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, 2021

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 x 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 x

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

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

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

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

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

Indicate by check mark whether the registrant 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. ☒

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

The aggregate market value of the shares of common stock held by non-affiliates of the registrant as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1.00 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 22, 2022 was 33,840,570 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, 2021, are incorporated by reference into Part III of this Report.

TABLE OF CONTENTS

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;
- Epidemic diseases, or the perception of their effects, may have (or, in the case of the COVID-19 pandemic, will continue to have during its duration) an adverse effect on our business, financial condition, results of operations, or cash flows;
- Prolonged inflation and supply chain disruptions could result in delayed product launches, lost revenue, higher costs and decreased profit margins;
- If hospitals, surgeons, and other healthcare providers are unable to obtain and maintain adequate or any coverage and reimbursement from third-party payors for procedures performed using our products, further adoption of our products may be delayed, and it is unlikely that they will gain further acceptance, and the prices paid for our implants may decline;
- If healthcare payors reverse decisions to cover minimally invasive sacroiliac joint fusion exclusively when performed with iFuse and choose to reimburse for procedures performed with competitive products, our market share could decline, adversely affecting our revenues;
- We may not be able to convince physicians that iFuse is an attractive alternative to our competitors' products and that our procedure is an attractive alternative to existing surgical and non-surgical treatments of the sacroiliac joint;
- Surgeons and payors may not find our clinical evidence to be compelling, which could limit our sales and revenue, and on-going and future research may prove our products to be less safe and effective than currently thought;
- Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the presence of "physician-owned distributorships" may impact our ability to sell our product at prices necessary to support our current business strategies;
- Practice trends or other factors, including the COVID-19 pandemic, may cause procedures to shift from the hospital environment to ambulatory surgical centers, or ASCs, where pressure on the prices of our products is generally more acute;
- We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be adversely affected;
- We are highly dependent on revenue from the sale of a single family of products focused on procedures, the goal of which is to stabilize and fuse the sacroiliac joint. Reliance on a single family of products and single family of procedures could negatively affect our results of operations and financial condition;
- If clinical experience with our iFuse Bedrock technique does not result in positive outcomes for patients, or if clinical trials involving the use of iFuse Bedrock fail to show meaningful patient benefit, sales of our iFuse implants could be adversely impacted;
- If we are unable to maintain our network of direct sales representatives and third-party distributors, we may not be able to generate anticipated sales;
- Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel;

- If use of our products results in adverse events, this may require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- Various factors outside our direct control may adversely affect manufacturing, sterilization, and distribution of our products;
- We are dependent on a limited number of third-party suppliers, some of them single-source and some of them in single locations, for most of our products and components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials in a timely and cost-effective manner, could materially adversely affect our business;
- We, our suppliers, and our third-party manufacturers are subject to extensive governmental regulation both in the U.S. and abroad, and failure to comply with applicable requirements could cause our business to suffer;
- We and our sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to healthcare provider kickbacks and false claims for reimbursement, and other applicable federal and state healthcare laws, as well as equivalent foreign laws, and failure to comply could negatively affect our business;
- If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired;

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:

- the impact the COVID-19 pandemic and governmental actions taken to combat the COVID-19 pandemic will have on us, including our operations, financial results, liquidity and capital resources, the existence and duration of state and local orders temporarily prohibiting elective procedures including procedures using our products, the ability and desire of patients and physicians to undergo and perform such procedures, the duration and any potential resurgence of the COVID-19 pandemic, and whether the COVID-19 pandemic will recur in the future;
- the impact the COVID-19 pandemic has on the global supply chain and our third-party manufacturers and suppliers, which could adversely impact the availability or cost of materials, which could disrupt our supply chain related to implants and instruments.
- our ability to maintain a healthy workforce in light of the ongoing COVID-19 pandemic;
- our expectation that a significant portion of our revenues will be derived from sales of the iFuse Implant System, or iFuse;
- our ability to develop additional revenue opportunities, including new indications for use and new devices;
- our ability to retain and grow our sales team based on the demand for our products;
- our ability to identify, train, and retain surgeons to perform procedures using our products;
- our ability to obtain and maintain favorable coverage and reimbursement determinations from third-party payors;
- our estimates of our market opportunity;
- our expectations regarding the scope of protection from intellectual property rights covering our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- timing of and results from clinical and other trials;
- marketing clearances and authorization from the FDA and regulators in other jurisdictions;

- timing of regulatory filings and feedback;
- competition in the markets we serve;
- our expectations of the reliability and performance of our products;
- our expectations of the benefits to patients, providers, and payors of our products;
- factors impacting the supply chains we rely on, including the availability of raw materials and skilled labor serving our suppliers, and the cost of these factors of production which may in turn impact the prices we pay for our devices;
- our reliance on a limited number of suppliers, including sole source suppliers, which may impact the availability of instruments and materials;
- our ability to sustain or increase demand for our products;
- our estimates regarding our costs and risks associated with our international operations and expansion;
- our expectations regarding our ability to retain and recruit key personnel;
- our ability to attract and retain employees, including those with specialized skills and experience;
- our expectations regarding acquisitions and strategic operations;
- our ability to 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. We have pioneered a proprietary minimally invasive surgical system with a family of implants, which we call iFuse, to address sacroiliac joint dysfunction and degeneration, adult deformity, pelvic ring traumatic fractures. Since we introduced our first generation iFuse implant in 2009, as of December 31, 2021, approximately 65,000 procedures have been performed of which over 18% were performed in 2021 by over 2,600 surgeons in the United States and more than 36 other countries.

The sacroiliac joint, which is the largest joint in the human body, can cause debilitating pain. Clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the sacroiliac joint. Studies have also shown that the disability that results from disease of the sacroiliac joint is comparable to the disability associated with a number of other serious orthopedic conditions, such as knee and hip arthritis and degenerative disc disease, each of which has surgical solutions in which an implant is used and a multi-billion dollar market exists. We believe that the iFuse Implant System is currently the market leading surgical system used in minimally invasive fusions of the sacroiliac joint in the United States.

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

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

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

In April 2019, we received clearance from the United States Food and Drug Administration, or FDA, to promote the use of our iFuse for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint. For this indication, surgeons typically use the posterior approach, through the sacrum and into the iliac bones, which we call the Bedrock technique. We received CE marking and began marketing iFuse for this indication and surgical technique in Europe in December 2019. In March 2020, we received FDA 510(k) clearance for an expanded indication for our triangular iFuse implants to support our trauma program. In January 2021, we received CE marking for a similarly expanded indication for use to support our trauma program in Europe.

In February 2021, we received clearance from the FDA for iFuse-TORQ, a set of 3D-printed threaded implants designed to treat fractures of the pelvis and for minimally invasive sacroiliac joint fusion. We believe there were previously unmet clinical needs in the treatment of pelvic ring fractures and chronic sacroiliac joint pain associated with pelvic ring trauma. iFuse-TORQ also provides an opportunity for us to expand our share in the minimally invasive sacroiliac joint fusion market by offering a device which is threaded, rather than impacted, into the pelvis, addressing a preference of some surgeons in this segment.

We market our products primarily with a direct sales force as well as a number of distributors in the United States, and with a combination of a direct sales force and distributors in other countries. We generate substantially all of our revenues from the sale of iFuse implants.

In 2021 and 2020, we generated revenue of $90.2 million and $73.4 million, respectively, representing a growth rate of 23% from 2020 to 2021, and incurred net losses of $56.6 million and $43.7 million, respectively. Our gross margins were 88% for 2021 and 2020.

In October 2018, we completed our initial public offering ("IPO") with net proceeds to us of $113.4 million. In January and February 2020, we received a total of $63.0 million of net proceeds from our first follow-on public offering of our common stock. In October 2020, we received a total of $71.6 million of net proceeds from our second follow-on offering of our common stock.

Market Opportunity

Over 30 million American adults are estimated to have chronic lower back pain. Our experience in both clinical trials and commercial settings indicates that at least 30% of patients whose chronic lower back pain stems from the sacroiliac joint 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 market for sacroiliac joint fusion in the United States could be 279,000 patients annually, for a potential annual market in the United States of approximately $2.5 billion.

We believe that approximately 65% of people who suffer from sacroiliac pain are women. Sacroiliac joint patients may have experienced one or more of the following events that have contributed to disruption and/or degeneration of the sacroiliac joint: pregnancy, falls, previous lumbar surgery, automobile accidents, and aging, which may cause degeneration of the cushioning in the joint much like other joints.

We have FDA clearance to promote the use of our triangular iFuse implant for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint. Based on the number of long level spinal constructs requiring spinopelvic fixation, we estimate the addressable market opportunity to be approximate $200 million annually.

We have FDA clearance for expanded indications for the use of our triangular iFuse implant in the treatment of pelvic trauma, including for stabilization of the sacroiliac joint in conjunction with the treatment of fractures involving the sacroiliac joint. In 2021, we introduced our iFuse-TORQ implant, which is specifically targeted for the pelvic trauma market which we estimate to be an approximately $350 million market opportunity.

We continue to invest in the development of products and techniques to help surgeons improve the treatment of these patients, and anticipate continuing to build products and pursue additional indications.

Since the introduction of our implants to the market in 2009, the number of procedures performed globally increased to approximately 65,000 from 53,000 as of December 31, 2021 and 2020, respectively.

Diagnosis

It is often difficult to identify the source of lower back pain. As a result, some surgical procedures performed on the spine have a sub-optimal success rate. For example, published studies of lumbar fusion have shown success rates of only approximately 60%. Unsuccessful spine surgery may result in failed back surgery syndrome, which has been shown to result in high healthcare costs with poor overall relief of pain. Published studies have shown that the sacroiliac joint is a cause of the pain in 32% to 43% of patients who have previously had lumbar fusion surgery and are experiencing recurrent low back pain. We believe low success rates of lumbar fusion are likely related, in many cases, to failure to diagnose the sacroiliac joint as the correct cause of pain.

Since we launched iFuse, we have made considerable investments in teaching healthcare professionals to accurately diagnose sacroiliac joint disorders. We provide instruction and training on how to perform the provocative maneuvers in a physician’s office that can help establish the sacroiliac joint as the source of pain. If provocative tests are positive, surgeons confirm the diagnosis by injecting a small amount of local anesthetic into the joint under fluoroscopic guidance. The sacroiliac joint is confirmed as a pain source if the local anesthetic produces immediate and significant pain reduction. In addition to the differentiated characteristics of our procedure and triangular iFuse implants, we believe that more accurate diagnosis is part of the reason for the high success and patient satisfaction rates of our procedure.

Surgical Treatment of Sacroiliac Joint Disease

Patients with sacroiliac joint dysfunction frequently experience significant pain simply from sitting, standing, or rolling over in bed. These activities result in small movements of the sacroiliac joints and pressure transferred across the joints. The pain can be exacerbated with activity - when a patient walks or runs, for example, the shock from each step is transmitted up the leg, through the iliac bones of the pelvis to the sacroiliac joint. The initial goal in fusion of the sacroiliac joint is to immediately stabilize the joint which rapidly reduces the pain. Following initial stabilization of the sacroiliac joint, the goal is to permanently fuse the joint. We believe our proprietary triangular implants stabilize the joint better and more quickly than competing technologies.

Surgical fusion of the sacroiliac joint with an open surgical technique was first reported in 1908, with further reports in the 1920s. The open procedure uses plates and screws, requires a 6- to 12-inch incision and is extremely invasive. The iFuse procedure involves a 1- to 2-inch incision and is much less invasive. Due to its infrequent use and invasive nature, resulting in post-operative pain and lengthy recovery, the open sacroiliac joint fusion procedure was rarely taught in medical school or residency programs. Prior

to our launch of iFuse, most spine surgeons were unfamiliar with the sacroiliac joint and had never performed a sacroiliac joint fusion. As a result, when patients presented with lower back pain, spine surgeons often did not include evaluation of the sacroiliac joint in their diagnostic work-up. Surgeons who did recognize the condition typically told their patients they had nothing to offer surgically.

Non-Surgical Treatment of Sacroiliac Joint Disease

Although a number of non-surgical treatments exist for sacroiliac joint pain, they did not provide the level of pain or disability relief seen with the iFuse procedure for the patients participating in our randomized controlled clinical trials. Non-surgical treatments include:

- Medical therapy, including opiates and non-steroidal anti-inflammatory medications.
- Physical therapy, which can involve exercises as well as massage.
- Intra-articular injections of steroid medications, which are typically performed by physicians who specialize in pain treatment or anesthesia.
- Radiofrequency ablation, or the cauterizing, of the lateral branches of the sacral nerve roots.

Our Solution - The iFuse Implant System

Our iFuse Implant System, which includes implants and instruments, is used with different surgical approaches for different indications. The iFuse system is designed to address the shortcomings of alternative treatments, including open surgery, non-surgical management, traditional screw-based and other minimally invasive stabilization and fusion procedures. Our implants are made of titanium and have a porous surface.

Our first-generation iFuse product is a triangular implant that is at least three times the strength of a typical eight-millimeter surgical screw, and the large porous surface area allows adherence of the bone to the implants. Three implants are typically used in each procedure. We introduced the original iFuse implants in 2009, and our second-generation iFuse-3D implants in 2017.

The iFuse procedure is typically performed under general anesthesia. The surgeon uses a custom instrument set we provide to prepare a triangular channel for each implant through the ilium, across the sacroiliac joint, and into the sacrum. An iFuse implant is then pressed into the triangular channel, which is slightly smaller than the implant, creating what is known as an interference fit. The triangular cross section of our iFuse implants, prevents them from rotating. Our triangular iFuse implants cross the sacroiliac joint and provide immediate joint stability, which is why we believe pain diminishes soon after the iFuse procedure. Over time, bone grows onto, and in the case of iFuse-3D into, the implants and across the joint, permanently stabilizing or fusing the joint.

By contrast, open and other techniques for sacroiliac joint fusion typically use screws, plates and/or bone graft for fixation. When placed across the sacroiliac joint, standard orthopedic screws, which lack features to encourage biologic fixation, tend to rotate and loosen over time. Because of the triangular shape, porous surface, strength, and other differentiating factors of our triangular iFuse implants, we believe that our published clinical data do not apply to other minimally invasive solutions. Little published evidence of safety, clinical effectiveness, durability, or economic utility currently exists for sacroiliac fusion devices other than our triangular iFuse implants. We are unaware of any data to show that our competitors' sacroiliac joint screws, with features allowing biologic fixation, have a lower rate of loosening than standard orthopedic screws. In addition, placement of plates for open fusion procedures typically requires larger incisions and more invasive dissection, which results in longer recovery times and increased morbidity. We believe that the differences between our iFuse implants and other products, as well as the substantial published clinical evidence showing the safety and effectiveness, are the reason why a growing number of payors have recommended that our triangular iFuse implants be reimbursed for sacroiliac surgery to the exclusion of other technologies that are designed for the procedure.

Typically, surgeons recommend protected weight-bearing for three weeks. However, post-operative instructions are patient-specific and some patients are allowed to perform weight-bearing activities sooner. Follow-up studies have shown that bony bridging across the sacroiliac joint is present in the majority of cases five years after the iFuse procedure.

Three implants are used in most lateral iFuse procedures. Each implant crosses the joint from the iliac bone into the sacrum. Placing each implant requires three or four basic steps:

- **Pin**. The surgeon inserts a guide pin through the iliac bone, across the sacroiliac joint and into the sacrum.
- **Drill or Tapping**. Surgeons drill or tap (manually create a channel) over the guide pin, through the iliac bone, across the sacroiliac joint and just into the sacrum.

- **Broach**. When triangular implants are used, the surgeon impacts a broach, or sharp cutting tool, over the pin which prepares a triangular channel that is slightly smaller than the iFuse implant.

- **Placement**. In the case of triangular iFuse implants, the surgeon impacts the implant into the triangular channel across the sacroiliac joint, docking the implant in the sacrum. The channel is slightly smaller than the implant, which produces an interference fit. In the case of iFuse-TORQ, the surgeon threads the implant into the patients ilium, across the sacroilac joint and into the sacrum, providing fixation to the bone on either side of the joint.

iFuse is a cannulated system, which means that the drill, broach and implants have hollow channels which fit over the pin for guidance purposes. As is typical in many orthopedic procedures, a member of our team is normally present in the operating suite during surgery to provide technical assistance for the use of iFuse.

We offer three custom instrument sets for surgical placement of our triangular iFuse implants in the body. The standard set comprises largely stainless steel materials; the XL (Extra Long) set is the same as the standard set but most instruments are elongated by three inches for treatment of larger patients; and the radiolucent set comprises instruments made with more radiolucent (transparent to X-rays) materials, such as PEEK and aluminum, to improve visualization under fluoroscopy during an iFuse procedure. The iFuse-TORQ system includes its own set of instruments designed for the threaded implants.

In addition to our iFuse platform technologies, we also provide enabling technologies for our surgeons. We introduced an instrument set that is cleared for use with Medtronic’s surgical navigation system, allowing the surgeon to visualize the 3D positioning of certain instruments and implants intra-operatively. In March 2018, we introduced surgical pins cleared for use with the Medtronic Mazor surgical robot, allowing the surgeon to robotically place the guide pin according to a computer-generated surgical plan. In early 2019, we introduced our decortication and graft delivery systems that allow surgeons to remove intra-articular cartilage and deliver flowable bone graft materials.

In April 2019, we received clearance from the United States Food and Drug Administration, or FDA, to promote the use of our triangular iFuse implants for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint. For this indication, surgeons typically use the posterior approach, through the sacrum and into the iliac bones, which we call the Bedrock technique. We received CE marking and began marketing our triangular iFuse implants for this indication and surgical technique in Europe in December 2019. The Bedrock technique utilizes our proprietary iFuse implants, with one implant placed across each sacroiliac joint (for a total of two implants per case) using a posterior approach, through the sacrum, across the sacroiliac joint, and into the ilium. The Bedrock technique differs from our traditional iFuse procedure, in which three iFuse implants are placed across one sacroiliac joint via a lateral transarticular approach through the ilium and into the sacrum. The Bedrock technique is performed to increase the overall strength and stability at the base of a long construct for multilevel spinal fusion. Biomechanical testing has shown that iFuse implants placed in this position reduce sacroiliac joint motion by approximately 30% in conjunction with a long construct. 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 iFuse implants to support our trauma program. In-early 2021, we introduced iFuse-TORQ in early 2021. Surgeons who prefer to use a screw technique to stabilize the sacroiliac joint can use our iFuse-TORQ, which includes options for implants with lags and washers for improved compression

Our Published Studies

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 100 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.

INSITE

INSITE is a prospective randomized controlled trial conducted in the US. 148 patients with chronic SI joint pain were randomly assigned to immediate SI joint fusion using iFuse implants or individually tailored non-surgical management. In the SI joint fusion group, large improvements were seen in pain, disability related to pain and quality of life. In contrast, in the control group, only small, clinically unimportant improvements in these parameters were observed. Moreover, after six months, more than 90% of subjects still participating in the non-surgical group decided to cross over to SI joint fusion surgery, indicating that non-surgical treatment provided ineffective relief of pain and disability related to pain. Two-year follow-up, published in *International Journal of Spine Surgery* in August 2016, showed sustained improvements in pain, disability and quality of life in the surgery group, with high levels of satisfaction. An embedded cost-effectiveness analysis within INSITE, *Clinicoeconomics and Outcomes Research* in December 2015, showed the procedure to be highly cost-effective for the treatment of chronic SI joint pain.

iMIA

iMIA iFuse Implant System Minimally Invasive Arthrodesis (“iMIA”) is a second prospective, randomized controlled trial of sacroiliac joint fusion using iFuse compared to non-surgical management with a design very similar to that of INSITE. iMIA was conducted at nine centers in Europe. Results, published in *Journal of Bone and Joint Surgery* in March 2019, were very similar to INSITE, with large, clinically important and statistically significant improvements in the SI joint fusion group and very few, clinically unimportant changes in the non-surgical control group. Improvements in the surgery group were sustained at 24 months.

