previous studies, STACI endpoints include improvement in pain, disability and quality of life. The study is currently enrolling and early study results are expected to be available in late 2024.

Other Published Clinical Studies

To date, several independent clinical studies have provided evidence to support the long-term safety and effectiveness of iFuse for sacroiliac joint fusion. These studies demonstrated pain reduction and/or ODI improvement that is statistically significant and clinically important and a safety file that was similar to that observed in prospective studies. One study showed marked reduction in opioid use after sacroiliac joint fusion compared to similar subjects who underwent non-surgical treatment, and in whom opioid use increased.

Coverage and Reimbursement

Coverage and reimbursement for procedures using our implants vary by setting of care, payor type and region. Outside the United States, reimbursement levels vary significantly by country and by region within some countries.

In addition to coverage policies, third-party payors regularly update reimbursement amounts and sometimes revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgical centers for procedures requiring our products.

Substantially all U.S. payors reimburse for minimally invasive sacroiliac joint fusion when performed using a lateral transfixing device, and a significant number of U.S. payors have issued positive coverage policies exclusive to our patented design of triangular titanium implants for sacroiliac joint fusion because of the clinical evidence. We believe that the coverage and reimbursement for our lateral transfixing procedure under CPT Code 27279 is generally adequate given the time and complexity of our procedures.

In addition to CPT code 27279, which is typically used to code for the iFuse procedure, effective January 1, 2024, the AMA adopted a separate Category 1 CPT code 27278 to describe minimally invasive sacroiliac fusion when performed using an intra-articular implant, placed directly in the joint generally from a posterior approach. This technique, developed more recently, is more commonly used by interventional spine physicians.

Healthcare Professional Training and Education

Since our inception, we have made considerable investments in teaching healthcare professionals to accurately diagnose sacroiliac joint disorders. Our surgeon training programs are for orthopedic spine surgeons, neurosurgeons, general orthopedic surgeons, and orthopedic trauma surgeons. Our medical affairs team works with leading spine surgeons to educate other orthopedic and neurosurgeons on the differential diagnosis of sacroiliac joint disorders and the use of our implants. Our non-surgeon physician training programs focus on interventionalists, who are generally trained as anesthesiologists, interventional radiologists, or physical medicine and rehabilitation specialists. We also work closely with medical specialty societies to raise the awareness of and teach the appropriate diagnosis of sacroiliac joint dysfunction and the associated treatment options.

We conduct many educational programs for the broader medical community including primary care physicians, pain management physicians and other healthcare practitioners that may manage a sacroiliac joint patient non-surgically, such as physical therapists and chiropractors. Our educational programs focus on helping healthcare professionals learn about the sacroiliac joint as a component of lower back pain, proper diagnosis of sacroiliac joint dysfunction, non-surgical treatment options and surgical treatment with our implants. In addition to these general educational programs, we provide continuing education programs focused on sacroiliac joint diagnosis and treatment. We can provide these programs in all 50 states and the District of Columbia.

In early 2020, we implemented a virtual education series for physicians and mid-level practitioners. In July 2020, we began using the SI-BONE SImulator; an innovative, fully portable surgery training simulator. The computer-based surgery training simulator provides quality haptics, or the realistic feel during the physician's use of the implants and instruments, and the training is performed without need for an operating room or a fluoroscope. The simulator is used to train physicians to perform sacroiliac joint injections, sacroiliac joint fusions, as well as iFuse Bedrock technique using iFuse-3D and iFuse-TORQ, and procedures using iFuse Bedrock Granite. We currently have 25 simulators used worldwide. We utilize the simulators and our existing programs to train new physicians, increase the knowledge and proficiency of existing iFuse physicians and re-engage inactive physicians.

We are targeting over 12,000 U.S. physicians including over 8,000 orthopedic and neurological surgeons and approximately 4,500 interventional spine physicians, to perform our procedures. As of December 31, 2023 and 2022, in the United States, more than 2,700 physicians and 2,200 physicians, respectively, have been trained on iFuse and have treated at least one patient using iFuse. Outside the United States, as of December 31, 2023 and 2022, more than 900 physicians and 800 physicians, respectively, have been trained on iFuse and have treated at least one patient using iFuse.

Sales and Marketing

We market and sell our implants primarily through a direct sales force and third-party sales agents. Our target customer base includes over 12,000 physicians who perform advanced spinal procedures.

Our direct sales organization in the United States covered eighteen sales regions as of December 31, 2023. In each region, a number of territory sales managers act as the primary customer contact. Our territory sales managers have extensive training and experience selling medical devices for spine problems and pain management, generally focusing on emerging technologies and markets. For large and/or high volume territories, we also employ territory representatives who cover cases. As of December 31, 2023, our U.S. sales force consisted of 82 territory sales managers and 69 clinical specialists directly employed by us, and 175 third-party sales agents. As of December 31, 2023, we had 28 employees working in our European operations across multiple countries. As of December 31, 2023, our international sales force consisted of 14 sales representatives directly employed by us and 31 third-party sales agents, which together had sales in 38 countries through December 31, 2023. We intend to continue to grow our specialized sales force to foster relationships with physicians and support revenue growth.

We believe it is essential to raise awareness among lower back pain sufferers that their symptoms may be the result of sacroiliac joint disorders and that minimally invasive surgical treatments are available. To raise patient awareness, we have implemented targeted marketing, education and direct outreach programs. We continually update our social media initiatives and post content to educate and engage patients who may be candidates for our procedures.

Research and Development

We remain focused on the development of products and techniques to help physicians improve the treatment of their patients and anticipate continuing to build products and pursue additional indications. Our development team, in consultation with physicians, has a pipeline of products in various stages to provide solutions that respond to the needs of our physician customers and their patients. We plan to seek regulatory clearances for additional indications as required. We anticipate that research and development expenses will continue to increase in the future.

Competition

We believe we are an industry leader in solving musculoskeletal disorders of the sacropelvic anatomy with our proprietary minimally invasive surgical implant systems. Over the past several years, other companies have subsequently recognized the multi-billion dollar addressable market opportunity and have entered the minimally invasive sacroiliac joint fusion market. We expect more competitors to enter into the market and an increased number of new product introductions by existing competitors. Some of our competitors are large, publicly traded companies that can dedicate far greater resources to the minimally invasive sacroiliac joint market than we can. These companies often have wide product offerings for spine and orthopedic surgery, which allow them to bundle products in order to win large hospital group contracts and can create a barrier to entry for us. For example, some of our competitors offer sacroiliac joint fusion products which integrate with their surgical navigation and robotics platforms, enabling navigation of their procedures or performance of aspects of these procedures by surgical robots. Some of these diversified companies also have much larger sales forces than ours, which allow them to reach more surgeons. Other competitors have entered the market with allograft bone implants marketed as human tissue products and intended for sacroiliac stabilization and/or fusion. Many of these competitors are smaller companies and target interventional pain and other physicians not trained as orthopedic and neurological surgeons for use of these products. We also expect there to be a continued push for non-surgical alternatives.

We believe that our largest competitors currently are Globus Medical, Inc. and Medtronic plc. However, these competitors sell screw-based products, which we believe lack the features, evidence and advantages of our implants. We also compete against non-hardware products, such as allograft bone implants. These allograft products comprise human cells or tissues and are generally regulated by the FDA differently from implantable medical devices made of metallic or other non-tissue based materials, unless these competitors' allograft products fail to meet the FDA's criteria for regulation as a human cell or tissue product.

Based on our commercial experience and market research, we believe our implants are currently used in the majority of minimally invasive surgical fusions of the sacroiliac joint in the United States. Our triangular titanium implant is differentiated from other screw-based technologies on the market. Our triangular iFuse is the only minimally invasive product for sacroiliac joint fusion commercially available in the United States that, to our knowledge, is supported by published clinical evidence including randomized controlled studies that demonstrate the safety, clinical effectiveness, durability, and economic utility. These benefits are supported by more than 125 published papers. We have received exclusive reimbursement coverage in the United States by certain payors based upon our differentiated product and quality of our evidence. We believe that we have the largest dedicated direct salesforce focused on spinopelvic solutions competing in our segment. We believe these factors provide competitive advantages to us in the market. The following are the primary competitive factors on which companies compete in our industry:

- product and clinical procedure effectiveness;
- ease of surgical technique and use of associated instruments;
- safety;
- published clinical outcomes and evidence;
- sales force effectiveness;
- product support and service, and customer service;
- comprehensive training, including disease, anatomy, diagnosis and treatment;
- product innovation and the speed of innovation;
- intellectual property;
- accountability and responsiveness to customers' demands;
- scientific (biomechanics) data; and
- pricing and reimbursement.

Intellectual Property

We protect our intellectual property through our pending patent applications and issued patents. As of December 31, 2023, we had been issued 59 issued U.S. patents and had 34 pending U.S. patent applications, and we owned 18 issued foreign patents and had 22 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 the design of our first generation iFuse implant, including its triangular shape, expire in December 2025. Our current U.S. patents on iFuse-3D, including the fenestrated design, expire in September 2035. Our current U.S. patents on the triangular cutting tool used to place our implants expire in February 2034, and our current U.S. patents protecting the design of our iFuse Bedrock Granite implants expire in February 2039. Our foreign patents will expire between August 2025 and September 2035.

As of December 31, 2023, we have 20 registered trademarks in the United States and have filed for three more. We have sought protection for at least two of these trademarks in 61 countries including the 27 European member countries of the Madrid Protocol.

We also rely upon trade secrets, know-how and continuing technological innovation, and may rely upon licensing opportunities in the future, to develop and maintain our competitive position. We may seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information, under which they are bound to assign to us inventions made during the term of their agreements.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. There can be no assurance that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents but that compete with our proprietary technology and products. Furthermore, numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications currently unknown to us, which may later result in issued patents that our existing or future products or proprietary technologies may be alleged and/or found to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how and brands, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Adverse determinations in litigation could reduce the barriers to entry that we have established for iFuse, or subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from manufacturing, selling or using iFuse, any of which could severely harm our business.

Regulation

Domestic Regulation of Our Products and Business

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act ("FDCA") as implemented and enforced by the FDA. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

There are numerous FDA regulatory requirements governing the clearance or approval and marketing of our products. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- investigational device exemptions to conduct premarket clinical trials, which include extensive monitoring, recordkeeping, and reporting requirements in compliance with good clinical practices ("GCP") and with institutional review board ("IRB") oversight;
- Quality System Regulation ("QSR"), which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k), clearance or approval of a pre-market approval ("PMA") from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either Class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring a PMA.

Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's "general controls" for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, though certain Class II devices are exempt from this premarket review process. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA may place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous premarketing requirements.

Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. The safety and effectiveness of Class III devices cannot be assured solely by general or special controls. Submission and FDA approval of a premarket approval, or PMA, application is required before marketing of a Class III device can proceed.

510(k) Clearance

To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a device that was legally marketed prior to May 28, 1976 for which a PMA is not required (known as a "pre-amendments device" based on the date of enactment of the Medical Device Amendments of 1976), a device that has been reclassified from Class III to Class II or Class I, or a device that was found substantially equivalent through the 510(k) process. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. A showing of substantial equivalence sometimes, but not always, requires clinical data.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, if the modification changes the classification of the product to Class III, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

Regulation of Human Cell and Tissue Based Products

Our iFuse Bone products are derived from human tissue (demineralized bone tissue). The FDA has specific regulations governing human cells, tissues, and cellular and tissue-based products ("HCT/Ps"). HCT/Ps regulated by the FDA under the authority of section 361 of the Public Health Service Act must be not more than minimally manipulated and be for homologous use. They are subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, Good Tissue Practice when processing, storing, labeling and distributing HCT/Ps, including required labeling information, stringent record keeping and adverse event reporting. Our bone tissue products are regulated as 361 HCT/Ps.

The AATB has issued operating standards for tissue banking. Accreditation is voluntary, but compliance with these standards is a requirement to become an AATB-accredited tissue establishment. In addition, some states have their own tissue banking regulations. As of December 31, 2023, we are licensed or have permits for tissue banking in California and Maryland.

Procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act (NOTA), which prohibits the transfer of certain human organs, including bone tissue for valuable consideration, but permits reasonable payments associated with removal, transportation, implantation, processing, preservation, quality control and storage.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply.

We have registered our facility with the FDA as a medical device manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees, 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 PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Promotional Materials - "Off-Label" Promotion

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or 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 claims for reimbursement. In that event, we could be subject to additional significant penalties, such as exclusion from participation in federal healthcare programs, and our reputation could be damaged and adoption of the products would be impaired.

In addition, under the federal Lanham Act and similar state laws, competitors, and others can initiate litigation relating to advertising claims.

International Regulation of Our Products

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in countries outside of the US.

In the European Economic Area ("EEA") (comprised of the 27 EU Member States, plus Iceland, Lichtenstein and Norway), Regulation (EU) 2017/745 on Medical Devices, or the Medical Device Regulation ("MDR") and its associated guidance documents and harmonized standards govern many aspects of the regulation of medical devices. This includes device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance.

Medical devices must comply with the General Safety and Performance Requirements ("GSPRs"), set out in Annex I to the Medical Device Regulation. Compliance with these requirements is a prerequisite to affixing the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the Medical Device Regulation and obtain the right to affix the CE mark, medical devices manufacturers must conduct a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low-risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires review by a Notified Body. A Notified Body is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical device. Following a successful assessment process, the Notified Body issues a CE Certificate of Conformity. This Certificate and completion of the related conformity assessment process

entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must include the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical investigations conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical investigations and scientific literature. Moreover, after a device is placed on the market, it remains subject to significant regulatory requirements that must commonly be fulfilled by the manufacturer or on their behalf.

The Medical Device Regulation includes a number of transitional provisions. Manufacturers of medical devices may only benefit from the transitional provisions if certain conditions are fulfilled.

The advertising and promotion of medical devices in the EEA is subject to the national laws of the individual EEA countries. Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA countries govern the advertisement and promotion of medical devices. The national legislation of individual EEA countries may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Moreover, outside the United States, interactions between medical device companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of EEA countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct.

In the UK, medical devices are governed by the Medical Device Regulations (UK MDR) 2002, as amended. In light of the fact that the CE Marking process discussed above is set out in EU law, which no longer applies in the United Kingdom, the United Kingdom has devised a new route to market culminating in a UKCA Mark to replace the CE Mark. The UK Government has established transitional provision to recognize the acceptance of CE marked medical devices on the Great Britain market.

Regulatory Status

In November 2008, we received 510(k) clearance to market our first generation iFuse implant from the FDA. Since 2008, we have received additional FDA 510(k) clearances for new instruments, additional implant sizes and labeling changes. In the United States, our first-generation iFuse implants and our iFuse-3D implants are intended for sacroiliac fusion for the following conditions: sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis, which includes conditions where symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months; to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion; and acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

In February 2021, we received 510(k) clearance to market our iFuse-TORQ from the FDA.

In June 2022, we received an additional 510(k) clearance from the FDA to extend the use of iFuse-TORQ to include fragility fractures. This clearance opens a new population that can benefit from sacroiliac joint fusion and fracture fixation using iFuse-TORQ.

In September 2022, we received 510(k) clearance from the FDA for use of iFuse-TORQ using the Bedrock technique. This clearance allows us to promote the use of a threaded implant (iFuse-TORQ) in a trajectory that is familiar to surgeons through a previous clearance for the same use for iFuse-3D. In the United States, the iFuse TORQ Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

In May 2022, we received 510(k) clearance from the FDA for iFuse Bedrock Granite. This implant combines benefits of a pelvic fixation screw with attachment to posterior rods of pedicle screw systems and simultaneous fusion of the sacroiliac joint related to the device's porous surface. This device previously received breakthrough device designation from the FDA in November 2021. The combination of breakthrough designation and FDA clearance allowed us to obtain a new technology add-on payment (NTAP) from CMS. NTAP provides an additional payment to hospitals for eligible cases that use iFuse Bedrock Granite.

In June 2023, we received 510(k) clearance from the FDA for iFuse-TORQ placement in the posterolateral or lateral oblique trajectory. The most recent FDA 510(k) premarket clearance was received in January 2024 for the iFuse Bedrock Granite® Implant System in a smaller (9.5 mm) diameter with both an expanded indication in pediatric patients, and an expanded application that includes use in the S1 trajectory.

In the future, we plan to pursue additional 510(k) clearances for new products and changes to the current indication for iFuse.

In November 2010, we obtained a CE Certificate of Conformity from our Notified Body (DEKRA) and affixed a CE mark to our iFuse Implant System in accordance with the MDD to allow commercialization of our triangular iFuse implants in the EEA. In the EEA and Switzerland, iFuse is intended for sacroiliac joint fusion, including use in high and low energy fractures of the pelvic ring. Since 2010, we have renewed our Certificates, added additional instruments, implant sizes and labeling updates and iFuse-3D, our second generation iFuse implant, to our product offerings in the EEA. We plan to continue to work with our Notified Body to update our Technical Files and incorporate updates to our products in the EEA in accordance with applicable legislative requirements.

In 2021, a UK Responsible Person was appointed and we registered the iFuse Implant System with the Medicines and Healthcare products regulatory agency. We rely on our CE marks to continue to place our devices on the market in Great Britain until the requirement to obtain a UK Conformity Assessed (UKCA) mark applies to our devices.

As of May 26, 2021, the European Union no longer applies the Mutual Recognition Agreement between the EEA and Switzerland. However, Switzerland continues to recognize marked medical devices CE marked in accordance with the relevant EU legislation. As a result, we rely on our CE mark to continue to place our devices on the market in Switzerland.. Manufacturers based outside of Switzerland are required to appoint a Swiss authorized representative in compliance with the Swiss Medical Device Ordinance. As a consequence, we have appointed an authorized representative in Switzerland and continue to work to meet Swiss requirements for the import of medical devices.

In 2022, we began the effort of obtaining approval for iFuse and iFuse-3D under EU MDR. As of December 2023, our quality system received MDR approval under ISO 13485:2016. We are awaiting issuance of our MDR Certificates of Conformity for the iFuse-3D implants.

We maintain approval for iFuse in regions beyond the United States and the EEA, including Australia, New Zealand, and Israel.

Environmental Regulations

We outsource substantially all the manufacturing of our products, therefore we have not incurred significant expenses relating to our compliance with federal, state, or local environmental laws and do not expect to incur significant expenses in the foreseeable future. However, due to the nature of our operations and the frequently changing nature of environmental compliance standards and technology, we cannot predict with any certainty that future material capital or operating expenditures will not be required in order to comply with applicable environmental laws and regulations.

Healthcare Fraud and Abuse

Federal and state governmental agencies and equivalent foreign authorities subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. These laws constrain the sales, marketing and other promotional activities of medical device manufacturers by limiting the kinds of financial arrangements we may have with hospitals, physicians and other potential purchasers and prescribers of our products. Federal healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursable under Medicare, Medicaid, or other federally funded healthcare programs. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, arrangement for, or recommendation of, items or services for which payment

may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of, or a specific intent to violate, the law;

- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds; knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease, or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Actions under the False Claims Act may be brought by the government or as a *qui tam* action by a private individual in the name of the government and to share in any monetary recovery. There are also criminal penalties for making or presenting a false or fictitious or fraudulent claim to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third-party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Physician Payment Sunshine Act, implemented by the Centers for Medicare & Medicaid Services ("CMS") as the Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS, information related to payments and other "transfers of value" made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (including physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners;

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers and patients; state and foreign laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign beneficiary inducement laws, and state and foreign laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our employees are found to have violated any of the above laws we may be subject to significant administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal health care programs, such as Medicare and Medicaid, and equivalents foreign penalties, significant fines, monetary penalties and damages, the restructuring or curtailment of our operations, imposition of compliance obligations and monitoring, and damage to our reputation. For a more detailed description of the federal and state health care fraud and abuse laws, see the risk factor "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" in the Risks Related to Our Legal and Regulatory Environment section of Item 1A of this Annual Report on Form 10-K.

The U.S. Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery laws in other countries, such as the United Kingdom Bribery Act ("UKBA"), generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws.

Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices.

Data Privacy and Security Laws

In the ordinary course of our business, we may process personal or sensitive data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy and security. Such obligations may include, without limitation, the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive. Several states within the United States have enacted or proposed data privacy laws. For example, California passed the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA"). Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collecting, using, and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the CPRA expanded the CCPA by giving California residents the ability to limit use of certain sensitive personal data, establishing restrictions on personal data retention, expanding the types of data breaches that are subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new law. Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

We are also 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 the Health Insurance Portability and Accountability Act, and its implementing regulations, as amended by Health Information Technology for Economic and Clinical Health Act enacted under the American Recovery and Reinvestment Act 2009 (collectively, "HIPAA"), in the United States.

HIPAA imposes obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also requires the notification of patients, reporting to the U.S. Department of Health and Human Services ("HHS"), and other compliance actions, in the event of a breach of unsecured Protected Health Information ("PHI"). Required notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach, under HIPAA. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, HHS would post the notification on its website, and we may be required to notify the media. Failure to comply with the HIPAA privacy and security standards can result in significant civil monetary penalties, and, in certain circumstances, criminal penalties, including imprisonment.

In addition, even when HIPAA does not apply other federal and state laws impose security obligations. For example, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Manufacturing and Supply

We use third-party manufacturers to produce our implants and instruments. To mitigate supply risk, we use a rolling twelve month forecast and take into consideration production lead times to maintain adequate levels of inventory for our iFuse-3D, iFuse-TORQ and iFuse Bedrock Granite implants. Most of our instruments have secondary manufacturing suppliers and we continually work with additional manufacturers as our secondary suppliers. Substantially all of our products, including all of our implants, are manufactured in the United States.

Our supplier for iFuse-3D and iFuse-TORQ is rms Company ("RMS"). We entered into an exclusive Manufacture and Supply Agreement with RMS in February 2024 (the "Manufacture and Supply Agreement") which supersedes and replaces our prior Manufacturing, Quality and Supply Agreement with RMS. Pursuant to the Manufacture and Supply Agreement, RMS manufactures certain of our implants in accordance with our specifications. The agreement provides us with the right to quality alternative sources from whom we may purchase products in the event of a supply failure by RMS. The prices we pay for products are fixed under the agreement through 2026. The agreement has a three-year initial term and automatically renews for successive one-year periods; provided, however, the agreement may be terminated early by either party, as specified in the agreement. RMS is currently our only supplier of iFuse-3D and iFuse-TORQ implants.

Our iFuse Bedrock Granite implant is manufactured and assembled by third-party suppliers, including RMS.

We believe that our manufacturing operations, and those of our suppliers, comply with regulations mandated by the FDA and the EU. Manufacturing facilities that produce medical devices or component parts intended for distribution world-wide are subject to regulation and periodic planned and unannounced inspection by the FDA and other domestic and foreign regulatory authorities as well as Notified Bodies.

In the United States, products we sell are required to be manufactured in compliance with the FDA's Quality System Regulation, codified at 21 CFR Part 820, which covers the methods used in, and the facilities used for, the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage, and shipping. In international markets, we are required to comply with similar requirements. Our status in FDA’s Establishment Registration and Device Listing is active and we also maintain the Medical Device Manufacturing License issued by the State of California’s Department of Public Health Food and Drug Branch. In the EEA, we are required to comply with Quality Management System (“QMS”) requirements established in EU medical device legislation. To demonstrate compliance with these requirements, we obtain and maintain ISO13485:2016 Quality Management System certification for our locations in Santa Clara, California, and Gallarate Italy, issued by DEKRA Certification, B.V.