SIFI

Sacroiliac Joint Fusion with iFuse Implant System (“SIFI”), is a prospective, multicenter single-arm clinical trial conducted at 26 centers in the US. Eligibility criteria and endpoints were identical to INSITE. Results from SIFI, published in *International Journal of Spine Surgery* in April 2016, showed marked, immediate and sustained improvements in pain, disability and quality of life similar to the above two studies. Like the other studies, improvements were sustained at 24 months.

LOIS Clinical Trial

Subjects participating in INSITE and SIFI were enrolled in a long-term follow-up study ("LOIS"). Five-year results, published in *Medical Devices Evidence and Research* in April 2018, showed sustained improvements in pain, disability and quality of life as well as a high satisfaction rate. 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 SI joint fusion (88% bridging bone) at five years. There were no reported adverse events related to the study device or procedure at five years.

SALLY Clinical Trial

Study of Bone Growth in the Sacroiliac Joint After Minimally Invasive Surgery with Titanium Implants (“SALLY”) is another prospective single-arm clinical study of the same patient population (chronic SI joint pain) who underwent SI joint fusion using iFuse-3D. Two-year results, published in *Medical Devices Evidence and Research* in June 2021, showed similar improvements in pain, disability and quality of life compared to prior studies of iFuse-3D as well as CT evidence of earlier fusion of the SI joint. The study also showed marked reduction in opioid use and improvement in objective functional tests.

SILVIA Clinical Trial

We are currently enrolling subjects in SI Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial ("SILVIA"). SILVIA is an ongoing prospective randomized trial of iFuse-3D placement during multilevel spine fusion with fixation to the pelvis. This 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 sacroalar-iliac trajectory (termed “Bedrock”). The goal of this study is to show that placement of iFuse-3D in the Bedrock configuration reduces the rate of postoperative SI joint pain and improves the longevity of pelvic fixation hardware, failures of which are fairly common. Follow-up results from the SILVIA trial have not been fully collected or published as of the date of this report.

Much of our clinical data, including INSITE, iMIA, SIFI and LOIS were developed using our first-generation iFuse implants. However, due to the consistent shape, implantation and method of action, as well as the consistent results observed in SALLY, we believe that the results observed in the prior studies can be generalized to include iFuse-3D, but cannot be generalized to include other minimally invasive sacroiliac joint fusion products, including screws, plants and implantable structural allograft products.

Other Published Clinical Studies

To date, several independent clinical studies have provided evidence to support the long-term safety and effectiveness of iFuse for SI joint fusion. These studies demonstrated pain reduction and/or ODI improvement that is statistically significant and clinically important and a safety profile that was similar to that observed in prospective studies. One study showed marked reduction in opioid use after SI 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 iFuse vary by setting of care, payor type and region. In the United States, healthcare providers that purchase iFuse products look to various third-party payors, such as Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, accountable care organizations, and other healthcare-related organizations, to cover and pay for all or part of the costs of these procedures. Outside the United States, reimbursement levels vary significantly by country and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Sales volumes and prices of company products will continue to depend in large part on the availability of coverage and reimbursement from such third-party payors for both the surgeon's professional fee and the facility fee which covers, among other things, the cost of implants used in iFuse procedures. Payors continually review the clinical evidence for new technologies and can change their coverage policies without notice or deny payment if the product was not used in accordance with the payor’s coverage policy. Payors also review and challenge the prices charged for products and procedures.

Third-party payors, whether governmental or commercial, are also developing increasingly sophisticated methods of controlling healthcare costs. No uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors in the United States. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. 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 during which our products are used. Even if favorable coverage and reimbursement status is attained for iFuse procedures, less favorable coverage policies and reimbursement rates may be implemented in the future.

There is near universal coverage of minimally invasive SI joint fusion with an estimate of over 300 million covered lives. Private payors representing more than approximately 160 million covered lives have adopted coverage policies exclusive to our triangular iFuse implants as of December 31, 2021.

Note that because many individuals are covered by more than one health insurance plan or may switch plans during the year, the total number of covered lives reported by the payors represented above may be larger than the number of individuals who have access to the iFuse procedure through their health insurance provider at any given time.

We believe that it generally takes between six and 24 months for a surgeon to fully incorporate sacroiliac joint diagnosis and treatment into his or her practice after payors initiate coverage and the surgeon is trained. Further, the administrative burden on surgical practices can be substantial for patients where reimbursement coverage is new, and some surgeons do not believe that the current average surgeon reimbursement is yet adequate to compensate them. However, as reimbursement coverage has improved, surgeon interest in learning to diagnose the sacroiliac joint and perform iFuse procedures has been increasing.

Medical Affairs and Education

Our medical affairs team provides high quality educational programs internally and externally. Internally, specialized medical knowledge, and practical experience with iFuse are used to help educate our sales, marketing, quality, reimbursement, clinical, regulatory, engineering, and product development teams. This same specialized medical knowledge and practical iFuse experience provides the foundation for a wide variety of educational programs provided to healthcare practitioners in various medical specialties, such as surgeons, pain management physicians, nurse practitioners/physician's assistants and physical therapists, to help educate healthcare professionals about the sacroiliac joint as a component of lower back pain, proper diagnosis of SI joint dysfunction, non-surgical treatment options and surgical treatment with iFuse.

Our surgeon training programs are for orthopedic spine surgeons, neurosurgeons, general orthopedic surgeons, and orthopedic trauma surgeons. As of December 31, 2021 and 2020, in the U.S., more than 1,800 surgeons and 1,600 surgeons, respectively, have been trained on our products and have treated at least one patient. Outside the U.S., as of December 31, 2021 and 2020, more than 700 surgeons and 600 surgeons, respectively, have been trained on iFuse and have treated at least one patient. We will continue to pursue the remainder of the approximately 7,500 target surgeons in the United States, as well as international surgeons for training in the future.

The COVID-19 pandemic has challenged our traditional method of hands-on cadaveric and dry-lab training. In early 2020, the medical affairs team implemented a virtual education series for surgeons and mid-level practitioners. In July 2020, we began using the Si-BONE SImulator; an innovative, fully portable surgeon training simulator. This training platform allows us to train surgeons without need for an operating room or a fluoroscope. The computer-based surgeon training simulator provides quality haptics, or the realistic feel during the surgeon's use of the instruments, and the training is performed without any radiation. One key advantage of this surgeon training simulator is that the surgeon can now be trained locally in their office or a hospital conference room in two to three hours, and the surgeon does not need to travel to a cadaver lab, which sometimes requires being away from their practice for as much as a day and a half. The simulator uses the same instruments and implants as those that are used during surgery. The simulator is used to train surgeons to perform SI joint injections and iFuse sacroiliac joint fusions, as well as the iFuse Bedrock procedure. The simulators are deployed to cover all US regions and European subsidiaries and we currently have 24 simulators. We plan to expand the use of simulators for training purposes both in the United States and internationally. We will utilize the simulators and our existing programs to train new surgeons, increase the knowledge and proficiency of existing iFuse surgeons, and re-engage inactive surgeons.

We conduct a large number of 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. In addition to these general educational programs, we provide continuing education programs focused on SI joint diagnosis and treatment to physical therapists and case managers. We are able to provide these programs for both groups in all 50 states and the District of Columbia. We have trained over 7800 physical therapists through our continuing education program as of December 31, 2021. Case managers, who typically are nurses, work in facilities where the iFuse procedure is performed, such as hospitals, or for payors or health plans. Case managers help patients navigate the healthcare system so that they receive the most appropriate treatment. As of December 31, 2021, we have trained over 1300 case managers in the United States through our continuing education program. 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 iFuse. 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.

Sales and Marketing

We market and sell our implants primarily through a direct sales force and a small number of third-party distributors. Our target customer base includes approximately 7,500 surgeons who perform spine and/or pelvic surgery, including orthopedic spine surgeons, neurosurgeons, general orthopedic surgeons, and orthopedic trauma surgeons.

Our direct sales organization in the United States covered sixteen sales regions as of December 31, 2021. 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 associate representatives who cover cases. As of December 31, 2021, our U.S. sales force consisted of 85 territory sales managers and 65 clinical specialists directly employed by us, and 59 third-party distributors. As of December 31, 2021, we had 40 employees working in our European operations, and have established operations in Italy (2010), Germany (2014), the United Kingdom (2015) and France (2019). As of December 31, 2021, our international sales force consisted of 20 sales representatives directly employed by us and 32 exclusive third-party distributors, which together had sales in 36 countries through December 31, 2021.

We have built a valuable sales team and have made it a top priority to support and retain our sales force through the COVID-19 pandemic. We limited new sales force hiring in the second and third quarter of 2020 due to uncertainty from the COVID-19 pandemic and focused on sales force productivity during this period, but resumed hiring of salespeople in the fourth quarter of 2020 and throughout 2021. Due to the COVID-19 pandemic, we focused on protecting key investments in our field force while curtailing most other areas of sales and marketing spend during the second and third quarters of 2020. For example, we guaranteed certain levels of incentive compensation to members of our field sales organization in order to retain these employees and partially mitigate the impact of the pandemic to their compensation. In contrast, we reduced certain other spending during the COVID-19 pandemic, such as travel and related expenses, regional surgeon training, trade shows, and discretionary marketing. As revenue growth returned to the levels that we were experiencing prior to the pandemic, we increased our sales and marketing expense accordingly in the third and fourth quarters of 2020 and into 2021.

We intend to continue to grow our specialized sales force to foster relationships with surgeons and support revenue growth. Our territory sales managers are senior representatives who educate surgeons on the sacroiliac joint as a primary cause of lower back pain. The territory sales manager identifies new surgeons who are interested in learning more about the sacroiliac joint and the iFuse procedure and/or the Bedrock technique. They work closely with our medical affairs team to train surgeons on the anatomy, diagnosis, and surgical technique. Once trained, the sales representative works with the surgeon to incorporate into their practices the diagnosis of sacroiliac joint pain and the iFuse procedure to treat patients suffering from sacroiliac joint pain. Our clinical support specialists assist the territory sales managers to identify surgeons interested in training. The clinical support specialists also regularly cover cases, bringing our implants and instrument trays into the operating room for use by surgeons.

Over 30 million American adults are estimated to have chronic lower back pain. It is often difficult to identify the source of the pain and traditional methods of spine surgery do not have high success rates. 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. 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. We plan to make additional investments to further increase patient awareness, primarily through digital and broadcast marketing, including TV and radio ads, paid search, display advertising, social media and public relations.

Our business is affected by seasonal variations. For instance, we have historically experienced lower sales in the summer months and higher sales in the last quarter of the fiscal year as patients have more time in the winter months to have the procedure completed or want to take advantage of their annual insurance coverage limits. However, taken as a whole, seasonality does not have a material impact on our financial results.

Research and Development

We are committed to developing enhancements to iFuse to meet our customers' changing needs and improve the surgery's effectiveness. Our development team, in consultation with surgeons, has a pipeline of products in various stages to provide solutions that respond to the needs of our surgeon customers and their patients. We plan to seek regulatory clearances for additional indications as required.

We continued our research and development activities during the COVID-19 pandemic. During 2020, timing of enrollment for clinical trials was impacted by reduced access to hospitals and clinical sites caused by the COVID-19 pandemic, but we believe enrollment is back on schedule. We anticipate that research and development expenses will continue to increase in the future.

Competition

We believe that we were the first company to develop, manufacture, and market a minimally invasive implant cleared by the FDA expressly for sacroiliac joint fusion other than a modified screw. Over the past several years, other companies have subsequently recognized the 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. Many 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. Many of these 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 intended for sacroiliac fusion and marketed as human tissue products. 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.

In the United States, we believe that our primary competitors currently are Globus Medical, Inc. and Medtronic plc. Our primary competitors in Europe are Globus Medical and SIGNUS Medizintechnik GmbH. However, these competitors sell screw-based products, which we believe to be weaker and less able to resist rotation than our triangular iFuse 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 iFuse is 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 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 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 knowledge;
- 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;
- pricing and reimbursement;
- scientific (biomechanics) data; and
- attracting and retaining key personnel.

Intellectual Property

We protect our intellectual property through our pending patent applications and issued patents. As of December 31, 2021, we had been issued 44 issued U.S. patents and had 33 pending U.S. patents applications, and we owned 15 issued foreign patents and had nine pending foreign patent applications. We have focused the majority of our foreign patent efforts in China, Europe, and Japan. Our current U.S. patents on iFuse, including the triangular shape, expire in November 2024. Competitors may market similar triangular shaped devices upon the expiration of the patents in late 2024. Our current U.S. patents on iFuse-3D, including the fenestrated design, expire in September 2035. Our foreign patents will expire between August 2025 and September 2035.

As of December 31, 2021, we have 15 registered trademarks in the United States and have filed for 12 more. We have sought protection for at least two of these trademarks in 60 countries including the 27 European member countries of the Madrid Protocol.

We 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. The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, research, development, and manufacture;
- product safety, testing, labeling, and storage;
- record keeping procedures;
- product marketing, promotion, advertising, sales, distribution, export, and import; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions, and repair or recall of products.

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;
- 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. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, typically including data from preclinical studies and human clinical trials.

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.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. By regulation, the FDA has 90 days from acceptance of the 510(k) submission for review to review and issue a determination. As a practical matter, clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

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. We are licensed or have permits for tissue banking in California, Florida, New York, Maryland, and other states that require specific licensing or registration.

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.

Clinical Trials

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials for implanted devices such as iFuse generally require an investigational device exemption application (“IDE”), approved in advance by the FDA for a specified number of subjects and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board (“IRB”), and the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the subjects’ informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA, or the IRB, could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high- risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation

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

- Product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- 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 indications;
- 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.

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 other countries. For example, in the European Economic Area ("EEA") our devices are currently required to comply with the Medical Device Regulation (Regulations 2017/745) in the EU Member States, Iceland, Lichtenstein and Norway. The Medical Device Regulation is, among other things, intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Device Regulation, among other things:

- strengthens the rules on placing medical devices on the market and reinforce surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;

- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthens the rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

The Medical Device Regulation substantially augments those aspects of the Medical Device Directive governing clinical investigations of medical devices. 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 exist to compensate clinical investigation participants who are harmed in that jurisdiction due to their participation.

Further, the advertising and promotion of our products in the EEA is currently subject to the provisions of Directive 2006/114/EC concerning misleading and comparative advertising, Directive 2005/29/EC on unfair commercial practices, and the Medical Device Regulation, as well as other national legislation in the EEA countries governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

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

In February 2021, we received 510(k) clearance to market our iFuse-TORQ from the FDA. In the United States, iFuse-TORQ is intended for fusion of the sacroiliac joint for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroilitis; and for fracture fixation of small and large bones of the pelvis.

In November 2010, we obtained a CE Certificate of Conformity and affixed a CE mark to our iFuse Implant System 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 added additional instruments, implant sizes and labeling updates and iFuse-3D, our second generation iFuse implant, to our product offerings in Europe. We plan to continue to work with our Notified Body to incorporate new products and labeling updates in our Technical Files for CE marking in Europe.

As of May 26, 2021, the European Union no longer applies the Mutual Recognition Agreement between the EEA and Switzerland. Accordingly, manufacturers 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.

Since July 2013, we have obtained approval for iFuse in regions beyond the United States and the EEA, including Australia, Canada, Hong Kong, Israel, Malaysia, New Zealand, Saudi Arabia, Singapore and Taiwan. We are currently collecting information to determine our regulatory strategy in Japan.

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 laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our employees are found to have violated any of the above laws we may be subject to significant administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal health care programs, such as Medicare and Medicaid, 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 U.S. and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices.

Data Privacy and Security Laws

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 ("ARRA") (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. Medical data is considered sensitive data that merits stronger safeguards.

In the European Union ("EU"), we are subject to laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to our operations. 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. The data privacy regime in the EU includes the EU General Data Protection Regulation, or the GDPR, effective on May 25, 2018 and the E-Privacy Directive 2002/58/EC and the national laws implementing it. Each EU Member State may adopt additional legislation implementing these regulations into 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.

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.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law. We depend on a number of third parties in relation to our 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. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously, as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

Manufacturing and Supply

We use third-party manufacturers to produce our implants and instruments. Our primary supplier for implants is rms Company ("RMS") for iFuse-3D. 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 both our iFuse-3D and iFuse. 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.

We entered into a non-exclusive Manufacturing, Quality and Supply Agreement with RMS in January 2017, which was amended in July 2020, and amended and restated in June 2021. Pursuant to this agreement, RMS manufactures certain of our implants in accordance with our specifications, including both purchased and sterilized iFuse-3D implants, as well as uncoated machined implants which are subsequently coated to become our finished first generation iFuse implants. While the agreement provides that we are required to purchase the amounts forecasted in a blanket purchase order, we are not required to purchase product in excess of such forecasted amounts. The prices we pay for products are fixed under the agreement provided that if order volumes deviate from forecasted amounts beyond certain thresholds, we or RMS may request to negotiate further price changes. The agreement 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 implants.

We believe that our manufacturing operations, and those of our suppliers, comply with regulations mandated by the FDA, as well as Medical Devices Directive regulations in the EEA. 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 international regulatory agencies.

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 obtain and maintain various quality assurance and quality management certifications, including those issued by DEKRA Certification, B.V., our notified body. DEKRA has issued the following international certifications: Quality Management System ISO13485:2016 for our locations in Santa Clara, California, and Gallarate Italy; Full Quality Assurance Certification for the design and manufacture of iFuse; and a Design Examination certificate for iFuse.

We are required to demonstrate continuing compliance with applicable regulatory requirements to maintain these certifications 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 international regulations 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 regulatory approvals, 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

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

intensifying competition in the labor markets in which we compete and a general increase in employee turnover experienced by many companies in the last twelve months, we have begun to more actively track and manage voluntary and involuntary employee turnover.

As of December 31, 2021, we had 352 employees, including sales and marketing, product development, general administrative and accounting, both domestically and internationally. As of December 31, 2021, we had a direct field sales organization of 150 in the United States and 20 in Europe. During 2021, our turnover rate was less than 20%.

Diversity and Inclusion

In order to realize our mission and vision, we are committed to actively fostering workforce diversity and an environment of cultural inclusion throughout the company. In 2020, we adopted a Diversity and Inclusion Plan, overseen by our Nominating and Corporate Governance Committee. Our program goal is to increase gender and ethnic diversity in our workforce and leadership over three years, while continuing to provide equal employment opportunities to all candidates and employees without regard to any protected status. Accordingly, we track gender diversity among our global and U.S. workforce, the percentage of employees above director level who are female, the representation of women and underrepresented communities on our Board of Directors and the diversity of 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.

Health, Safety, and Wellness

The health, safety, and wellness of our employees is a priority in which we have always invested and intend to continue to do. We provide our employees and their families with 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 by providing tools and resources to help them improve or maintain their health status, encourage engagement in healthy behaviors, and offer choices where possible so they are customized to meet their needs and the needs of their families.

In light of the COVID-19 pandemic, the prioritization of employee health, safety, and wellness took on particular significance in 2020 and 2021. We implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, in compliance with government regulations. 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 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), healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among many others. As a response to the COVID-19 pandemic, we supported employees with standard merit increases, paid full-time wages to hourly employees when they were not able to access our facilities, and guaranteed certain commissions to our salespeople. We did not furlough or terminate any of our employees due to economic concerns arising from COVID-19 in 2020 or 2021.

Ensuring fair and equitable pay is integral to our commitment to our employees. Our executive team and Board of Directors strongly support this commitment. In 2020, we conducted our first pay equity review with the assistance of an independent consulting firm. The consultant reviewed our employee compensation to determine whether any statistically significant pay differences existed between women and men and between minorities and non-minorities performing similar job functions. The review provided information to help us understand whether our compensation structure was appropriate and to identify what improvements can be made. In areas where pay disparities were identified, we conducted further evaluation to determine where adjustments were appropriate.

As part of our Diversity and Inclusion Program, we implemented an applicant tracking system in 2021. In addition to automating our recruiting and onboarding processes, the applicant tracking system also helps us determine whether there is a mix of new hire candidates in the system from different genders and ethnicities for open positions.

Talent Development

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

Our human resources and sales enablement teams transitioned much of our leadership training from in-person sessions to remote learning due to COVID-19. Our scaled learning platforms of on-demand and virtual classroom learning eliminates travel and allows employees to access development at their convenience.

We have robust annual performance review processes for reviewing employees' performance and pay. To support our managers, we train them on conducting effective performance reviews and making compensation recommendations, which take into consideration market pay data and performance, as well as experience in an employee's respective role.

Community Programs

We believe that building connections between our employees, their families, and our communities creates a more meaningful, fulfilling, and enjoyable workplace. Through our engagement programs, our employees can pursue their interests and hobbies, connect to volunteering and giving opportunities, and enjoy unique recreational experiences with family members.

Our employees engage in a variety of activities to support their local communities. We acknowledge that community involvement is important to our employees and we support their interests in the communities in which they live. Prior to COVID-19, we hosted events at our corporate campus, including food, clothing, and toy drives. During 2020 and 2021, 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.

Emerging Growth Company Status

Prior to December 31, 2021, we were an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act). As a result of our public float (the market value of our common shares held by non-affiliates) exceeding $700 million as of June 30, 2021, we became a large accelerated filer as of December 31, 2021 and therefore no longer qualified as an "emerging growth company" as defined in the JOBS Act, and have ceased to be a "smaller reporting company" as defined in the Exchange Act. However, 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 ended March 31, 2022. Additionally, we are no longer able to use the extended transition period for complying with new or revised accounting standards available to emerging growth companies and therefore we are required to adopt new or revised accounting standards as of the effective dates for public companies. All new accounting pronouncements recently adopted as discussed in Note 2 - Summary of Significant Accounting Policies, in the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K were adopted in the fourth quarter of 2021 with an effective date of January 1, 2021. However, 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 ended March 31, 2022.

Company History

SI-BONE was founded in 2008 by the main inventor of iFuse, orthopedist Mark A. Reiley, M.D., our then President and Chief Executive Officer, Jeffrey W. Dunn, and orthopedic surgeon Leonard Rudolf, M.D. Dr. Reiley previously invented balloon kyphoplasty and founded Kyphon Inc., which was sold to Medtronic plc in 2007. Dr. Reiley also invented the INBONE total ankle replacement system, which was sold to Wright Medical Technology, Inc. in 2008.

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, 2021 and 2020, we had net losses of $56.6 million and $43.7 million, respectively. As of December 31, 2021, we had an accumulated deficit of $295.8 million. We have financed our operations primarily through the net proceeds of our public offerings of our common stock, private placements of equity securities, certain debt-related financing arrangements, and from sales of our products. We have devoted substantially all of our resources to research and development of our products, sales and marketing activities, investments in training and educating surgeons and other healthcare providers, and clinical and regulatory matters for our products. There can be no assurances that we will be able to generate sufficient revenue from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flows, and even if we are able to do so, our ability to do so has been delayed by the COVID-19 pandemic. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance, and commercialize our existing and new products. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives.

Our expected future capital requirements may depend on many factors including expanding our surgeon base, the expansion of our sales force, investment in implants and instruments, and the timing and extent of spending on the development of our technology to increase our product offerings. 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. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations.

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

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

To date, COVID-19 has had, and we expect will continue to have, an adverse impact on our operations as a result of preventive and precautionary measures that we, other businesses, health systems and governments are taking. Due to these measures, we have experienced and expect to continue to experience significant and unpredictable reductions in the demand for our products, negative impact on hospital admission rates and delay in the decision by patients to undergo elective surgery, each of which has decreased and may continue to impact the demand for procedures using our implants. There are numerous uncertainties associated with the COVID-19 pandemic, including the number of individuals who will become infected, the effectiveness of vaccines or one or more therapies that mitigate the effect of the virus, the availability of vaccines and the vaccination rates in the U.S. and worldwide, the emergence of variants of the COVID-19 virus such as the delta and omicron variants, the extent of the protective and preventative measures that have been put in place by both governmental entities and other businesses and those that may be put in place in the future, the effect that testing for COVID-19 and antibodies will enable relaxation of protective measures for a subset of the population, and numerous other uncertainties. We intend to continue to execute on our strategic plans and operational initiatives during the COVID-19 pandemic. However, these uncertainties may result in delays or modifications to these plans and initiatives.

Travel restrictions, and the risk that countries may continue to close borders, impose prolonged quarantines, and further restrict travel, limit our ability to reach surgeons with our goal of increasing surgeon activity by providing education and support.

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

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

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, 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.

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

Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Hospitals, surgeons, and other healthcare providers that purchase or use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices. When a procedure using our implants is performed, both the surgeon and the healthcare facility, either a hospital or ambulatory surgical center, submit claims for reimbursement to the healthcare payor. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if reimbursement levels are insufficient to support use of our products by healthcare facilities or to compensate surgeons for their time spent diagnosing patients and performing procedures using our products.

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

The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they chose to cover. Payors may adopt policies in the future restricting access to medical technologies like ours and/or the procedures performed using such technologies. Therefore, we cannot be certain that the procedures performed with each of our products will be reimbursed. There can be no guarantee that, should we introduce additional products in the future, payors will cover those products or the procedures in which they are used.

Effective January 1, 2022, the Medicare physician fee reimbursement for minimally invasive fusion with our iFuse implants, described as CPT Code 27279, is $860. Commercial payors generally set their physician fee reimbursement with reference to Medicare reimbursement rates. We believe that some surgeons may continue to view the Medicare and commercial reimbursement amounts as insufficient for the procedure, given the work effort involved with the procedure, including the time to diagnose the patient and obtain prior authorization from the patient's health insurer if necessary. We believe that some private payors apply their own coverage policies and criteria inconsistently, and surgeons may not be able to consistently have minimally invasive sacroiliac fusions approved and covered. The perception by physicians that the reimbursement for minimally invasive sacroiliac joint fusion is insufficient to compensate them for the work required, including diagnosis, documentation, obtaining payor approval for the procedure, and burden on their office staff, may negatively affect the number of procedures performed and may therefore adversely affect our revenues.

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

Recent political, economic, and regulatory influences are subjecting the healthcare industry to fundamental changes that can impact coverage and reimbursement from third-party payors. We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products. CMS budget neutrality requirements may impose cuts to the Medicare physician fee schedule, which may be mitigated by acts of Congress or other changes to regulations. Other federal laws, known as budget sequestration, further reduce Medicare's payments to providers by two percent through 2030. However, COVID-19 relief support legislation suspended the 2% Medicare reductions from May 1, 2020 through April 2022, and reduced the Medicare reductions to 1% from April 1 to June 30, 2022. These reductions may reduce reimbursement for procedures performed using our products, which could potentially negatively impact our revenue, and may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales, which could adversely affect our business, results of operations and financial condition.

Market acceptance of our products in foreign markets may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. We may not obtain additional international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

If healthcare payors reverse decisions to cover minimally invasive sacroiliac joint fusion exclusively when performed with iFuse and choose to reimburse for procedures performed with competitive products, our market share could decline, adversely affecting our revenues.

As of December 31, 2021, 36 of the largest 65 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. If healthcare payors covering a significant number of covered lives reverse their policies of covering minimally invasive sacroiliac joint fusion exclusively when performed with triangular titanium implants, sales of our triangular iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

We may not be able to convince physicians that iFuse is an attractive alternative to our competitors' products and that our procedure is an attractive alternative to existing surgical and non-surgical treatments of the sacroiliac joint.

Surgeons, in consultation with their patients, play the primary role in determining the course of treatment and, ultimately, any product that will be used in treatment. In order for us to sell our iFuse system successfully, we must demonstrate to surgeons through education and training that treatment with iFuse is beneficial, safe, and cost-effective for patients as compared to our competitors' products. If we are not successful in demonstrating the merits of iFuse to surgeons, their use of our products may decline, adversely affecting our revenues and profitability.

Historically, most spine surgeons did not include an evaluation of the sacroiliac joint in their diagnostic work-up because they did not have an adequate surgical procedure to perform for patients diagnosed with sacroiliac joint dysfunction. We believe that educating surgeons and other healthcare professionals about the clinical merits and patient benefits of iFuse is an important element of building our business. If we fail to effectively educate surgeons and other medical professionals, they may not include a sacroiliac joint evaluation as part of their diagnosis and, as a result, those patients may continue to receive unnecessary surgical procedures or only non-surgical treatment.

Surgeons may also hesitate to change their medical treatment practices for other reasons, including the following:

- lack of experience with minimally invasive procedures;
- perceived liability risks generally associated with the use of new products and procedures;
- costs associated with the purchase of new products; and
- time commitment that may be required for training.

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

Many patients with sacroiliac joint dysfunction are cared for by pain physicians, who are generally trained as anesthesiologists or physical medicine and rehabilitation specialists. Pain physicians often offer a variety of non-surgical and surgical interventions to sacroiliac joint dysfunction patients, including, but not limited to, steroid injections, radiofrequency ablation of the nerves serving the sacroiliac joint and implantation of neurostimulation devices, allografts, and other products intended to treat the sacroiliac joint or the pain it can cause. Our professional education program seeks to teach pain physicians, and other health care providers, about the benefits of iFuse, in order to prompt these providers to refer their patients with sacroiliac joint dysfunction to surgeons who have been trained to perform the iFuse procedure. These providers may, however, prefer to continue to treat these patients with the interventions they offer because they feel these interventions are superior or because they have a financial interest in offering additional treatments to these patients. If we are unable to demonstrate to potential referring health care providers the comparative benefits of iFuse, and we are therefore unable to prompt sufficient numbers of these providers to refer their patients with sacroiliac joint dysfunction for treatment by surgeons trained to perform the iFuse procedure, sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

Surgeons and payors may not find our clinical evidence to be compelling, which could limit our sales and revenue, and on-going and future research may prove our products to be less safe and effective than currently thought.

The products we currently market in the United States have either received premarket clearance under Section 510(k) of the United States. Federal Food, Drug, and Cosmetic Act ("FDCA"), or are exempt from premarket review. Those marketed in the European Union ("EU") have been the subject of a CE Certificate of Conformity. The 510(k) clearance process of the U.S. Food and Drug Administration ("FDA") requires us to document that our product is "substantially equivalent" to another 510(k)-cleared product. The 510(k) process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes, such as a premarket approval ("PMA"), and does not usually require pre-clinical or clinical studies. As a result, while there are a number of published studies relating to iFuse and minimally invasive sacroiliac joint surgery that support the safety and effectiveness of our products and the benefits they offer, our clinical studies may lack the size and scope of randomized controlled clinical trials required to support approval of a PMA. For these reasons, surgeons may be slow to adopt our products, third-party payors may be slow to provide coverage, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by surgeons, significantly reduce our ability to achieve expected sales, and could prevent us from achieving profitability.

Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the presence of "physician-owned distributorships" may impact our ability to sell our product at prices necessary to support our current business strategies.

If competitive forces drive down the prices we are able to charge for our product, our profit margins will shrink, which will adversely affect our ability to invest in and maintain and grow our market share. The sacroiliac joint fusion market has attracted numerous new companies and technologies. As a result of this increased competition, we believe there will be continuing increased pricing pressure, resulting in lower gross margins, with respect to our products.

Even to the extent our product and procedures using our product are currently covered and reimbursed by third-party private and public payors, adverse changes in coverage and reimbursement policies that affect our products, discounts, and number of implants used may also drive our prices and revenue down and harm our ability to market and sell our products.

Consolidation in the healthcare industry, including both third-party payors and healthcare providers, could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations, or financial condition. Because healthcare costs have risen significantly over the past several years, numerous initiatives and reforms initiated by legislators, regulators, and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage, and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products, and adversely impact our business, results of operations, or financial condition. As we continue to expand into international markets, we will face similar risks relating to adverse changes in coverage and reimbursement procedures and policies in those markets.

Practice trends or other factors, including the COVID-19 pandemic, may cause procedures to shift from the hospital environment to ambulatory surgical centers, or ASCs, where pressure on the prices of our products is generally more acute.

To protect health care professionals involved in surgical care and their patients, we anticipate that more outpatient eligible procedures will be performed in ASCs during the COVID-19 pandemic, and as its acuity declines and the healthcare system returns to a more normalized state. We anticipate that this trend will nevertheless continue as a cost control measure with the healthcare system. Since patients do not stay overnight in ASCs and COVID-19 patients would not otherwise be treated in ASCs, it is likely that the ASC will be viewed as a safer site of service for patients and health care providers, where the risk of transmission of the novel coronavirus can be more effectively controlled. In addition, ASC are generally more economically favorable site of service, and surgeons performing the procedures sometimes have ownership interests in the ASC. Because ASC facility fee reimbursement is typically less than facility fee reimbursement for hospitals and due to surgeons' economic interest in ASCs, we typically experience more pressure on the pricing of our products by ASCs than by hospitals, and the average price for which we sell our products to ASCs is less than the average prices we charge to hospitals. In addition, some surgeons may choose to use fewer implants due to their interest in the profitability of the ASC. An accelerated shift of procedures using our products to ASCs as a result of the COVID-19 pandemic could adversely impact the average selling prices of our products and our revenues could suffer as a result.

We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be adversely affected.

Our currently marketed products are, and any future products we commercialize will likely be, subject to intense competition. Our field is subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors, and are safer, less invasive, and more effective than alternatives available for similar purposes as demonstrated in peer-reviewed clinical publications. Because of the size of the potential market, we anticipate that other companies will dedicate significant resources to developing competing products.

The number of competitors that we are aware of marketing sacroiliac joint fusion products in the United States has grown from zero to more than 20 since 2008. Some of our current and potential competitors are major medical device companies that have substantially greater financial, technical, and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly longer operating history and more established reputations than we do. Some of these companies sell a broad suite of products that can be used together in the operating room in order to facilitate surgery, such as surgical imaging, navigation and robotic systems, or a large number of implants intended to treat different conditions affecting the spine and pelvis. The ability of these competitors to sell these products together or as part of larger purchasing arrangements may put us at a disadvantage. In addition, if these competitors use technology, contracts, or intellectual property measures to limit or eliminate the compatibility of their surgical imaging, navigation and robotic systems with our products, sales of our products could decline or fail to grow, which could adversely affect our business and results of operations.

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

New participants have increasingly entered the medical device industry. Many of these new competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our current or planned future products may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the market generally.

As a result, without the timely introduction of new products and enhancements, our products may become obsolete over time. If we are unable to develop innovative new products, maintain competitive pricing, and offer products that surgeons and other physicians perceive to be as reliable as those of our competitors, our market share or product margins could decrease, thereby harming our business.

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

Substantially all of our revenue comes from the sale of iFuse, iFuse-3D and iFuse-TORQ implants, and related tools and instruments. Therefore, we are dependent on widespread market adoption of iFuse and we will continue to be dependent on the success of this single product family for some time. There can be no assurance that iFuse will maintain a substantial degree of market acceptance among surgeons, patients or healthcare providers. Our failure to successfully grow the market for iFuse and increase our share within that market or any other event impeding our ability to sell iFuse, could adversely affect our results of operations, financial condition and continuing operations.

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

In November 2018, we introduced our iFuse Bedrock technique, in which spine surgeons place iFuse 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. To date, clinical experience with the iFuse Bedrock technique is limited and we have yet to complete a clinical trial to evaluate the iFuse Bedrock technique. Surgeons do not know if the addition of iFuse implants to the implants used to fuse multiple levels of the lumbar spine will result in patient benefit. If surgeons' clinical experience with iFuse Bedrock is not positive, or if our clinical trials do not show meaningful benefits to the patients undergoing this procedure, sale of our iFuse implants for this indication could be adversely impacted, which could negatively affect our operations and financial condition.

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

As of December 31, 2021, our U.S. sales force consisted of 85 territory sales managers and 65 clinical support specialists directly employed by us and 59 third-party distributors. As of December 31, 2021, our international sales force consisted of 20 sales representatives directly employed by us and 32 exclusive third-party distributors, which together have had sales in 37 countries through December 31, 2021. Our operating results are directly dependent upon the sales and marketing efforts of both our direct sales force and of our third-party distributors.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and third-party distributors with significant technical knowledge in various areas, such as spine health and treatment. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. If a direct sales representative or third-party distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified third-party distributors or to hire additional direct sales representatives to work with us. Furthermore, we may not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or third-party distributors would prevent us from expanding our business and generating sales. If our direct sales representatives or third-party distributors fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease.

If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations, and financial condition.

Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel.

We are dependent upon the continued services of key members of our senior management and a limited number of key advisors and personnel. The loss of members of our senior management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations, and financial condition. We do not maintain “key person” insurance for any of our executives or employees. In addition, several of the members of our executive management team are not subject to non-competition agreements that restrict their ability to compete with us. Accordingly, the adverse effect resulting from the loss of certain executives could be compounded by our inability to prevent them from competing with us.

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

If use of our products results in adverse events, this may require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen adverse events related to our products could arise either during clinical development or, if cleared, approved, or subject to CE Certificate of Conformity, after the product has been marketed. In clinical research, the most common adverse event related to our implant was leg pain resulting from misplacement. The most common adverse event for our implant procedure has been minor wound infections. Additional adverse effects from iFuse or any of our other products could arise either during clinical development or, if approved, cleared, or subject to CE Certificate of Conformity, after the product has been marketed.

If we or others later identify adverse events caused by our products:

- sales of the product may decrease significantly, and we may not achieve the anticipated market share;
- regulatory authorities or our Notified Body may require changes to the labeling of our product. This may include the addition of labeling statements, specific warnings, and contraindications and issuing field alerts to physicians and patients;
- we may be required to change instructions regarding the way the product is implanted or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- regulatory authorities may require us to temporarily or permanently take our approved product off the market or to conduct other field safety corrective actions;
- we may be required to modify our product;
- we may be subject to litigation fines or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

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

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

Various factors outside our direct control may adversely affect manufacturing, sterilization, and distribution of our products.

The manufacture, sterilization, and distribution of our products is challenging. Changes that our suppliers may make outside the purview of our direct control can have an impact on our processes, quality of our products, and the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include:

- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk;
- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;
- large-scale epidemics of communicable diseases such as COVID-19;
- supply chain disruptions, including those caused by material and labor supply shortages in the wake of COVID-19;
- natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment, or other forms of disruption to business operations affecting our manufacturers or suppliers; and

- latent defects that may become apparent after products have been released and that may result in a recall or field safety corrective action with respect to such products.

If any of these risks were to materialize, our ability to provide our products to customers on a timely basis could be adversely impacted.

We are dependent on a limited number of third-party suppliers, some of them single-source and some of them in single locations, for most of our products and components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials in a timely and cost-effective manner, could materially adversely affect our business.

We rely on third-party suppliers to manufacture and supply substantially all of our products. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable prices, and on a timely basis. We do not have long-term supply contracts for some of our suppliers, and in some cases, even where we do have agreements in place, we purchase important parts of the iFuse Implant System, including our implants, from a single supplier. Therefore, we cannot assure investors that we will be able to obtain sufficient quantities of product in the future.

In addition, future growth could strain the ability of our suppliers to deliver products, materials, and components. Suppliers often experience difficulties in scaling up production, including financial issues, or problems with production yields and quality control and assurance. For example, from time to time, we have experienced certain delays and may experience delays from our suppliers in the future.