We obtain and maintain appropriate CE Certificates of Conformity delivered by our Notified Body, DEKRA, for any medical devices we placed on the EU market in accordance with applicable EU medical device legislation.

We are required to demonstrate continuing compliance with applicable requirements to maintain these certifications and CE Certificates of Conformity and will continue to be periodically inspected by international regulatory authorities for certification purposes. Further, we and certain of our suppliers are required to comply with all applicable regulations and current good manufacturing practices. As set forth above, these FDA and EU regulatory requirements cover, among other things, the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If we or our manufacturers fail to adhere to current good manufacturing practice requirements, this could delay production of our products and lead to fines, difficulties in obtaining or renewing regulatory approvals or CE Certificates of Conformity, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

Product Liability and Insurance

The manufacture and sale of our products subjects us to the risk of financial exposure to product liability claims. Our products are used in situations in which there is a risk of serious injury or death. We carry insurance policies which we believe to be customary for similar companies in our industry. We cannot assure you that these policies will be sufficient to cover all or substantially all losses that we experience.

We endeavor to maintain executive and organization liability insurance in a form and with aggregate coverage limits that we believe are adequate for our business purposes, but our coverage limits may prove not to be adequate in some circumstances.

Human Capital Resources

Our ability to recruit, develop and retain highly skilled talent is a significant determinant of our success. To attract, retain, and develop our talent, we seek to create a diverse and inclusive workplace with opportunities for our employees to thrive and advance in their careers. We support this with market-competitive compensation, comprehensive benefits, and health and wellness programs.

In addition to ensuring workforce diversity and equitable compensation for our employees, we maintain a strong focus on enhancing employee retention and job satisfaction. To achieve this, we have established a feedback mechanism to continually monitor and respond to employee sentiment. Using this feedback, we deploy strategies that enhance the skills of our people managers and improve internal communications with employees. Furthermore, we provide ongoing learning and leadership training opportunities to support professional growth.

In 2023, we conducted instructor-led trainings designed to build people leadership capabilities and train managers on delivering actionable feedback. We have also adopted a goal for each of our managers to have regular check-ins with employees to discuss their personal goals and career plans in furtherance of our commitment to career and professional development.

We maintain a commitment to employee retention by leveraging insights from exit interviews and engagement surveys to continuously enhance the workplace experience.

As of December 31, 2023, we had 344 employees, including sales and marketing, product development, general administrative and accounting, both domestically and internationally. As of December 31, 2023, we had a direct field sales organization of 151 in the United States and 14 in Europe. During 2023, our voluntary attrition rate was approximately 10%.

Diversity and Inclusion

To realize our mission and vision, we are committed to actively fostering workforce diversity and an environment of cultural inclusion throughout the company. We maintain a Diversity and Inclusion Plan which is overseen by our Nominating and Corporate Governance Committee. Our program goal is to promote diversity, inclusion, equal employment opportunities, and a work environment free of harassment and hostility. Accordingly, we track and report annually to the Board of Directors the gender, ethnicity, disability, and protected veteran status among our U.S. workforce.

We aim to maintain a mix of backgrounds, skills, and experiences in our board composition to understand and reflect the needs of our diverse stakeholders. Currently, four of our nine board members are women and two of our board members self-identify as Asian American.

Workplace Health and Safety

The health and safety of our employees is a priority in which we have always invested and intend to continue to do. Following the pandemic, we have implemented health and safety measures that include maximizing personal workspaces, providing personal protective equipment and holding on-site vaccinations events.

Compensation and Benefits

We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to base compensation, these programs, which vary by country, include annual bonuses, restricted stock unit awards, an Employee Stock Purchase Plan, 401(k), health and wellness benefits, health savings and flexible spending accounts, paid time off, family leave, paid parental leave, flexible work schedules, and others.

Our employees and their families have access to a variety of innovative, flexible, and convenient health and wellness programs. These benefits are intended to provide protection and security, so employees can have peace of mind concerning events that may require time away from work or that may impact their financial well-being. Additionally, we offer programs to help support employee physical and mental health and offer choices where possible, so they are customized to meet their needs and the needs of their families.

Ensuring fair and equitable pay is integral to our commitment to our employees. Our executive team and Board of Directors strongly support this commitment. On an ongoing basis we monitor pay equity to identify any pay disparities and then to determine appropriate adjustments.

Learning and Talent Development

We value our employees and the passion, commitment, and professional expertise they provide. To enhance employee retention and job satisfaction, we offer ongoing learning and leadership training opportunities that support growth and development.

We also regularly evaluate our workforce and plan to address key skill and leadership gaps through a talent management process. In 2022, we implemented a new career development program which includes a formalized framework that reflects how an employee can advance their career within the company. This provides many benefits including clarity, structure, and direction for employees and managers for career advancement and their future at SI-BONE which increases employee motivation, engagement, and retention.

We have a robust annual performance review process for reviewing employees' performance and compensation. To support our managers, we train them on conducting effective performance reviews and making compensation recommendations, which take into consideration external and internal benchmarks and performance.

Employee Engagement

We believe that building connections between our employees, their families, and our communities creates a more meaningful and fulfilling workplace. Through our engagement programs, our employees can pursue their interests and connect to volunteering and giving opportunities. On an ongoing basis we sponsor philanthropic and volunteer events in which our employees can participate. During 2023, we organized employee cash donations to food banks to support the neediest individuals in San Francisco Bay Area communities.

We encourage you to review our ESG Shareholder Letter in the Governance Documents of the Corporate Governance section of our Investor website for more detailed information regarding our human capital programs and initiatives. Nothing on our website, including our ESG Shareholder Letter, shall be deemed part of or incorporated by reference into this Annual Report.

Company History

SI-BONE was founded in 2008 by the principal inventor of the iFuse triangle, orthopedist Mark A. Reiley, M.D., our current Chairman of the Board, Jeffrey W. Dunn, and orthopedic surgeon Leonard Rudolf, M.D.

Corporate Information

We were incorporated in March 2008 in Delaware. Our principal executive offices are located at 471 El Camino Real, Suite 101, Santa Clara, California 95050 and our telephone number is (408) 207-0700. Our website address is www.si-bone.com. We completed our initial public offering in October 2018, and our common stock is listed on the Nasdaq Global Market under the symbol "SIBN."

Our Annual Report on Form 10-K, Quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge on our website. The information contained on or that can be accessed through our website is not incorporated by reference into this report, and you should not consider information on our website to be part of this report.

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

Risks Related to Our Business and Our Industry

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

We have incurred net losses since our inception in 2008. For the years ended December 31, 2023 and 2022, we had net losses of $43.3 million and $61.3 million, respectively. As of December 31, 2023, we had an accumulated deficit of $400.4 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. 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 physician 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, physicians, 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, physicians, 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 physicians 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 physicians for their time spent diagnosing patients and performing procedures using our products. Even if favorable coverage and reimbursement status is attained for procedures using our implants, less favorable coverage policies and reimbursement rates may be implemented in the future.

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.

The American Medical Association (AMA) develops and maintains Current Procedural Terminology ("CPT") codes that are used by third-party payors to determine the amount of reimbursement that a healthcare provider and facility will receive for a particular service. CPT codes are divided into three categories: Category I codes represent existing services or procedures that are widely used. Category II codes are supplemental tracking codes, and Category III codes are temporary codes that represent new technologies, services, and procedures. A Category III code does not have a payment rate established and reimbursement is at the payor's discretion.

CPT Code 27279, which describes minimally invasive surgical fusion of the sacroiliac joint performed with our laterally placed transfixing iFuse implants, is a Category I CPT code. This CPT code has been clarified to describe procedures in which implants pass through the ilium, go across the sacroiliac joint, and into the sacrum (transfixation). 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. Effective January 1, 2024, the AMA CPT Editorial panel adopted an additional Category I code, CPT Code 27278, to describe procedures using intra-articular, non-transfixing implants, including bone allograft products and/or metal plugs. Effective January 1, 2024, the Medicare physician fee reimbursement for minimally invasive fusion with our laterally placed transfixing iFuse implants, described as CPT Code 27279, is $791; and for our intra-articular non-transfixing iFuse implants, described as CPT 27278, the Medicare physician fee is $459 when performed in the facility setting, and $11,934 when performed in the physician office (e.g., office-based lab) setting. Minimally invasive sacroiliac fusion performed with a transfixing device is not eligible for the office-based lab site-of-service and there is therefore no corresponding value for office-based reimbursement for CPT Code 27279.

Commercial payors generally set their physician fee reimbursement with reference to Medicare reimbursement rates. We believe that some physicians may continue to view the Medicare and commercial reimbursement amounts as insufficient for the lateral procedure described by CPT Code 27279, 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 physicians may not be able to consistently have minimally invasive sacroiliac fusion procedures utilizing laterally placed transfixing devices approved and covered. The perception by physicians performing the lateral procedure described by CPT Code 27279 that the reimbursement for minimally invasive sacroiliac joint fusion is insufficient to compensate them for the work required, including diagnosis, documentation, obtaining payor approval for the procedure, and burden on their office staff, may negatively affect the number of procedures performed and may therefore adversely affect our revenues. If the levels of reimbursement for, and consistency of coverage associated with, procedures performed with our medical devices under CPT Code 27279 decreases 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.

Medicare Administrative Contractors have not yet fully evaluated the evidence for CPT 27278 procedures and may engage in reviews of the evidence and coverage advisory activities which may lead to revising or adding Local Coverage Determinations and Coverage Articles, which may limit or qualify their coverage of them. Private payors evaluating these procedures may decide not to cover them until more evidence is developed. We do not yet have sufficient experience with the new reimbursement rates for CPT Code 27278 to determine if physicians will judge the reimbursement rates for that procedure to be sufficient and the impact this will have on demand for the products used in these procedures.

Future action by the Centers for Medicare and Medicaid Services ("CMS") or third-party payors may 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.

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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Further, CMS budget neutrality requirements may impose cuts to the Medicare physician fee schedule, which may be mitigated by acts of Congress or other changes to regulations. Other federal laws, known as budget sequestration, further reduce Medicare's payments to providers by 2%, which, due to subsequent legislative amendments, will stay in effect through 2032. 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 United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales, 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 triangular implants and choose to reimburse for procedures performed with competitive products, our market share and average selling prices could decline, adversely affecting our revenues.

As of December 31, 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 physicians 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, the average selling price of our triangular iFuse implants could decline and their sales could decline or fail to grow. If physicians choose to substitute our triangular iFuse implants with competitors' products, this 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.

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 COVID-19 may also further exacerbate certain of the risks described herein.

Natural disasters and man-made business disruptions such as war and terrorism could seriously harm our future revenue and financial condition and increase our costs and expenses.

We operate our business in regions subject to natural and man-made disasters or business interruptions. Our corporate headquarters are located in Santa Clara, California, a region which has experienced and will continue to experience earthquakes, fires, power shortages, telecommunications failures, water shortages, floods, shifting climate patterns, and extreme weather conditions. We also rely on third-party manufacturers to produce our products and on third-party logistics companies to transport our products. A major earthquake, fire, tornado, blizzard or other disaster (such as a flood, storm, drought or terrorist attack) could significantly disrupt our operations, ranging from production and shipping delays to lost revenue and increased costs. The occurrence of any of these natural or man-made disasters or other business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Additionally, if our facilities or any of our customers' facilities are negatively impacted by a disaster, procedures using our products could be delayed or canceled. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts or brownouts, which could disrupt the operations of our affected facilities and harm our business. Further, concerns about terrorism, the effects of a terrorist attack, or political turmoil could have a negative effect on our operations, those of our suppliers and customers, and the ability to travel, which could harm our business, financial condition, and results of operations.

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.

Physicians, 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. For us to sell our products successfully, we must demonstrate to physicians 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 physicians, their use of our products may decline, adversely affecting our revenues and profitability.

Historically, many physicians 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 physicians 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 physicians 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.

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

We believe that training is particularly important in instances of newly launched products or the introduction of a product into a new market. If physicians are not properly trained, they may misuse our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products.

Patients with sacroiliac joint dysfunction are cared for by a variety of health care providers, including spine surgeons and pain physicians and other interventionalist spine physicians, who are generally trained as anesthesiologists, interventional radiologists, or physical medicine and rehabilitation specialists. These interventionalists 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 been educated on or adopted our procedures may prefer to continue to treat these patients with other interventions they offer because of physician preference or their view that these interventions are superior.

Effective January 1, 2024, the AMA CPT Editorial Panel introduced a new permanent Category 1 CPT Code, 27278, to describe minimally invasive sacroiliac fusion achieved with placement of an intra-articular implant, typically from a posterior approach, and without the use of a transfixing device. While we offer products that can be used in procedures described by both CPT Codes 27278 and 27279, historically our primary focus has been on products used in procedures described by CPT Code 27279. If more physicians elect to offer, or more patients elect to undergo, procedures described by CPT Code 27278, or if we are unable to demonstrate to physicians the comparative benefits of our products, sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

Physicians 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 EEA 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, physicians 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 physicians, 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, market dynamics, 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 to control costs and expand patient access to medical procedures. 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 physicians 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 physicians' 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 physicians 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 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 titanium implants as interchangeable, we risk increased pricing pressure on our products. It is unclear how the Category I Code 27278 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 physicians, 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 does 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, the 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. Physicians do not yet know if pelvic fracture fixation and sacroiliac joint fusion using iFuse-TORQ is superior to nonsurgical management in this class of patients. If physicians' 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 December 31, 2023, our U.S. sales force consisted of 82 territory sales managers and 69 clinical support specialists directly employed by us and 175 third-party sales agents. As of December 31, 2023, our international sales force consisted of 14 sales representatives directly employed by us and a total of 31 third-party sales agents and resellers, which together have had sales in 38 countries through December 31, 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 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 remains significant. If we experience turnover among our employees at a higher rate than expected, managing our labor force could become difficult and more costly, 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 and CE marked, 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 and CE marked, 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;
- our Notified Body may suspend, amend, or withdraw our CE Certificate of Conformity or refuse or delay any ongoing applications relating to the issuance or renewal of CE Certificates of Conformity;
- 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.

iFuse Bone is an implantable bone product manufactured from sterilized recovered cadaveric bone tissue. 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 and iFuse-TORQ 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 affect the safety or effectiveness of our products or cause or 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, other foreign regulatory authorities, or applicable QMS requirements and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to delays in obtaining clearances approvals or CE Certificates of Conformity, regulatory action including warning letters, product recalls, termination of distribution, operating restrictions, interruption of production, delays in the introduction of products into the market, 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 physicians 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 physician 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; and
- provide sufficient infrastructure needed for product commercialization.

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 physicians 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 addition, market demand for our new products may be less than expected, resulting in excess inventory from the supply purchased for launch. For example, in the quarter ending December 31, 2023 we took a $1.7 million in reserves for excess inventory related to the "lag" configuration of our iFuse-TORQ product, reflecting its below-expected market demand. 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 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 United States, including the Office of Foreign Asset Control of the U.S. Treasury. Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

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

- exposure to different legal and regulatory standards;
- lack of stringent protection of intellectual property;
- 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.

We are a large accelerated filer and may no longer provide scaled disclosures as a smaller reporting company beginning with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024, which will increase our costs and demands on management.

We are a large accelerated filer and beginning with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024, we may no longer provide scaled disclosure as a "smaller reporting company" as defined under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

As a smaller reporting company, we had the option to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

In addition, as a non-accelerated filer and smaller reporting company, we have availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial

reporting under Section 404(b) of the Sarbanes Oxley Act ("Section 404"). However, we may no longer avail ourselves of this exemption as a large accelerated filer, which will increase our expenses and require a significant amount of management time.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the market price of our common shares.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. We are also required to obtain an independent assessment of the effectiveness of our internal controls which could detect problems that our management's assessment might not. Going forward, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses or significant deficiencies with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements, investors may lose confidence in our reported financial information, which could cause the market price of our common shares to decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation.

Risks Related to Our Legal and Regulatory Environment

We, our suppliers, and our third-party manufacturers are subject to extensive governmental regulation both in the United States. and abroad, and failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory authorities. The FDA and other U.S. and foreign regulatory authorities 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 and the issue of related CE Certificates of Conformity;
- 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 United States, 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.

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. If current or future products that we seek to commercialize are determined to require a PMA or De Novo 510(k) clearance, FDA may require evidence from clinical trials conducted under an investigational device exemption ("IDE"). Trials conducted under an IDE and a PMA or De Novo 510(k) submission to the FDA can be lengthy and costly processes, which could delay and add to the cost of commercializing our products, which could adversely affect our financial results.

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 United States

In the EU, the Medical Device Regulation became applicable on May 26, 2021, repealing and replacing the MDD. The Medical Device Regulation establishes transitional provisions. However, the changes to the regulatory system implemented in the EU by the Medical Device Regulation include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined QMS assessment procedures and additional requirements for the QMS, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfillment of the obligations imposed by the Medical Device Regulation may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the Medical Device Regulation.

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 physicians 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 authority, 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 physicians, 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".

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 physicians 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 physicians 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, and foreign equivalents, 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. In addition, most of these laws apply to not only the actions taken by us, but also actions taken by our distributors and other third party agents, and healthcare providers with whom we interact. We have limited control over the business practices of our distributors and agents, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations, and financial condition. 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.

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers; and other adverse business consequences.

In the ordinary course of our business, we collect and process personal data and other sensitive information. We process data of our employees, consultants, certain individuals who may be affiliated with our customers, including physician users of our products and, in the context of clinical investigations, patients. The personal data may include sensitive personal data including health information. We collect this kind of information for several purposes, such as billing, reimbursement support, marketing purposes, post-marketing safety vigilance, servicing potential warranty claims and during the course of clinical trials. We are subject to various federal, state and foreign laws that protect the confidentiality of certain sensitive information including patient health information, such as patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA in the United States and regulations in the European Union ("EU"), which are described in detail in "Item 1. Business - Data Privacy and Security Laws."

Many U.S. states have enacted laws regulating the collection, use and disclosure of personal data and requiring that companies implement reasonable data security measures. Laws in all states and U.S. territories also require businesses to notify affected individuals, governmental entities and/or credit reporting agencies of certain security breaches affecting personal data. These laws are not consistent, and increase our compliance costs and potential liability in the event of a data breach.

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA"), (collectively, "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires

businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. 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 data we collect about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("GDPR") and the United Kingdom's GDPR ("UK GDPR") impose strict requirements for processing personal data. The GDPR is directly applicable in each EU Member State. This should, in principle, result in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and to disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR will be significant — the greater of € 20 million or 4% of global turnover. The GDPR provides that EU Member States may introduce further conditions, including limitations, to the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. Each EU Member State may also adopt additional related legislation and guidance in its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are, or may become subject to such obligations in the future. For example, we may also be subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from $5,000 to $100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We also rely on vendors to process payment card data, who may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance.

We depend on a number of third parties in relation to the provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions and applicable laws, and that they have sufficient technical and organizational security measures in place to fulfil their related obligations. These third party service providers may breach their contractual or legal obligations, which could negatively effect our business and/or our reputation.

We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

We have in the past, and could be in the future, subject to data breaches. Our failure (or perceived failure) to comply with applicable data privacy and security obligations, or to protect such data, could result in significant consequences to 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. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Evolving and changing definitions of personal data, within the European Union, the United States, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products.

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

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

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

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

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 EU QMS requirements applicable to medical devices 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 applications for or conduct of 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 or QMS, 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.

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,and 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 foreign regulatory 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 foreign regulatory 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 authority 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 and comparable foreign regulatory authorities, 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, field safety corrective actions and trend reports through the EUDAMED module on vigilance and post-market surveillance. However, EUDAMED is not yet fully functional and the related module on vigilance and post-market surveillance is not available yet. Until the entire EUDAMED system is fully functional, serious incidents and field safety corrective actions must be reported to the national competent authorities through national systems.

If we fail to report these events to the FDA or comparable foreign regulatory authorities within the required timeframes, or at all, FDA, or the competent foreign regulatory authority 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 action by competent regulatory authorities, 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 United States or abroad could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or action by competent regulatory authorities, 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 regulatory authority, including foreign regulatory authorities, or the discovery of serious safety issues or malfunctions with our products, can result in voluntary corrective actions or regulatory enforcement actions, which could have a significant adverse impact on us.

The FDA and similar foreign regulatory 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 significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. The Notified Body will then assess the changes and determine whether additional audits or actions are required prior to their implementation. Obtaining variation of existing CE Certificates of Conformity or a new CE Certificate of Conformity can be a time-consuming process, and delays in obtaining required future clearances, certifications or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Moreover, any substantial changes that take place in the coming years may impact the continuing validity 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 approval or CE Certificates of Conformity for future products. Some of them may require 510(k) clearance by the FDA or a new CE Certificate of Conformity by a Notified Body. 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 CE 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.

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. 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 Device Regulation entered into application on May 26, 2021, and introduced substantial changes to the obligations with which medical device manufacturers must comply in the EEA. Examples of the changes introduced by the Medical Device 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 of our products from the regulatory framework of the MDD to the regulatory framework of the Medical Devices Regulation has required and will continue to require a substantial transition effort by us. In the EU, Notified Bodies must be officially designated by a Competent Authority of an EEA country. While several Notified Bodies have been designated, the currently designated Notified Bodies are facing a large amount of requests for (re)certification under the MDR and as a consequence, review times have lengthened. Furthermore, failure to update our quality system and regulatory documentation could delay our compliance with the Medical Devices Regulation and delay or prevent us from obtaining new CE Certificates of Conformity issued in accordance with the Medical Device Regulation. Transition 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, the exit of the UK from the EU, commonly referred to as "Brexit" could lead to regulatory divergence between the EU and the UK. On May 26, 2021, the Medical Device Regulation became applicable in the EU. However, the Medical Device Regulation is not applicable in the UK. In the UK, medical devices are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, for the time being, retains a regulatory framework similar to the framework set out by the MDD. The UK government plans to introduce new legislation governing medical devices with an aim for core aspects of the future regime for medical devices to apply from July 1, 2025. New legislation has been proposed and is also anticipated for adoption in 2024 to bring into force strengthened post-market surveillance requirements ahead of the wider future regulatory regime. These post-market surveillance requirements are expected to apply from mid-2024. Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK.

Moreover, in the EU, some EU Member States may, after a medical device is CE marked, require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies and providing the basis for cooperation at EU level for joint clinical assessments in these areas. If the conclusions of these assessments are negative, or compare our products unfavorably with competing products, this may impact our pricing and reimbursement status. If we are unable to obtain or maintain favorable pricing and reimbursement status in EU Member States for our medical devices or medical devices that we may successfully develop and for which we may obtain certification, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Inadequate funding for the FDA and other government agencies, or a work slowdown or stoppage at those agencies as part of a broader federal government shutdown, or comparable scenarios with foreign regulatory authorities, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve or clear new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Disruptions

at FDA and other agencies may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Average review times at FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

If a prolonged government shutdown occurs, or if global health concerns or other political or world events prevent the FDA or other regulatory authorities from conducting their regular reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns or delays could also impact our ability to access the public markets and obtain capital to fund the growth of our operations. Similar considerations and concerns apply to foreign regulatory authorities.

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.