We generally use a small number of suppliers for our instruments and currently rely on RMS for iFuse-3D implants and Orchid for iFuse implants. Our dependence on such a limited number of suppliers exposes us to risks, including, among other things:

- third-party contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the safety or effectiveness of our products or cause delays in shipments of our products;
- third-party contract manufacturers or suppliers may fail to maintain good manufacturing practices, leading to quality control problems or regulatory findings that could cause disruptions in their manufacturing processes and lead to delays in shipments of our products;
- we or our third-party manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
- we or our third-party manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- we or our third-party manufacturers and suppliers may lose access to critical services, raw materials and components, or experience significant delays in obtaining them, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- we or our third-party manufacturers could experience plant closures due to local epidemics of communicable diseases, such as COVID-19, or local outbreaks of such diseases among their workforce, thereby shuttering a plant in which our products are manufactured;
- we may experience delays in delivery by our third-party manufacturers and suppliers due to changes in demand from us or their other customers;
- fluctuations in demand for products that our third-party manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our third-party manufacturers and suppliers may wish to discontinue supplying components or services to us for risk management reasons;
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our third-party manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

If any one or more of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products and to launch new products. If we are unable to satisfy commercial demand for our system in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products. Additionally, we could be forced to seek alternative sources of supply.

In addition, most of our supply and manufacturing agreements do not have minimum manufacturing or purchase obligations. As such, with many of our suppliers, we have no obligation to buy any given quantity of products, and the suppliers have no obligation to sell us or to manufacture for us any given quantity of components or products. As a result, our ability to purchase adequate quantities of components or our products may be limited and we may not be able to convince suppliers to make components and products available to us in some instances. Our suppliers may also encounter problems that limit their ability to supply components or manufacture products for us, including financial difficulties, damage to their manufacturing equipment or facilities, product discontinuations or adverse findings in quality audits. As a result, there is a risk that certain components could be discontinued and no longer available to us. We may be required to make significant "last time" purchases of component inventory that is being discontinued by the supplier to ensure supply continuity. If we fail to obtain sufficient quantities of high quality components to meet demand for our products in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Securing a replacement third-party manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our iFuse system that are subject to domestic and international regulatory clearances or approvals and the review of our Notified Body.

Because of the nature of our internal quality control requirements, regulatory requirements, and the custom and proprietary nature of the parts, we may not be able to quickly engage additional or replacement suppliers for many of our critical components. We may also be required to assess any potential new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Failure of any of our third-party suppliers to meet our product demand level would limit our ability to meet our sales commitments to our customers and could have a material adverse effect on our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA, our Notified Body and the competent authorities in the countries of the EEA, or other foreign regulatory authorities, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to delays in obtaining clearances or approvals, regulatory action including warning letters, product recalls, termination of distribution, product seizures, civil, administrative, or criminal penalties and the suspension, variation, or withdrawal of our CE Certificates of Conformity. We could incur delays while we locate and engage qualified alternative suppliers, and we may be unable to engage alternative suppliers on favorable terms or at all. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate sales.

In addition, each of our third-party suppliers operates at a facility in a single location and substantially all of our inventory of component supplies and finished goods is held at these locations. A local outbreak of COVID-19 cases, vandalism, terrorism, or a natural or other disaster, such as an earthquake, fire, or flood, could damage or destroy equipment or our inventory of component supplies or finished products, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our suppliers' facilities could harm our business, financial condition, and operating results.

We may encounter problems or delays in the assembly of our products or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results.

After the impacts of the COVID-19 pandemic subside, to become profitable we must assemble our products in adequate quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to assemble and test our products will require us to improve internal efficiencies. We may encounter a number of difficulties in increasing our assembly and testing capacity, including:

- managing production yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, federal, and foreign regulations.

If we are unable to satisfy commercial demand for our iFuse system due to our inability to assemble and test, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use our competitors' products.

If we do not enhance and broaden our product offerings through our research and development efforts, we may be unable to compete effectively.

In order to increase our market share in the sacroiliac joint fusion and related markets, we must enhance and broaden our product offerings in response to customer demands and competitive pressures and technologies. We might not be able to successfully develop, obtain domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for, or market new products, and our future products might not be accepted by the surgeons or the third-party payors who reimburse for many of the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and effectiveness of new products; and
- obtain the necessary domestic and international regulatory clearances or approvals and CE Certificates of Conformity for new products or product enhancements.

If we do not develop and obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our business could be adversely affected. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In some cases, following a successful product development effort, we may need to invest substantial resources in surgical instrumentation and implant inventory, prior to launch of the product, and before we understand the demand for such product. If we overestimate the demand for such products and invest too heavily in inventory to support the product line, the additional revenue and product margins may not produce a positive return on such investments, which could cause our financial results to suffer. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

We are required to maintain adequate levels of inventory, the failure of which could consume our resources and reduce our cash flows.

As a result of the need to maintain adequate levels of inventory, we are subject to the risk of inventory obsolescence. Many of our products come in sets, which feature components in a variety of sizes so that the implant or device may be chosen for size based on the patient's needs. In order to market our products effectively, we often maintain and provide surgeons and hospitals with back-up products and products of different sizes. For each surgery, fewer than all of the components of the set are used, and therefore certain portions of the set may become obsolete before they can be used. In addition, as we introduce new implants and instruments with the same intended uses as existing products, the older products may fall out of favor with our customers, causing them to become obsolete. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

The size and future growth in the market for iFuse has not been established with precision and may be smaller than we estimate, possibly materially. In addition, we estimate cost savings to the economy and healthcare system as a result of the iFuse procedure based on our market research. If our estimates and projections overestimate the size of this market or these benefits and cost savings, our sales growth may be adversely affected.

We are not aware of an independent third-party study that reliably reports the potential market size for iFuse or cost savings as a result of the iFuse procedure. Therefore, our estimates of the size and potential for future growth in the market for our iFuse products, cost savings to patients, the healthcare system and the economy overall from its use, and the number of people currently suffering from lower back pain who may benefit from and be amenable to our iFuse procedure, is based on a number of internal and third-party studies, surveys, reports, and estimates. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our iFuse products and procedures and health cost savings, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual incidence of lower back pain, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions and estimates are incorrect. As a result, our estimates of the size and future growth in the market for our iFuse products may prove to be incorrect. In addition, actual health cost savings to the healthcare system as a result of the iFuse procedure may materially differ from those we expect. If the actual number of people with lower back pain who would benefit from our iFuse products and the size and future growth in the market for iFuse products and related costs savings to the healthcare system is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business.

Our results of operations could suffer if we are unable to manage our international business effectively.

Expansion into international markets is an element of our business strategy and involves risk. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import, and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly affect us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), and the United Kingdom Bribery Act ("UKBA"), anti-boycott laws, anti-money laundering laws, and regulations relating to economic sanctions imposed by the U.S., including the Office of Foreign Asset Control of the U.S. Treasury. Any failure to comply with applicable legal and regulatory obligations in the U.S. or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

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

- exposure to different legal and regulatory standards;
- lack of stringent protection of intellectual property;
- inability of the local healthcare system to absorb prices for our product that would enable our business to become profitable in those markets;
- obstacles to obtaining domestic and foreign export, import, and other governmental approvals, permits, and licenses and compliance with foreign laws;
- potentially adverse tax consequences and the complexities of foreign value-added tax systems;
- adverse changes in tariffs and trade restrictions;
- limitations on the repatriation of earnings;
- difficulties in staffing and managing foreign operations;
- insufficient numbers of patients requiring procedures that use our products;
- transportation delays and difficulties of managing international distribution channels;
- longer collection periods and difficulties in collecting receivables from foreign entities;
- increased financing costs;
- currency risks; and
- political, social, and economic instability and increased security concerns.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation.

Our successful conduct of our international business depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we plan to do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

In the future our products may become obsolete, which would negatively affect operations and financial condition.

The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices, and products that are more effective than our iFuse system or that would render the iFuse system obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our product. Accordingly, our success will depend in part on our ability to respond quickly to changes in technology and the practice of medicine through the development and introduction of new products. Product development involves a high degree of risk and there can be no assurance that our new product development efforts will result in any commercially successful products.

If we experience significant disruptions in our information technology systems, our business, results of operations, and financial condition could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage:

- sales and marketing, accounting, and financial functions;
- inventory management;
- engineering and product development tasks; and
- our research and development data.

Our information technology systems are vulnerable to damage or interruption from:

- earthquakes, fires, floods, and other natural disasters;
- terrorist attacks and attacks by computer viruses or hackers or breach of our cybersecurity;
- power losses; and
- computer systems, or Internet, telecommunications, or data network failures.

The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, and legal liability issues, all of which could have a material adverse effect on our reputation, business, results of operations, and financial condition.

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

In addition, we accept payments for many of our sales through credit card transactions, which are handled through third-party payment processors. As a result, we are subject to a number of risks related to credit card payments. As a result of these transactions, we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our products or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our customers' credit card information to our third-party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our customers' credit card information if the security of our third-party credit card payment processors are breached. We and our third-party credit card payment processors are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. If we or our third-party credit card payment processors fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our ability to accept credit card payments from our customers, and there may be an adverse impact on our business.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

From time to time, we expect to consider opportunities to acquire or make investments in other technologies, products, and businesses that may enhance our capabilities, complement our current products, or expand the breadth of our markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including:

- problems assimilating the purchased technologies, products, or business operations;
- issues maintaining uniform standards, procedures, controls, and policies;
- unanticipated costs and liabilities associated with acquisitions;
- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product, or technology into our business or retain any key personnel, suppliers, or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete, and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to successfully integrate any acquired businesses, products, or technologies effectively, our business, results of operations, and financial condition will be materially adversely affected.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenue.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships, or other arrangements to develop products and to pursue new markets. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

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

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

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

The covenants in the SVB Term Loan, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in, expand, or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under our credit facility agreements. If not waived, future defaults could cause all of the outstanding indebtedness under our Loan and Security Agreement with SVB to become immediately due and payable.

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

Effective as of December 31, 2021, we became a large accelerated filer and are no longer an emerging growth company, which will impose additional costs on us.

As a result of our public float as of June 30, 2021, we became a large accelerated filer as of December 31, 2021. We therefore no longer qualified as an "emerging growth company," as defined in the JOBS Act. Additionally, due to our public float as of June 30, 2021, we no longer qualified as a "smaller reporting company" as defined in the Exchange Act. However, 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, 2022.

As a large accelerated filer, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company, such as the necessity of our independent registered public accounting firm providing an attestation on our internal control over financial reporting.

We expect that compliance with the additional requirements of being a large accelerated filer will increase our legal and financial compliance costs and may cause management and other personnel to devote more time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources.

Risks Related to Our Legal and Regulatory Environment

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

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices:

- design, development, and manufacturing;
- testing, labeling, content, and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales, and distribution;
- premarket clearance and approval;
- conformity assessment procedures;
- record keeping procedures;
- advertising and promotion;
- compliance with good manufacturing practices requirements;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, difficulties achieving new product clearances, higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated product or make a significant modification to an existing product in the U.S., with only limited exceptions, we must obtain either clearance under Section 510(k) of the FDCA for Class II devices or approval of a PMA application from the FDA for a Class III device. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology, and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Both the 510(k) and PMA processes can be expensive and lengthy and require the payment of significant fees, unless exempt. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining domestic and international regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

In the U.S., our currently commercialized products have either received premarket clearance under Section 510(k) of the FDCA or are exempt from premarket review. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy, and uncertain PMA process. Although we do not currently market any devices under PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from premarket review, the FDA may require us to submit a 510(k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure investors that we will be able to obtain the 510(k) clearances with respect to those products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay clearance or approval of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. These studies can be very expensive and time consuming to conduct. Failure to comply with those studies in a timely manner could result in the revocation of the 510(k) clearance for a product that is subject to such a 522 Order and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the U.S.

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

The FDA and other regulatory authorities, including foreign authorities, have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and effectiveness of our products.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;

- delays in the introduction of products into the market;
- total or partial suspension of production;
- facility closures;
- refusal of the FDA or our Notified Body or other regulator to grant future clearances or approvals or to issue CE Certificates of Conformity;
- withdrawals, variation, or suspensions of current clearances or approvals and CE Certificates of Conformity, resulting in prohibitions on sales of our products; and
- in the most serious cases, criminal penalties.

Adverse action by an applicable regulatory agency, our Notified Body or the FDA could result in inability to produce our products in a cost-effective and timely manner, or at all, decreased sales, higher prices, lower margins, additional unplanned costs or actions, damage to our reputation, and could have material adverse effect on our reputation, business, results of operations, and financial condition.

We and our sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to healthcare provider kickbacks and false claims for reimbursement, and other applicable federal and state healthcare laws, as well as equivalent foreign laws, and failure to comply could negatively affect our business.

Healthcare providers, distributors and third-party payors play a primary role in the distribution, recommendation, ordering, and purchasing of any implant or other medical device for which we have or obtain marketing clearance or approval. Through our arrangements with customers and third-party payors, we are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, or third-party distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete, and accurate reporting of financial information or data, other commercial or regulatory laws or requirements, and equivalent foreign rules. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations, and government authorities may conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance despite our good faith efforts to comply.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Our relationships and our distributors' relationships with surgeons, other healthcare professionals, and hospitals are subject to scrutiny under these laws. For example, we are subject to the federal health care Anti-Kickback Statute, the federal civil False Claims Act, the Health Insurance Portability and Accountability Act ("HIPAA") and the federal Physician Payment Sunshine Act, each of which is described in detail in Item 1 Business - Healthcare Fraud and Abuse" and "-Data Privacy and Security Laws" in our Annual Report on Form 10-K filed with the SEC on March 10, 2021.

Certain states also have enacted analogous state and foreign law equivalents of each of the above federal laws and certain states may also mandate implementation of corporate compliance programs, require compliance with the industry's voluntary compliance guidelines, impose restrictions on device manufacturer marketing practices, and/or require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities. Many of these state laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our employees are found to have violated any of the above laws we may be subject to significant administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare, Medicaid, and equivalent foreign programs, significant fines, monetary penalties and damages, imposition of compliance obligations and monitoring, the curtailment or restructuring of our operations, and damage to our reputation.

We have entered into consulting agreements and royalty agreements with physicians and healthcare executives, including some who are customers. We also engage in co-marketing arrangements with certain surgeons who use our products. In addition, prior to our IPO, a small number of our current customer surgeons acquired from us less than 1.0% of our current outstanding common stock, which they either purchased in an arm's length transaction on terms identical to those offered to others or received from us as fair market value consideration for consulting services performed. While all of these transactions were structured to comply with applicable laws, including the federal Anti-Kickback Statute, state anti-kickback laws and other applicable laws, it is possible that regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to significant penalties and criminal, civil and administrative liability. We would be materially and adversely affected if regulatory agencies interpret our financial relationships with surgeons who order our products to be in violation of

applicable laws and we were unable to comply with such laws, which could subject us to, among other things, monetary penalties for non-compliance, the cost of which could be substantial.

Various state and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. To enforce compliance with the federal laws, the U.S. Department of Justice has continued its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare company settles an investigation with the Department of Justice or other law enforcement agencies, it may need to agree to additional onerous compliance and reporting requirements as part of a consent decree, deferred or non-prosecution agreement, or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

The scope and enforcement of these laws is uncertain and subject to rapid change. The shifting compliance environment and the need to build and maintain robust and expandable systems and processes to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business.

In the ordinary course of our business, we collect and store sensitive data, including legally protected personally identifiable information. We collect this kind of information for billing, reimbursement support, marketing purposes, post-marketing safety vigilance, servicing potential warranty claims and during the course of clinical trials. In doing so, we are subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA in the U.S. and regulations in the European Union ("EU"), which are described in detail in Item 1 Business - Data Privacy and Security Laws".

The California Consumer Privacy Act ("CCPA"), which became effective on January 1, 2020, requires a broad range of businesses to honor the requests of California residents to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used and shared. The CCPA provides for civil penalties of up to $7,500 for intentional violations, and a private right of action for data breaches that allows private plaintiffs to seek the greater of actual damages or statutory damages of up to $750 per consumer per data breach. These remedies are expected to increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and protected health information governed by HIPAA, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Our compliance costs and potential liability with respect to personal information may also increase in response to other states adopting and considering initiative regarding protection of personal information. In March 2021, Virginia passed the Consumer Data Protection Act ("CDPA") which will take effect on January 1, 2023. Virginia is the second state to pass comprehensive privacy litigation. Colorado passed the Colorado Privacy Act ("CPA") on July 7, 2021 with enforcement to begin on July 1, 2023. While the CDPA and CPA emulate the GDPR and the CCPA in certain respects, the laws differ and compliance with one law does not equate to compliance with the other laws. Several other states (including Washington, New York, and Minnesota) also are considering comprehensive privacy legislation that could further complicate and increase the cost of complying with various state privacy laws. If states pass a patchwork of privacy laws, this also could increase pressure on the U.S. Congress to harmonize privacy laws through federal legislation.

We have in the past, and could be in the future, subject to data breaches. Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end-customers, and other affected individuals, and the imposition of integrity obligations and agency oversight, damage to our reputation, and loss of goodwill, any of which could harm our operations, financial performance, and business. Depending on the nature of the information compromised, we may also have obligations to notify users, law enforcement, government authorities, payment companies, consumer reporting agencies, or the media about the incident and may be required to expend additional resources in connection with investigating and remediating such an incident, and otherwise complying with applicable privacy and data security laws. Evolving and changing definitions of personal data and personal information, within the European Union, the U.S., and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products.

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

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

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

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

For any product for which we obtain regulatory clearance or approval, or a CE Certificate of Conformity, the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product will be subject to continued regulatory review, oversight and periodic inspections by the FDA, our Notified Body and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations ("QSR") and International Standards Organization ("ISO") regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain regulatory clearance or approval, or a CE Certificate of Conformity.

The failure by us or one of our suppliers to comply with applicable statutes and regulations, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval and conformity assessments of new products or modified products;
- limitations on the intended uses for which the product may be marketed;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- suspension, variation or withdrawal of CE Certificates of Conformity;
- refusal to grant export approval for our products; and

- criminal prosecution.

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace, or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation, or withdrawal of regulatory approvals or CE Certificates of Conformity, product seizures, injunctions, or the imposition of civil, administrative, or criminal penalties which would adversely affect our business, operating results, and prospects.

If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds. Any of these actions would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue.

Our employees, independent contractors, consultants, manufacturers, and third-party distributors may engage in misconduct or other improper activities, relating to regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, manufacturers, and third-party distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal, state and foreign healthcare laws and regulations, data privacy laws and laws that require the true, complete and accurate reporting of financial information or data. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, disgorgement of profits, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

We may be subject to enforcement action, including fines, penalties or injunctions, if we are determined to be engaging in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable national and foreign laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA and equivalent third country authorities do not restrict or regulate a physician's choice of treatment within the practice of medicine. In the U.S., the full indication for the iFuse Implant System is: "The iFuse Implant System is intended for sacroiliac fusion for the following conditions: (i) Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. (ii) To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. (iii) Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint." In the U.S., our marketing strategies must adhere to the above statements. In all other countries, the indication statement for the iFuse Implant System (including iFuse-3D) more broadly indicates that the device is indicated for sacroiliac joint fusion. The above-described potential limitation in indication statements in the U.S. does not apply in other geographies.

We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA and our notified body. However, if the FDA or an equivalent third country authority determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, require us to stop promoting our products for those specific procedures until we obtain FDA or third country authority clearance or approval for them, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines, and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or

fraudulent claims for payment of government fund. In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

We are required to report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's medical device reporting, regulations, and equivalent rules of other countries we are required to report to the FDA or a similar authority in such other country, any information that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In the EEA, we must report serious incidents and field safety corrective actions through the Commission's electronic system on vigilance and post-market surveillance, which reports are transmitted to the competent authority of the Member State in which the incident occurred.