In addition, procurement of certain human organs and tissue for transplantation is subject to the National Organ Transplant Act ("NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment for costs associated with the removal, transportation, implantation, processing, preservation, quality

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

Risks Related to Our Intellectual Property

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

We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and nondisclosure agreements and other methods, to protect our proprietary technologies and know-how. As of December 31, 2023, we owned 59 issued U.S. patents and had 34 pending U.S. patent applications, and we owned 18 issued foreign patents and had 22 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 December 31, 2023, we have 20 registered trademarks in the United States and have filed for three more. We have sought protection for at least two of these trademarks in 61 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 United States Even if patents are granted outside the United States, effective enforcement in those countries may not be available. Since most of our issued patents are for the United States only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our products.

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

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

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

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

We may be subject to damages resulting from claims that we, our employees, or our third-party 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, or 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 United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make and sell our products. We have conducted a limited review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and the uncertainty of litigation increase the risk of 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 United States, foreign countries, or both;
- lock-up releases and sales of large blocks of our common stock;
- additions or departures of key employees or scientific personnel; and
- general economic conditions and trends.

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

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

As of December 31, 2023, we had net operating loss ("NOL") carryforwards of $331.6 million and $259.6 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in 2030 and 2023, 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.

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 ("SVB"), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("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 loan and security agreement 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, which intellectual property is subject to a negative pledge under the terms of the Amended Loan Agreement. 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 (the "Revolving Line"), in an aggregate principal amount of up to $15.0 million. The Revolving Line matures on July 6, 2025. As of December 31, 2023, we had not drawn on this credit facility. On March 10, 2023, we violated certain 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, as amended, 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 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 December 31, 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 certain such customer payments to third party operating accounts are re-directed to the cash collateral accounts with First-Citizens, and certain account balances are moved back to cash collateral accounts and other accounts held at First-Citizens, we will be unable to obtain credit advances under the Revolving Line. See "Note 7. Borrowings" to the "Notes to 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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk management and strategy

We recognize the importance of protecting our critical information technology ("IT") systems and data from material risks from cybersecurity threats. Risk management for cybersecurity threats is integrated into our overall enterprise risk management system. We consider cybersecurity risks alongside other business risks. Our risk management framework includes risk assessments, internal controls, and systems monitoring mechanisms. We have established processes designed to assess, identify, and manage material risks from cybersecurity threats to our IT systems and critical data, including intellectual property, confidential information, and personal

data (“Information Systems and Data”). Third parties also play a role in our cybersecurity efforts. We engage third-party services to assist us from time to time to conduct evaluations of our security controls, whether through penetration testing, independent audits or consulting on practices to address new challenges. We conduct audits and evaluations of our IT infrastructure, network architecture, and software applications to help us identify vulnerabilities, potential entry points, and areas for improvement. We perform assessments considering principles from the National Institute of Standards and Technology Cybersecurity Framework and by using an external third-party security assessor from time to time.

Depending on the environment, we employ strategies and practices designed to protect and mitigate cybersecurity material risks to our Information Systems and Data, including but not limited to:

- Utilizing third-party tools to monitor threats and cybersecurity vulnerabilities, reduce risk, and enhance governance, risk, and compliance management.
- Engaging a managed cybersecurity service provider to monitor and assess cybersecurity threats, serve as a point of contact for incident notification, and collaborate with our in-house IT team.
- Maintaining security policies, procedures, and standards considering evolving threats and industry standards.
- Engaging external subject matter experts and advisors to inform us of current cyber practices, policies, and programs.
- Conducting tabletop exercises focused on scenarios such as ransomware, disaster recovery, and business continuity.
- Providing mandatory annual security and privacy awareness training to all employees who have access to company email and connected devices.
- Conducting phishing simulations and cyber hygiene training sessions to educate employees and promote responsible cybersecurity practices.
- Maintaining an incident response plan and conducting tabletop exercises.

We have established an incident response team, which is led by our IT, legal, and compliance leaders and is comprised of stakeholders from various departments in the Company. A designated member from our IT team is responsible for conducting incident assessments, determining severity levels, informing relevant stakeholder, such as the incident response team and senior management, and maintaining documentation of the remediation activity.

In the event of a security incident, our incident response processes are designed to escalate certain cybersecurity incidents to senior leadership, the audit committee and the board of directors, as deemed appropriate.

Governance

Our audit committee is responsible for overseeing our cybersecurity risk management processes, including regarding cybersecurity threats. Our CFO, Anshul Maheshwari, and Senior Vice President of Operations & Technology, Jeff Bertolini, provide briefings to our audit committee on the effectiveness and progress of our cybersecurity risk management program on regular basis. Mr. Bertolini has completed the Chief Technology Officer program at the Wharton School of the University of Pennsylvania and has over 30 years of experience leading all aspects of operations and IT. Our board of directors receives regular reports from our audit committee chair regarding our cyber risk management programs, potential cybersecurity risks, efforts to mitigate such risks, and the audit committee’s oversight of these activities.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see Item 1A. “Risk Factors”, including “If we experience significant disruptions in our information technology systems, our business, results of operations, and financial condition could be adversely affected".

Item 2. Properties.

Our leased headquarters in Santa Clara, California, comprises approximately 21,848 square feet, and the lease for this space expires in May 2025. Our headquarters houses our product development, marketing, finance, education, and administration functions. We also lease research and development and warehouse space in another building in Santa Clara, California under a lease that will expire in October 2026, and office spaces in Gallarate, Italy which expires in August 2027 to accommodate our European sales and marketing team. We believe our facilities are adequate and suitable for our current needs but in the future we may need additional space.

Item 3. Legal Proceedings

We may be subject to legal proceedings and claims in the ordinary course of business. We cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact on us due to diversion of management time and attention as well as the financial costs related to resolving such disputes.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Price of Common Stock

Our common stock is listed on the Nasdaq Global Market under the symbol "SIBN".

Holders of Record

As of February 20, 2024, we had 132 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K, 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, as well as implantable bone products. Since launching our first generation iFuse in 2009, we have launched new titanium 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 United States, and with a combination of a direct sales force and sales agents in other countries. As of December 31, 2023, more than 95,000 procedures have been performed by over 3,600 physicians in the United States and 38 other countries since we introduced iFuse in 2009.

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 physician 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 physician 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 placing instrument trays and implants at select 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 placed at 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 December 31, 2023, our U.S. sales force consisted of 82 territory sales managers and 69 clinical support specialists directly employed by us and 175 third-party sales agents, compared to 88 territory sales managers and 73 clinical support specialists directly employed by us and 105 third-party sales agent as of December 31, 2022. As of December 31, 2023, our international sales force consisted of 14 sales representatives directly employed by us and 31 third-party sales agents and resellers, compared to 18 sales representatives directly employed by us and 30 third-party sales agents and resellers as of December 31, 2022.

As of December 31, 2023, over 20 percent of our procedures for sacroiliac joint dysfunction were performed at ambulatory surgery centers, or ASCs. 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 with these facilities to educate their management groups on our clinical evidence, exclusive commercial payor coverage and focus on driving improved education and pathways between pain physicians and surgeons.

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 physicians in their area who perform minimally invasive sacroiliac 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 physicians. Our data-driven approach enables us to focus our investment on the most cost-effective programs.

Physician Engagement

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

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 physician productivity.

We are targeting over 12,000 U.S. physicians including over 8,000 orthopedic and neurological surgeons and approximately 4,500 interventional spine physicians, to perform our procedures. As of December 31, 2023 and 2022, in the United States more than 2,700 physicians and 2,200 physicians, respectively, have been trained on iFuse and have treated at least one patient. Outside the United States, as of December 31, 2023 and 2022, more than 900 and 800 physicians, respectively, have been trained on iFuse and have treated at least one patient. Since launching our academic training program in August 2018, we have trained residents and fellows in over 240 academic programs in the United States, resulting in the training of approximately 1,600 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 physicians with a comprehensive set of alternatives, and positions us as the top choice for physicians for sacropelvic solutions. We also offer an allograft bone implant for physicians who believe that this kind of implant can be important to obtaining stabilization and /or 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 multi-segmental, or long-construct, spinal fusion. We anticipate the results for the primary endpoint in 2025. 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 iFuse-TORQ.

We continue to invest in research and development 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. In 2023, we spent $15.0 million on research and development, equating to 11% of our 2023 revenue.

Enhance Employee Experience and Engagement

Our ability to recruit, develop and retain highly skilled talent is a significant determinant of our success. To attract, retain, and develop our talent, we seek to create a diverse and inclusive workplace with opportunities for our employees to thrive and advance in their careers. We support this with market-competitive compensation, comprehensive benefits, and health and wellness programs.

In addition to ensuring workforce diversity and equitable compensation for our employees, we maintain a strong focus on enhancing employee retention and job satisfaction. To achieve this, we have established a feedback mechanism to continually monitor and respond to employee sentiment. Using this feedback, we deploy strategies that enhance the skills of our people managers and improve internal communications with employees. Furthermore, we provide ongoing learning and leadership training opportunities to support professional growth.

In 2023, we conducted instructor-led trainings designed to build people leadership capabilities and train managers on delivering actionable feedback. We have also adopted a goal for each of our managers to have regular check-ins with employees to discuss their personal goals and career plans in furtherance of our commitment to career and professional development.

We maintain a commitment to employee retention by leveraging insights from exit interviews and engagement surveys to continuously enhance the workplace 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 territory 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. Our average revenue per territory sales manager has increased to approximately $1.6 million in fiscal year 2023, from $1.2 million in fiscal year 2022.

We have made significant investments in instrument trays used to perform surgeries. Our goal is to deploy instrument trays to the market where the demand exists to increase our asset utilization rates over time and use capital more effectively by having our instrument trays 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 physician 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, product launches, and seasonality. 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, ASCs and OBLs. 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 limits on deductibles, co-payments and other out-of-pocket payments specified in their insurance plans. However, taken as a whole, seasonality does not have a material impact on our financial results from year to year.

Cost of Goods Sold, Gross Profit, and Gross Margin

We utilize third-party manufacturers for production of our implants and instrument trays. Cost of goods sold consists primarily of costs of the components of implants and instruments, instrument tray 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 and from changes in our product mix.

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, 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 consolidated financial statements:

	Year ended December 31, 2023		Year ended December 31, 2022	
	Amount	%	Amount	%
	(in thousands, except for percentages)			
Consolidated Statements of Operations Data:				
Revenue	$ 138,886	100 %	$ 106,409	100 %
Cost of goods sold	29,466	21 %	15,705	15 %
Gross profit	109,420	79 %	90,704	85 %
Operating expenses:				
Sales and marketing	110,254	79 %	107,726	101 %
Research and development	15,028	11 %	13,627	13 %
General and administrative	31,069	22 %	28,960	27 %
Total operating expenses	156,351	113 %	150,313	141 %
Loss from operations	(46,931)	(34)%	(59,609)	(56)%
Interest and other income (expense), net:				
Interest income	6,916	5 %	1,304	1 %
Interest expense	(3,462)	(2)%	(2,819)	(3)%
Other income (expense), net	141	— %	(132)	— %
Net loss	$ (43,336)	(31)%	$ (61,256)	(58)%

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

	Year ended December 31, 2023		Year ended December 31, 2022	
	Amount	%	Amount	%
	(in thousands except for percentages)			
United States	$ 130,621	94 %	$ 98,751	93 %
International	8,265	6 %	7,658	7 %
	$ 138,886	100 %	$ 106,409	100 %

Comparison of the years ended December 31, 2023 and 2022

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

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands except for percentages)			
Revenue	$ 138,886	$ 106,409	$ 32,477	31 %
Cost of goods sold	29,466	15,705	13,761	88 %
Gross profit	$ 109,420	$ 90,704	$ 18,716	21 %
Gross margin	79 %	85 %		

Revenue. The increase in revenue for the year ended December 31, 2023 compared to the year ended December 31, 2022 comprised a $31.9 million increase in our U.S. revenue and an increase of $0.6 million in our international revenue. The increase in revenue is due to the increase in case volumes, driven by a seasoned and growing base of active physicians and an expanded product portfolio.

Gross Profit and Gross Margin. Gross profit increased $18.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 driven by higher revenue. Gross margin was 79% for the year ended December 31, 2023 compared to 85% in the prior year. Gross margin decreased due to procedure and product mix given the higher total costs of iFuse-TORQ and iFuse Bedrock Granite implants including royalties, the increase in inventory reserve expense and the increase in depreciation costs to support the growth of the business.

Operating Expenses:

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 110,254	$ 107,726	$ 2,528	2 %
Research and development	15,028	13,627	1,401	10 %
General and administrative	31,069	28,960	2,109	7 %
Total operating expenses	$ 156,351	$ 150,313	$ 6,038	4 %

Sales and Marketing Expenses. The increase in sales and marketing expenses for the year ended December 31, 2023 as compared to the year ended December 31, 2022 was primarily due to a $6.1 million increase in commissions driven by higher revenues, partially offset by a $3.6 million decrease in employee related costs and travel related costs driven by lower headcount within sales and marketing as well as timing of certain commercial activities.

Research and Development Expenses. The increase in research and development expenses for the year ended December 31, 2023 as compared to the year ended December 31, 2022 was primarily due to a $0.9 million increase in employee related costs and stock-based compensation due to higher compensation, a $0.4 million increase in consulting costs and travel related costs driven by more projects in development, and a $0.1 million increase in facilities and other related costs resulting from the research and development facility.

General and Administrative Expenses. The increase in general and administrative expenses for the year ended December 31, 2023 as compared to the year ended December 31, 2022 was primarily due to a $1.6 million increase in employee related costs and stock-based compensation, a $0.6 million increase in the allowance for credit losses and a $0.3 million increase in accounting and audit fees primarily associated with Sarbanes-Oxley compliance requirements, partially offset by a $0.4 million decrease in consulting costs.

Interest and Other Income (Expense), Net:

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 6,916	$ 1,304	$ 5,612	430 %
Interest expense	(3,462)	(2,819)	(643)	(23)%
Other income (expense), net	141	(132)	273	207 %
Total interest and other income (expense), net	$ 3,595	$ (1,647)	$ 5,242	318 %

Interest Income. The increase in interest income for the year ended December 31, 2023 as compared to the year ended December 31, 2022 was mainly due to higher interest earned on our investments in marketable securities, primarily as a result of higher interest rates earned on higher cash and investment balances.

Interest Expense. The increase in interest expense for the year ended December 31, 2023 as compared to the year ended December 31, 2022 was primarily due to higher interest rates associated with the First-Citizens Term Loan.

Other Income (Expense), Net. Other income (expense), net changed from expense to income for the year ended December 31, 2023 as compared to the year ended December 31, 2022 due to foreign currency fluctuations.

Liquidity and Capital Resources

As of December 31, 2023, we had cash and marketable securities of $166.0 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 December 31, 2023 and 2022 we had $36.1 million and $35.2 million outstanding debt, respectively.

As of December 31, 2023, we had an accumulated deficit of $400.4 million. During the years ended December 31, 2023 and 2022, we incurred a net loss of $43.3 million and $61.3 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 financial impact of a potential economic downturn or capital market disruptions pose risks and uncertainties in our future available capital resources. 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 (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 trays 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 trays required to support procedures nationwide.

Term Loan

Our 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 a term loan in the aggregate principal amount of $35.0 million to us (the "Original Term Loan").

On January 6, 2023, we entered into a First Amendment to Loan and Security Agreement (the "Amendment") with SVB, which amends our Original 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 new 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 "Revolving Line"). 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 "Revolving Line Maturity Date"). Borrowings under the Revolving Line are based on 80% of eligible domestic accounts receivable borrowing base. Interest on the outstanding balance of the Revolving Line 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 Revolving Line Maturity Date, provided that when Revolving Line 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 Revolving Line borrowings. We will pay a total commitment fee of $187,500 on account of the Revolving Line payable in installments, but fully earned at close. We will also be required to pay a fee of $150,000 if we terminate the Amended Loan Agreement or the Revolving Line prior to Revolving Line Maturity Date, or if First-Citizens terminates the Loan Agreement or the Revolving Line following an event of default. No termination fee would be due if the Revolving Line is replaced with a new facility with First-Citizens. No amounts were outstanding under the Revolving Line as of December 31, 2023.

On March 10, 2023, we violated certain 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 December 31, 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 redirect certain customer payments and transfer certain cash management account balances, in each case, back to First-Citizens. As of December 31, 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 customer payments are directed back to certain First-Citizens cash collateral accounts, and certain balances and funds are moved back to the First-Citizens cash collateral accounts and other accounts held at First-Citizens, we will be unable to obtain credit advances under the Revolving Line.

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' 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 during which we are subject to financial covenants under the Amended Loan Agreement 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 Revolving Line, require the immediate payment of all loans and other amounts outstanding under the Amended Loan Agreement, and foreclose on all collateral.

Cash Requirements

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. Expected timing of those payments are as follows:

		Payments Due By Period			
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
		(in thousands)			
Principal obligations and final fee on long-term debt (1)	$ 36,720	$ —	$ 22,800	$ 13,920	$ —
Interest obligations (2)	8,899	3,294	5,006	599	—
Operating leases obligations	3,118	1,543	1,566	9	—
Purchase obligations	430	430	—	—	—
Total	$ 49,167	$ 5,267	$ 29,372	$ 14,528	$ —

(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 9.0% as of December 31, 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:

	Year Ended December 31,		
	2023	2022	$ Change
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (18,713)	$ (41,655)	$ 22,942
Investing activities	(59,798)	(2,815)	(56,983)
Financing activities	90,933	2,197	88,736
Effects of exchange rate changes on cash and cash equivalents	132	(429)	561
Net increase in cash and cash equivalents	$ 12,554	$ (42,702)	$ 55,256

Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 of $18.7 million resulted from cash outflows due to net loss of $43.3 million, adjusted for $29.5 million of non-cash items and cash outflows from changes in operating assets and liabilities of $4.8 million. Net cash used in operation activities for the year ended December 31, 2022 of $41.7 million resulted from cash outflows due to net loss of $61.3 million, adjusted for $27.6 million of non-cash items and cash outflows from changes in operating assets and liabilities of $8.0 million. The decrease in net loss, net of non-cash items for the year ended December 31, 2023 compared to the year ended December 31, 2022 was mainly due to increased revenues. Net cash outflows from changes in operating assets and liabilities for year ended December 31, 2023 were primarily due to higher accounts receivable due to timing of collections and the increase in revenue in the fourth quarter of 2023, higher inventory build-up related to our implants, higher prepaid expenses due to timing of payments, and lower accounts payable attributable to the normal course timing of expenses, offset in part by an increase in accrued liabilities and other due to timing of other third-party payments and higher compensation and benefits accruals. Net cash outflows from changes in operating assets and liabilities for the year ended December 31, 2022 were primarily due to higher inventory build-up related to our iFuse-TORQ and iFuse Bedrock Granite implants and higher accounts receivable due to timing of collections and the increase in revenue in the fourth quarter of 2022, offset in part by a decrease in prepaid expenses due to timing of payments for software subscriptions and lower prepaid annual insurance premiums, an increase in accounts payable due to the timing of vendor payments, and an increase in accrued liabilities and other due to timing of other third-party payments and higher compensation and benefits accruals.

Cash Used In Investing Activities

Net cash used in investing activities in the year ended December 31, 2023 was $59.8 million compared to net cash used in investing activities of $2.8 million in the year ended December 31, 2022. Net cash used in investing activities for the year ended December 31, 2023 consisted of purchases of property and equipment of $7.8 million related to individual components in instrument trays to support increased case volumes and capitalized costs related to the lease in Santa Clara and equipment and purchases of our marketable securities, net of maturities, of $52.0 million. Net cash used in investing activities for the year ended December 31, 2022 consisted of purchases of property and equipment of $9.5 million related to individual components in instrument trays to support increased case volumes, increased demand for iFuse-TORQ and the launch of iFuse Bedrock Granite, as well as capitalized costs related to the lease in Santa Clara, partially offset by maturities of our marketable securities, net of purchases of $6.7 million.

Cash Provided by Financing Activities

Cash provided by financing activities in the year ended December 31, 2023 was $90.9 million resulting from proceeds of $83.7 million from the issuance of common stock under our follow-on public offering, proceeds of $6.6 million from the issuance of common stock under our stock-based incentive compensation plans, and net proceeds of $0.7 million from the refinancing of our term loan with First-Citizens. Cash provided by financing activities for the year ended December 31, 2022 was $2.2 million related to 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 generally accepted accounting principles in the United States of America ("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. We base our estimates on our historical experience, current market conditions 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. We believe that the accounting policy discussed below is critical to understanding our historical and future performance, as it relates to the more significant area involving management's judgments. For more comprehensive discussion of our significant accounting policies, refer to "Note 2 - Summary of Significant Account Policies" in the accompanying Notes to Consolidated Financial Statements in Item 8 of this Form 10-K.

Revenue Recognition

We derive our revenue from the sale of our products to medical groups and hospitals through our direct sales force and third-party sales agents throughout the United States and Europe. We receive payment for the implants consumed during the surgery and do not receive additional or separate consideration for the use of the instrument tray furnished for the physicians's use. We identify the instrument trays as a lease component and the implants as a non-lease component in our arrangements with our customers. We determine 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, we recognize revenue when control is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for the goods or services. To recognize revenue, we apply 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 majority of our revenue consisting of product sales where our sales representative delivers the product at the point of implantation at hospital or medical facilities, we recognize the revenue upon completion of the procedure and authorization by the customer, net of rebates and price discounts. We also generate a small portion of our revenue from sale of products through third-party sales agents and hospital or medical facilities where the product is ordered in advance of a procedure. The performance obligation is the delivery of the product and therefore, we recognize revenue upon shipment to the customers, net of rebates and price discounts. We account for rebates and price discounts as a reduction to revenue, calculated based on the terms agreed to with the customer. Sales prices are specified in either customer contract, agreed price list, or purchase order, which is executed prior to the transfer of control to the customer. For certain hospitals and medical facilities, we have agreements in place consisting of either a master services agreement or an approved 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. We also have agreements in place with its third-party sales agents, 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. Our standard payment terms are generally net 30 to 90 days. We consider sales commissions and related expenses as incremental and recoverable costs of acquiring customer contracts. Our sales commissions are paid to our sales representatives in connection with each surgery performed. The period of benefit is concurrent when we recognize our revenue, as such, we also recognize sales commission as expense when incurred.

Stock-Based Compensation

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

Seasonality

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

Recent Accounting Pronouncements

See Note 2 of Notes to Consolidated Financial Statements for related discussions on recently adopted accounting standards and updates on recently issued accounting standards not yet effective, which information is incorporated by reference here.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

While we became a large accelerated filer as of December 31, 2023, we are not required to reflect the change in our smaller reporting company status and comply with the associated increased disclosure obligations until our quarterly report for the three-month period ending March 31, 2024. As a result, we are not required to provide the information otherwise required by this Item

Item 8. Financial Statements and Supplementary Data

SI-BONE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of SI-BONE, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of SI-BONE, Inc. and its subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of changes in stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – U.S. Implantation Product Sales

As described in Note 2 to the consolidated financial statements, product sales where the Company's sales representative delivers the product at the point of implantation at the hospital or medical facilities represent the majority of the Company's consolidated revenue. The Company's consolidated revenue was $138.9 million for the year ended December 31, 2023, of which, $130.6 million is related to the U.S. Management recognizes the revenue from these sales 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 principal consideration for our determination that performing procedures relating to revenue recognition - U.S. implantation product sales is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's revenue recognition.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the recording of product sales upon completion of the procedure and authorization by the customer. These procedures also included, among others, (i) evaluating revenue transactions by testing the issuance and settlement of invoices and credit memos, (ii) tracing transactions not settled to a detailed listing of accounts receivable, (iii) confirming a sample of outstanding customer invoice balances at year end and obtaining and inspecting source documents, including invoices, sales contracts, and proof of implantation for unpaid invoices, and obtaining subsequent cash receipt for paid invoices, where applicable, for confirmations not returned, and (iv) testing the completeness and accuracy of data provided by management.