If we fail to report these events to the FDA or applicable authority in another country within the required timeframes, or at all, FDA, or the applicable authority in the other country could take enforcement action against us. Any such adverse event involving our products or repeated product malfunctions may result in voluntary or involuntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations, and financial condition.

Any adverse event involving our products, whether in the U.S. or abroad could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, including foreign governmental authorities, or the discovery of serious safety issues or malfunctions with our products, can result in voluntary corrective actions or agency enforcement actions, which could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found.

In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is an unreasonable risk of substantial public harm. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us or one of our third-party distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted. Equivalent procedures and penalties have been established in other countries including EU Member States.

Modifications to our products may require new 510(k) clearances or premarket approvals and new conformity assessment by our Notified Body, or may require us to cease marketing or recall the modified products until clearances, approvals, or CE Certificates of Conformity are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make and document this determination in the first instance. A manufacturer may determine that a modification could not significantly affect safety or effectiveness and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. FDA may review any manufacturer's decision and may not agree with our decisions regarding whether new clearances or approvals are necessary. The FDA may also on its own initiative determine that a new clearance or approval is required.

We have modified some of our 510(k) cleared products and have determined based on our review of the applicable FDA guidance that in certain instances new 510(k) clearances or PMAs are not required. If the FDA disagrees with our determination and requires us to submit new 510(k) clearances or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval. In these circumstances, we may be subject to significant enforcement actions, regulatory fines, or penalties, which could require us to redesign our products and harm our operating results.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions.

In the EEA, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial changes to our quality system, manufacturing process, or changes to our devices which could affect compliance with the essential requirements or the devices' intended use. The Notified Body will then assess the changes and verify whether they affect the products' conformity with Essential Requirements and related applicable laws. There can be no assurances that the assessment will be favorable and that the Notified Body will attest to our compliance with the essential requirements, which will prevent us from selling our products in the EEA. Moreover, any substantial changes that take place in the coming years may impact the continuing effectiveness of our CE Certificates of Conformity that were issued on the basis of the Medical Device Directive.

There is no guarantee that the FDA will grant 510(k) clearance or premarket approval of our future products or that our Notified Body will issue the required CE Certificate of Conformity, and failure to obtain necessary clearances or approvals for our future products would adversely affect our business prospects.

We are in the process of developing our regulatory strategies for obtaining clearance or approval for future products. Some of them may require 510(k) clearance by the FDA or a new CE Certificate of Conformity. Other future products may require premarket approval. In addition, some of our new products may require clinical trials or significant clinical evidence to support regulatory approval and we may not successfully complete these clinical trials. Obtaining regulatory clearances or approvals and CE Certificates of Conformity can be a time-consuming process, and delays in obtaining required future regulatory clearances or approvals, and CE Certificates of Conformity would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would adversely affect our business prospects. The FDA may not approve or clear these products or our Notified Body may not issue CE Certificate of Conformity for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products, new intended uses, or modifications to existing products and our Notified Body may refuse to issue new CE Certificates of Conformity. Failure to receive clearance, approval, or Certificates of Conformity for our new products would have an adverse effect on our ability to expand our business.

We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.

We currently market our products internationally and intend to expand our international marketing. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. For example, we intend to continue to seek domestic and international regulatory clearance to market our primary products Asia, the Middle East and other key markets. The approval procedures vary among countries and may involve requirements for substantial additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain FDA clearance or approval or to obtain CE Certificates of Conformity.

Clearance or approval by the FDA or obtaining a CE Certificate of Conformity does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not

ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval, or a CE Certificate of Conformity for a medical device in the EEA, in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA clearance or approval, or a CE Certificate of Conformity in the EEA, and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations, and financial condition could be adversely affected.

Clinical trials necessary to support a De Novo 510(k) or PMA application or a conformity assessment procedure will be expensive and may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products, or new indications for use for existing products, and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support a De Novo 510(k) or PMA application for our possible future products or to support a conformity assessment procedure for a new CE Certificate of Conformity would be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product, or new indication for use, we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity of patients to clinical sites, and the ability to comply with the inclusion and exclusion criteria for participation in the clinical trial and patient compliance. Development of sufficient and appropriate clinical protocols to demonstrate safety and effectiveness are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA or our Notified Body may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. For example, the COVID-19 pandemic has caused substantial delays in site initiation and patient enrollment in our SILVIA trial designed to assess the safety and efficacy of our Bedrock technique. In addition, despite considerable time and expense invested in our clinical trials, the FDA or our Notified Body may not consider our data adequate to demonstrate safety and effectiveness. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Our facility and our clinical investigational sites operate under procedures that govern the conduct and management of FDA-regulated clinical studies under 21 CFR Parts 50 and 812, and Good Clinical Practices. The FDA may conduct Bioresearch Monitoring inspections of us and/or our clinical sites to assess compliance with 21 CFR Parts 50 and 812, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action, as well as refusal to accept all or part of our data in support of our 510(k) or PMA, or we may need to conduct additional studies.

The results of our clinical trials may not support our product candidate claims or may result in the occurrence of adverse events.

Even if our clinical trials are completed as planned, or on a delayed basis, we cannot be certain that their results will support our product candidate claims or that the FDA, foreign authorities, or our Notified Body will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenue. It is also possible that patients enrolled in clinical trials will experience adverse events that are not currently part of the product candidate’s profile.

U.S. legislative or FDA or foreign regulatory reforms may make it more difficult and costly for us to obtain regulatory clearances or approvals, or CE Certificates of Conformity for our product candidates and to manufacture, market, and distribute our products after approval is obtained.

From time to time, Congress introduces legislation that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Moreover, the new Medical Device Regulation in Europe entered into application on May 26, 2021. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

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

Another example can be found in the EEA. The Medical Devices Regulation (“MDR”) entered into application on May 26, 2021. MDR introduced substantial changes to the obligations with which medical device manufacturers must comply in the EEA. Examples of the changes which will be introduced by these regulations include the following:

- additional scrutiny during the conformity assessment procedure for high risk medical devices;
- strengthening of the clinical data requirements related to medical devices;
- strengthening of the designation and monitoring processes governing notified bodies;
- the obligation for manufacturers and authorized representative to have a person responsible for regulatory compliance continuously at their disposal;
- authorized representatives held legally responsible and liable for defective products placed on the EU market;
- increased traceability of medical devices following the introduction of a Unique Device Identification (“UDI”), system;
- new rules governing the reprocessing of medical devices; and
- increased transparency with the establishment of European database on medical devices (“EUDAMED”) III as information from several databases concerning economic operators, CE Certificates of Conformity, conformity assessment, clinical investigations, the UDI system, adverse event reporting and market surveillance would be available to the public.

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

Transition from the regulation of our products under the Medical Device Directive, and implementing legislation in each EU Member State, to regulation under the Medical Devices Regulation has required and will continue to require a substantial transition effort by us. In addition, detail as to how certain aspects of the Medical Devices Regulation will be applied remains unclear. Failure to update our quality system and regulatory documentation could delay our transition to compliance with the Medical Devices Regulation and delay or prevent us from obtaining new CE Certificates of Conformity under the Regulation. Transition from compliance with the Medical Device Directive to the Medical Devices Regulation could result in disruption to our business in the EEA which could adversely affect our business, results of operation and financial condition.

In addition, any changes to the membership of the European Union, such as the departure of the United Kingdom from the EU, may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries. For example, pursuant to guidance issued by the UK Government as a result of the UK formally withdrawing from the European Union, the Medicines and Healthcare products Regulatory Agency (“MHRA”) became the standalone

medicines and medical devices regulator for the UK as of January 1, 2021. A new mark referred to as "UKCA" (UK Conformity Assessed) has also been introduced and will replace the CE conformity mark. Although CE conformity marketing and certificates issued by Notified Bodies will continue to be recognized in the UK through June 2023, all medical devices must be registered with the MHRA as of January 1, 2021. Complying with this new regulatory framework will require us to invest in additional resources and could be expensive, time-consuming and disruptive to our existing operations in the UK.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture, and sale of surgical devices. Sacroiliac joint and other orthopedic spine surgeries involve significant risk of serious complications, including bleeding, nerve injury, paralysis, and even death. Surgeons may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. In addition, if longer-term patient results and experience indicate that our products or any component of a product cause tissue damage, motor impairment, or other adverse effects, we could be subject to significant liability. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects, or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts, or product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation, our ability to attract and retain customers and our results of operations or financial condition.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial retentions or deductibles that we are responsible for. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, results of operations, and financial condition.

In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities.

The manufacture of certain of our products, including our implants and products, and the handling of materials used in the product testing process involve the use of biological, hazardous and/or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state, and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling, and disposal of, and exposure to, such materials and wastes. We own and operate certain x-ray equipment at our facilities which requires adoption of a radiation safety plan. Our failure to follow such safety plan or otherwise use this equipment properly could be hazardous to our employees and expose us to liability as the employer. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations, and financial condition.

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

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

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

be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.

Risks Related to Our Intellectual Property

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

We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and non- disclosure agreements and other methods, to protect our proprietary technologies and know-how. As of December 31, 2021, we owned 44 issued U.S. patents and had 33 pending U.S. patent applications, and we owned 15 issued foreign patents and had nine pending foreign patent applications. We have focused the majority of our foreign patent efforts in China, Europe, and Japan. Our current U.S. patents on iFuse, including the triangular shape, expire in November 2024. Competitors may market similar triangular shaped devices upon the expiration of the patents in late 2024. Our current U.S. patents on iFuse-3D, including the fenestrated design, expire in September 2035. Our foreign patents will expire between August 2025 and September 2035.

As of December 31, 2021, we have 15 registered trademarks in the U.S. and have filed for 12 more. We have sought protection for at least two of these trademarks in 60 countries including the 27 European member countries of the Madrid Protocol.

We have applied for patent protection relating to certain existing and proposed products and processes. While we generally apply for patents in those countries where we intend to make, have made, use, or sell our products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. Furthermore, we cannot assure investors that any of our patent applications will be approved. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested, or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the U.S. Even if patents are granted outside the U.S., effective enforcement in those countries may not be available. Since most of our issued patents are for the U.S. only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our products.

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

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

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

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

We may be subject to damages resulting from claims that we, our employees, or our third-party distributors have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. Some of our third-party distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees, or our third-party distributors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Even if we are successful in defending against these claims, litigation could result in substantial costs, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not occur, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations, and financial condition.

The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, and/or prevent us from developing or marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make and sell our products. We have conducted a limited review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and the uncertainty of litigation increase the risk of management's attention being diverted to patent litigation. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. Further, as the number of participants in the medical device industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, including treble, or triple, damages if an infringement is found to be willful, and/or royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations, and financial condition. If passed into law, patent reform legislation currently pending in the U.S. Congress could significantly change the risks associated with bringing or defending a patent infringement lawsuit.

In addition, we generally indemnify our customers and third-party distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or third-party distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or third-party distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or third-party distributors or may be required to obtain licenses to intellectual property owned by such third parties. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers and third-party distributors may be forced to stop using or selling our products.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile, and the value of an investment in our common stock could decline.

Medical device stocks have historically experienced volatility, and the trading price of our common stock may fluctuate substantially. These fluctuations could cause our stockholders to lose all or part of their investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following:

- the impact that the COVID-19 pandemic has on our business;
- actual or anticipated changes or fluctuations in our results of operations;
- results of our clinical trials and that of our competitors' products;
- regulatory actions with respect to our products or our competitor's products;
- announcements of new offerings, products, services or technologies, commercial relationships, acquisitions, or other events by us or our competitors;
- price and volume fluctuations in the overall stock market from time to time;
- significant volatility in the market price and trading volume of healthcare companies, in general, and of companies in the medical device industry in particular;
- fluctuations in the trading volume of our shares or the size of our public float;
- negative publicity;
- whether our results of operations meet the expectations of securities analysts or investors or those expectations change;
- litigation involving us, our industry, or both;
- regulatory developments in the U.S., foreign countries, or both;
- lock-up releases and sales of large blocks of our common stock;
- additions or departures of key employees or scientific personnel; and
- general economic conditions and trends.

In addition, if the market for healthcare stocks or the stock market, in general, experience a further loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations, and financial condition.

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

We have experienced and continue to experience meaningful variability in our sales and gross profit from quarter to quarter, as well as within each quarter. Our sales and results of operations will be affected by numerous factors, including, among other things:

- the impact that the COVID-19 pandemic has on our business;
- payor coverage and reimbursement;

- the number of products sold in the quarter and our ability to drive increased sales of our products;
- our ability to establish and maintain an effective and dedicated sales force;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products and products in development;
- the mix of our products sold because profit margins differ amongst our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of materials and components;
- the evolving product offerings of our competitors;
- the demand for, and pricing of, our products and the products of our competitors;
- factors that may affect the sale of our products, including seasonality and budgets of our customers;
- domestic and international regulatory clearances or approvals, or CE Certificates of Conformity, and legislative changes affecting the products we may offer or those of our competitors;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- our ability to expand the geographic reach of our sales and marketing efforts;
- the costs of maintaining adequate insurance coverage, including product liability insurance;
- the availability and cost of components and materials;
- the number of selling days in the quarter;
- fluctuation in foreign currency exchange rates; and
- impairment and other special charges.

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

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

As of December 31, 2021, we had net operating loss ("NOL") carryforwards of $255.5 million and $203.2 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in 2029 and 2021, respectively, subject to the recent California franchise tax law change affecting California state NOLs mentioned below. Portions of these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under legislation enacted in 2017, as modified by legislation enacted in 2020, unused U.S. federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which generally occurs if the percentage of the corporation's stock owned by 5% stockholders increases by more than 50% over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We updated our Section 382 ownership change analysis through December 31, 2020. The analysis determined that we have experienced Section 382 ownership changes in 2010 and 2020. A total of $1.4 million of our NOLs and tax credit carryforwards are subject to limitation as a result of the ownership change. The equity shift between December 31, 2020 to December 31, 2021 was not material, considering the changes in the outstanding number of shares during the period. We will continually assess the need to update our Section 382 ownership change analysis, as we may experience ownership changes in the future that could materially limit our ability to use our NOL carryforwards, which may harm our future operating results by effectively increasing our future tax obligations.

The California Assembly Bill 85 (AB 85) was signed into law by Governor Gavin Newsom on June 29, 2020. The legislation suspends the California NOL deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation of certain California Tax Credits for 2020, 2021, and 2022. The legislation disallows the use of California NOL deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $1.0 million. The carryover periods for NOL deductions disallowed by this provision will be extended.

The California Senate Bill 113 (SB 113) was signed into law by Governor Newsom on February 9, 2022. The legislation contains important California tax law changes, including reinstatement of business tax credits and net NOL deductions limited by AB 85 mentioned above. The new tax law should be accounted for under ASC 740 in the period of enactment (2022) but is not expected to have a material impact on our tax provision due to our taxable loss position.

Our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions include:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors, or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and

- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time.

A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of, and do not currently intend to opt out of, this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which restricts our stockholders' ability to bring a lawsuit against us or our directors, officers, or employees in jurisdictions other than Delaware and federal district courts.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for these types of disputes with us or our directors, officers, or other employees.

Our amended and restated certificate of incorporation also provides that the U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Item 1B. Unresolved Staff Comments.

None.

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 research, product development, marketing, finance, education, and administration functions. We believe our facilities are adequate and suitable for our current needs but in the future we may need additional space. 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 (lease expires in August 2027), Mannheim, Germany (lease can be terminated on six months notice), and Knaresborough, United Kingdom (lease expires in December 2025) to accommodate our European sales and marketing team.

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 22, 2022, we had 154 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.

Use of Proceeds from our Initial Public Offering of Common Stock

On October 16, 2018, our registration statement on Form S-1 (File No. 333-227445) relating to our initial public offering ("IPO") of common stock became effective. The IPO closed on October 16, 2018 at which time we issued 8,280,000 shares of our common stock at an initial offering price of $15.00 per share for gross proceeds of $124.2 million. We received net proceeds from the IPO of approximately $113.4 million, after deducting the underwriting discount of $8.7 million and other offering-related expenses of $2.1 million. None of the expenses associated with our IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 16, 2018. As of December 31, 2021, approximately $85.4 million of the net proceeds had been used for general corporate purposes including cash used in operations and capital expenditures.

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. We have pioneered a proprietary minimally invasive surgical implant system, which we call iFuse, to addresss sacroiliac joint dysfunction and degeneration, adult deformity, pelvic ring traumatic fractures. Since we introduced iFuse in 2009, as of December 31, 2021, approximately 65,000 procedures have been performed by over 2,600 surgeons, in the U.S. and 36 other countries.

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

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

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

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

In February 2021, we received clearance from the FDA for iFuse-TORQ, a 3D-printed portfolio of threaded implants designed to meet the needs of pelvic trauma and minimally invasive sacroiliac joint fusion applications. iFuse-TORQ is targeted to address an unmet clinical need for low energy pelvic ring fractures and chronic sacroiliac joint pain after high energy pelvic ring trauma. iFuse-TORQ also provides an opportunity for us to capture competitive screw business for minimally invasive sacroiliac joint fusions.

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

In October 2018, we completed our initial public offering ("IPO") resulting in net proceeds of $113.4 million after deducting underwriting discounts and commissions and offering expenses. In January and February 2020, we received a total of $63.0 million of net proceeds, after deducting the underwriting discounts, commissions and offering expenses, from our first follow-on public offering of our common stock. In October 2020, we received a total of $71.6 million of net proceeds from our second follow-on offering of our common stock.

Impact of COVID-19 Pandemic

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

Access to many hospitals and other customer sites continues to be impacted by prevalence of COVID-19, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and ambulatory surgery centers have in the past suspended and may continue to suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers reside. Quarantines, shelter-in-place, elective procedure moratoria and similar government orders have also impacted, and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain. Periodic resurgence of the COVID-19 pandemic negatively impacted our revenues at various periods throughout 2020 and 2021 as evidenced by case deferrals attributed to COVID-19.

We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. Essential staff in operations and limited support functions worked from our Santa Clara headquarters throughout the pandemic, following appropriate hygiene and social distancing protocols. To reduce risk to our employees and families from potential exposure to COVID-19, other staff in our Santa Clara headquarters worked from home. We also restricted non-essential travel to protect the health and safety of our employees and customers. Starting June 15, 2021, we began the return to work for many of our headquarter-based personnel based upon new guidelines from the State of California. In December 2021, amid the rising cases related to the Omicron variant, we again required non-essential staff to work remotely. We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate, and will take further actions that are considered prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products.

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

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

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

Factors Affecting Results of Operations and Key Performance Indicators

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

Leverage our sales force

We have made significant investments in our sales force since our initial public offering in 2018. We have built a valuable sales team, and we believe they are the key to expand the market and deliver revenue growth. We limited new sales force hiring in the second and third quarter of 2020 due to uncertainty from the COVID-19 pandemic and focused on sales force productivity during this period, but resumed hiring of salespeople in the fourth quarter of 2020 and into 2021.

As of December 31, 2021, our U.S. sales force consisted of 85 territory sales managers and 65 clinical support specialists directly employed by us and 59 third-party distributors, compared to 64 territory sales managers and 58 clinical support specialists directly employed by us and 41 third-party distributors as of December 31, 2020. As of December 31, 2021, our international sales force consisted of 20 sales representatives directly employed by us and 32 exclusive third-party distributors, compared to 20 sales representatives directly employed by us and 31 exclusive third-party distributors as of December 31, 2020.

Increase surgeon activity and training

Our medical affairs team works closely with our sales team to increase surgeon activity and training. Surgeon activity includes both the number of surgeons performing iFuse procedures as well as the number of procedures performed per surgeon. As of December 31, 2021 and 2020, in the U.S. more than 1,800 surgeon and 1,600 surgeons, respectively, have been trained on iFuse and have treated at least one patient. Outside the U.S., as of December 31, 2021 and 2020, more than 700 surgeons and 600 surgeons, respectively, have been trained on iFuse and have treated at least one patient. We will continue to pursue the remainder of the approximately 7,500 target surgeons in the U.S., as well as international surgeons for training in the future.