/s/PricewaterhouseCoopers LLP
San Jose, California
February 27, 2024

We have served as the Company's auditor since 2013.

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

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 33,271	$ 20,717
Short-term investments	132,748	76,573
Accounts receivable, net of allowance for credit losses of $1,118 and $400, respectively	21,953	20,674
Inventory	20,249	17,282
Prepaid expenses and other current assets	3,173	2,365
Total current assets	211,394	137,611
Property and equipment, net	16,000	15,564
Operating lease right-of-use assets	2,706	4,002
Other non-current assets	325	375
TOTAL ASSETS	$ 230,425	$ 157,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 4,588	$ 6,279
Accrued liabilities and other	17,452	13,511
Operating lease liabilities, current portion	1,416	1,388
Total current liabilities	23,456	21,178
Long-term borrowings	36,065	35,171
Operating lease liabilities, net of current portion	1,511	2,871
Other long-term liabilities	18	30
TOTAL LIABILITIES	61,050	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; 40,693,299 and 34,731,577 shares issued and outstanding, respectively	4	3
Additional paid-in capital	569,477	455,172
Accumulated other comprehensive income	335	232
Accumulated deficit	(400,441)	(357,105)
TOTAL STOCKHOLDERS' EQUITY	169,375	98,302
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 230,425	$ 157,552

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

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

	Year Ended December 31,	
	2023	**2022**
Revenue	$ 138,886	$ 106,409
Cost of goods sold	29,466	15,705
Gross profit	109,420	90,704
Operating expenses:		
Sales and marketing	110,254	107,726
Research and development	15,028	13,627
General and administrative	31,069	28,960
Total operating expenses	156,351	150,313
Loss from operations	(46,931)	(59,609)
Interest and other income (expense), net:		
Interest income	6,916	1,304
Interest expense	(3,462)	(2,819)
Other income (expense), net	141	(132)
Net loss	(43,336)	(61,256)
Other comprehensive income (loss):		
Unrealized gain (loss) of marketable securities	166	(65)
Changes in foreign currency translation	(63)	(55)
Comprehensive loss	$ (43,233)	$ (61,376)
Net loss per share, basic and diluted	$ (1.13)	$ (1.79)
Weighted-average number of common shares used to compute basic and diluted net loss per share	38,427,419	34,201,824

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

SI-BONE, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances 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	80,571	—	379	—	—	379
Issuance of common stock related to employee stock purchase plan	170,717	—	1,818	—	—	1,818
Issuance of common stock upon vesting of restricted stock units	806,204	—	—	—	—	—
Stock-based compensation	—	—	23,061	—	—	23,061
Foreign currency translation	—	—	—	(55)	—	(55)
Net unrealized loss on marketable securities	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	(61,256)	(61,256)
Balances as of December 31, 2022	**34,731,577**	**3**	**455,172**	**232**	**(357,105)**	**98,302**
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	698,627	—	4,386	—	—	4,386
Issuance of common stock related to employee stock purchase plan	178,918	—	2,191	—	—	2,191
Issuance of common stock upon vesting of restricted stock units	993,077	—	—	—	—	—
Issuance of common stock upon exercise of warrant, net of shares withheld	22,603	—	—	—	—	—
Stock-based compensation	—	—	24,057	—	—	24,057
Foreign currency translation	—	—	—	(63)	—	(63)
Net unrealized gain on marketable securities	—	—	—	166	—	166
Net loss	—	—	—	—	(43,336)	(43,336)
Balances as of December 31, 2023	**40,693,299**	**$ 4**	**$ 569,477**	**$ 335**	**$ (400,441)**	**$ 169,375**

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

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (43,336)	$ (61,256)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	24,057	23,061
Depreciation and amortization	5,428	3,452
Accounts receivable credit losses	761	150
Inventory reserve	1,709	319
Accretion (amortization) of discount and premium on marketable securities	(4,009)	229
Amortization of debt issuance costs	208	198
Loss on disposal of property and equipment	1,302	153
Changes in operating assets and liabilities		
Accounts receivable	(2,122)	(6,479)
Inventory	(4,719)	(6,028)
Prepaid expenses and other assets	(762)	810
Accounts payable	(1,118)	2,529
Accrued liabilities and other	3,888	1,207
Net cash used in operating activities	(18,713)	(41,655)
Cash flows from investing activities		
Maturities of marketable securities	137,500	126,200
Purchases of marketable securities	(189,499)	(119,508)
Purchases of property and equipment	(7,799)	(9,507)
Net cash used in investing activities	(59,798)	(2,815)
Cash flows from financing activities		
Proceeds from follow-on public offering, net of underwriting discounts, commissions and offering costs	83,671	—
Proceeds from debt financing	36,000	—
Repayments of debt financing	(35,275)	—
Payments of debt issuance costs	(40)	—
Proceeds from the exercise of common stock options	4,386	379
Proceeds from issuance of common stock under employee stock purchase plan	2,191	1,818
Net cash provided by financing activities	90,933	2,197
Effect of exchange rate changes on cash and cash equivalents	132	(429)
Net increase (decrease) in cash and cash equivalents	12,554	(42,702)
Cash and cash equivalents at		
Beginning of year	20,717	63,419
End of year	$ 33,271	$ 20,717
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,263	$ 2,621
Supplemental disclosure of non-cash information		
Unpaid purchases of property and equipment	501	1,115

The accompanying notes are an integral part of these 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 United States, 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 3-D, 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. As such the Company's future results of operations and liquidity could be adversely impacted by a variety of factors including those discussed in the section entitled "Risk Factors" in this report. As of the date of issuance of these consolidated financial statements, the extent to which the current macroeconomic environment 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 consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The consolidated financial statements include the Company's accounts, as well as those of the Company's wholly-owned international subsidiaries. All inter-company accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant accounting estimates and management judgments reflected in the consolidated financial statements 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.

Reclassification of prior year presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications are limited to the consolidated statements of cash flows and have no effect on the reported results of operations.

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 United States 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 United States are immaterial. Following table summarizes the Company's revenue by geography:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
United States	$ 130,621	$ 98,751
International	8,265	7,658
	$ 138,886	$ 106,409

Foreign Currency

The Company’s foreign subsidiaries use local currency as their functional currency. Assets and liabilities are translated at exchange rates prevailing at the balance sheet dates. Revenue, costs and expenses are translated into U.S. dollars using average exchange rates for the period. Gains and losses from foreign currency translation are recorded as a component of accumulated other comprehensive income (loss). Gains and losses from foreign currency transactions are recognized as a component of other income (expense), net.

Concentration of Credit Risk

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

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

Fair Value of Financial Instruments

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 Company's marketable securities are classified as Level 1 or Level 2 of the fair value hierarchy as defined below. The carrying value of the Company’s long-term debt also approximates fair value based on management’s estimation that a current interest rate would not differ materially from the stated rate.

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Quoted prices (unadjusted) in active market that are accessible at measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability.

Cash and Cash Equivalents

The Company considers all highly liquid investments with remaining maturities at the date of purchase of three months or less to be cash equivalents.

Marketable Securities

The Company's marketable securities primarily consist of investments in money market funds, U.S. treasury securities, U.S. agency bonds, corporate bonds and commercial paper. All of the Company's marketable securities are available-for-sale debt securities and are 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 or remaining maturity is greater than three months and not more than twelve months. Long-term investments are securities that original or remaining maturity is more than twelve months. All marketable securities are recorded at their estimated fair value. When the fair value of a security is below its amortized cost, the amortized cost will be reduced to its fair value if it is more likely than not that the Company will be required to sell the potentially impaired security before recovery of its amortized cost basis, or the Company has the intention to sell the security. If neither of these conditions are met, the Company determines whether the impairment is due to credit losses by comparing the present value of the expected cash flows of the security with its amortized cost basis. The amount of impairment recognized is limited to the excess of the amortized cost over the fair value of the security. An allowance for credit losses for the excess of amortized cost over the expected cash flows is recorded in other income, net in the consolidated statements of operations. Impairment losses that are not credit-related are included in accumulated other comprehensive income (loss) in stockholders' equity.

Accounts Receivable and Allowance for Credit Losses

Trade accounts receivable are recorded at the invoiced amount, net of allowances for credit losses for any potential uncollectible amounts. The allowance for credit losses is based on our assessment of the collectability of accounts. Management regularly reviews the adequacy of the allowance for credit losses on a collective basis by considering the age of each outstanding invoice, each customer's expected ability to pay and collection history, current market conditions, and reasonable and supportable forecasts of future economic conditions to determine whether the allowance is appropriate. Accounts receivable are written-off and charged against an allowance for credit losses when the Company has exhausted collection efforts without success.

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

	Year ended December 31,	
	2023	2022
	(in thousands)	
Balance at beginning of year	$ 400	$ 264
Provision	761	150
Write-offs	(43)	(14)
Balance at end of year	$ 1,118	$ 400

Inventory

Inventory is stated at lower of cost or net realizable value. The Company establishes the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. The excess and obsolete inventory is estimated based on future demand and market conditions. Inventory write-downs are charged to cost of goods sold.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. All property and equipment is depreciated on a straight-line basis over the estimated useful lives of the assets, which are as follows:

Computer and office equipment	3 – 5 years
Instrument trays	3 years
Machinery and equipment	3 – 5 years
Furniture and fixtures	7 years

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 surgical equipment

and instrument trays 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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets (or asset group) may not be fully recoverable. Whenever events or changes in circumstances suggest that the carrying amount of long-lived assets may not be recoverable, the Company estimates the future cash flows expected to be generated by the assets (or asset group) from its use or eventual disposition. If the sum of the expected future cash flows is less than the carrying amount of those assets, the Company recognizes an impairment loss based on the excess of the carrying amount over the fair value of the assets. Significant management judgment is required in the grouping of long-lived assets and forecasts of future operating results that are used in the discounted cash flow method of valuation. For the years ended December 31, 2023 and 2022, the Company has not experienced impairment losses on its long-lived assets.

Leases

The Company determines if an arrangement is a lease at inception. The classification of leases is evaluated at commencement and, as necessary, at modification. Operating leases are included in operating lease right-of-use assets and operating lease liabilities on the consolidated balance sheets. The Company does not have any material finance leases in any of the periods presented.

Under Accounting Standards Update ("ASU") 2016-02, Leases Topic 842 ("Topic 842"), operating lease expense is recognized on a straight-line basis over the term of the lease. Variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The lease term represents the non-cancelable period of the lease. For certain leases, the Company has an option to extend the lease term. These renewal options are not considered in the remaining lease term unless it is reasonably certain that the Company will exercise such options.

The Company elected certain practical expedients under Topic 842 which are: (i) to not record leases with an initial term of twelve months or less on the balance sheet; (ii) to combine the lease and non-lease components in determining the lease liabilities and right-of-use assets, and (iii) to carry forward prior conclusions about lease identification and classification. The Company’s lease contracts do not provide an implicit borrowing rate; hence the Company determined the incremental borrowing rate based on information available at lease commencement to determine the present value of lease liability. The Company determines its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. The Company uses its headquarters in the United States ("parent entity")’s incremental borrowing rates as the treasury operations are managed centrally by the parent entity.

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 United States 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 physicians’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 third-party sales agents 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. 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 third-party sales agents, 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.

Shipping and Handling Costs

Shipping and handling costs are treated as fulfillment costs, which are expensed as incurred and are included in cost of goods sold.

Costs to Obtain Customer Contracts

Sales commissions and related expenses are considered incremental and recoverable costs of acquiring customer contracts. The Company's sales commissions paid to its sales representatives are generally based on the surgeries performed. The Company applied the practical expedient that permits an entity to expense the cost to obtain a contract as incurred when the expected amortization is one year or less. The period of benefit is concurrent with when the Company recognizes its revenue and as such, the Company recognizes sales commissions as expense when incurred.

Warranty

The Company has a warranty program that provides a purchaser a one-time replacement of any iFuse implant at no additional cost for a revision procedure within a one-year period following the original procedure and is accounted for as a warranty accrual. The Company also provides a purchaser with a one-time credit equal to the purchase price paid for use on future purchases for any revision procedure within the one-year period following an original procedure where an implant is not required. The warranty is not priced or sold separately and is intended to safeguard the customer against defects and it does not provide incremental service to the customer. As such, it is considered an assurance type warranty and is not accounted as a service type warranty, which could represent a separate performance obligation. The Company accounts for these one-time credits as sales reserves and is included in accrued liabilities and other in the consolidated balance sheets. Sales and warranty reserves from the warranty program were immaterial as of December 31, 2023 and 2022.

Research and Development

Research and development costs are charged to operations as incurred and consist of costs incurred by the Company for the development of the Company's product which primarily include: (1) employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; (2) external research and development expenses; and (3) other expenses, which include direct and allocated expenses for facilities and other costs.

Advertising Expenditures

The cost of advertising is expensed as incurred and is included under sales and marketing expense in the consolidated statements of operations. Advertising expenses were $1.1 million and $1.6 million for the years ended December 31, 2023 and 2022, respectively.

Loss Contingency

The Company is subject to various potential loss contingencies arising in the ordinary course of business. From time to time, the Company may be involved in certain proceedings, legal actions and claims. Such matters are subject to many uncertainties, and the outcomes of these matters are not within the Company's control and may not be known for prolonged periods of time. In some actions, the claimants may seek damages, as well as other relief, including injunctions which may prohibit the Company to engage in certain activities, which, if granted, could require significant expenditures and/or result in lost revenues. The Company records a liability in the consolidated financial statements when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

Stock-Based Compensation

The Company applies the fair value recognition provisions of stock-based compensation. Stock-based compensation expense is recognized over the requisite service period using the straight-line method and is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period that the estimates are revised.

The Company estimates the grant date fair value of stock options using the Black-Scholes option valuation model. The model requires management to make a number of assumptions including expected volatility, expected term, risk-free interest rate and expected dividends. A number of these assumptions are subjective, and their determination generally require judgment.

- *Expected Term* - The expected term represents the period that the share-based awards are expected to be outstanding. The Company uses the simplified method to determine the expected term as permitted by the guidance. The simplified method is calculated as the average of the time to vesting and the contractual life of the options.
- *Expected Volatility* - The expected volatility is measured using the historical daily changes in the market price of the Company's common stock over a period consistent with the expected term.
- *Risk-Free Interest Rate* - The risk-free interest rate is based on the U.S. Treasury zero coupon issued in effect at the time of grant for periods corresponding with the expected term of the option.
- *Dividend Yield* - The Company has not paid any dividends and has no current plans to pay dividends on its common stock. As such, the Company uses expected dividend yield of zero.

The fair value of the restricted stock unit ("RSU") grant is based on the market price of the Company's common stock on the date of grant.

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

In the event the underlying terms of stock awards are modified on which stock-based compensation was granted, additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement at the modification date.

Income Taxes

The Company accounts for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company recognizes uncertain tax positions when it meets a more-likely-than-not threshold. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits as income tax expense.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, common stock options, restricted stock units, ESPP purchase rights and warrants are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, common stock options, restricted stock units, ESPP purchase rights and warrants are anti-dilutive and therefore diluted net loss per common share is the same as basic net loss per common share for those periods.

Comprehensive Loss

Comprehensive loss represents changes in the stockholders' equity except those resulting from distributions to stockholders. The Company's unrealized foreign currency translation income (losses) and unrealized gains (losses) on marketable securities represent the two components of other comprehensive income that are excluded from the reported net loss for each of the reporting periods and has been presented in the consolidated statements of operations and comprehensive loss.

Warrants

The Company accounts for warrants for shares of common stock as equity in accordance with the accounting guidance for derivatives. The accounting guidance provides a scope exception from classifying and measuring as a financial liability a contract that would otherwise meet the definition of a derivative if the contract is both (i) indexed to the entity's own stock and (ii) classified in the stockholders' equity section of the consolidated balance sheet. The Company determined that the warrants for shares of common stock issued in connection with its prior debt arrangements are required to be classified in equity. Warrants classified as equity are recorded as additional paid-in capital on the consolidated balance sheet and no further adjustments to their valuation are made.

Recently Issued Accounting Standards Not Yet Adopted

In October 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-06, Disclosure Agreements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative ("ASU 2023-06"). This amendment will impact various disclosure areas, including the statement of cash flows, accounting changes and error corrections, earnings per share, debt, equity, derivatives, and transfers of financial assets. The amendments in this ASU 2023-06 will be effective on the date the related disclosures are removed from Regulation S-X or Regulation S-K by the SEC, and will no longer be effective if the SEC has not removed the applicable disclosure requirement by June 30, 2027. Early adoption is prohibited. The Company is currently evaluating the impacts of the amendment on its disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 requires companies with a single reportable segment to provide all existing segment disclosures, as well as requires incremental segment information to be disclosed. The guidance is effective for fiscal years beginning after December 15, 2023 on a retrospective basis, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the guidance to determine the impact on its disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 requires public business entities to disclose additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciliation to the extent the impact of those items exceeds a specified threshold. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, and for interim periods for fiscal years beginning after December 15, 2025. The Company is currently evaluating the impacts of ASU 2023-09 on its disclosures.

3. Marketable Securities

All of the Company's marketable securities were available-for-sale debt securities 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:

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 23,331	$ —	$ —	$ 23,331
Cash equivalents	23,331	—	—	23,331
U.S. treasury securities	129,695	67	—	129,762
U.S. agency bonds	2,988	—	(2)	2,986
Short-term investments	132,683	67	(2)	132,748
Total marketable securities	$ 156,014	$ 67	$ (2)	$ 156,079

	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. As of December 31, 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 consolidated balance sheets during the years ended December 31, 2023 and 2022.

The Company elected to present accrued interest receivable separately from short-term and long-term investments on its consolidated balance sheets. Accrued interest receivable was $0.2 million as of December 31, 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 during the years ended December 31, 2023 and 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 requires 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:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 23,331	$ —	$ —	$ 23,331
U.S. treasury securities	129,762	—	—	129,762
U.S. agency bonds	—	2,986	—	2,986
Total marketable securities	$ 153,093	$ 2,986	$ —	$ 156,079

	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 December 31, 2023, inventory consisted of finished goods of $18.8 million and work-in-progress and components of $1.4 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:

	December 31, 2023	December 31, 2022
	(in thousands)	
Instrument trays	$ 18,205	$ 13,092
Machinery and equipment	3,067	1,828
Construction in progress	3,856	7,854
Computer and office equipment	1,856	976
Leasehold improvements	3,873	1,631
Furniture and fixtures	389	390
	31,246	25,771
Less: Accumulated depreciation and amortization	(15,246)	(10,207)
	$ 16,000	$ 15,564

As of December 31, 2023, construction in progress pertains to 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 $3.5 million and software costs of $0.4 million. Depreciation expense was $5.4 million and $3.4 million for the years ended December 31, 2023 and 2022, respectively.

Accrued Liabilities and Other:

	December 31, 2023	December 31, 2022
	(in thousands)	
Accrued compensation and related expenses	$ 13,464	$ 11,365
Accrued royalty	1,360	818
Accrued professional services	929	355
Others	1,699	973
	$ 17,452	$ 13,511

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 2022 to 2026.

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Operating lease expense	$ 1,552	$ 1,599
Variable lease expense	465	461
Total lease expense	$ 2,017	$ 2,060
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,632	$ 1,600
Leased assets obtained in exchange for new operating lease liabilities	$ 143	$ 127
Weighted average remaining lease term (in years)	2.20	3.05
Weighted average discount rate	5.87%	5.77%

Future minimum lease payments under non-cancelable operating leases as of December 31, 2023 was as follows:

Year Ending December 31,	(in thousands)
2024	$ 1,543
2025	1,019
2026	547
2027	9
2028	—
Thereafter	—
Total operating lease payments	$ 3,118
Less: imputed interest	(191)
Total operating lease liabilities	$ 2,927

As of December 31, 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 December 31, 2023 and 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 the periods presented:

	December 31, 2023	December 31, 2022
	(in thousands)	
Principal outstanding and final fee	$ 36,720	$ 35,700
Less: Unamortized debt issuance costs	(81)	(73)
Unaccreted value of final fee	(574)	(456)
Outstanding debt, net of debt issuance costs and unaccreted value of final fee	$ 36,065	$ 35,171
Classified as:		
Long-term borrowings	$ 36,065	$ 35,171

The outstanding debt is related to a term loan pursuant to the Loan and Security Agreement dated August 12, 2021 entered into by the Company with Silicon Valley Bank (“SVB”). Pursuant the agreement, SVB provided a term loan in the aggregate principal amount of $35.0 million to the Company (the “Original 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 Original Term Loan pursuant to which the Company had a new 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 “Revolving Line”). 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 “Revolving Line Maturity Date”). Borrowings under the Revolving Line are based on 80% of eligible domestic accounts receivable borrowing base. Interest on the outstanding balance of the Revolving Line 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 Revolving Line Maturity Date, provided that when Revolving Line 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 Revolving Line borrowings. The Company will pay a total commitment fee of $187,500 on account of the Revolving Line 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 Revolving Line prior to Revolving Line Maturity Date, or if First-Citizens terminates the Loan Agreement or the Revolving Line following an event of default. No termination fee would be due if the Revolving Line is replaced with a new facility with First-Citizens. No amounts were outstanding under the Revolving Line as of December 31, 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 the years ended December 31, 2023 was 9.0%. The effective interest rate related to the Original Term Loan was 7.8% for the year ended December 31, 2022.

The table below summarizes the future principal and final fee payments under the Term Loan as of December 31, 2023:

Year ending December 31,	(in thousands)
2024	$ —
2025	8,400
2026	14,400
2027	13,920
2028	—
Total principal and final fee payments	$ 36,720

The Term Loan includes affirmative and negative covenants applicable to the Company and certain of its foreign subsidiaries. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental compliance, deliver certain financial reports, and maintain insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging the Company's intellectual property to other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions. As of December 31, 2023, the Company was in compliance with all debt covenants.

In January 2023, the Company's outstanding amount under the Original Term Loan was refinanced on a long-term basis and was accordingly classified as term note, non-current as of December 31, 2022.

8. 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 issued and outstanding at December 31, 2023 and 2022:

Date		Outstanding Balance at December 31, 2022	Price per Share	Warrants Issued	Warrant Exercised	Warrant Expired	Outstanding Balance at December 31, 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. Common and Preferred Stock

The Company's certificate of incorporation as amended and restated in October 2018, authorizes the Company to issue 100,000,000 shares of common stock and 5,000,000 shares of preferred stock, each having a par value of $0.0001. Common stock issued and outstanding as of December 31, 2023 and 2022 were 40,693,299 shares and 34,731,577 shares, respectively. As of December 31, 2023 and 2022, there was no preferred stock issued and outstanding.

The holders of common stock are entitled to receive dividends whenever funds are legally available, as, when, and if declared by the Board of Directors. There have been no dividends declared to date.