The COVID-19 pandemic has challenged our traditional method of hands-on cadaveric and dry-lab training. Therefore, in addition to utilizing a virtual education series for surgeons and mid-level practitioners for training activities, we began using the SI-BONE SImulator - a portable, radiation-free, haptics and computer-based simulator for training purposes. Starting in July 2020 we began deploying the SImulators to cover all US regions and European subsidiaries and had 24 SImulators in our offices and the field as of the date of this report.

Launch new products

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

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

Engage key opinion leaders

We conduct training courses in several academic centers in the U.S. and engage key opinion leaders to support our development efforts. Interest in the Bedrock technique among deformity surgeons, including many key opinion leaders, has provided our sales representatives with access to important academic medical centers in the U.S. This enables our representatives to train a broader group of spine surgeons, including residents and fellows at these centers, on both the Bedrock technique and minimally invasive sacroiliac fusion. To date, we have trained residents and fellows in over 160 academic programs in the U.S., resulting in the training of over 850 surgical residents and fellows since August 1, 2018.

Leverage broad coverage

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

As of December 31, 2021, substantially all U.S. payors reimburse for sacroiliac joint fusion. As of December 31, 2021, over 35 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.

Effective July 3, 2021, Centene established positive coverage for minimally invasive SI joint fusion. Centene is a major intermediary for both government-sponsored and privately insured health care programs and covers more than 25 million members. Anthem adopted coverage guidelines that are exclusive to triangular titanium implants for minimally invasive SI joint fusion which begin taking effect on July 30, 2021. Anthem is the second largest private payor in the U.S. with over 40 million members. Effective October 1, 2021, UnitedHealthcare has changed its minimally invasive SI joint fusion policy from covering all devices to covering exclusively our triangular titanium implants. UnitedHealthcare is the largest commercial payor in the U.S. with over 45 million members. With this updated policy, UnitedHealthcare joins more than 35 other health plans that collectively cover approximately 160 million insured, requiring the use of titanium triangular implants for minimally invasive SI joint fusion. We believe that the full impact of each coverage decision grows over time as surgeons gain confidence that they will receive reimbursement for the majority of their diagnosed patients. With recent payor decisions, over 300 million people in the U.S. now have access to minimally invasive SI joint fusion, representing nearly universal coverage of the procedure.

Components of Results of Operations

Revenue

We generate most of our revenue from sales of iFuse triangular titanium implants. Our revenue from sales of implants fluctuate based on volume of cases (procedures performed), discounts, mix of international and U.S. sales, and the number of implants used for a particular patient. Similar to other orthopedic companies, our case volume can vary from quarter to quarter due to a variety of factors including reimbursement, sales force changes, physician activities, seasonality, and the impact of COVID-19. In addition, our revenue is impacted by changes in average selling price as we respond to the competitive landscape and price differences at different medical facilities, such as hospitals and ambulatory surgical centers, or ASCs. Further, revenue results can differ based upon the mix of business between U.S. and international sales and mix of our products either delivered at the point of implantation at the hospital or other medical facilities or delivered through distributors or to hospitals where the products were ordered in advance of the procedure. Our revenue from international sales is impacted by fluctuations in foreign currency exchange rates between the U.S. dollar (our reporting currency) and the local currency.

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

Cost of Goods Sold, Gross Profit, and Gross Margin

We utilize third-party manufacturers for production of our implants and instrument sets. Cost of goods sold consists primarily of costs of the components of implants and instruments, instrument set depreciation, scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs. Our cost of goods sold has historically increased as case levels increase.

Our gross profit and gross margin are affected by factors impacting revenue and cost of goods sold. In addition, our gross margins are typically higher on products we sell directly as compared to products we sell through third-party distributors. As a result, changes in the mix of direct versus distributor sales can directly influence our gross margins.

Operating Expenses

Our operating expenses consist of sales and marketing, research and development, and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consist of salaries, sales commissions and other cash and stock-based compensation related expenses. During the second quarter of 2020, we took steps to reduce variable expenses that were ineffective and slowed down hiring due to the impact to our revenue from COVID-19. We returned to more normalized spending levels in the fourth quarter of 2020 and throughout 2021. We intend to make investments to execute our strategic plans and operational initiatives. We anticipate operating expenses will continue to increase to support our growth.

Sales and Marketing Expenses

Sales and marketing expenses primarily consist of salaries, stock-based compensation expense, and other compensation related costs, for personnel employed in sales, marketing, medical affairs, reimbursement and professional education departments. In addition, our sales and marketing expenses include commissions and bonuses, generally based on a percentage of sales, as well as certain commission guarantees paid to our senior sales management, direct territory sales managers, clinical support specialists and third-party distributors.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, clinical and regulatory expenses (including clinical study expenses), consulting services, outside prototyping services, outside research activities, materials, depreciation, and other costs associated with development of our products. Research and development expenses also include related personnel compensation and stock-based compensation expense. We expense research and development costs as they are incurred.

Research and development expenses for engineering projects fluctuate with project timing. Based upon our broader set of product development initiatives and the stage of the underlying projects, we expect to continue to make investments in research and development. As such, we anticipate that research and development expenses will continue to increase in the future.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, stock-based compensation expense, and other costs for finance, accounting, legal, insurance, compliance, and administrative matters.

Interest Income

Interest income is primarily related to our investments of excess cash in money market funds and marketable securities.

Interest Expense

Interest expense is primarily related to borrowings, amortization of debt issuance costs, accretion of final fees on the Solar and SVB Term Loan and the loss on extinguishment on the Pharmakon and Solar Term loan.

Other Income (Expense), Net

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

Results of Operations

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

	Year ended December 31, 2021		Year ended December 31, 2020	
	Amount	%	Amount	%
	(in thousands, except for percentages)			
Consolidated Statements of Operations Data:				
Revenue	$ 90,152	100 %	$ 73,387	100 %
Cost of goods sold	10,428	12 %	8,902	12 %
Gross profit	79,724	88 %	64,485	88 %
Operating expenses:				
Sales and marketing	93,884	104 %	73,790	101 %
Research and development	12,441	14 %	9,459	13 %
General and administrative	25,069	28 %	19,803	27 %
Total operating expenses	131,394	146 %	103,052	141 %
Loss from operations	(51,670)	(58)%	(38,567)	(53)%
Interest and other income (expense), net:				
Interest income	186	— %	1,097	1 %
Interest expense	(5,365)	(6)%	(6,101)	(8)%
Other income (expense), net	277	— %	(126)	— %
Net loss	$ (56,572)	(64)%	$ (43,697)	(60)%

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

	Year ended December 31, 2021		Year ended December 31, 2020	
	Amount	%	Amount	%
	(in thousands except for percentages)			
United States	$ 82,739	92 %	$ 68,118	93 %
International	7,413	8 %	5,269	7 %
	$ 90,152	100 %	$ 73,387	100 %

Comparison of the years ended December 31, 2021 and 2020

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

	Year Ended December 31,			
	2021	2020	$ Change	% Change
	(in thousands except for percentages)			
Revenue	$ 90,152	$ 73,387	$ 16,765	23 %
Cost of goods sold	10,428	8,902	1,526	17 %
Gross profit	$ 79,724	$ 64,485	$ 15,239	24 %
Gross margin	88 %	88 %		

Revenue. The increase in revenue for the year ended December 31, 2021 compared to the year ended December 31, 2020 comprised a $14.6 million increase in our U.S. revenue and an increase of $2.1 million in our international revenue. The increase in revenue is due to the increase in domestic and international case volumes, higher number of sales personnel as we continue to invest in our sales organization and increased active surgeons, which benefited from the use of our SImulator to train both new surgeons and re-engage inactive surgeons. This increase was partially offset by lower average selling prices in the U.S. Fiscal year 2021 continued to be impacted by deferral of elective surgeries due to COVID-19, but the impact was lower compared to the deferral of elective cases in fiscal year 2020.

Gross Profit and Gross Margin. Gross profit increased $15.2 million for the year ended December 31, 2021 compared to the year ended December 31, 2020 driven by higher revenue. Gross margin remained consistent at 88% for the year ended December 31, 2021 compared to the prior year mainly due to higher employee related costs of $0.8 million to support the growth of the business, partially offset by $0.8 million decrease in inventory write-downs due to the write-down of iFuse related inventory in 2020 resulting from the faster than anticipated adoption of iFuse-3D.

Operating Expenses:

	Year Ended December 31,			
	2021	2020	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 93,884	$ 73,790	$ 20,094	27 %
Research and development	12,441	9,459	2,982	32 %
General and administrative	25,069	19,803	5,266	27 %
Total operating expenses	$ 131,394	$ 103,052	$ 28,342	

Sales and Marketing Expenses. The increase in sales and marketing expenses for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was due to (a) increases in employee related costs, commissions and stock-based compensation of $11.2 million driven by increased headcount and higher revenues, (b) higher consulting fees of $1.1 million associated with more surgeon training programs and (c) as COVID-19 pandemic restrictions eased, we experienced higher levels of travel, marketing, training activities, facilities and other related costs resulting in an increase of $7.8 million.

Research and Development Expenses. The increase in research and development expenses for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was due to an increase of $1.6 million in employee related costs and stock-based compensation driven by increased headcount and an increase of $1.4 million due to consulting, clinical study and research and development activities driven by investments in our product roadmap and progress of our SILVIA clinical trial.

General and Administrative Expenses. The increase in general and administrative expenses for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was due to an increase of $3.4 million in employee related costs and stock-based compensation driven by increased headcount, and an increase of $1.9 million in consulting, accounting and audit fees primarily associated with SOX compliance requirements.

Interest and Other Income (Expense), Net:

	Year Ended December 31,			
	2021	2020	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 186	$ 1,097	$ (911)	(83)%
Interest expense	(5,365)	(6,101)	736	(12)%
Other income (expense), net	277	(126)	403	nm
Total interest and other income (expense), net	$ (4,902)	$ (5,130)	$ 228	(4)%

*not meaningful

Interest Income. The decrease in interest income for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was mainly due to lower interest earned on our investments in marketable securities, primarily as a result of lower interest rates.

Interest Expense. The decrease in interest expense for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was primarily due to $1.0 million of lower interest associated with the SVB Term Loan and Solar Term Loan in 2021 compared to the Pharmakon and Solar Term Loans in 2020, offset in part by the loss on extinguishment of the Solar Term Loan of $1.8 million in 2021 compared to the loss on extinguishment of the Pharmakon Term Loan of $1.5 million in 2020.

Other Income (Expense), Net. Other income, net increased for the year ended December 31, 2021 as compared to the year ended December 31, 2020 due to foreign currency fluctuations.

Liquidity and Capital Resources

As of December 31, 2021, we had cash and marketable securities of $147.0 million compared to $196.4 million as of December 31, 2020. We have financed our operations through our public offerings and debt financing arrangements. As of December 31, 2021 and 2020 we had $35.0 million and $39.5 million outstanding debt, respectively.

As of December 31, 2021, we had an accumulated deficit of $295.8 million. During the years ended December 31, 2021 and 2020, we incurred a net loss of $56.6 million and $43.7 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date.

Based upon our current operating plan, we believe that our existing cash and marketable securities will enable us to fund our operating expenses and capital expenditure requirements over the next 12 months and beyond. However, the economic impact of the duration and severity of the COVID-19 pandemic, and our responses thereto (including such actions we have taken or may take in the future as disclosed elsewhere in this Report) pose risks and uncertainties in our future available capital resources. Further, we may face challenges and uncertainties and, as a result, need to raise additional capital as our available capital resources may be consumed more rapidly than currently expected due to, but not limited to, the following as a result of the COVID-19 pandemic or otherwise: (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products; (e) changes we may make in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources.

Term Loan

The outstanding debt as of December 31, 2021 is related to a term loan pursuant to the Loan and Security Agreement dated August 12, 2021, entered into by us with Silicon Valley Bank ("SVB"). Pursuant the Loan and Security Agreement with SVB, SVB provided a term loan with an aggregate principal amount of $35.0 million to us. Prior to Loan and Security Agreement with SVB, our outstanding debt was related to a $40.0 million term loan (the "Solar Term Loan") with Solar Capital Partners ("Solar") entered into in May 2020. In accordance with the Loan and Security Agreement with SVB, we paid in full and terminated the Loan and Security Agreement with Solar, which we accounted for as debt extinguishment in accordance with the accounting standards. As of December 31, 2021 and 2020, there was no amount available that could be borrowed under the applicable credit facility. We paid in full the principal outstanding and final fee totaling of $41 million and terminated the Solar Term Loan in August 2021.

The SVB Term Loan matures (the "Maturity Date") on either (a) August 1, 2025 or (b) August 1, 2026 dependent on our achievement of a certain financial performance milestone as of December 31, 2022, as set forth in the Loan Agreement. Interest on the SVB Term Loan will be payable monthly at an annual rate set at the greater of (a) 5.75% and (b) prime rate as published in the Wall Street Journal plus 2.5%. Commencing on September 1, 2023, we will be required to make monthly principal amortization payments. We may elect to prepay the SVB Term Loan prior to the Maturity Date subject to a prepayment fee equal to 1% if the prepayment occurs prior to the second anniversary of the Effective Date and 0% if the prepayment occurs on or at any time after the second anniversary of the Effective Date. The SVB Term Loan is secured by substantially all our assets other than our intellectual property. We are also obligated to pay a final payment equal to $0.7 million or 2% of the aggregate principal amount of the SVB Term Loan, which was fully earned by SVB on the effective date of the Loan and Security Agreement with SVB. With respect to the SVB Term Loan, this final payment shall be due and payable on the earliest of (i) the maturity date, (ii) the full repayment of the loan, (iii) permitted prepayment and mandatory prepayment upon an acceleration as specified in the agreement or (iv) the termination of the agreement. The final payment was included within the long-term borrowings and is accreted to interest expense using straight-line method over the life of the term loan.

The 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. As of December 31, 2021, we were in compliance with all debt covenants. Though there are uncertainties surrounding the impact of the COVID-19 pandemic that may impact our future revenue, we believe that we have sufficient cash and cash equivalents to meet the minimum liquidity requirements in the foreseeable succeeding periods.

Our material cash requirements include various contractual and other obligations consisting of long-term debt obligations with SVB, operating lease obligations and purchase obligations with some of our suppliers. Expected timing of those payments are as follows:

		Payments Due By Period			
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
		(in thousands)			
Principal obligations and final fee on long-term debt (1)	$ 35,700	$ —	$ 24,792	$ 10,908	$ —
Interest obligations (2)	5,356	2,040	3,119	197	—
Operating leases	6,186	1,620	3,035	1,521	10
Purchase obligations	1,194	1,194	—	—	—
Total	$ 48,436	$ 4,854	$ 30,946	$ 12,626	$ 10

(1) Represents the principal obligations and the final fee at maturities of our SVB Term Loan.
(2) Represents the future interest obligations on our SVB Term Loan estimated using an interest rate of 5.75% as of December 31, 2021.

This compared to $59.2 million of contractual obligations as of December 31, 2020.

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,		
	2021	2020	$ Change
	(in thousands, except for percentages)		
Net cash provided by (used in):			
Operating activities	$ (39,533)	$ (30,662)	$ (8,871)
Investing activities	51,580	(62,916)	114,496
Financing activities	(1,711)	136,401	(138,112)
Effects of exchange rate changes on cash and cash equivalents	(498)	323	(821)
Net increase in cash and cash equivalents	$ 9,838	$ 43,146	$ (33,308)

Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 of $39.5 million resulted from cash outflows due to net loss of $56.6 million, adjusted for $22.8 million of non-cash items and cash outflows from changes in operating assets and liabilities of $5.7 million. Net cash used in operation activities for the year ended December 31, 2020 of $30.7 million resulted from cash outflows due to net loss of $43.7 million, adjusted for $15.6 million of non-cash items and cash outflows from changes in operating assets and liabilities of $2.5 million. The increase in net loss, net of non-cash items for the year ended December 31, 2021 compared to the year ended December 31, 2020 was mainly due to the higher operating expenses from the growth of the business. Net cash outflows from changes in operating assets and liabilities for year ended December 31, 2021 were primarily due to higher inventory build-up related to our iFuse-TORQ implants and timing of accounts receivable collections due to the increase in revenue in the fourth quarter of 2021, an increase in prepaid expenses due to higher prepaid insurance related to annual insurance premiums, and a decrease in accounts payable due to the timing of vendor payments, partially offset 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, 2020 were primarily due to timing of prepayments of certain expenses, higher accounts receivable due to the timing of collections, higher inventory due to the timing of inventory build-up, higher accounts payable due to timing of vendor payments, and a decrease in accrued liabilities and other due to timing of payments

Cash Provided by (Used In) Investing Activities

Net cash provided by investing activities in the year ended December 31, 2021 was $51.6 million compared to net cash used in investing activities of $62.9 million in the year ended December 31, 2020. Net cash provided by investing activities for the year ended December 31, 2021 consisted of maturities of our marketable securities, net of purchases of $58.0 million, partially offset by purchases of property and equipment of $6.4 million related to individual components in instrument to support increased case volumes and the launch of iFuse-TORQ, as well as capitalized costs related to the new lease in Santa Clara. Net cash used in investing activities for the year ended December 31, 2020 consisted of maturities of our marketable securities, net of purchases of $60.4 million, partially offset by purchases of property and equipment of $2.6 million for individual components in instrument sets.

Cash Provided by (Used In) Financing Activities

Cash used in financing activities in the year ended December 31, 2021 was $1.7 million and includes the paydown of our debt by $5.0 million and $1.6 million of other payments associated with refinancing of our debt, partially offset by proceeds from the issuance of common stock under our stock-based incentive compensation plans of $4.9 million. This compares to the cash provided by financing activities in the year ended December 31, 2020 of $136.4 million which consisted of proceeds, net of underwriting discounts, commissions and offering costs of $134.6 million from our follow-on public offerings in January and October 2020 and proceeds from the issuance of common stock under our stock-based incentive compensation plans of $3.4 million, partially offset by payments associated with refinancing of our debt of $1.6 million.

Critical Accounting Policies, Significant Judgments, and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with 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 adopted ASC Topic 606, Revenue from Contracts with Customers ("ASC 606") effective January 1, 2019. The adoption of ASC 606 did not have a material effect on our revenue recognition. We derive our revenue from the sale of our products to medical groups and hospitals through our direct sales force and distributors throughout the U.S. and Europe. 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 distributors 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 reduction to revenue, calculated based on the terms agreed to with the customer. Historically, there had been no significant price discounts. Sales prices are specified in either 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 distributors, which include standard terms that do not allow for payment contingent on resale of the product, obtaining financing, or other terms that could impact the distributor's payment obligation. 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 paid to our sales representatives commensurate for 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.

Off-Balance Sheet Arrangements

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

Seasonality

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

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, 2021, 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, 2022. 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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for 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, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2021.

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 $90.2 million for the year ended December 31, 2021, of which, $82.7 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 the 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, proof of implantation, and subsequent cash receipts, where applicable, for confirmations not returned, and (iv) testing the completeness and accuracy of data provided by management.