10. Stock-Based Compensation

2008 Stock Option Plan and 2018 Equity Incentive Plan

In April 2008, the Company adopted the 2008 Stock Option Plan (the "2008 SOP"), as amended, under which the Board of Directors may issue incentive and non-qualified stock options to employees, directors and consultants. In October 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 EIP"), which serves as the successor to the 2008 SOP, under which the Board of Directors may issue incentive and non-qualified stock options, RSUs and PSUs to employees, directors and consultants. No new options have been granted under the 2008 SOP since August 2018. Outstanding options under the 2008 SOP continue to be subject to the terms and conditions of that plan.

The number of shares of common stock reserved for issuance under the 2018 EIP will automatically increase on January 1 of each year, beginning January 1, 2019, and continuing through and including January 1, 2028, by 5% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's Board of Directors. As of December 31, 2023, a total of 4,454,432 shares of common stock are available for future grants under the 2018 EIP. On January 1, 2024, the total number of shares of common stock reserved for issuance under the 2018 EIP automatically increased by 2,034,664 shares.

The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and the exercise price. If an individual owns stock representing more than 10% of the outstanding shares, the price of each share shall be at least 110% of the fair market value, as determined by the Board of Directors. The exercise price of an incentive stock option and a non-qualified stock option shall not be less than 100% and 85%, respectively, of the fair market value on the date of grant.

Options granted have a term of 10 years, except, options granted to individuals holding more than 10% of the outstanding shares have a term of five years. Options generally vest over a four-year period. RSUs granted under the 2018 EIP generally vest over two to four years based upon continued services and are settled at vesting in shares of the Company's common stock.

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2023 and 2022:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Remaining Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	2,009,513	$8.73		
Exercised	(80,571)	$4.70		
Canceled and forfeited	(25,601)	$15.05		
Outstanding as of December 31, 2022	1,903,341	$8.82		
Exercised	(698,627)	$6.28		
Canceled and forfeited	(16,006)	$21.22		
Outstanding as of December 31, 2023	1,188,708	$10.14	3.51	$ 13,197
Options vested and exercisable as of December 31, 2023	1,188,708	$10.14	3.51	$ 13,197
Options vested and expected to vest as of December 31, 2023	1,188,708	$10.14	3.51	$ 13,197

The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 amounted to $11.7 million and $1.0 million, respectively, representing the difference between the fair value of the Company's common stock at the date of exercise and the exercise price paid. The aggregate intrinsic values of options outstanding, options vested and exercisable, and options vested and expected to vest as of December 31, 2023 represents the difference between the exercise price and the closing price of the Company's common stock on the last trading day of the year.

Outstanding options and exercisable options information by range of exercise prices as of December 31, 2023 was as follows:

Exercise Price			Options Outstanding			Options Vested and Exercisable	
			Number of Shares	Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
$3.24	-	$4.41	375,262	1.91	$4.14	375,262	$4.14
$4.42	-	$5.31	300,673	3.31	$4.68	300,673	$4.68
$5.32	-	$18.10	198,341	4.41	$11.28	198,341	$11.28
$18.11	-	$20.51	18,838	5.08	$18.71	18,838	$18.71
$20.52	-	$22.00	295,594	5.04	$22.00	295,594	$22.00
			1,188,708	3.51	$10.14	1,188,708	$10.14

There were no stock options granted during the years ended December 31, 2023 and 2022.

As of December 31, 2023, there is no unrecognized compensation cost related to stock options.

Restricted Stock Units

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

The Company has granted performance-based restricted stock unit awards subject to market and service vesting conditions to certain executive officers under SI-BONE's 2018 Equity Incentive Plan ("PSUs"). The shares subject to the PSUs vest over a three-year performance period. 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:

	Year Ended December 31,					
	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%

The following table summarizes RSU and PSU activity for the years ended December 31, 2023 and 2022:

	RSUs		PSUs	
	Number of Shares	Weighted-Average Grant Date Fair Value	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2021	1,566,522	$25.17	—	—
Granted	1,264,835	$20.66	155,596	$19.50
Vested	(806,204)	$24.03	—	—
Canceled and forfeited	(230,225)	$23.46	—	—
Outstanding as of December 31, 2022	1,794,928	$22.72	155,596	$19.50
Granted	1,235,471	$16.92	255,458	$12.33
Vested	(967,145)	$21.01	(25,932)	$19.50
Canceled and forfeited	(163,464)	$21.41	—	—
Outstanding as of December 31, 2023	1,899,790	$19.93	385,122	$14.74

As of December 31, 2023, the unrecognized compensation cost related to the RSUs was $30.2 million, which is expected to be recognized over a period of approximately 2.3 years. As of December 31, 2023, the unrecognized compensation cost related to the PSUs was $2.2 million, which is expected to be recognized over a period of approximately 1.8 years.

Employee Stock Purchase Plan

The Company's 2018 Employee Stock Purchase Plan (the "ESPP") allows eligible employees to purchase shares of the Company's common stock through payroll deductions at the price equal to 85% of the lesser of the fair market value of the stock as of the first date or the ending date of each six month offering period. The offering period generally commences in May and November. On March 26, 2020, the Company's Compensation Committee approved the amendment of the terms of future offerings under the ESPP which, among other things, increased the maximum number of shares that may be purchased on any single purchase date and provided for automatic enrollment in a new offering.

As of December 31, 2023, a total of 1,218,576 shares of common stock are available for future grants under the ESPP. On January 1, 2024, the total number of shares of common stock reserved for issuance under the ESPP Plan increased by 406,932 shares.

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 178,918 shares and 170,717 shares under the ESPP during the years ended December 31, 2023 and 2022, respectively, representing $2.2 million and $1.8 million in employee contributions. For each of the years ended December 31, 2023 and 2022, total accumulated ESPP related employee payroll deductions amounted to $0.4 million and $0.3 million, respectively, which were included within accrued compensation and related expenses in the consolidated balance sheets. For the years ended December 31, 2023 and 2022, the Company recognized $1.0 million and $0.7 million, respectively, of stock-based compensation expense related to ESPP. As of December 31, 2023, the unrecognized compensation cost for the ESPP was $0.4 million.

The Company estimated the fair value of ESPP purchase rights during the offering period using a Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,					
	2023			2022		
Expected term (years)	0.5			0.5		
Expected volatility	41.9%	to	54.4%	49.5%	to	62.1%
Risk-free interest rate	5.26%	to	5.38%	0.07%	to	1.54%
Dividend yield	—%			—%		

Stock-Based Compensation

The following table sets forth stock-based compensation expense recognized for the periods presented:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Cost of goods sold	$ 672	$ 484
Sales and marketing	10,931	11,006
Research and development	2,933	2,637
General and administrative	9,521	8,934
	$ 24,057	$ 23,061

11. Employee Benefit Plan

The Company sponsors a 401(k) plan covering all employees. Contributions made by the Company are discretionary and are determined annually by the Board of Directors. Effective January 1, 2019, the Company made a discretionary matching contribution equal to dollar for dollar employee contribution, up to 3% eligible compensation of the employee, with a maximum annual contribution from the Company of one thousand dollars per employee. Further, in order for an employee to receive the matching contribution, the employee must be at least 21 years old, work at least 1,000 hours per year, and must be employed by the Company at the beginning through the end of the year.

12. Net Loss Per Share of Common Stock

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

	Year Ended December 31,	
	2023	2022
	(in thousands, except share and per share data)	
Net loss	$ (43,336)	$ (61,256)
Weighted-average shares used to compute basic and diluted net loss per share	38,427,419	34,201,824
Net loss per share, basic and diluted	$ (1.13)	$ (1.79)

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:

	Year Ended December 31,	
	2023	2022
Stock options	1,188,708	1,903,341
Restricted stock units	2,284,912	1,950,524
ESPP purchase rights	102,172	134,226
Common stock warrants	85,139	118,122
	3,660,931	4,106,213

13. Income Taxes

The components of the Company's loss before income taxes are as follows:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Domestic	$ (43,491)	$ (61,396)
Foreign	155	140
Loss before income taxes	$ (43,336)	$ (61,256)

There was no provision for income taxes recorded for the years ended December 31, 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. The Company periodically evaluates the realizability of its net deferred tax assets based on the expected realization and is dependent on the Company's ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets.

The components of deferred income taxes are as follows:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Federal	$ 10,606	$ 13,085
State	1,856	2,997
Foreign	(28)	(92)
Total deferred income taxes	12,434	15,990
Change in deferred tax valuation allowance	(12,434)	(15,990)
Net deferred income tax	$ —	$ —

Income tax expense differs from the amount computed by applying the statutory federal income tax rate due to the following:

	Year Ended December 31,	
	2023	2022
Tax at statutory federal rate	(21.0)%	(21.0)%
State tax, net of federal benefit	(4.3)%	(4.9)%
Tax credits	(1.3)%	(0.7)%
Change in deferred tax valuation allowance	28.7 %	26.1 %
Stock compensation	(2.8)%	0.3 %
Foreign rate differences	(2.1)%	0.1 %
Other	2.8 %	0.1 %
Total income tax expense	— %	— %

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are presented below:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net operating loss carryforwards	$ 85,173	$ 77,057
Research and development credits	5,342	4,464
Accruals and reserves	3,698	2,616
Interest limitation	4,378	4,447
Depreciation and amortization	474	263
Stock compensation	3,474	3,378
Operating lease liabilities	735	1,079
Capitalized research and development	4,614	2,486
Total deferred tax assets	107,888	95,790
Operating lease right-of-use assets	(678)	(1,014)
Total deferred tax liabilities	(678)	(1,014)
Less: Valuation allowance	(107,210)	(94,776)
Total deferred tax asset, net of valuation allowance	$ —	$ —

The following table summarizes changes in the valuation allowance for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Beginning balance	$ 94,776	$ 78,786
Net changes during the period	12,434	15,990
Ending balance	$ 107,210	$ 94,776

As of December 31, 2023, the Company had net operating loss ("NOL") carryforwards of approximately $331.6 million and $259.6 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. If not utilized, the Company's federal NOL carryforward begins to expire in 2030, and the state NOL carryforward began to expire in 2023.

As of December 31, 2023, the Company had credit carryforwards of approximately $4.6 million and $3.8 million available to reduce future taxable income, if any, for both federal and state income tax purposes, respectively. The federal credits begin to expire in 2029, and the state credits have no expiration date.

The Company updated its Section 382 ownership change analysis through December 31, 2020 and determined that the last ownership change was in February 2020 due to the follow-offering. The analysis concluded that no additional NOL carryforwards will expire due to the Section 382 limitation from the ownership change for both federal and state tax purposes. The Company maintains the reduction of $1.4 million of its NOL carryforwards from the previous ownership change. The Company has reviewed changes in the outstanding number of shares and equity transactions for the period January 1, 2021 through December 31, 2023 to determine if an additional ownership change occurred for Section 382 purposes. The Company reasonably believes no additional ownership change occurred in the current year, however, noted there has been a material increase to the equity shift. The Company will continually assess the need to update its Section 382 ownership change analysis. An ownership change in the future could materially limit the Company's ability to utilize its NOL carryforwards and other tax attributes.

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 €750 million 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 €750 million.

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. The changes in the Company's uncertain income tax positions for the years ended December 31, 2023 and 2022 consisted of the following:

	Year ended December 31,	
	2023	2022
	(in thousands)	
Balance at beginning of the year	$ 2,944	$ 2,655
Increases related to tax positions taken prior to current year	(726)	$ (12)
Increases related to current year's tax positions	411	301
Balance at end of the year	$ 2,629	$ 2,944

The Company has elected to recognize interest and penalties related to uncertain tax positions as a component of income tax expense. The Company has no accrued interest related to unrecognized tax benefits as of December 31, 2023 and 2022. None of the Company's unrecognized tax benefits that, if recognized, would affect its effective tax rates for the years ended December 31, 2023 and 2022. The Company does not anticipate the total amounts of unrecognized tax benefits will significantly increase or decrease in the next 12 months.

The Company currently has no federal, state or foreign tax examinations in progress nor has it had any federal or state examinations since inception. As a result of the Company's net operating loss carry forwards, all of its tax years are subject to federal and state tax examinations.

14. Related Party Transactions

On February 24, 2020, the Company entered into a joint development agreement (the “Development Agreement”) with SeaSpine Orthopedics Corporation (“SeaSpine”), which recently merged with Orthofix Medical, Inc. ("Orthofix"), 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. On October 4, 2023, Keith C. Valentine resigned as a member of the Board of Directors of Orthofix. As such, subsequent to October 4, 2023, SeaSpine is no longer a related party 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 year ended December 31, 2023, the Company did not incur any reimbursement charges but purchased an immaterial amount of instrument components from Seaspine. For the year ended December 31, 2022, the Company expensed $38,725 of reimbursement charges from SeaSpine. The reimbursement charges were recorded within research and development expense in the consolidated statement 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 $0.3 million of royalty for the year ended December 31, 2023. The Company recorded an immaterial amount of royalty for the year ended December 31, 2022.

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

15. Subsequent Events

On January 25, 2024, the Company entered into a Second Amendment to Loan and Security Agreement (the “Second Amendment”) with SVB which amends the Company's First Amendment. The Second Amendment revised certain provisions related to financial covenants and the periods in which the covenants apply.

On February 23, 2024 the Company entered into a Manufacture and Supply Agreement with RMS Company, for the manufacture and supply of our requirements for iFuse-3D, iFuse-TORQ and components of iFuse Bedrock Granite implants. Pricing is set forth in the agreement through the end of 2026. The agreement has a three year initial term with automatic one-year renewals.

Supplementary Data

Selected Quarterly Consolidated Financial Data (Unaudited)

Pursuant to the amendments to Item 302 of Regulation S-K, since we do not have any material retrospective change to the statements of comprehensive income for any of the quarters within the two most recent fiscal years either individually or in the aggregate, we are not required to disclose the quarterly financial data.

Schedule II - Valuation and Qualifying Accounts

All schedules are omitted because they are not applicable, or the required information is shown in the financial statements or notes thereto.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 December 31, 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, as amended). Based on that evaluation, our CEO and our CFO have concluded that, as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria set forth in "Internal Control-Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2023 based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by our independent registered public accounting firm, PricewaterhouseCoopers LLP, as stated in their report, which appears in Part II, Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the fiscal quarter ended December 31, 2023, the following Section 16 officer and director adopted, modified or terminated a "Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K of the Exchange Act) as set forth in the table below.

			Type of Trading Arrangement				
Name of Position	**Action**	**Adoption/Termination Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares of Common Stock to be Sold**	**Total Shares of Common Stock to be Purchased**	**Expiration Date**
Jeffrey W. Dunn, Chairman	Adoption	November 8, 2023	X		262,239		May 15, 2025
Anthony Recupero, President of Commercial Operations	Adoption	December 13, 2023	X		12,687		December 31, 2024
*Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act							
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.							

None of the Company's other directors or executive officers adopted a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as defined in Item 408 of Regulation S-K under the Exchange Act during the three-month period ended December 31, 2023.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2024 Annual Meeting of Stockholders, or the 2024 Proxy Statement, which will be filed not later than 120 days after the end of our fiscal year ended December 31, 2023, under the headings "Management," "Proposal 1 - Election of Directors," "Information Regarding the Board of Directors and Corporate Governance", and, if applicable, "Delinquent Section 16(a) Reports", and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our website at www.si-bone.com. The Code of Business Conduct and Ethics is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose on our website in the future (1) the nature of any substantive amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be incorporated by reference to the information set forth in the sections titled "Executive Compensation" and "Compensation of Non-Employee Board Members" in our 2024 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management will be incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in our 2024 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence will be incorporated by reference to the information set forth in the sections titled "Certain Relationships and Related Party Transactions" and "Information Regarding the Board of Directors and Corporate Governance", respectively, in our 2024 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item regarding principal accountant fees and services will be incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our 2024 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

The following exhibits, as required by Item 601 of Regulation S-K are attached or incorporated by reference as stated below.

EXHIBIT INDEX

Exhibit Number	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38701	3.1	10/19/2018
3.2	Second Amended and Restated Bylaws	8-K	001-38701	3.1	9/20/2023
4.1	Form of Common Stock Certificate of the Company.	S-1/A	333-227445	4.1	10/5/2018
4.2	Reference is made to Exhibits 3.1 and 3.2.				
4.3	Description of SI-BONE, Inc. Common Stock	10-Q	001-38701	4.3	5/5/2020
10.1+	Form of Indemnity Agreement between the Registrant and each of its directors and executive officers.	S-1	333-227445	10.1	9/20/2018
10.2+	2008 Stock Plan and forms of agreements thereunder.	S-1/A	333-227445	10.2	10/5/2018
10.3+	2018 Equity Incentive Plan.	S-1/A	333-227445	10.3	10/5/2018
10.4+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2018 Equity Incentive Plan.	S-1/A	333-227445	10.4	10/5/2018
10.5+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2018 Equity Incentive Plan.	10-Q	001-38701	10.1	11/8/2022
10.6+	2018 Employee Stock Purchase Plan.	S-1/A	333-227445	10.6	10/5/2018
10.7+	Offer Letter Agreement, dated December 15, 2009, between the Registrant and Jeffrey W. Dunn.	S-1	333-227445	10.7	9/20/2018
10.8+	Offer Letter Agreement, dated June 19, 2016, between the Registrant and Anthony J. Recupero.	S-1	333-227445	10.18	9/20/2018
10.9	Amended and Restated Investors' Rights Agreement, dated June 2, 2016, by and among the Registrant and the parties thereto, as amended on October 4, 2018.	S-1/A	333-227445	10.21	10/5/2018
10.10+	Amendment to Restricted Stock Units of Laura Francis	10-Q	001-38701	10.2	11/12/2019
10.11+	Amendment to Offer Letter with Jeffrey Dunn	8-K	001-38701	10.1	1/7/2021
10.12+	2023 Non-Employee Directors' Compensation Policy	10-Q	001-38701	10.1	8/08/2023
10.13+	SI-BONE, Inc. Severance Benefit Plan and Form of Participation Agreement	10-K	001-38701	10.24	3/10/2021

10.14+	Offer Letter Agreement, dated April 19, 2021, between the Registrant and Helen Loh	10-Q	001-38701	10.2	5/4/2021
10.15+	Offer Letter Agreement, dated March 4, 2021, between the Registrant and Mika Nishimura	10-Q	001-38701	10.3	5/4/2021
10.16	Office Lease Agreement, dated February 2, 2018, between the Registrant and Bixby SPE Finance 11, LLC, as amended on April 16, 2018.	S-1	333-227445	10.21	9/20/2018
10.17	Loan and Security Agreement, dated August 12, 2021, between SI-BONE, Inc. and Silicon Valley Bank	10-Q	001-38701	10.1	11/9/2021
10.18+	Second Amendment to the Offer Letter Agreement and Severance Plan Participation Agreement with Jeffery Dunn	10-Q	001-38701	10.2	11/9/2021
10.19+	Offer Letter Agreement, dated April 20, 2021, between the Registrant and Anshul Maheshwari	8-K	001-38701	10.1	4/20/2021
10.20+	Amended and Restated Participation Agreement dated April 20, 2021, between the Registrant and Laura Francis	8-K	001-38701	10.2	4/20/2021
10.21+	Form of Performance-Based Restricted Stock Unit Agreement	10-Q	001-38701	10.2	11/8/2022
10.22#	First Amendment to Loan and Security Agreement, dated January 6, 2023 between SI-BONE, Inc. and Silicon Valley Bank	10-K	001-38701	10.29	3/2/2023
10.23	Letter Agreement, dated March 24, 2023 between SI-BONE, Inc. and Silicon Valley Bridge Bank	10-Q	001-38701	10.20	5/2/2023
10.24	Office Lease Agreement, dated February 2, 2018, between the Registrant and Bixby SPE Finance 11, LLC, as amended on April 16, 2018.	S-1	333-227445	10.21	9/20/2018
10.25+	Performance Stock Unit Grants to Executive Officers or Key Executives	8-K	001-38701	Item 5.02	1/10/2022
10.26*#	Second Amendment to Loan and Security Agreement, dated January 25, 2024 between SI-BONE, Inc. and Silicon Valley Bank				
10.27*#	Manufacture and Supply Agreement, dated February 23, 2024, between SI-BONE, Inc. and RMS Company				
97.1*	2023 Recoupment (Clawback) Policy				
21.1*	List of Subsidiaries of Registrant				
23.1*	Consent of PricewaterhouseCoopers, Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (contained in the signature page of this report)				
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1**	Certification of Principal Executive Officer and Principal Financial Officer 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.

\+ Indicates a management contract or compensatory plan.

\# Confidential treatment has been granted with respect to certain portions of this exhibit.

(b) We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the Exhibit Index immediately above.

(c) See Item 15(a)2 above.

Item 16. Form 10-K Summary.

Not provided.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SI-BONE, Inc.

Date: February 27, 2024

By: /s/ Laura A. Francis
Laura A. Francis
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

SI-BONE, Inc.

Date: February 27, 2024

By: /s/ Anshul Maheshwari
Anshul Maheshwari
Chief Financial Officer
(Principal Financial and Accounting Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Laura A. Francis, and Michael A. Pisetsky, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Laura A. Francis Laura A. Francis	Chief Executive Officer and Director (*Duly Authorized Officer and Principal Executive Officer*)	February 27, 2024
/s/ Anshul Maheshwari Anshul Maheshwari	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 27, 2024
/s/ Timothy E. Davis, Jr. Timothy E. Davis, Jr.	Director	February 27, 2024
/s/ Jeffrey W. Dunn Jeffrey W. Dunn	Chairman of the Board of Directors	February 27, 2024
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	February 27, 2024
/s/ Jeryl L. Hilleman Jeryl L. Hilleman	Director	February 27, 2024
/s/ Gregory K. Hinckley Gregory K. Hinckley	Director	February 27, 2024
/s/ Helen Loh Helen Loh	Director	February 27, 2024
/s/ Mika Nishimura Mika Nishimura	Director	February 27, 2024
/s/ Keith C. Valentine Keith C. Valentine	Director	February 27, 2024

EXHIBIT 10.26

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

This **SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "Agreement") is entered into as of January 25, 2024, by and between **SILICON VALLEY BANK**, a division of First-Citizens Bank & Trust ("Bank") and SI-BONE, INC., a Delaware corporation ("Borrower").

Recitals

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of August 12, 2021, (as the same may from time to time be amended, modified, supplemented or restated, including without limitation by that certain First Amendment to Loan and Security Agreement by and between Bank and Borrower dated January 6, 2023 and that certain Letter Agreement by and between Bank and Borrower dated as of March 24, 2023, the "Loan Agreement"). Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower has requested that Bank amend the Loan Agreement to make certain other revisions to the Loan Agreement as more fully set forth herein. Bank has agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

Agreement

Now, Therefore, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Agreement shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.a Section 5.10 (Financial Covenant (Net Revenue)). Section 5.10 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

> "**5.10 Financial Covenant (Net Revenue).** When a Financial Covenant Measuring Period is in effect, Borrower shall achieve Net Revenue (measured in accordance with GAAP on a trailing six (6) month basis), tested quarterly on the last day of each calendar quarter, in an amount equal to or greater than the levels to be agreed upon between Borrower and Bank with respect to which Borrower hereby agrees: (i) shall be documented in an amendment to this Agreement, in form and substance acceptable to Bank, which amendment shall be executed no later than: (x) for the fiscal year ending on December 31, 2025, the earlier to occur of 1) the date when Borrower's unrestricted cash and Cash Equivalent held with Bank and Bank's Affiliates is equal to or falls below [***] Dollars, and 2) May 31, 2025, with Borrower's failure to enter into such amendment to this Agreement to reset such covenant levels on or prior to such date being an immediate and non-curable Event of Default hereunder; and (y) for the fiscal year ending on December 31, 2026 and any fiscal year after that, February 28th of each year beginning with February 28, 2026, with Borrower's failure to enter into such amendment to this Agreement to reset such covenant levels on or prior to February 28th of each year being an immediate and non-curable Event of Default hereunder; (ii) shall be based on Borrower's projections delivered to Bank in accordance with Section 5.3(e) hereof and acceptable to Bank in its commercially reasonable discretion with such projections for Borrower's 2025 fiscal year showing a year-over-year growth satisfactory to Bank in its sole discretion."