/s/PricewaterhouseCoopers LLP
San Jose, California
March 1, 2022

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, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 63,419	$ 53,581
Short-term investments	83,560	142,851
Accounts receivable, net of allowance for credit losses of $264 and $263, respectively	14,246	13,611
Inventory	11,498	5,633
Prepaid expenses and other current assets	3,143	2,565
Total current assets	175,866	218,241
Property and equipment, net	8,992	4,527
Operating lease right-of-use assets	5,248	—
Other non-current assets	400	374
TOTAL ASSETS	$ 190,506	$ 223,142
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,198	$ 3,271
Accrued liabilities and other	12,353	10,199
Operating lease liabilities, current portion	1,339	—
Total current liabilities	16,890	13,470
Long-term borrowings	34,973	39,455
Operating lease liabilities, net of current portion	4,166	—
Other long-term liabilities	57	854
TOTAL LIABILITIES	56,086	53,779
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; 33,674,085 and 32,583,220 shares issued and outstanding, respectively	3	3
Additional paid-in capital	429,914	408,113
Accumulated other comprehensive income	352	524
Accumulated deficit	(295,849)	(239,277)
TOTAL STOCKHOLDERS' EQUITY	134,420	169,363
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 190,506	$ 223,142

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,	
	2021	**2020**
Revenue	$ 90,152	$ 73,387
Cost of goods sold	10,428	8,902
Gross profit	79,724	64,485
Operating expenses:		
Sales and marketing	93,884	73,790
Research and development	12,441	9,459
General and administrative	25,069	19,803
Total operating expenses	131,394	103,052
Loss from operations	(51,670)	(38,567)
Interest and other income (expense), net:		
Interest income	186	1,097
Interest expense	(5,365)	(6,101)
Other income (expense), net	277	(126)
Net loss	(56,572)	(43,697)
Other comprehensive income (loss):		
Unrealized loss of marketable securities	(31)	(59)
Changes in foreign currency translation	(141)	119
Comprehensive loss	$ (56,744)	$ (43,637)
Net loss per share, basic and diluted	$ (1.71)	$ (1.50)
Weighted-average number of common shares used to compute basic and diluted net loss per share	33,145,930	29,059,171

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, 2019	**25,163,803**	**$ 3**	**$ 258,121**	**$ 464**	**$ (195,580)**	**$ 63,008**
Issuance of common stock from public offerings, net of underwriting discounts, commissions and offering costs	6,613,560	—	134,616	—	—	134,616
Issuance of common stock upon exercise of stock options, net of shares withheld	323,701	—	1,463	—	—	1,463
Issuance of common stock related to employee stock purchase plan	137,377	—	1,915	—	—	1,915
Issuance of common stock upon vesting of restricted stock units	344,779	—	—	—	—	—
Stock-based compensation	—	—	11,927	—	—	11,927
Vesting of early exercised stock options	—	—	71	—	—	71
Foreign currency translation	—	—	—	119	—	119
Net unrealized loss on marketable securities	—	—	—	(59)	—	(59)
Net loss	—	—	—	—	(43,697)	(43,697)
Balances as of December 31, 2020	**32,583,220**	**3**	**408,113**	**524**	**(239,277)**	**169,363**
Issuance of common stock upon exercise of stock options, net of shares withheld	369,375	—	2,565	—	—	2,565
Issuance of common stock related to employee stock purchase plan	147,295	—	2,343	—	—	2,343
Issuance of common stock upon vesting of restricted stock units	574,195	—	—	—	—	—
Stock-based compensation	—	—	16,866	—	—	16,866
Vesting of early exercised stock options	—	—	27	—	—	27
Foreign currency translation	—	—		(141)		(141)
Net unrealized loss on marketable securities	—	—	—	(31)	—	(31)
Net loss	—	—	—	—	(56,572)	(56,572)
Balances as of December 31, 2021	**33,674,085**	**$ 3**	**$ 429,914**	**$ 352**	**$ (295,849)**	**$ 134,420**

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,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (56,572)	$ (43,697)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	16,866	11,927
Depreciation and amortization	2,086	1,130
Bad debt expense	14	234
Accretion of discount on marketable securities	1,294	115
Realized gain on marketable securities	—	(46)
Amortization of debt issuance costs	288	292
Loss on extinguishment of debt	1,848	1,534
Loss on sale and disposal of property and equipment	399	376
Changes in operating assets and liabilities		
Accounts receivable	(569)	(2,186)
Inventory	(5,784)	(274)
Prepaid expenses and other assets	(594)	(136)
Accounts payable	(532)	835
Accrued liabilities and other	1,723	(766)
Net cash used in operating activities	(39,533)	(30,662)
Cash flows from investing activities		
Maturities of marketable securities	159,990	104,716
Sales of marketable securities	—	14,095
Purchases of marketable securities	(102,021)	(179,166)
Purchases of property and equipment	(6,389)	(2,561)
Net cash (used in) provided by investing activities	51,580	(62,916)
Cash flows from financing activities		
Proceeds from follow-on public offering, net of underwriting discounts, commissions and offering costs	—	134,616
Proceeds from debt financing	35,000	45,297
Repayments of debt financing	(41,000)	(45,297)
Payments of debt issuance costs	(111)	(750)
Payments of prepayment penalty and lender fees	(508)	(843)
Proceeds from the exercise of common stock options	2,565	1,463
Proceeds from issuance of common stock under employee stock purchase plan	2,343	1,915
Net cash (used in) provided by financing activities	(1,711)	136,401
Effect of exchange rate changes on cash and cash equivalents	(498)	323
Net increase in cash and cash equivalents	9,838	43,146
Cash and cash equivalents at		
Beginning of year	53,581	10,435
End of year	$ 63,419	$ 53,581
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,230	$ 4,276
Supplemental disclosure of non-cash information		
Vesting of early exercised stock options	27	71
Unpaid purchases of property and equipment	509	26

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 U.S., in 2010 in certain countries in the European Union, and in 2015 in certain countries in the rest of the world.

In the first quarter of 2020, the Company received $63.0 million of net proceeds from its first follow-on public offering of 4,300,000 shares of the Company's common stock, of which 2,490,053 shares were offered and sold by the Company, and the exercise of underwriter's option to purchase from the Company an additional 645,000 shares of the Company's common stock, at a public offering price of $21.50 per share. The total public offering costs incurred in connection with the follow-on offering were allocated based on the gross proceeds received by the Company and the selling stockholders on a pro-rated basis. Public offering cost of $0.4 million allocated to selling of shares by the Company was charged against the gross proceeds received from the follow-on offering. Public offering costs of $0.2 million allocated to selling of shares by the selling stockholders was recognized as transaction costs within general and administrative expenses on the consolidated statements of operations in the year ended December 31, 2020.

In October 2020, the Company received $71.6 million of net proceeds from its second follow-on public offering of shares of the Company's common stock, of which 3,000,000 shares were offered and sold by the Company, and the exercise of underwriter's option to purchase from the Company an additional 478,507 shares of the Company's common stock, at a public offering price of $22.00 per share. In addition to the shares sold by the Company in this second follow-on offering, the selling stockholder sold 190,053 shares of the Company's common stock previously held by the selling stockholder at a price to the public of $22.00 per share. The Company did not receive any proceeds from the sale by the selling stockholder.

Risks and Uncertainties

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

Segments

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

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

	Year Ended December 31,	
	2021	2020
	(in thousands)	
United States	$ 82,739	$ 68,118
International	7,413	5,269
	$ 90,152	$ 73,387

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 U.S. and in Europe. The majority of the Company's cash and marketable securities are deposited with a single financial institution in the U.S. 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 U.S., 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, corporate bonds and commercial paper. All of the Company's marketable securities are available-for-sale 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. For the years ended December 31, 2021 and 2020, the allowance for credit losses activity was not significant.

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

	Year ended December 31,	
	2021	2020
	(in thousands)	
Balance at beginning of year	$ 263	$ 238
Provision	14	234
Write-offs	(13)	(209)
Balance at end of year	$ 264	$ 263

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
Machinery and equipment	3 – 5 years
Furniture and fixtures	7 years

Leasehold improvements are amortized over the lesser of their useful lives or the life of the lease. Upon sale or retirement of the 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. Through December 31, 2021 and 2020, 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 U.S. ("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 distributors throughout the U.S. and Europe.

The Company adopted the revenue standard in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606") effective for the fiscal year ended December 31, 2019. Revenue is recognized when control is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for the goods or services. Under the revenue recognition standard, the Company applies the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied. As it relates to product sales where the Company's sales representative delivers the product at the point of implantation at the hospital or medical facilities, the Company continues to recognize the revenue upon completion of the procedure and authorization by the customer, net of rebates and price discounts. This represents the majority of the Company's consolidated revenue. The Company also generates a small portion of revenue from the sale of products through distributors and to certain hospital or medical facilities where the products are ordered in advance of a procedure. The performance obligation is the delivery of the products and therefore, revenue is recognized upon shipment to the customers, net of rebates and price discounts. The Company accounts for rebates and price discounts as a reduction to revenue, calculated based on the terms agreed to with the customer. Historically, there had been no significant price discounts. Sales prices are specified in either the customer contract or agreed price list, which is executed prior to the transfer of control to the customer. For certain hospitals and medical facilities, the Company has agreements in place consists of either a master services agreement or an agreed price list, which defines the terms and conditions of the arrangement, including the pricing information, payment terms and pertinent aspects of the relationship between the parties. The Company also has agreements in place with its distributors, which include standard terms that do not allow for payment contingent on resale of the product, obtaining financing, or other terms that could impact the distributor's payment obligation. The Company's standard payment terms are generally net 30 to 90 days.

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 commission 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, 2021 and 2020.

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 non-cash 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 $1.2 million and $0.3 million for the year ended December 31, 2021 and 2020, 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 since the Company has no sufficient historical exercise patterns to estimate the expected life. 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.

Prior to the Company's initial public offering (“IPO”), the fair value of the shares of the Company's common stock has historically been determined by its Board of Directors since there were no public market information available for the Company's common stock. The estimated fair value of the Company's common stock was determined at each valuation date in accordance with the guidelines outlined in the *American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Subsequent to its IPO, the Company uses the market closing price for its common stock as reported on the Nasdaq Global Market on the date of grant.

Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustments as the underlying equity instruments vest. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services received. Stock-based compensation related to stock options granted to non-employees is recognized as the stock options are earned.

In the event the underlying terms of stock options 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

The Company calculates basic and diluted net loss per common share attributable to shareholders in conformity with the two-class method required for companies with participating securities. The Company considers all early exercised stock options to be participating securities as the holders are entitled to receive dividends on a pari passu basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stock is not allocated to the early exercised stock options as the holders do not have a contractual obligation to share in losses.

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 and warrants are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, common stock options 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 all 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 Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842), which requires that lessee's recognize a right-of-use asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. In July 2018, the FASB issued ASU 2018-10 and ASU 2018-11, which provides clarification on the narrow aspects of the guidance and provide an additional transition method to adopt the new leases standard. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. The new leases standard must be adopted using a modified retrospective transition method and allows for the application of the new guidance at the beginning of the earliest comparative period presented or at the adoption date. In November 2019, the FASB issued ASU 2019-10, which revised the mandatory effective dates of the new leases standard. Further, due to the impact of the COVID-19, in June 2020, the FASB issued ASU 2020-05 to further defer the effective date for one year for entities in the "all other" categories.

In the fourth quarter of 2021, the Company adopted Topic 842 for leases, using the modified retrospective method, applying Topic 842 to all leases existing at the date of initial application. The Company elected to use the effective date of January 1, 2021 as the date of initial application. Under the modified retrospective method, balances and disclosures prior to January 1, 2021 have not been restated. The Company elected certain practical expedients, which among other things, allowed the Company to carry forward prior conclusions about lease identification and classification. The adoption of ASC 842 had a material impact on the consolidated balance sheet as the standard requires the Company to measure and recognize a right of use asset and lease liability. The Company recognized $3.8 million of operating lease liabilities and approximately $3.5 million of operating lease right-of-use assets on the consolidated balance sheet as of January 1, 2021. The difference between the operating lease right-of-use assets and operating lease liabilities represented the existing deferred rent liability balance as of the adoption date of $0.3 million. The adoption of the standard did not have a material impact on the consolidated statement of operations and comprehensive loss and there was no impact to cash from or used in operating, financing or investing activities on the consolidated statement of cash flows. The adoption of ASC Topic 842 had no income tax impact to the financial statements. The Company accounted for the basis differences arising from ASC Topic 842 adoption in deferred taxes which was offset by a valuation allowance.

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). FASB issued ASU 2019-05 in May 2019, ASU 2019-08 and ASU 2019-11 in November 2019 for codification improvements of Topic 326. In November 2019, the FASB issued ASU 2019-10, which defers the effective date of ASU 2016-13 for public companies that are eligible to be smaller reporting companies and all other companies, to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. In February 2020, the FASB issued ASU 2020-02, which provides guidance regarding methodologies, documentation, and internal controls related to expected credit losses. ASU 2016-13 revises the existing incurred loss impairment model with a forward-looking expected credit loss model which will result in earlier recognition of credit losses for certain financial instruments and financial assets. For trade receivables, the Company is required to estimate lifetime expected credit losses. For available-for-sale debt securities, the Company will recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. ASU 2016-13 is effective for the Company’s fiscal year beginning January 1, 2021 on a modified retrospective basis. The Company adopted this standard effective for the year ended December 31, 2021, and the adoption did not have a material impact on the Company’s consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. ASU 2019-12 simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, the methodology for calculating incomes taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 is effective in 2021 and interim periods within that year and permits for an early adoption. The Company adopted ASU 2019-12 effective January 1, 2021. The adoption of the guidance did not have a material impact on its financials statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

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

3. Marketable Securities

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

The table below summarizes the marketable securities:

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

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 45,948	$ —	$ —	$ 45,948
Commercial paper	1,400	—	—	1,400
Cash equivalents	47,348	—	—	47,348
U.S. treasury securities	74,779	4	(7)	74,776
Corporate bonds	8,940	4	(6)	8,938
Commercial paper	59,137	—	—	59,137
Short-term investments	142,856	8	(13)	142,851
Total marketable securities	$ 190,204	$ 8	$ (13)	$ 190,199

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, 2021 and 2020, 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 year ended December 31, 2021 and 2020.

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 $0.3 million as of December 31, 2021, 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 twelve months ended December 31, 2021 and 2020.

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

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 45,948	$ —	$ —	$ 45,948
U.S. treasury securities	74,776	—	—	74,776
Corporate bonds	—	8,938	—	8,938
Commercial paper	—	60,537	—	60,537
Total marketable securities	$ 120,724	$ 69,475	$ —	$ 190,199

5. Balance Sheet Components

Inventory

As of December 31, 2021 and 2020, inventory consisted entirely of finished goods.

Property and Equipment, net:

	December 31, 2021	December 31, 2020
	(in thousands)	
Machinery and equipment	$ 10,573	$ 6,342
Construction in progress	3,657	1,692
Computer and office equipment	916	714
Leasehold improvements	503	503
Furniture and fixtures	309	233
	15,958	9,484
Less: Accumulated depreciation and amortization	(6,966)	(4,957)
	$ 8,992	$ 4,527

As of December 31, 2021, 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 $3.3 million and construction costs related to the lease in Santa Clara of $0.4 million. Depreciation expense was $2.1 million and $1.1 million for the years ended December 31, 2021 and 2020, respectively.

Accrued Liabilities and Other:

	December 31, 2021	December 31, 2020
	(in thousands)	
Accrued compensation and related expenses	$ 10,055	$ 9,175
Accrued professional services	995	511
Others	1,303	513
	$ 12,353	$ 10,199

6. Commitments and Contingencies

Operating Leases

The Company has a non-cancelable operating lease for an office building space, located in Santa Clara, California which expires in May 2025. The Company also has non-cancelable operating leases for its office building spaces in Gallarate, Italy and Knaresborough, United Kingdom, which expire in August 2027 and December 2025, respectively.

Effective April 30, 2021, the Company terminated its office lease in Mannheim, Germany, and commenced a new lease that can be terminated at any time with six months written notice to the landlord. Further, the Company also leases vehicles under operating lease arrangements for certain of its personnel in Europe which expire at various times throughout 2022 to 2027.

In August 2021, the Company signed a new lease for 19,534 square feet of research and development and warehouse space in Santa Clara, California. The term of the new lease commenced on November 1, 2021 and will terminate on October 31, 2026, with an option to renew for one additional three year term.

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

	December 31, 2021
	(in thousands)
Operating lease expense	$ 1,181
Variable lease expense	266
Total lease expense	$ 1,447
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,225
Leased assets obtained in exchange for new operating lease liabilities	$ 2,896
Weighted average remaining lease term (in years)	3.98
Weighted average discount rate	5.75%

Future minimum lease payments under non-cancelable operating leases as of December 31, 2021 was as follows:

Year Ending December 31,		(in thousands)
2022	$	1,620
2023		1,544
2024		1,491
2025		990
2026		531
Thereafter		10
Total operating lease payments	$	6,186
Less: imputed interest		(681)
Total operating lease liabilities	$	5,505

As of December 31, 2021, the Company had no operating lease liabilities that had not commenced.

As required, the following disclosure is provided for periods prior to adoption of Topic 842. Minimum lease commitments as of December 31, 2020 that had initial or remaining lease terms in excess of one year were as follows:

Year Ending December 31,		(in thousands)
2021	$	1,081
2022		1,001
2023		908
2024		893
2025		381
Thereafter		24
	$	4,288

Rent expense charged to operations under operating leases totaled approximately $1.2 million for the year ended December 31, 2020.

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 $1.2 million and $0.3 million as of December 31, 2021 and 2020, 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, 2021	December 31, 2020
	(in thousands)	
Principal outstanding and final fee	$ 35,700	$ 41,000
Less: Unamortized debt issuance costs	(100)	(661)
Unaccreted value of final fee	(627)	(884)
Outstanding debt, net of debt issuance costs and unaccreted value of final fee	$ 34,973	$ 39,455
Classified as:		
Long-term borrowings	$ 34,973	$ 39,455

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

The outstanding debt as of December 31, 2020 is related to a term loan pursuant to the Loan and Security Agreement dated May 29, 2020, entered into by the Company with Solar Capital Partners (“Solar”). Pursuant to the Loan and Security Agreement, Solar provided an aggregate principal amount of $40.0 million term loan (the “Solar Term Loan”). The total debt issuance costs of $0.8 million associated with the Solar Term Loan were recorded in the condensed consolidated balance sheet as a direct deduction from the carrying amount of the loan, and are amortized as a component of interest expense using straight-line method over the life of the term loan. In accordance with the Loan and Security Agreement with Solar, the Company paid in full and terminated the Pharmakon Term Loan, which was accounted for as debt extinguishment in accordance with the accounting standards. The Company recognized the unamortized debt issuance costs of $0.7 million and the prepayment penalty and lender fees of $0.8 million related to Pharmakon Term Loan as a loss on debt extinguishment. The costs and fees are reflected as interest expense in the consolidated statement of operations for the year ended December 31, 2020. The Solar Term Loan bore interest at a rate per annum equal to 9.40% plus London Interbank Offered Rate (“LIBOR”), payable monthly in arrears. LIBOR means the greater of (i) 0.33% or (ii) one-month LIBOR (or a comparable replacement rate to be determined by the collateral agent if the LIBOR is no longer available), which rate shall reset monthly. The Solar Term Loan included an interest-only period of 36 months through June 2023, and then repaid in equal monthly principal payments plus interest through June 1, 2025. Pursuant to the Loan and Security Agreement with Solar, the Company could voluntarily prepay the Solar Term Loan, in full or in part, but only in increments of $10.0 million, for a prepayment premium in an amount equal to 3.0% of the principal if prepaid in year one, 1.25% of the principal if prepaid in year two, and 0.50% of the principal if prepaid in year three or later. The Solar Term Loan was secured by substantially all of the Company’s assets.-The Company was also obligated to pay a final fee equal to $1.0 million or 2.5% of the aggregate principal amount of the Solar Term Loan, which was fully earned by Solar on the effective date of the Loan and Security Agreement with Solar. With respect to the Solar Term Loan, this final fee shall be due and payable on the earliest of (i) the maturity date, (ii) the acceleration of the loan balance or (iii) its full prepayment, refinancing, substitution or replacement. The final fee was included within the long-term borrowings and was accreted to interest expense using straight-line method over the life of the term loan. The Company paid in full and terminated the Solar Term Loan in August 2021.