2.b Section 12.2 (Definitions). The following term and its definition hereby is amended and restated in its entirety in Section 12.2 of the Loan Agreement to read as follows:

""**Financial Covenant Measuring Period**" is any period of time (a) commencing on the later to occur of (i) the date on which the aggregate value of the Borrower's unrestricted and unencumbered (except for Liens in favor of Bank) cash and Cash Equivalents held at Bank and Bank's Affiliates falls below [***] Dollars, and (ii) January 1, 2025 and (b) terminating on the date on which Borrower has achieved two (2) consecutive quarters of Adjusted EBITDA greater than Zero Dollars ($0). After the termination of a Financial Covenant Measuring Period, if both (X) Borrower's Adjusted EBITDA is equal to or less than Zero Dollars ($0) for the most recently completed fiscal quarter and (Y) the aggregate value of the Borrower's unrestricted and unencumbered (except for Liens in favor of Bank) cash and Cash Equivalents held at Bank and Bank's Affiliates is less than [***] Dollars, then a new Financial Covenant Measuring Period shall start and shall not terminate until Borrower again achieves Adjusted EBITDA Balance greater than Zero Dollars ($0) for two (2) new consecutive quarters."

3. Limitation of Agreement.

3.a This Agreement is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

3.b This Agreement shall be construed in connection with and as part of the Loan Documents, and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Bank to enter into this Agreement, Borrower hereby represents and warrants to Bank as follows:

4.a Immediately after giving effect to this Agreement (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Default or Event of Default has occurred and is continuing. Borrower understands and agrees that in modifying the existing Obligations, Bank is relying upon Borrower's representations, warranties, and agreements, as set forth in the Loan Documents;

4.b Borrower has the power and authority to execute and deliver this Agreement and to perform its obligations under the Loan Agreement, as amended by this Agreement;

4.c The organizational documents of Borrower delivered to Bank on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.d The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Agreement, have been duly authorized by all necessary action on the part of Borrower;

4.e The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Agreement, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.f The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Agreement, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.g This Agreement has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Release by Borrower.

5.a **FOR GOOD AND VALUABLE CONSIDERATION**, Borrower hereby forever relieves, releases, and discharges Bank and its present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Agreement (collectively "Released Claims"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.b In furtherance of this release, Borrower expressly acknowledges and waives any and all rights under Section 1542 of the California Civil Code, which provides as follows:

> "**A general release** does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party." (Emphasis added.)

5.c By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Bank with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.d This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Bank to enter into this Agreement, and that Bank would not have done so but for Bank's expectation that such release is valid and enforceable in all events.

5.e Borrower hereby acknowledges and agrees that Borrower has no offsets, defenses, claims, or counterclaims against Bank with respect to the Obligations, or otherwise, and that if Borrower now has, or ever did have, any offsets, defenses, claims, or counterclaims against Bank, whether known or unknown, at law or in equity, all of them are hereby expressly WAIVED and Borrower hereby RELEASES Bank from any liability thereunder.

5.f Borrower hereby represents and warrants to Bank, and Bank is relying thereon, as follows:

(i) Except as expressly stated in this Agreement, neither Bank nor any agent, employee or representative of Bank has made any statement or representation to Borrower regarding any fact relied upon by Borrower in entering into this Agreement.

(ii) Borrower has made such investigation of the facts pertaining to this Agreement and all of the matters appertaining thereto, as it deems necessary.

(iii) The terms of this Agreement are contractual and not a mere recital.

(iv) This Agreement has been carefully read by Borrower, the contents hereof are known and understood by Borrower, and this Agreement is signed freely, and without duress, by Borrower.

(v) Borrower is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and Borrower has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Borrower shall indemnify Bank, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Ratification of Perfection Certificate. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated on or prior to the Effective Date and acknowledges, confirms and agrees that the disclosures and information Borrower provided to Bank in such Perfection Certificate have not changed, as of the date hereof.

7. Prior Agreement. The Loan Documents are hereby ratified and reaffirmed and shall remain in full force and effect. Borrower hereby ratifies, confirms, and reaffirms all terms and conditions of all security or other collateral granted to the Bank, and confirms that the indebtedness secured thereby includes, without limitation, the Obligations. This Agreement is not a novation and the terms and conditions of this Agreement shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. In the event of any conflict or inconsistency between this Agreement and the terms of such documents, the terms of this Agreement shall be controlling, but such document shall not otherwise be affected or the rights therein impaired.

8. Integration. Except as expressly modified pursuant to this Agreement, the terms of the Loan Documents remain unchanged and in full force and effect. This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

9. Fees and Expenses. Borrower shall pay to Bank on the date first listed above all Bank Expenses due and owing as of the date hereof. The fees and expenses listed in the previous sentence may be debited from any of Borrower's accounts at Bank.

10. Conditions to Effectiveness. The parties agree that the obligations of Bank herein shall be effective upon the satisfaction of each of the following conditions precedent, each in form and substance satisfactory to Bank in its sole discretion, on or prior to the date first listed above:

1.a this Agreement duly executed on behalf of Borrower;

1.b Borrower's payment of Bank's legal fees and expenses incurred in connection with this Agreement; and

1.c such other documents as Bank may reasonably request to effectuate the terms of this Agreement.

11. Miscellaneous.

11.a This Agreement shall constitute a Loan Document under the Loan Agreement; the failure to comply with the covenants contained herein shall constitute an Event of Default under the Loan Agreement; and all obligations included in this Agreement (including, without limitation, all obligations for the payment of principal, interest, fees, and other amounts and expenses) shall constitute obligations under the Loan Agreement and secured by the Collateral.

11.b Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

11.c This Agreement may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

11.d The Loan Documents are hereby amended wherever necessary to reflect the changes described above.

11.e Section 11.9 of the Loan Agreement applies to this Agreement.

11.f This Agreement and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

[Signature page follows.]

In Witness Whereof, the parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

BANK

FIRST-CITIZENS BANK & TRUST COMPANY

By: /s/ Mark Davis
Name: Mark Davis
Title: Senior Vice President

BORROWER

SI-BONE, INC.

By: /s/ Anshul Maheshwari
Name: Anshul Maheshwari
Title: CFO

EXHIBIT 10.27

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

MANUFACTURE AND SUPPLY AGREEMENT

THIS MANUFACTURE AND SUPPLY AGREEMENT ("***Agreement***") is entered into as of February 23, 2024 (the "***Effective Date***"), between **SI-BONE, INC.**, a Delaware corporation having an address of 471 El Camino Real, Suite 101, Santa Clara, CA 95050 ("***Company***") and **RMS COMPANY,** a Minnesota corporation having an address of 8600 Evergreen Boulevard, Coon Rapids, MN 55433 ("***Supplier***").

RECITALS

WHEREAS, Company and Supplier desire for Supplier to manufacture and supply certain products to Company, and for Company to purchase certain products from Supplier, on the terms and conditions set forth below, and

WHEREAS, the Parties previously entered into the Amended and Restated Manufacturing, Quality and Supply Agreement, as amended and/or addended from time to time, effective June 11, 2021 (the "***June 2021 Agreement***"), and

WHEREAS, the Parties desire to enter into a new Manufacture and Supply Agreement which will supersede the June 2021 Agreement in its entirety as of the Effective Date.

NOW THEREFORE, the parties, intending to be legally bound, agree as follows.

AGREEMENT

1. PURCHASE AND SALE

1.1 **Purchase and Sale**. Subject to the terms of this Agreement, during the Term, Company shall purchase from Supplier, and Supplier shall supply to Company, the products listed on **Exhibits A through D** (the "***Products***"). **Exhibits A through D** shall include (a) a detailed description of the Product(s), (b) the purchase price of the Product(s), and (c) any other relevant information pertaining to the Products. From time to time, the parties may mutually agree to add additional products to **Exhibits A through D** pursuant to a writing signed by both parties, at which time such products will become Products for purposes of this Agreement.

1.2 **Specifications**. Company shall define the specifications for each Product (the "***Specifications***"), The Specifications may be paper documents, electronic documents or other appropriate media. The parties may change the Specifications from time to time by mutual written agreement. Supplier shall deliver the Product in full conformance to the Specifications.

1.3 **Requirements Contract; Alternative Source**.

a. Unless otherwise specified in writing by the Parties, Company shall purchase from Supplier, and Supplier shall manufacture and sell to Company 100% of Company's requirements for the Products.

b. For the avoidance of doubt, accessories used in connection with the Product may be purchased by Company from Supplier or a third-party vendor, or manufactured directly by, or otherwise obtained through, Company.

c. Company retains the right to qualify alternative sources of supply of Products ("***Alternative Sources***"), which Alternative Sources of supply shall only be used by Company to supply Products in the event of a Supply Failure. For clarity, Company itself or an affiliate of Company may be an Alternative Source.

1.4 **Forecasts**. Within ten days after the Effective Date, Company shall deliver to Supplier a 12- month rolling forecast of its anticipated demand for the Product (the "***Forecast***"). No later than ten days following the end of each calendar quarter during the Term, Company shall update the Forecast in writing and include estimated quantities, delivery schedules, and any other relevant information reasonably requested by Supplier. Forecasts shall be nonbinding and used and relied upon by Supplier only for Supplier's internal capacity planning purposes. Supplier acknowledges that these Forecasts are specifically aligned with the terms outlined in Sections 3 and 6 of the Vendor Managed Inventory Addendum in **Exhibit H**. Supplier agrees not to use or rely upon these Forecasts for any other purpose, and any actions taken by Supplier outside of this agreement shall be at Supplier's own risk.

Supplier shall make commercially reasonable efforts to meet the forecasted demand. If Supplier determines that it will not be able to meet the forecasted demand specified in the forecasts provided, Supplier shall promptly notify Company in writing. Such notification shall include the reasons for the anticipated shortfall, the revised estimated quantities that can be supplied, and any proposed alternative solutions, if applicable. Supplier shall make reasonable efforts to mitigate any anticipated shortfall and minimize the impact on Company's operations. This may include expedited production, allocation of available inventory, or other appropriate measures to meet the revised estimated quantities to the extent commercially feasible.

2. ORDERING PROCEDURE

2.1 **Purchase Orders**. All purchases shall be pursuant to purchase orders submitted by Company to Supplier (an "***Order***"). An Order shall specify the Products ordered (including part numbers and revision levels if applicable), quantities of each Product ordered, price, requested delivery date and requested Product recipient. The delivery date is subject to the requirements of Section 2.2 (Lead Time). Supplier shall provide written notice to Company no later than five days after receipt of the Order confirming receipt of the Order and its delivery date ("***Confirmed Delivery Date***"). Orders may be changed only by the mutual written agreement of the parties.

2.2 **Lead Time**. Supplier shall provide Company with a mutually agreed-upon standard lead time for the supply of the Products. The lead time shall represent the estimated time required for Supplier to fulfill the Orders placed by Company based on current manufacturing schedules. The lead time shall include manufacturing, packaging, quality control processes, and any necessary transportation or logistics considerations. Any changes to the lead time shall be communicated in writing by Supplier to Company in advance. The parties understand that the standard lead time is impacted by changes in the Supplier's backlog of orders, production capacity, availability of raw materials, or other relevant circumstances. Supplier shall make commercially reasonable efforts to adhere to the agreed-upon lead time, however, the Confirmed Delivery Date provided by the Supplier upon receipt of the Order shall prevail. The parties may periodically review and assess Supplier's performance in meeting the communicated lead time and Confirmed Delivery Dates. Any recurring or significant deviations from the communicated lead time and agreed-upon Confirmed Delivery Dates shall be promptly

communicated between the parties, and appropriate corrective measures shall be discussed and implemented, if necessary.

2.3 **Order of Precedence**. The parties hereby agree to terminate the June 2021 Agreement as of the Effective Date. The parties intend for the express terms and conditions contained in this Agreement (including any Schedules and Exhibits hereto) and in any Order that are consistent with this Agreement to exclusively govern and control the parties' respective rights and obligations regarding the manufacture, purchase, and sale of the Products, and the parties' agreement is expressly limited to such terms and conditions. Notwithstanding the foregoing, if any terms and conditions contained in an Order conflict with any terms and conditions contained in this Agreement, the applicable term or condition of this Agreement will prevail and such contrary or different terms will have no force or effect.

3. SHIPMENT, DELIVERY, ACCEPTANCE, INSPECTION

3.1 **Delivery**. Unless otherwise specified in an Order, all shipments of Products pursuant to this Agreement shall be shipped by Supplier, EXW (incoterms 2020) Supplier's facility to Company's Santa Clara, CA facility at 471 El Camino Real, Santa Clara, CA 95050. Delivery shall be deemed to have occurred, and risk of loss transferred from Supplier to Company, when Products are delivered to the freight forwarder.

3.2 **Packing**. Products shall be packed at Supplier's sole cost and expense in accordance with Company's reasonable written instructions and reasonable commercial practices. Products shall be shipped at Company's sole cost and expense in accordance with Company's reasonable written instructions and reasonable commercial practices. Each shipment of Product shall be clearly marked as per Company's instructions.

3.3 **On Time Delivery**. Supplier shall adhere to the delivery schedule specified in an Order issued by Company. On-time delivery shall be defined as the delivery of the Products within the specified delivery dates, taking into account the Confirmed Delivery Date and communicated lead time per Section 2.2. If Supplier does not comply with any of its delivery obligations under this Section 3, Company may, in Company's sole discretion, (a) approve a revised delivery date, (b) require commercially reasonable expedited or premium shipment at Supplier's expense, or (c) cancel the applicable Order and obtain similar goods from other sources and all such Products will be deemed to have been purchased under this Agreement for purposes of satisfying Company's quantity requirements hereunder. In the event that the Company decides to cancel an order placed with the Supplier, both parties agree to collaborate in good faith to determine and address any obligations or liabilities that may have arisen prior to the cancellation. This includes but is not limited to raw materials that cannot be repurposed elsewhere, work in process, and finished goods. Unless otherwise expressly agreed to by the Parties in writing, Suppler may not make partial shipments of Products. The parties shall monitor Supplier's on-time delivery performance on a periodic basis. Company may request delivery performance reports from Supplier, detailing the actual delivery dates versus the scheduled delivery dates, along with any reasons for delays. If Supplier fails to achieve a satisfactory level of on-time delivery performance of at least 95%, Company may, at its sole discretion, pursue remedies available under this Agreement, including but not limited to adjustments to future Orders or termination of this Agreement in accordance with the provisions outlined herein.

3.4 **Inspection**. All Products are subject to Company's inspection prior to acceptance. Company shall have 60 days following the delivery of Products to Company to reject any Products received by Company from Supplier that: (a) do not conform to the product number or other product identifier listed in the applicable Order; (b) on visual inspection using mutually agreed

upon Specifications, Company reasonably determines the Products do not meet the Product Specifications; or (c) exceed (or be lesser than) the quantity of Products ordered by Company pursuant to this Agreement or any Order by more than plus or minus [*** of the order quantity for a non-instrument Product or plus or minus [*** of the order quantity for an instrument Product (a "***Nonconformity***," or "***Nonconforming Product***"). Where the context requires, Nonconforming Product is deemed to be Product for purposes of this Agreement. Upon detection of a Nonconformity, Company shall give written notice (which may be given by e-mail) to Supplier specifying the nature and type of alleged Nonconformity and upon notice of a Nonconformance, Supplier may request Nonconforming Product samples from Company for evaluation and verification of the Nonconformance. Upon confirmation and agreement between the parties that the Products are Nonconforming, the Company may withhold payment for properly rejected Nonconforming Products. In addition to any other remedies available to Company at law, in equity or hereunder, in the event Supplier delivers Nonconforming Products to Company, Company may select, and Supplier shall provide, one of the following remedies: (a) replacement of the Nonconforming Products with conforming Products, (b) the refund of the purchase price of, and shipping costs for, the Nonconforming Products, (c) the removal of any Nonconforming Products from Company's or its customers' facility and replacement with conforming Products, or (d) the cost of reconditioning or reworking any Nonconforming Products to conforming Products.

3.5 **Defects**. With respect to latent Nonconformities and Nonconformities not discovered by Company pursuant to Section 3.4 through the use of reasonable inspection methods and procedures, Company shall give notice within 15 days to Supplier following detection of any Nonconformity specifying the nature and type of alleged Nonconformity. Upon notice of a Nonconformance, Supplier may request Nonconforming Product samples from Company for evaluation and verification of the Nonconformance. Upon confirmation and agreement between the parties that the Products are Nonconforming, Company may withhold payment for any such Nonconforming Products or deduct the amount previously paid for such Products from any amounts then due to Supplier as an offset. Supplier shall have 30 days from such notice to cure such Nonconformities. In the event that Company properly rejects Nonconforming Products and payment has already been made by Company for such Nonconforming Products, Supplier shall reimburse Company such payment amount if Supplier is unable to cure such defect within the 30-day period.

3.6 **Notification of Nonconformity**. Supplier agrees to promptly notify Company in writing after Supplier obtains knowledge of its delivery to Company of any Nonconforming Product. In addition to the foregoing, Supplier shall notify Company within (a) two business days of learning of any situation which may require a recall of Products and (b) five business days of obtaining knowledge of any failure of any batch of Products to meet the standards set forth in Section 3.4.

4. PRICING; PAYMENT TERMS.

4.1 **Pricing**. During the Term, Supplier's sales price to Company for each Product unit shall be as described in Exhibits A-D.

4.2 **Invoices**. Supplier shall issue an invoice to Company for all Products ordered under this Agreement after they have been shipped from the Supplier's premises. Each invoice must set forth in reasonable detail the amounts payable by Company under this Agreement and contain the following information, as applicable: a reference to this Agreement; Order number, amendment number, and line-item number; Supplier's name; Supplier's identification number; carrier name; ship-to address; quantity of Product shipped; number of cartons or containers in shipment; bill of lading number; country of origin; and any other information necessary for

identification and control of the Product. Company reserves the right to return and withhold payment due to any invoices or related documents that are inaccurate or incorrectly submitted to Company. The parties shall seek to resolve any invoice disputes expeditiously and in good faith. Any payment by Company of an invoice is not an acceptance of any nonconforming element or terms on such invoice or the related Product.

4.3 **Payment.** Unless otherwise specified in writing, Company shall make payment to Supplier within 45 days from the date of receipt of a valid invoice. Payment shall be made in U.S. Dollars, unless otherwise mutually agreed upon by the parties. Company shall make all payments by check, wire transfer, or automated clearing house in accordance with the following instructions:

ABA Routing Number: [***
Account Name: [***
Account Number: [***
Bank Name and Address:
Wells Fargo Bank
420 Montgomery Street
San Francisco, CA 94105
E-Mail address for Remittance: [***

5. TERM; TERMINATION

5.1 **Term; Renewal**. Unless earlier terminated in accordance with this Section 5, the term of this Agreement shall commence on the Effective Date and continue for an initial term of three (3) years (the "***Initial Term***"). This Agreement shall automatically renew for successive one-year periods (each, a "***Renewal Term***" and collectively, together with Initial Term, the "***Term***") unless terminated by either party with no less than ninety (90) days' prior written notice prior to the beginning of such Renewal Term.

5.2 **Material Breach**. Either party may terminate this Agreement upon written notice in the event the other party commits a material breach, or threatens to commit a material breach, of this Agreement and either (i) if the breach can be cured, the breaching party has not cured such breach within 30 days of written notice thereof from the non-breaching party, or (ii) if the breach cannot be cured, the non-breaching party can terminate immediately without providing an opportunity to cure.

5.3 **Termination by Company**. Company may terminate this Agreement upon written notice to Supplier:

a. if Supplier fails to deliver a shipment of conforming Products in the quantities and by the delivery date specified in an Order submitted in accordance with this Agreement and such failure results in a delay or Product backorder of an aggregate total (together with any other delays in the same 12-month period) of more than thirty (30) days (a "***Supply Failure***");

b. if Supplier changes the site of manufacture of any Products to a site that has not been previously approved by Company in writing;

c. in the event of a Change in Control of Supplier or Supplier sells all or substantially all of its assets relating to the manufacturing of the Products; or

d. if Supplier breaches Section 11 hereof (Non-Compete Covenant).

5.4 **Change of Control and Last Time Buy Allowance**. In the event of a Change of Control of Supplier, Supplier shall promptly notify Company in writing of such change. "***Change of Control***" shall mean any direct or indirect transfer or acquisition of ownership, control, or voting rights that results in a change in the majority ownership or control of the affected party. Upon the occurrence of a Change of Control of Supplier, Company shall have the option, at its sole discretion, to issue a "Last Time Buy" notice within 30 days of receiving the Change of Control notification. The Last Time Buy notice shall specify the quantity of Products Company intends to purchase as a final order, up to a maximum of 18 months of the forecasted demand, as specified in the mutually agreed-upon forecasts provided under Section 1.5. The pricing for the Last Time Buy order shall be based on the pricing terms in effect at the time of the Change of Control, unless otherwise agreed upon by the parties. Payment for the Last Time Buy order shall be made in accordance with the payment terms specified in Section 4 of this Agreement. The Supplier shall use its best efforts to fulfill the Last Time Buy order within a reasonable period specified in the Last Time Buy notice. The parties shall agree upon the delivery terms, including shipment, packaging, and any additional terms necessary for the fulfillment of the Last Time Buy order. In the event of a Change of Control of the Company, there will be no changes to the purchase obligations described in Section 1.3(a).

5.5 **Insolvency**. Either party may terminate this Agreement immediately if the other party files, or has filed against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law, or the other party makes or seeks to make a general assignment for the benefit of its creditors or applies for or consents to the appointment of a trustee, receiver or custodian for it or a substantial part of its property, and, in the case of an involuntary bankruptcy, such situation is not cured within 60 days from its occurrence, such termination to take effect upon delivery of notice of termination to the other party.

5.6 **Effect of Termination**. Immediately upon the effectiveness of a notice of termination delivered by Company to Supplier, Supplier shall, unless otherwise directed by Company, terminate all performance under this Agreement and transfer title and deliver to Company all finished Products under open Orders. Upon termination of this Agreement, the license under Section 9.3 shall terminate.

5.7 **Resourcing Cooperation.** Upon the expiration or termination of this Agreement, or in the event of a Supply Failure, to the extent requested by Company in writing, Supplier shall:

a. deliver all Company purchased tooling, molds or print files relating to the Products and any other Company property to Company or its designees as soon as possible, but in no event more than 30 days, following termination or expiration of this Agreement so as to avoid any interruption in the continuous supply of Products; and

b. manufacture, deliver, and sell Products to Company for a period of up to eighteen (18) months, quantities of Products not to exceed the average number of units purchased per month during the preceding twelve (12) month period, to ensure that the transition will proceed smoothly and without interruption or delay to Company or Company's production of products incorporating the Products, with pricing equivalent to the pricing in effect immediately before expiration or termination.