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

and nine months ended December 31, 2021. The total debt issuance costs of $0.1 million associated with the SVB Term Loan were recorded in the condensed consolidated balance sheet as a direct deduction from the carrying amount of the loan, and are amortized as a component of interest expense using straight-line method over the life of the term loan. The SVB Term Loan matures (the "Maturity Date") on either (a) August 1, 2025 or (b) August 1, 2026 dependent on the Company's achievement of a certain financial performance milestone as of December 31, 2022, as set forth in the Loan Agreement. Interest on the SVB Term Loan is payable monthly at an annual rate set at the greater of (a) 5.75% and (b) prime rate as published in the Wall Street Journal plus 2.5%. Commencing on September 1, 2023, the Company will be required to make monthly principal amortization payments. The Company may elect to prepay the SVB Term Loan prior to the Maturity Date subject to a prepayment fee equal to 1% if the prepayment occurs prior to the second anniversary of the Effective Date and —% if the prepayment occurs on or at any time after the second anniversary of the Effective Date. The SVB Term Loan is secured by substantially all the Company's assets other than the Company's intellectual property. The Company is also obligated to pay a final payment equal to $0.7 million or 2% of the aggregate principal amount of the SVB Term Loan, which is considered fully earned by SVB on the effective date of the Loan and Security Agreement with SVB. This final payment shall be due and payable on the earliest of (i) the maturity date, (ii) the full repayment of the loan, (iii) permitted prepayment and mandatory prepayment upon an acceleration as specified in the agreement or (iv) the termination of the agreement. The final payment is included within the long-term borrowings and is accreted to interest expense using straight-line method over the life of the term loan.

The effective interest rate related to the SVB Term Loan and Solar Term Loan (excluding the write-down of unamortized debt issuance costs and prepayment penalty related to the Solar Term Loan) was 6.3% and 10.3%, respectively, for the year ended December 31, 2021. The effective interest rate related to the Pharmakon Term Loan and Solar Term Loan were 12.4% and 10.6%, respectively, for the year ended December 31, 2020.

The table below summarizes the future principal and final fee payments under the SVB Term Loan as of December 31, 2021:

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

The Loan Agreement includes affirmative and negative covenants applicable to the Company and certain of its foreign subsidiaries. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental compliance, deliver certain financial reports, and maintain insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging the Company's intellectual property to other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions. As of December 31, 2021, the Company was in compliance with all debt covenants.

CARES Act

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

The CARES Act also allowed employers to defer the deposit and payment of an employer's share of social security taxes through December 31, 2020. As of December 31, 2021, the Company recorded a liability of $0.5 million related to the deferral of the social security taxes that is included in accrued liabilities in the consolidated balance sheet. As of December 31, 2020, the Company recorded a total liability of $1.0 million related to the deferral of the social security taxes of which $0.5 million is included in each accrued liabilities and other and other long-term liabilities in the consolidated balance sheet.

8. Warrants

The table below summarizes common stock warrants issued and outstanding at December 31, 2021 and 2020:

Date			Number of Shares Underlying Warrants	Price per Share	Fair Value (in thousands)	
Issuance	Expiration					
3/1/2017	3/1/2027	[a]	1,388	$5.94	$ 5	[b]
7/22/2013	7/22/2023	[a]	32,983	$9.10	122	[b]
11/26/2014	11/26/2024	[a]	6,680	$16.47	49	[b]
10/20/2015	10/20/2025	[a]	41,650	$16.47	396	[c]
11/9/2015	11/9/2025	[a]	25,709	$16.47	244	[c]
12/22/2016	12/22/2026	[a]	9,712	$10.03	45	[c]
			118,122		$ 861	

[a] Common stock warrants will remain outstanding until the earlier of the expiration date or the date exercised by the holder.

[b] Fair value at the date of issuance.

[c] Fair value at the date of conversion from redeemable convertible preferred stock to common stock warrants in conjunction with the IPO on October 16, 2018.

9. Common and Preferred Stock

The Company's certificate of incorporate 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, 2021 and 2020 were 33,674,085 shares and 32,583,220 shares, respectively. As of December 31, 2021 and 2020, 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 and RSUs 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, 2021, a total of 3,520,102 shares of common stock are available for future grants under the 2018 EIP. On January 1, 2022, the total number of shares of common stock reserved for issuance under the 2018 EIP automatically increased by 1,683,704 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. Certain stock options are exercisable immediately, but are subject to a right of repurchase by the Company for any unvested shares. 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, 2021 and 2020:

	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, 2019	2,718,971	$8.02		
Granted	26,236	$17.31		
Exercised	(323,701)	$4.52		
Canceled and forfeited	(15,549)	$17.07		
Outstanding as of December 31, 2020	2,405,957	$8.54		
Exercised	(369,375)	$6.94		
Canceled and forfeited	(27,069)	$15.85		
Outstanding as of December 31, 2021	2,009,513	$8.73	4.90	$ 27,089
Options vested and exercisable as of December 31, 2021	1,870,352	$7.81	4.73	$ 26,933
Options vested and expected to vest as of December 31, 2021	2,031,988	$8.61	5.12	$ 27,633

The aggregate intrinsic value of options exercised during the years ended December 31, 2021 and 2020 amounted to $8.1 million and $5.6 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, 2021 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, 2021 was as follows:

	Options Outstanding			Options Vested and Exercisable	
Exercise Price	Number of Shares	Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
$2.11 - $3.69	405,476	2.45	$3.36	405,476	$3.36
$3.70 - $4.41	517,272	3.98	$4.30	517,272	$4.30
$4.42 - $5.31	423,154	5.36	$4.67	421,812	$4.67
$5.32 - $20.51	254,817	6.44	$11.71	235,053	$11.29
$20.52 - $22.00	408,794	7.04	$22.00	290,739	$22.00
	2,009,513	4.90	$8.73	1,870,352	$7.81

There were no stock options granted during the year ended December 31, 2021. The table below summarizes the weighted average grant date fair value per share and the assumptions used to estimate the grant date fair value using the Black-Scholes option-pricing model of the stock options granted during the periods presented:

	Year ended December 31,		
	2020		
Weighted average grant date fair value per share	$8.16		
Expected term (years)	5.5	to	7
Expected volatility	46.7%	to	47.2%
Risk-free interest rate	1.6%	to	1.6%
Dividend yield	—%		

As of December 31, 2021, there was $1.4 million of unrecognized compensation cost related to stock options granted. These costs are expected to be recognized over a period of approximately 1.0 years.

Early Exercise of Unvested Stock Options

Early exercises of stock options under the Company's 2008 SOP are subject to a right of repurchase by the Company of any unvested shares. The repurchase rights lapse over the original vesting period of the options. The Company accounts for the cash received in consideration for the early exercised options as a liability included in accrued liabilities, which is then reclassified to stockholders' equity as the options vest. As of December 31, 2021, the Company had no shares subject to repurchase. As of December 31, 2020, the Company had a total 5,836 shares of common stock subject to repurchase under the 2008 SOP.

Restricted Stock Units

The following table summarizes restricted stock units activity for the years ended December 31, 2021 and 2020:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2019	543,041	$19.72
Granted	1,016,432	$20.17
Vested	(344,779)	$19.87
Canceled and forfeited	(49,399)	$19.73
Outstanding as of December 31, 2020	1,165,295	$20.07
Granted	1,187,143	$28.46
Vested	(574,195)	$21.76
Canceled and forfeited	(211,721)	$24.76
Outstanding as of December 31, 2021	1,566,522	$25.17

As of December 31, 2021, there was a total unrecognized compensation cost of $32.6 million. These costs are expected to be recognized over a period of approximately 2.7 years.

Employee Stock Purchase Plan

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

As of December 31, 2021, a total of 884,155 shares of common stock are available for future grants under the 2018 EIP. On January 1, 2022, the total number of shares of common stock reserved for issuance under the ESPP Plan increased by 336,741 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 147,295 shares and 137,377 shares under the ESPP during the years ended December 31, 2021 and 2020, respectively, representing approximately $2.3 million and $1.9 million in employee contributions. As of December 31, 2021 and 2020, total accumulated ESPP related employee payroll deductions amounted to $0.3 million and $0.4 million, respectively, which were included within accrued compensation and related expenses in the consolidated balance sheets. For the years ended December 31, 2021 and 2020, the Company recognized $0.8 million and $1.2 million, respectively, of stock-based compensation expense related to ESPP. As of December 31, 2021, the unrecognized compensation cost for the ESPP was $0.3 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,					
	2021			2020		
Expected term (years)	0.5			0.5	to	1.0
Expected volatility	48.8%	to	49.5%	38.3%	to	79.4%
Risk-free interest rate	0.04%	to	0.07%	0.10%	to	1.60%
Dividend yield	—%			—%		

Stock-Based Compensation

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

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Cost of goods sold	$ 530	$ 331
Sales and marketing	8,448	5,527
Research and development	1,710	1,139
General and administrative	6,178	4,930
	$ 16,866	$ 11,927

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. For the years ended December 31, 2021 and 2020, the Company made $0.2 million contributions to the 401(k) plan.

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,	
	2021	2020
	(in thousands, except share and per share data)	
Net loss	$ (56,572)	$ (43,697)
Weighted-average shares used to compute basic and diluted net loss per share	33,145,930	29,059,171
Net loss per share, basic and diluted	$ (1.71)	$ (1.50)

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

	Year Ended December 31,	
	2021	2020
Stock options	2,009,513	2,405,957
Restricted stock units	1,566,522	1,165,295
Shares subject to repurchase	—	5,836
ESPP purchase rights	61,264	83,040
Common stock warrants	118,122	118,122
	3,755,421	3,778,250

13. Income Taxes

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

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Domestic	$ (57,035)	$ (41,708)
Foreign	463	(1,989)
Loss before income taxes	$ (56,572)	$ (43,697)

There was no provision for income taxes recorded for the years ended December 31, 2021 and 2020. 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,	
	2021	2020
	(in thousands)	
Federal	$ 12,994	$ 9,855
State	1,878	2,711
Foreign	461	583
Total deferred income taxes	15,333	13,149
Change in deferred tax valuation allowance	(15,333)	(13,149)
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,	
	2021	2020
Tax at statutory federal rate	(21.0)%	(21.0)%
State tax, net of federal benefit	(3.3)%	(6.2)%
Tax credits	(0.8)%	(0.7)%
Change in deferred tax valuation allowance	27.1 %	30.1 %
Stock compensation	(1.7)%	(1.2)%
Foreign rate differences	0.1 %	(1.3)%
Other	(0.4)%	0.3 %
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,	
	2021	2020
	(in thousands)	
Net operating loss carryforwards	$ 66,015	$ 52,331
Research and development credits	3,837	3,160
Accruals and reserves	1,994	2,669
Interest limitation	3,995	2,781
Stock compensation	2,728	2,395
Depreciation and amortization	152	117
Operating lease liabilities	1,376	—
Total deferred tax assets	80,097	63,453
Operating lease right-of-use assets	(1,311)	—
Total deferred tax liabilities	(1,311)	—
Less: Valuation allowance	(78,786)	(63,453)
Total deferred tax asset, net of valuation allowance	$ —	$ —

The following table summarizes changes in the valuation allowance for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Beginning balance	$ 63,453	$ 50,304
Net changes during the period	15,333	13,149
Ending balance	$ 78,786	$ 63,453

As of December 31, 2021, the Company had net operating loss ("NOL") carryforwards of approximately $255.5 million and $203.2 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 2029, and the state NOL carryforward began to expire in 2021.

As of December 31, 2021, the Company had credit carryforwards of approximately $3.2 million and $2.9 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 equity shift between December 31, 2020 to December 31, 2021 was not material, considering the changes in the outstanding number of shares during the period. The Company reasonably believes no additional ownership change occurred in the current year. The Company will continually assess the need to update its Section 382 ownership change analysis, as the Company may experience ownership changes in the future that could materially limit its ability to use its NOL carryforwards.

The CARES Act includes provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company deferred the payment of an employer's share of social security taxes through December 31, 2021 of $0.5 million.

On June 29, 2020, Governor Gavin Newsom signed California Assembly Bill 85 (AB 85) into law. The legislation suspends the California net operating loss deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation of certain California Tax Credits for 2020, 2021, and 2022. The legislation disallows the use of California net operating loss deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $1.0 million. The carryover periods for net operating loss deductions disallowed by this provision will be extended. Additionally, any business credit will only offset a maximum of $5.0 million of California tax. The Company will continue to monitor the possible California net operating loss and credit limitations in future periods.

On February 9, 2022, Governor Gavin Newsom signed California Senate Bill 113 (SB 113) into law. The legislation contains important California tax law changes, including reinstatement of business tax credits and net NOL deductions limited by AB 85 mentioned above. The new tax law should be accounted for under ASC 740 in the period of enactment (2022) but is not expected to have a material impact on the Company's tax provision due to its taxable loss position.

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, 2021 and 2020 consisted of the following:

	Year ended December 31,	
	2021	2020
	(in thousands)	
Balance at beginning of the year	$ 1,513	$ 1,287
Increases related to tax positions taken prior to current year	817	—
Increases related to current year's tax positions	325	226
Balance at end of the year	$ 2,655	$ 1,513

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, 2021 and 2020. None of the Company's unrecognized tax benefits that, if recognized, would affect its effective tax rates for the years ended December 31, 2021 and 2020. 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") to develop a next generation device for sacropelvic fixation. Mr. Keith Valentine, who serves as the President, Chief Executive Officer and a member of the board of directors of SeaSpine, also serves as a member of the Company's Board of Directors since August 2015. On April 27, 2021, Addendum No.1 to the Development Agreement was entered into by and between the Company and SeaSpine to extend certain obligations as described under the Development Agreement to a consultant of the Company.

Pursuant to the development plan, SeaSpine shall use reasonable efforts to assist in the development of the potential product offering, including licensing certain existing intellectual property to be incorporated into such product. Under the terms of the Development Agreement, the Company agreed to make monthly payments to SeaSpine to reimburse for full time resources employed by SeaSpine responsible to conduct the development activities. For the years ended December 31, 2021 and 2020, the Company expensed $29,000 and $118,000, respectively, of the reimbursement charges from SeaSpine. The reimbursement charges were recorded within research and development expense in the consolidated statement of operations. There was no outstanding liabilities to SeaSpine as of December 31, 2021.

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.

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, 2021, 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, 2021, 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, 2021 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, 2021 based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2021 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 2022 Annual Meeting of Stockholders, or the 2022 Proxy Statement, which will be filed not later than 120 days after the end of our fiscal year ended December 31, 2021, 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 2022 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 2022 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 2022 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 2022 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	Amended and Restated Bylaws.	S-1/A	333-227445	3.4	10/5/2018
4.1	Form of Common Stock Certificate of the Company.	S-1/A	333-227445	4.1	10/5/2018
4.2	Reference is made to Exhibits 3.1 and 3.2.				
4.3	Description of SI-BONE, Inc. Common Stock	10-Q	001-38701	4.3	5/5/2020
10.1+	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.	S-1/A	333-227445	10.5	10/5/2018
10.6+	2018 Employee Stock Purchase Plan.	S-1/A	333-227445	10.6	10/5/2018
10.7#	Manufacturing, Quality and Supply Agreement, dated January 31, 2017, between the Registrant and rms Company and Addendum No. 1 dated July 7, 2017.	S-1	333-227445	10.6	9/20/2018
10.8+	Offer Letter Agreement, dated December 15, 2009, between the Registrant and Jeffrey W. Dunn.	S-1	333-227445	10.7	9/20/2018
10.9+	Offer Letter Agreement, dated February 19, 2015, between the Registrant and Michael A. Pisetsky	S-1	333-227445	10.8	9/20/2018
10.10+	Letter Regarding Change to Employment Terms, dated June 20, 2016, between the Registrant and Michael A. Pisetsky.	S-1	333-227445	10.9	9/20/2018
10.11+	Offer Letter Agreement, dated June 19, 2016, between the Registrant and Anthony J. Recupero.	S-1	333-227445	10.18	9/20/2018
10.12	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

10.13	Addendum No. 2 to Manufacturing, Quality and Supply Agreement, dated July 1, 2020, between the Registrant and rsm Company.	10-K	001-38701	10.16	3/10/2021
10.14#	Amended and Restated Manufacturing, Quality and Supply Agreement, dated June 11, 2021, between the Registrant and rms Company	10-Q	001-38701	10.4	8/4/2021
10.14	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
10.15+	Form of Restricted Stock Unit Grant Notice and Award Agreement.	S-1	333-227445	10.30	9/20/2018
10.16+	Amendment to Restricted Stock Units of Laura Francis	10-Q	001-38701	10.2	11/12/2019
10.17+	Amendment to Offer Letter with Jeffrey Dunn	8-K	001-38701	10.1	1/7/2021
10.18+	2020 Non-Employee Directors' Compensation Policy	10-K	001-38701	10.22	3/10/2021
10.19	Loan and Security Agreement, dated May 29, 2020, between SI-BONE, Inc. and Solar Capital Ltd., as collateral agent, and the lenders from time to time party thereto.	10-Q	001-38701	10.1	8/4/2020
10.20+	SI-BONE, Inc. Severance Benefit Plan and Form of Participation Agreement	10-K	001-38701	10.24	3/10/2021
10.21+	Offer Letter Agreement, dated April 19, 2021, between the Registrant and Helen Loh	10-Q	001-38701	10.2	5/4/2021
10.22+	Offer Letter Agreement, dated March 4, 2021, between the Registrant and Mika Nishimura	10-Q	001-38701	10.3	5/4/2021
10.23	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
10.24	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
10.25+	Second Amendment to the Offer Letter Agreement and Severance Plan Participation Agreement with Jeffery Dunn	10-Q	001-38701	10.2	11/9/2021
10.26+	Offer Letter Agreement, dated April 20, 2021, between the Registrant and Anshul Maheshwari	8-K	001-38701	10.1	4/20/2021
10.27+	Amended and Restated Participation Agreement dated April 20, 2021, between the Registrant and Laura Francis	8-K	001-38701	10.2	4/20/2021
10.28+	Form of Performance-Based Restricted Stock Unit Agreement	8-K	001-38701	10.1	1/20/2022
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. Omitted portions have been filed separately with the Securities and Exchange Commission.

(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: March 1, 2022

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

SI-BONE, Inc.

Date: March 1, 2022

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*)	March 1, 2022
/s/ Anshul Maheshwari Anshul Maheshwari	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 1, 2022
/s/ Timothy E. Davis, Jr. Timothy E. Davis, Jr.	Lead Independent Director, Director	March 1, 2022
/s/ Jeffrey W. Dunn Jeffrey W. Dunn	Executive Chairman, Director	March 1, 2022
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	March 1, 2022
/s/ Jeryl L. Hilleman Jeryl L. Hilleman	Director	March 1, 2022
/s/ Gregory K. Hinckley Gregory K. Hinckley	Director	March 1, 2022
/s/ Helen Loh Helen Loh	Director	March 1, 2022
/s/ Mika Nishimura Mika Nishimura	Director	March 1, 2022
/s/ Keith C. Valentine Keith C. Valentine	Director	March 1, 2022

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. 333-235714) and Form S-8 (Nos. 333-227907, 333-230473, 333-237091 and 333-254086) of SI-BONE, Inc. of our report dated March 1, 2022 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
March 1, 2022

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 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.

/s/ Laura A. Francis

Date: March 1, 2022

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Anshul Maheshwari, certify that:

1. I have reviewed this Form 10-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.

/s/ Anshul Maheshwari

Date: March 1, 2022

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 certify 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, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Laura A. Francis
Date: March 1, 2022
Laura A. Francis
Chief Executive Officer
(Principal Executive Officer)

/s/ Anshul Maheshwari
Date: March 1, 2022
Anshul Maheshwari
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 Securities Exchange Act of 1934, 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.