6. CERTAIN OBLIGATIONS OF SUPPLIER

6.1 **Capacity.** Supplier shall maintain capacity adequate to fulfill the Product requirements of Company as specified in the most recent 12-month rolling Forecast. In the event of any significant changes in Supplier's production capacity or resources that may impact its ability to fulfill its obligations under this Agreement, Supplier shall promptly notify Company in writing.

Such notification shall include details of the capacity constraints, the expected duration of the constraints, and any proposed alternative solutions, if applicable. Supplier shall obtain and maintain all equipment and resources required to fulfill its obligations under this Agreement at Supplier's sole cost, unless such equipment or resources were purchased by Supplier exclusively to supply Company.

6.2 Quality. Supplier agrees to the quality provisions, as set forth in **Exhibit G** hereto.

6.3 Vendors and Subcontractors. Supplier shall not (i) change the vendors from whom Supplier sources components of the Products as of the Effective Date or (ii) subcontract its obligations to manufacture Products to subcontractors, in each case without the prior written consent of Company; provided, that Company hereby acknowledges its consent to Supplier's purchase of Product components from vendors identified in **Exhibit E** ("***Approved Vendors***") and use of subcontractors identified in **Exhibit F** ("***Approved Subcontractors***"). Company may order through Supplier, components sourced from Supplier's approved vendors (which vendors may include affiliates of Company) and Supplier agrees to provide those components to Company at Supplier's cost plus a reasonable mark-up for processing and handling. Subject to the requirements of Section 1.3, Company may request or otherwise require Supplier to approve and utilize Alternative Sources including the Approved Vendors and Approved Subcontractors provided that any commercially reasonable costs associated with the addition and qualification of Company-specified Approved Vendors and Approved Subcontractors, i.e. validation costs, test samples, etc. will be at the Company's expense.

7. COMPLIANCE WITH LAWS.

7.1 Compliance. The parties shall comply with all applicable federal, state and local statutes, laws, regulations, rules, code, governmental order, ordinances and policies (collectively, "***Law***") that pertain to the activities for which Supplier and Company are responsible under this Agreement, including those enforced by the FDA. With respect to the Products, Company shall be the "finished device manufacturer" (as such term is used by the FDA).

7.2 Permits, Licenses, and Authorizations. Supplier shall obtain and maintain all permits, licenses, approvals, authorizations, registrations, certificates and similar rights necessary for the exercise of its rights and performance under this Agreement.

8. REPRESENTATIONS AND WARRANTIES; PRODUCT WARRANTY

8.1 Supplier's Representations and Warranties.

a. it is duly organized, validly existing, and in good standing under the laws of its organization;

b. it is duly qualified to do business and is in good standing in every jurisdiction in which such qualification is required for purposes of this Agreement;

c. it has the full right, corporate power and authority to enter into this Agreement and to perform its obligations hereunder;

d. the execution of this Agreement by its representative whose signature is set forth at the end of this Agreement, and the delivery of this Agreement by Supplier, have been duly authorized by all necessary action on the part of Supplier;

e. the execution, delivery, and performance of this Agreement by Supplier will not violate, conflict with, require consent under or result in any breach or default under (i) any of Supplier's organizational documents, (ii) any applicable Law or (iii) with or without notice or lapse of time or both, the provisions of any material Supplier third-party agreement;

f. this Agreement has been executed and delivered by Supplier and (assuming due authorization, execution, and delivery by Company) constitutes the legal, valid, and binding obligation of Supplier, enforceable against Supplier in accordance with its terms, except as may be limited by any applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws and equitable principles related to or affecting creditors' rights generally or the effect of general principles of equity;

g. it is in compliance with all material applicable Laws and third-party agreements relating to this Agreement, the Products, and the operation of its business (including all loan covenants and other financing obligations to which it is subject);

h. it has obtained all licenses, authorizations, approvals, consents, or permits required by applicable Laws to conduct its business generally and to exercise its rights and perform its obligations under this Agreement;

i. it is not insolvent and is paying all of its debts as they become due; and

j. all financial information that it has provided to Company is true and accurate and fairly represents Company's financial condition, and has been prepared in accordance with GAAP, uniformly and consistently applied.

8.2 Company's Representations and Warranties.

a. it is duly organized, validly existing, and in good standing under the laws of its organization;

b. it is duly qualified to do business and is in good standing in every jurisdiction in which such qualification is required for purposes of this Agreement;

c. it has the full right, corporate power and authority to enter into this Agreement and to perform its obligations hereunder;

d. the execution of this Agreement by its representative whose signature is set forth at the end of this Agreement, and the delivery of this Agreement by Company, have been duly authorized by all necessary action on the part of Company;

e. the execution, delivery, and performance of this Agreement by Company will not violate, conflict with, require consent under or result in any breach or default under (i) any of Company's organizational documents, (ii) any applicable Law or (iii) with or without notice or lapse of time or both, the provisions of any material Company third-party agreement;

f. this Agreement has been executed and delivered by Company and (assuming due authorization, execution, and delivery by Supplier) constitutes the legal, valid, and binding obligation of Company, enforceable against Company in accordance with its terms, except as may be limited by any applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws and equitable principles related to or affecting creditors' rights generally or the effect of general principles of equity;

g. it is in compliance with all material applicable Laws and third-party agreements relating to this Agreement, the Products, and the operation of its business (including all loan covenants and other financing obligations to which it is subject);

h. it has obtained all licenses, authorizations, approvals, consents, or permits required by applicable Laws to conduct its business generally and to exercise its rights and perform its obligations under this Agreement;

i. it is not insolvent and is paying all of its debts as they become due; and

j. all financial information that it has provided to Supplier is true and accurate and fairly represents Company's financial condition, and has been prepared in accordance with GAAP, uniformly and consistently applied.

8.3 Product Warranty. The Supplier warrants and represents to Company that for a period of one year from the date of delivery, the Products will:

a. conform in all material respects to the Specifications/specifications, standards, drawings, samples, descriptions, quality requirements, performance requirements statements of work, specified or approved by Company for the Products;

b. conform with Company's quality standards as set forth in **Exhibit G**;

c. be merchantable and free from defects, latent or otherwise, in materials, and workmanship; and

d. not infringe upon, violate or misappropriate the Intellectual Property rights of any third party, limited to the manufacturing process, and excluding infringement that is a direct result of the Specifications, design or its intended use as provided by Company; and

e. be new and conveyed to Company with good title, free and clear of all liens, security interests, claims, conditions or restrictions of any kind.

8.4 Additional Terms. The Product Warranty survives Supplier's delivery of the Products, Company's receipt, inspection, acceptance, use of the Products and payment for the Products, and the termination or expiration of this Agreement subject to the terms of this Section 8.3.

9. INTELLECTUAL PROPERTY.

9.1 Definitions.

a. "***Intellectual Property Rights***" means all industrial and other intellectual property rights in any inventions, improvements, developments, or innovations (including all rights to patents, copyrights, trademarks, and trade secrets and know-how inherent therein and appurtenant thereto) and other creative works (whether or not patentable or copyrightable, conceived or made or reduced to practice), know-how, technical information, pending patent applications, registrations, divisions and continuations thereof, registered and unregistered copyrights, and all associated goodwill, designs, drawings, specifications, vendor lists, manufacturing methods and processes, and all other information pertinent to this Agreement, which is proprietary to a party.

b. "***Foreground Intellectual Property Rights***" means any and all of the Intellectual Property Rights developed with respect to, or for incorporation into, the Products, that are either

developed by Company alone, by Company and Supplier jointly in the performance of this Agreement or by Supplier alone as requested by Company in connection with this Agreement.

9.2 **Ownership**. Each Party retains exclusive ownership of its existing Intellectual Property Rights as of the Effective Date. All Foreground Intellectual Property Rights shall be owned by Company.

9.3 **Limited License**. Company hereby grants Supplier a non-exclusive, nontransferable, worldwide license, without the right to sublicense, to use Company's Intellectual Property Rights solely in connection with the manufacture and sale of the Products to Company or parties designated by Company. This license shall not include the right to modify, make derivative works of or improvements to the Products and shall terminate upon the termination or expiration of this Agreement.

9.4 **Assistance**. Supplier shall execute all papers, including patent applications, invention assignments and copyright assignments, and otherwise shall assist Company as reasonably required to perfect in Company the rights, title and other interests held by Company under this Agreement. Company shall pay for reasonable costs related to such assistance. If Company is unable for any reason, after reasonable effort, to secure Supplier's signature on any document needed in connection with the actions specified above, Supplier hereby irrevocably designates and appoints Company and its duly authorized officers and agents as its agent and attorney in fact, which appointment is coupled with an interest, to act for and in its behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by Supplier.

9.5 **Trade Names**. Each of Company and Supplier hereby acknowledges and agrees that it does not have, and shall not acquire, any interest in the other party's trademarks except as expressly provided herein. Any violation of this Section shall constitute a material breach of this Agreement.

10. INSURANCE

Supplier shall maintain commercial general and product liability insurance adequate to cover a liability (including an alleged manufacturing defect, failure to warn, or breach of implied or express warranty) arising in connection with any Product manufactured by Supplier and supplied to Company under this Agreement in coverage amounts consistent with normal business practices of prudent companies similarly situated and the insurance coverage shall in no event be less than [*** Dollars per loss occurrence and [*** Dollars in the aggregate. Supplier shall provide Company with written evidence of such insurance upon request. If coverage is on a "claims made" basis, then Supplier shall maintain continuous coverage for five years after the termination or expiration of this Agreement, or Supplier shall purchase "tail coverage" providing such insurance for no less than five years after the policy terminates, or lapses. Supplier shall provide Company with written notice at least 30 days prior to the cancellation, nonrenewal or material change in such insurance which materially adversely affects the scope or amount of such insurance coverage.

11. NON-SOLICITATION.

The parties agree that each have an important interest in maintaining a stable work force and in protecting its Confidential and Proprietary Information (as described below). Therefore, parties agree that, during the Term of this Agreement and for a period of twelve months thereafter (the "***Restricted Period***"), not to directly or indirectly, solicit, induce, recruit or encourage any of the other party's employees or consultants to terminate their relationship with the other party, or attempt to solicit,

induce, recruit, encourage or take away employees or consultants of the other party, either for the benefit of other party or for the benefit of any other person or entity. This restriction shall not apply to employees responding to commercially reasonable employment advertisements in common national or regional recruiting media.

12. CONFIDENTIALITY; PUBLICITY.

12.1 **Confidential and Proprietary Information**. The Company and Supplier will have access to each other's Confidential and Proprietary Information. "***Confidential and Proprietary Information***" means any trade secret, other information viewed by the party disclosing it (the "***Disclosing Party***") as confidential and/or proprietary, and any and all information or proprietary materials (in every form and media) not generally known in the relevant trade or industry made available by either party to the party receiving such information (in such case, the "***Receiving Party***") in connection with the efforts contemplated hereunder and which the Disclosing Party has marked as confidential (or with other similar designation) at the time of disclosure; and/or disclosed by Disclosing Party in any other manner and identified as confidential at the time of disclosure and/or may reasonably be understood as confidential, including, but not limited to (i) all non-public Intellectual Property of either party; (ii) existing or contemplated products, services, designs, inventions, technology, processes, technical data, engineering, techniques, methodologies and concepts and any information related thereto; and (iii) information relating to business plans, sales, consultants, employees, or marketing methods and customer lists or requirements. The Receiving Party shall maintain the Disclosing Party's Confidential and Proprietary Information using the same standard of care it uses to maintain its own Confidential and Proprietary Information in confidence, but in any case, no less than reasonable care; not use or permit to be used the Disclosing Party's Confidential and Proprietary Information for any purpose other than the performance of its rights and obligations under this Agreement; and not disclose such information to any third parties except to those who need to know the information to assist the Receiving Party to exercise its rights or perform its obligations under this Agreement. Such obligation of confidentiality and non-use shall not apply to information which (a) is known to the Receiving Party prior to the disclosure as demonstrated by documentary evidence, (b) is publicly known as of the date of the disclosure, (c) becomes publicly known after the date of disclosure through no fault of the Receiving Party, (d) is received by the Receiving Party from a third party who has, to the Receiving Party's knowledge, no obligation of confidentiality to the Disclosing Party, or (v) is developed independently by the Receiving Party without reference to the Disclosing Party's Confidential and Proprietary Information as demonstrated by documentary evidence. Such obligation of confidentiality and non-use shall survive any expiration or termination of this Agreement for a period of ten (10) years; provided that Disclosing Party's information that meets the legal definition of a trade secret, will indefinitely survive the termination of this agreement pursuant only to the terms in this Section 12.1. The Receiving Party shall be responsible for any breach of this section caused by any of its affiliates, employees, officers, directors, agents, or third parties to whom the Receiving Party disclosed the Disclosing Party's Confidential and Proprietary Information. The restrictions on disclosure contained in this Section 12.1 shall not apply to any information which is required to be disclosed by a valid court order or governmental law or regulation, provided that the Receiving Party gives the Disclosing Party prompt notice of any such requirement and cooperates with the Disclosing Party, at the Disclosing Party's expense, in attempting to limit such disclosure and obtain confidential treatment thereof.

12.2 **Misuse of Confidential and Proprietary Information**. Each Receiving Party understands and agrees that this provision prohibits it from rendering services to another party to the extent that such Receiving Party would use, disclose, or rely upon the Disclosing Party's Confidential and Proprietary Information in any way other than for the Disclosing Party's benefit and in the furtherance of the objectives of this Agreement. Such unauthorized use of

Confidential and Proprietary Information shall include, but not be limited to use or disclosure of Confidential and Proprietary Information to: (i) discourage any of the Disclosing Party's clients, customers or distributors, or prospective clients, customers or distributors from purchasing such Disclosing Party's products or services; or (ii) solicit, influence, or attempt to solicit or influence any client, customer, distributor or other person, either directly or indirectly, to direct any purchase of products to any person, firm, corporation, institution or other entity in competition with the business of the Disclosing Party as such business is conducted or proposed throughout the Term of this Agreement.

12.3 **Publicity**. Except as otherwise provided in this Agreement or required by Law, neither party shall use the other's name or refer to it directly or indirectly in an advertisement, news release or release to any professional or trade publication without written approval from such party, which approval may not be unreasonably withheld or delayed. Neither party shall use the name of the other for advertising or promotional claims without the prior written consent of the other party.

12.4 **Damages Inadequate**. The parties acknowledge that monetary damages may be an inadequate remedy for any breach by a party of its obligations under this Section 12 and that the non-breaching party shall be entitled to seek injunctive relief and specific performance to enforce the breaching party's obligations, in addition to any other remedies the non-breaching party may be entitled to at law.

13. REMEDIES; INDEMNIFICATION.

13.1 **Indemnification by Supplier**. Supplier agrees to indemnify, defend and hold Company, its affiliates, officers, directors, agents and employees ("***Company Indemnitees***") harmless from and against all actions, liabilities, damages, claims and demands whatsoever, including, but not limited to, attorney fees and other expenses ("***Claims***") that are brought or communicated by third parties against the Company Indemnitees and to the extent caused by Supplier's or Supplier Indemnitee's: (a) breach of this Agreement; (b) violation of Law; (c) breach of representations and warranties; (d) any claim of Intellectual Property Rights infringement arising from Supplier's manufacturing processes or Supplier's services provided hereunder, provided such infringement is not a direct result of the Specifications provided by Company; or (e) negligence, recklessness or willful misconduct. The duty to indemnify will not apply to the extent that any Claim arises from the negligence, recklessness, or willful misconduct of a Company Indemnitee or Company's breach of this Agreement.

13.2 **Indemnification by Company**. Company agrees to indemnify, defend and hold Supplier, its affiliates, officers, directors, agents and employees ("***Supplier Indemnitees***") harmless from and against all Claims that are brought or communicated by third parties against Supplier Indemnitees to the extent caused by to: (a) Company's breach of this Agreement; (b) Company's violation of Law; (c) defects or alleged defects in the design of the Products, provided such design defects are a result of Specifications or instructions provided by Company and not Supplier's manufacturing process; (d) the use, misuse or inability to use Products arising from the Company's design or Specifications; (e) infringement of the Intellectual Property Rights of third parties, provided such infringement is a direct result of the Specifications or instructions provided by Company; or (f) Company's negligence, recklessness or willful misconduct. The duty to indemnify will not apply to the extent that any Claim arises from the negligence, recklessness, or willful misconduct of a Supplier Indemnitee or Supplier's breach of this Agreement.

13.3 **Indemnification Procedure**. The party claiming indemnity (the "***Indemnified Party***") shall provide the party from whom indemnity is being sought (the "***Indemnifying Party***") with

reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the claim for which indemnity is being sought. The Indemnifying Party shall have the right to assume sole control over the defense of such claim and conduct the defense of the claim with counsel of its choice. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money.

13.4 **Limitations of Damages**. Notwithstanding anything to the contrary contained in this Agreement, neither party shall be liable to the other party or its affiliates (except with respect to either party's breach of its obligations of Section 12, or indemnification obligations of Section 13.1 or 13.2 with respect to third party claims) for any indirect, special, incidental (including, without limitation, lost profits) or punitive damages of the other party or its affiliates from any breach or default of a party's obligations hereunder or the breach of any representation or warranty made hereunder. Except with respect to either party's breach of its obligations of Section 12, or indemnification obligations of Section 13.1 or 13.2 with respect to third party claims, the collective liability of either party to the other under this Agreement shall be limited on an aggregate basis (not per claim or occurrence) to the lesser of the preceding 12 months revenue of Supplier from Company or [***, except that with respect to damages or liabilities arising out of personal injury or death due to gross negligence or willful misconduct, such collective liability shall be limited to [***. Upon payment(s) by the Supplier and/or Supplier Indemnitees to the Company and/or Company Indemnitees, or payment(s) by Company and/or the Company Indemnitees to Supplier and/or the Supplier Indemnitees, the party having made such payments shall be relieved and discharged from any further liability to the other party and/or its Indemnitees under this Agreement, or otherwise for contribution or to defend, indemnify, and/or hold harmless the other party and/or its Indemnitees.

14. MISCELLANEOUS

14.1 **Assignment; Binding Effect**. This Agreement shall not be assignable or otherwise transferable by Supplier without the prior written consent of Company and shall be binding upon and inure to the benefit of the parties and their respective successors and permitted assigns. This Agreement shall not be assignable or otherwise transferable by Company without the prior written consent of Supplier, provided that Company may assign this Agreement to any affiliate of Company without Supplier's consent or in connection with a merger, acquisition or sale of the stock of, or all or substantially all of the assets of, Company. Notwithstanding anything in this Agreement, the parties acknowledge and agree that Company may perform its obligations under this Agreement through an affiliate of Company.

14.2 **Notices**. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) when received if delivered personally, including by recognized overnight delivery service, (b) when transmitted by facsimile or electronic mail (email), with confirmation of successful transmission, provided that such delivery is followed by physical delivery, (c) upon receipt, if sent by registered or certified mail (postage prepaid, return receipt requested) and (d) the next business day after it is sent, if sent for next-day delivery to a domestic address by overnight mail or courier, to the parties at the following addresses:

If to Company, to: SI-BONE, Inc.
471 El Camino Real, Suite 101
Santa Clara, CA 95050
ATTN: CFO
legal@si-bone.com

If to Supplier, to: rms COMPANY
8600 Evergreen Boulevard
Coon Rapids, MN 95050
ATTN: Director of Sales & Marketing

With a copy to:
[***]
311 Lowell Ave
Elk River, MN 55330
ATTN: Contract Manager

provided, however, that if any party shall have designated a different address by notice to the others, then to the last address so designated.

14.3 **Survival**. All of the representations, warranties, and indemnifications made in this Agreement, and all terms and provisions hereof intended to be observed and performed by the parties after the termination hereof, including Sections 3.4, 3.5, 3.6, 4.3, 5.7, 8.3, 9, 11, 12, 13, and 14 and Sections 1.7 and 1.8 of Exhibit G.

14.4 **Severability**. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be invalid, void, unenforceable or against its regulatory policy such determination shall not affect the enforceability of any others or of the remainder of this Agreement; and in connection with such term, provision, covenant or restriction of this Agreement which is held invalid, void, unenforceable or against regulatory policy, the parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid term, provision, covenant or restriction and, absent any agreement by the parties, such court of competent jurisdiction or other authority shall substitute therefore such term, provision, covenant or restriction as is legal, valid and enforceable but otherwise similar to the invalid term, provision, covenant or restriction.

14.5 **Entire Agreement**. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by Company and Supplier. This Agreement contains the entire agreement of the parties hereto with respect to its subject matter, superseding all negotiations, prior discussions and preliminary agreements made prior to the date hereof.

14.6 **No Third-Party Beneficiaries**. This Agreement is solely for the benefit of the parties hereto and their respective affiliates and no provision of this Agreement shall be deemed to confer upon any third parties (other than permitted assigns) any remedy, claim, liability, reimbursement, claim of action or other right in excess of those existing without reference to this Agreement.

14.7 **Waiver**. The failure of any party to enforce any condition or part of this Agreement at any time shall not be construed as a waiver of that condition or part, nor shall it forfeit any rights to future enforcement thereof.

14.8 **Governing Law; Jurisdiction**. This Agreement (including any claim or controversy arising out of or relating to this Agreement) shall be governed by the law of the State of New York without regard to conflict of law principles that would result in the application of any Law other than the Laws of the State of New York.

14.9 **Injunctive Relief**. The parties acknowledge that damages may be an inadequate remedy for any material breach of Sections 6.3 (Vendors & Subcontractors), 9 (Intellectual Property), 11

(Non-competition), or 12 (Confidentiality; Publicity). Accordingly, notwithstanding anything to the contrary in this Agreement, either party will have the right to obtain injunctive relief in any court of competent jurisdiction to enforce Sections 6.3 (Vendors & Subcontractors), 9 (Intellectual Property), 11 (Non-competition), or 12 (Confidentiality; Publicity) in the event of a party's failure to perform its obligations thereunder, as well as the right to pursue any and all other rights and remedies available at law or in equity for such a breach. The breaching party hereby expressly waives the defense that a remedy in damages will be adequate and any requirement in an action for specific performance or injunction for the posting of a bond by the party seeking injunctive relief.

14.10 **Counterparts**. This Agreement may be executed manually or by facsimile by the parties, in any number of counterparts, each of which shall be considered one and the same agreement and shall become effective when a counterpart hereof shall have been signed by each of the parties and delivered to each of the other parties.

14.11 **Construction**. The language in all parts of this Agreement shall be construed, in all cases, according to its fair meaning. The parties acknowledge that each party and its counsel have reviewed and revised this Agreement and that any rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement.

14.12 **Further Assurances**. Company and Supplier covenant and agree that subsequent to the execution and delivery of this Agreement and without any additional consideration, each of Company and Supplier shall execute and deliver any further legal instruments and perform such acts which are or may become necessary to effectuate the purposes of this Agreement.

14.13 **Relationship**. Supplier is an independent contractor engaged by Company for the provision of the Products. Nothing in this Agreement shall constitute either party as an employee, agent or general representative of the other, nor shall either Company or Supplier have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against, or in the name of or on behalf of, the other.

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IN WITNESS WHEREOF, the parties hereto have caused this Manufacturing and Supply Agreement to be executed by their respective duly authorized officers as of the date set forth below their names.

SI-BONE, Inc.
By: /s/ Jeff Bertolini
Name: Jeff Bertolini
Title: SVP, Operations & Technology
Dated: 2/23/2024

rms COMPANY
By: /s/ Jon Jepko
Name: Jon Jepko
Title: Director of Sales and Marketing
Dated: 2/23/2024

PRICING ADDENDUM
EXHIBIT A

[***]

Products will be ordered in volume increments equal to either **[***]** or **[***]** quantities.

PRICING ADDENDUM
EXHIBIT B

[***]

PRICING ADDENDUM
EXHIBIT C

[***]

PRICING ADDENDUM
EXHIBIT D

[***]

EXHIBIT E

APPROVED VENDORS

[***]

EXHIBIT F

APPROVED SUBCONTRACTORS

[***]

EXHIBIT G

QUALITY AGREEMENT ADDENDUM

This Quality Agreement Addendum ("***Quality Addendum***") supplements the Manufacture and Supply Agreement (the "***Agreement***") between the parties. Unless otherwise specified, capitalized terms in this Quality Addendum have the same meaning as defined in the Agreement, and those definitions are incorporated by reference.

1. QUALITY CONTROL MATTERS.

1.1 **Implementation of Quality Control and Risk Management Program**. At all times during the Term, Supplier shall submit to and comply with Company's vendor qualification requirements, as Company may establish from time to time ("***Qualification Requirements***"). In addition, Supplier shall maintain and comply with a quality control program that conforms with all applicable laws and is consistent with current good manufacturing practices applicable to Products ("***GMPs***") and as required by any governmental or quasi-governmental agency having regulatory authority over the Products, including, without limitation, 21 CFR Part 820, the current released versions of ISO 13485 and 14971 and the Medical Device Directive 93/42/EEC or Medical Device Regulation (MDR EU 2017/745) (collectively, the "***Quality Management System***" or "***QMS***"). In addition, Supplier shall maintain a risk management system which is integrated into its QMS. Supplier shall notify Company of revisions to its manufacturing procedures to the extent necessary to remain in compliance with the Qualification Requirements, GMPs or QMS, as applicable, in accordance with this Section; provided, however, that Supplier may not make any changes to its manufacturing procedures that are inconsistent with the Specifications without the prior written consent of Company. Supplier shall also have a quality agreement with each Approved Vendor and Approved Subcontractor. Upon Company's request, Supplier will provide a copy of such quality agreement(s).

1.2 **Process Validation/Software Validation**. Supplier agrees that all special processes and software-controlled equipment, as defined below, applicable to the Product shall be validated by Supplier in accordance with 21 CFR Part 820 Sec. 820. 75 and ISO 13485:2016.

a. Examples of special processes include but are not limited to: Formulation, QC tests, chemical tests, etc.
b. Examples of software-controlled equipment include but are not limited to: automated inspection, measuring equipment, automated assembly equipment, labeling, etc.

1.3 **Qualification of Alternative Sources**. When requested to do so by Company, or otherwise required to do so by this Agreement, Supplier shall utilize its purchasing control/vendor qualification processes and procedures in effect at the time, to qualify ISO 13485:2016 FDA registered third party suppliers and/or third-party manufacturers to manufacture and provide components, parts or sub-assemblies for the Product, or to manufacture and supply the Product to Company Supplier may also be requested to qualify Company as an Alternative Source.

1.4 **Audits**. Company shall have the right, but not the obligation, at its expense, to audit, or have audited, Supplier's facilities, and plants that are used to manufacture and store the Products. Supplier shall support unannounced audits by SI-BONE's notified body with reasonable access to relevant facilities and documentation. The Supplier agrees to cooperate fully during such audits and provide necessary information, records, and access to personnel as required

by SI-BONE's notified body to ensure compliance with applicable regulatory standards. Such audits will be conducted during Supplier's normal business hours by Company and/or its Supplier approved independent third-party designee or other representatives. Supplier shall issue a plan to determine the correction, cause, and corrective action for any negative finding of any audit report issued by Company within 30 days of such audit report's issue date. Supplier shall assist Company, or its authorized representative, in securing permission to perform audits of any third-party supplier's facilities, systems, documentation, and other requirements related to this Agreement at mutually agreed dates and times. Supplier, Company, any outside auditor, and such third-party supplier shall agree on reasonable methods to protect intellectual property, such as non-disclosure agreement or the like.

1.5 **Inspections**. Supplier shall promptly notify Company of any inspections, audits, formal visits, etc. of any regulator, notified body, or certification body acting in a formal capacity. In the US this includes, but is not limited to Food and Drug Administration, Environmental Protection Agency, and Occupational Safety and Health Administration. It also includes corresponding state agencies. Upon Company's request, Supplier shall disclose the results of any inspections or audits and the associated cause and corrective action. Supplier shall promptly notify Company of any inspection or audit findings that impact the safety, conformity, or availability of Product.

1.6 **Process Improvements**. As required by 21 CFR Part 820 Sec. 820.50, Supplier shall not make significant changes to the Specifications, manufacturing process, tooling design, processing conditions, materials or manufacturing location of the Products without Company's prior written consent. Notwithstanding the foregoing, Company will consider in good faith reasonable written requests by Supplier to change the materials or manufacturing process of the Products, provided Company shall make final determination on such change(s) in its sole discretion.

1.7 **Complaint Handling and Adverse Event Reporting**. Each party shall cooperate fully with the other party in dealing with customer complaints concerning the Product(s) and shall take such action to promptly resolve such complaints as may be reasonably requested by the other party. Company is responsible for complying with all FDA and applicable foreign regulatory requirements pertaining to the receipt, review, evaluation, and where applicable, investigation of all complaints received pertaining to the Products, and for the reporting of adverse device events, including FDA's Medical Device Reporting requirements, codified at 21 C.F.R Part 803. Supplier shall reasonably cooperate with Company to enable Company to fulfill such requirements. Supplier shall promptly, but in no event more than three business days after receipt of such information, provide complaint information regarding the Products.

1.8 **Record Retention; Traceability.** Supplier shall maintain all records and procedures on the Product including proper identification and traceability of Product during all stages of receipt, production and distribution. Product records shall include traceability and reference to: raw material Lot, Supplier components, purchase order, gauging, and reference to use of any major equipment and processes utilized. Supplier warrants that Product records shall be maintained by Supplier in accordance with the following:

a. Records shall be protected from deterioration, damage or loss, and shall be available to Company for review upon request.

b. Supplier shall notify Company in writing if Supplier determines that it may discontinue maintenance of these records, or such records are scheduled for destruction pursuant to its own record retention policies, and facilitate alternative methods and/or

responsibilities for the continued maintenance of such records including but not limited to transfer of the records to Company upon Company's request.

c. Records may be paper or electronic form and shall include but are not limited to the following quality records which are required to be maintained for a period of fifteen (15) years after the last Product has been manufactured:

(i) Product Quality Planning documents (purchase order Agreements, Specifications, Material Certificates or analysis reports, Pre-Production Approval packages, Validation Records, Tooling, Calibration Records and MSDS), DMR / DHR (Device Master / History);

(ii) Manufacturing Records to include SPC charts, Inspection Records (Problem Solving / Corrective Action Responses).

2. PRODUCT IMPROVEMENTS.

2.1 General. In the event that Company notifies Supplier that it desires to have Supplier incorporate changes or improvements to a Product to (a) address a Product defect, integrity, safety or quality concern or compliance matter (each a "***Required Improvement***") or (b) incorporate a feature enhancement or other improvement that is a not a Required Improvement (each an "***Optional Improvement***," and together with the Required Improvements, an "***Improvement***"), the parties shall promptly discuss in good faith the feasibility of implementing such Improvement. In addition, the parties shall evaluate the cost of implementing the Required Improvement, which the Company will be responsible for, as well as its impact on the cost of the Product. In the event that the cost of the Product increases or decreases the parties agree to negotiate in good faith a new Product price.

2.2 Implementation of Required Improvements. Upon agreement by the parties that (a) the Required Improvement is feasible, and (b) any changes to the price are agreed, the Company may request that the Supplier implement the Required Improvement and upon receipt of such a request from Company, Supplier shall use best efforts to implement the Required Improvement as soon as possible. All such improvements shall be evaluated and implemented in accordance with Company's applicable Design Control processes and procedures that are in effect at the time that the improvements are made. Supplier shall update the Design History File, Device Master Record, provide first article inspection ("***FAI***") samples and first article inspection report, as applicable, and provide copies of such documentation to Company upon implementation of the Required Improvement and if required, the parties will incorporate the new Pricing in Exhibit's A through D as an amendment to this Agreement. To the extent that Supplier provides input on Required Improvements and changes to the Specifications, it is understood by the parties that such activity does not intend to make Supplier a "Specifications Developer" or a "finished device manufacturer" as such terms are used by FDA.

2.3 Implementation of Optional Improvements. In evaluating and implementing Optional Improvements, Supplier shall use commercially reasonable efforts to minimize the cost of implementing the Optional Improvements. Supplier shall provide Company with a detailed analysis (together with supporting documentation) of the estimated costs (if any) and effect on the supply price for the applicable Product (if any) of implementing such Optional Improvement. Supplier shall implement such Optional Improvement only with Company's prior written consent. If Supplier notifies Company that implementation of an Optional Improvement will require any modification to the pricing set forth on Exhibit's A through D, as revised from time to time, and Company agrees, the parties will negotiate in good faith an appropriate modification to the pricing in an amendment to this Agreement. If Supplier does not notify Company that it will implement an Optional Improvement within 30 days after

receiving notice of an Optional Improvement from Company or the parties cannot agree on updated pricing, Company may obtain the Product with the Optional Improvement incorporated therein from an Alternative Source or manufacture it in-house, in either case without any liability to Supplier hereunder. All such improvements shall be evaluated and implemented in accordance with Company's applicable Design Control processes and procedures that are in effect at the time that the improvements are made. Supplier shall update the Design History File, Device Master Record, provide first article inspection ("***FAI***") samples and first article inspection report, as applicable, and provide copies of such documentation to Company upon implementation of the Optional Improvement. To the extent that Supplier provides input on Optional Improvements and changes to the Specifications, it is understood by the parties that such activity does not intend to make Supplier a "Specifications Developer" or a "finished device manufacturer" as such terms are used by FDA.

2.4 **Regulatory Determination**. Company shall be responsible for making the final decision as to whether a proposed design or manufacturing change may be implemented for the Product(s). Supplier is not permitted to make any modification that affects the Product(s) without notifying Company. Company shall be responsible for making the final determination as to whether such changes require regulatory approval or clearance prior to implementation and shall be responsible for filing and obtaining any required approvals and/or clearances, as necessary.

2.5 **Registration and Listing**. Supplier shall comply with applicable establishment registration requirements applicable to the Products and the manufacture of the Products.

3. **PACKAGING AND LABELING**. Supplier shall be responsible for labeling and packaging Product for shipment to Company or to its designee(s), in accordance with applicable laws, Company requirements and instructions and the additional specifications included in the Specifications, which labeling may include "Manufactured for Company." Company may request changes to the packaging and labeling requirements and Specifications upon reasonable prior written notice to Supplier. To the extent that Supplier provides input on the Product labeling or Specifications, it is understood by the parties that such activity is not intended to make Supplier a "Specifications developer" or a "finished device manufacturer" as such terms are used by FDA. Supplier is responsible for release of product labeling, provided, however, that in the case of initial release of any new label or labeling change, Supplier shall obtain Company's consent to such release. Company is responsible for compliance with applicable FDA product labeling requirements.

EXHIBIT H

Vendor Managed Inventory Addendum

This Vendor Managed Inventory Addendum ("***VMI Addendum***") supplements the Manufacture and Supply Agreement (the "***Agreement***") between the parties. Unless otherwise specified, capitalized terms in this VMI Addendum have the same meaning as defined in the Agreement, and those definitions are incorporated by reference.

Whereas, Supplier sells Products to Company under the Agreement; and

Whereas, Supplier and Company wish to have Supplier take over the management, maintenance, and replenishment of Company's stock of certain Products.

Now, therefore, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the parties agree as follows.

1. DEFINITIONS

a. "***Managed Inventory***" means those Products described on **Attachment A** hereto.

b. "***Maximum Inventory Level***" means the maximum number of units of VMI Products to be in Company's stock at any time, as set forth on **Attachment A**.

c. "***OTD***" or "***On-Time Delivery***" means the timely delivery of Order quantities as per the agreed-upon delivery schedule, including the specified delivery dates and lead times outlined in the Orders.

d. "***Re-order Level***" means the stock level of units of Products at which Company's inventory of Products is to be replenished by Supplier, as set forth in **Attachment A**.

e. "***VMI Products***" means Products described on **Attachment A.**

f. "***Closed Lines***" refers to specific line items within a purchase order that have been completed, fulfilled, or otherwise processed to the extent that an obligation has been successfully concluded and no further action or deliveries are expected or required.

2. INVENTORY MANAGEMENT

2.1 Company shall purchase all its requirements for the VMI Products from Supplier and shall provide Supplier with sufficient information to allow Supplier to maintain the Managed Inventory. This information shall include, at a minimum,

a. Company's existing stock of VMI Products;

b. Company's quarterly forecast for VMI Products, as set forth in the Agreement Section 1.5; and

c. Plans that may impact the Company's forecast for VMI Products.

2.2 Supplier shall use its best efforts to maintain Company's stock of VMI Products so that it does not fall below the Re-Order Level and does not exceed the Maximum Inventory Level.

3. PURCHASE ORDERS

On a weekly cadence, Company shall provide Supplier with updated inventory levels of the VMI Products in its possession. Based on the inventory levels provided by Company, Supplier shall determine the quantities of VMI Products needed to maintain Company's inventory between the Maximum Inventory Level and the Re-order Level and shall communicate this determination to the Company in writing. Company shall provide to Supplier approval to release an agreed upon quantity from blanket purchase orders, specifying the quantities, in increments equal to the full of half build plate quantity for a particular Product, of VMI Products for purchase. Supplier shall promptly review and confirm the Orders within 3 business days.

4. DELIVERY; INVOICING

4.1 **Delivery**. Supplier will deliver VMI Product to Company subject to the terms of the Agreement, except as explicitly set forth herein:

a. Supplier shall ship VMI Products purchased under a blanket Order, within fifteen (15) business days from receipt of the approval to release the Products for shipment.

b. Requested delivery dates may be changed only by mutual written agreement of the parties, which agreement shall not be unreasonably withheld or delayed. In the event that Supplier has reason to believe that it will be unable to meet the agreed upon delivery dates, Supplier will notify COMPANY promptly and state the reasons for the anticipated delay.

4.2 **Invoices**. Supplier shall issue invoices to Company upon shipment of VMI Products. Invoice, pricing and payment terms shall be in accordance with those set forth in the Agreement.

5. ON-TIME DELIVERY

Supplier shall maintain a minimum On-Time Delivery (OTD) performance of [***] for the VMI Products. Any number of closed lines with a delivery tolerance greater than [***], which is defined as a variation in the quantity of parts delivered by up to [***] less than the originally specified line quantity, will have a negative impact on the On-Time Delivery (OTD) performance. If Supplier's OTD performance falls below [***], Company may issue a written notice to Supplier, highlighting the deficiency and requesting immediate remedial action. Supplier shall have a maximum of three months from the date of the notice to rectify the OTD performance and achieve the minimum required level of [***]. During this period, Supplier shall implement necessary measures to improve delivery performance and work closely with Company to address any underlying issues. If Supplier fails to remedy the OTD performance deficiency within the stipulated three-month period, Company reserves the right to terminate this VMI Addendum or the Agreement without further liability or obligation, subject to any other remedies available under applicable laws or provisions of the Agreement.

6. SUPPLIER VMI STOCKING LEVELS

Supplier shall maintain stocking levels of the VMI Products based on the forecast provided by Company. Supplier shall ensure that the stocking levels are sufficient to meet the anticipated demand while avoiding excessive inventory buildup. Supplier shall hold a maximum of no more than three months' forecasted demand in stock and no less than one months' forecasted demand in stock at any given time. In the event that the stocking levels fall below the minimum requirement of one months' forecasted demand, Supplier shall promptly replenish its inventory to ensure continuous availability of the VMI Products. If the stocking levels exceed the maximum threshold of three months' forecasted

demand, Supplier shall consult with Company to determine the appropriate course of action. Company shall not be responsible for the cost or liability associated with such excess inventory if in excess of more than 3 months forecasted demand according to the forecast provided no earlier than one quarter prior to the date of manufacture of the VMI. The Supplier shall review in quarterly intervals and adjust the stocking levels based on the changing demand patterns, market conditions, and any modifications to the forecast provided by Company. Such adjustments shall be made in a timely manner to ensure optimal inventory, management provided that if the maximum quantity level is reduced below a current inventory level, then Company is responsible for any existing inventory at the prior maximum level until the excess is consumed and the new maximum quantity level goes into effect. If the Company fails to release any VMI Products for a period of 12 consecutive months the Supplier, at its option, may request Company to release and pay for any such Products and remove such Product from Attachment A by amendment to this Exhibit H. The Supplier shall maintain proper record-keeping and reporting mechanisms to track and report the stocking levels, including quarterly reporting on inventory quantities, utilization rates, and any adjustments made to align with the forecasted demand.

7. PRICING

The pricing for the VMI Products covered under this Vendor Managed Inventory (VMI) Agreement shall be as specified under the Agreement. The prices listed in the Agreement shall remain valid for the duration of the Agreement, unless otherwise specified or agreed upon in writing by both parties.

8. REVISIONS TO VMI PRODUCTS

In the event of revisions changes, or updates to the VMI Products, Company and Supplier shall work together to manage the disposition of any affected Managed Inventory held by Supplier. Company shall promptly notify Supplier of any revisions, changes, or updates to parts or components that may impact the Managed Inventory held by Supplier. Such changes may include product design modifications, specification updates, or discontinuation of specific parts. Upon receiving such notification, Supplier shall assess the existing Managed Inventory and collaborate with the Company to determine the appropriate disposition for the affected VMI Products. Disposition options may include, but are not limited to, utilizing the existing inventory as "use as is" until depletion or scrapping the affected Managed Inventory. If the disposition of the affected parts results in the need to scrap any affected Managed Inventory, Company acknowledges that it shall be solely responsible for the costs associated with scrapping and disposing of such inventory, including payment of the Product price as defined in Exhibit's A through D of the Agreement for the units being scrapped. The Supplier shall not be liable for any expenses incurred in the disposition of scrap inventory unless it exceeds the maximum threshold of three months' forecasted demand according to the forecast provided by Company no earlier than one quarter prior to the date of manufacture of the affected Managed Inventory, as detailed in Section 1.5 and Section 6 of the Agreement and as provided for in Section 6 of this Exhibit H.

9. INSPECTION

9.1 **Inspection Rights**. Company shall have the right, no more often than one time during any one-month period, upon a minimum of 10 business days prior notice, during normal business hours, to inspect or have its representatives inspect the physical inventory of VMI products at Supplier's facilities to confirm the accuracy of its information regarding the Managed Inventory. During any such inspection, Company shall have the right to:

a. enter Supplier's facilities where the Managed Inventory is being stored to conduct physical counts and inspection of the Managed Inventory; and

b. enter into Supplier's offices or facilities to inspect Supplier's books and records, including relevant electronic information, relating solely to stock and supply of VMI Products.

9.2 **Minimize Disruption**. During any such inspection, Company shall use its commercially reasonable efforts to minimize disruption of Supplier's business.

10. TERM; TERMINATION

10.1 **Term**. The term of this VMI Addendum begins on the Effective Date of the Agreement and continues thereafter in perpetuity unless and until sooner terminated as provided in Section 10.2.

10.2 **Termination**.

a. This VMI Addendum shall terminate automatically upon the expiration or termination of the Agreement.

b. This VMI Addendum may be terminated before its expiration date by the non-breaching party if the other party breaches any provision of this VMI Addendum and either the breach cannot be cured, or if the breach can be cured, it is not cured by the breaching Party within thirty (30) days after receipt of written notice of such breach.

10.3 **Effect of Termination**.

a. The expiration or termination of this VMI Addendum, for any reason, shall not release either party from any obligation or liability to the other party, including any payment and delivery obligation, that (i) has already accrued hereunder; (ii) comes into effect due to the expiration or termination of this VMI Addendum; or (iii) otherwise survives the expiration or termination of this VMI Addendum.

b. Following the expiration or termination of this VMI Addendum, Supplier shall promptly invoice Company for any outstanding amounts due and owing under this VMI Addendum, and Company shall pay all such amounts in accordance with the Agreement. If a deposit or advance payment has been made by Company for any VMI Products that have not and will not be delivered to Company following expiration or termination, Supplier shall promptly reimburse such payment to Company.

10.4 **Remaining VMI Stock**. Upon the expiration or termination of this VMI Addendum, Company shall have the option, at its sole discretion to issue a "VMI Inventory Purchase" notice. The VMI Inventory Purchase notice shall specify the quantity of VMI Products Company intends to purchase, up to a maximum of three months' of supply. The parties shall agree upon the delivery terms, including shipment, packaging, and any additional terms necessary for the fulfillment of the VMI Inventory Purchase order.

11. PRECEDENCE.

If there is any inconsistency between the terms of this VMI Addendum and any terms in the Agreement, then, except where a provision of this VMI Addendum states otherwise, this VMI Addendum controls. However, if a subject is addressed in the Agreement and not in this VMI Addendum, then the terms in the Agreement control.

Attachment A
to the VMI Addendum

1. List of products included in Managed Inventory and prices including reference numbers like product numbers
2. Maximum Inventory Level (to be held by Company): **[***]**
3. Re-order Level (minimum level to be held by Company): **[***]**

[***]

Exhibit 21.1

List of subsidiaries of the Registrant

Subsidiary	Jurisdiction
SI-BONE S.R.L.	Italy
SI-BONE Deutschland GmbH	Germany
SI-BONE UK LTD	United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-271635) and Form S-8 (Nos. 333-227907, 333-230473, 333-237091, 333-254086, 333-263189 and 333-270230) of SI-BONE, Inc. of our report dated February 27, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 27, 2024

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-K 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:

    1) 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;

    2) 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;

    3) 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

    4) 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):

    1) 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

    2) 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: February 27, 2024

/s/ Laura A. Francis
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-K 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:

    1) 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;

    2) 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;

    3) 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

    4) 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):

    1) 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

    2) 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: February 27, 2024

/s/ Anshul Maheshwari
Anshul Maheshwari
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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 certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 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
Laura A. Francis
Chief Executive Officer
(Principal Executive Officer)

Date: February 27, 2024

/s/ Anshul Maheshwari
Anshul Maheshwari
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 27, 2024

This certification is being furnished to the Securities and Exchange Commission as an exhibit to the Annual Report and shall not be deemed filed by the Company for purposes of §18 of the Exchange Act, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 97.1

SI-BONE, INC.
Incentive Compensation Recoupment Policy
(Effective October 2, 2023)

1. Introduction

The Board of Directors (the "***Board***") of SI-BONE, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). This Policy shall replace and supersede the Company's Policy for Recoupment of Incentive Compensation that was adopted on September 9, 2021 (the "***Prior Clawback Policy***") with respect to all Incentive Compensation that is received by a Covered Officer on or after the Effective Date; for clarity, the Prior Clawback Policy shall continue to apply to any Incentive Compensation that is received by a Covered Officer prior to the Effective Date. Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a(1(1 policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(1) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(2) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the

Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(3) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(a) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(b) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(4) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(5) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(6) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as

to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

SI-BONE, INC.

Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the SI-BONE, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with SI-BONE, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

__

Name: __

Title: __

Date: __