UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-38701

SI-BONE, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-2216351**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

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

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

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

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

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

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

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 o	Accelerated filer x	Non-accelerated filer o
Smaller reporting company x	Emerging growth company x	

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. o

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 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $391.3 million, 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 March 6, 2020 was 28,384,633 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, 2019, are incorporated by reference into Part III of this Report.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions, including those described under the sections in this Annual Report on Form 10-K entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements include, but are not limited to, statements about the following:

- our expectation that a significant portion of our revenues will be derived from sales of the iFuse Implant System, or iFuse;
- our ability to develop additional revenue opportunities, including new indications for use and new devices;
- our ability to expand our sales team to increase demand for our products and expand geographically;
- 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 U.S. Food and Drug Administration or 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 product;
- our expectations of the benefits to patients, providers, and payors of our products;
- our reliance on a limited number of suppliers, including sole source suppliers, which may impact the availability of instruments and materials;
- our ability to sustain or increase demand for our products;
- our estimates regarding our costs and risks associated with our international operations and expansion;
- our expectations regarding our ability to retain and recruit key personnel;
- our expectations regarding acquisitions and strategic operations;
- our ability to fund our working capital requirements;
- our compliance with, and the cost of, federal, state, and foreign regulatory requirements;
- the factors that may impact our financial results; and
- anticipated trends and challenges in our business and the markets in which we operate.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. 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. 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 focused on the development of implantable devices used in the surgical treatment of the sacropelvic anatomy. We have pioneered a proprietary minimally invasive surgical implant system, which we call iFuse, to fuse the sacroiliac joint to treat sacroiliac joint dysfunction that often causes severe lower back pain. Since we introduced iFuse in 2009, as of December 31, 2019, more than 44,000 procedures have been performed by over 2,000 surgeons in the U.S. and 35 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 where an implant is used and a multi-billion dollar market exists. We believe iFuse is currently the market leading implantable device used in minimally invasive surgical fusions of the sacroiliac joint in the U.S.

The iFuse system includes a series of patented triangular implants and the instruments we have developed to enable the procedure. The surgeon places our implants across the sacroiliac joint, either from a lateral approach through the iliac, or hipbones into the sacrum, or from a posterior approach, through the sacrum and into the iliac bone in the Bedrock technique. Surgeons typically use three iFuse implants to fuse a sacroiliac joint in the lateral procedure, and the Bedrock technique involves placement of one iFuse implant in each sacroiliac joint, alongside another device crossing the joint and joining to the spinal construct.

Our iFuse Implants have a triangular cross section which resists twisting of the implant within the bone in which it is implanted, regardless of the surgical approach and technique used to place the implants. The triangular shape helps stabilize the joint, and the implants' porous surface enables biologic fixation of the bone onto the implant, or bony ingrowth, which results in fusion. We hold issued patents on implants with cross-sections of many non-round shapes, including the triangular shape we use for iFuse. 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. Each titanium iFuse implant is at least three times as strong as a typical eight-millimeter surgical screw and the larger porous surface area of our implants allows for bony ingrowth.

We introduced our second-generation implant, the iFuse-3D, in 2017. This patented titanium implant combines the triangular cross-section of the iFuse implant with a proprietary 3D-printed porous surface and fenestrated design. These fenestrations allow the host bone to grow directly into the implant structure, or bony through-growth, and allow the surgeon to fill the implant with ground-up bone before implanting it, which some surgeons believe accelerates bony through-growth. iFuse-3D implants have shown positive bony ingrowth and through-growth in cell culture and animal studies, whether or not ground-up bone is used.

In April 2019, we received clearance from the U.S. Food and Drug Administration, or FDA, to promote the use of our iFuse system with the iFuse Bedrock technique for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures, to provide further stabilization and immobilization of the sacroiliac joint. We received CE marking and began marketing our iFuse system for the same indication in Europe in December 2019.

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 2019 and 2018, we generated revenue of $67.3 million and $55.4 million, respectively, a growth rate of 22%, and incurred net losses of $38.4 million and $17.5 million, respectively. Our gross margins were 90% and 91% for 2019 and 2018, respectively. The number of iFuse procedures performed globally in 2019 and 2018 was over 8,000 and 6,600, respectively. We generate our revenues from sales of the iFuse system.

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 surgery with iFuse. 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 iFuse in the U.S. could be 279,000 patients annually, for a potential annual market in the U.S. of approximately $2.7 billion. While we have made significant progress in penetrating this market, U.S. patients received only over 6,400 and 5,000 iFuse procedures in 2019 and 2018, respectively.

Frequently, sacroiliac joint patients are aging and/or may have experienced one or more of the following events that have contributed to disruption or degeneration of the sacroiliac joint: falls, previous lumbar surgery, automobile accidents, and/or pregnancies. We believe that Americans spend approximately $85.9 billion per year on spine problems and that approximately 65% of people who suffer from sacroiliac pain are women. In the U.S., iFuse is intended for sacroiliac joint fusion for conditions including 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 six months. The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

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 iFuse 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 the iFuse 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 such as screws.

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. For these reasons, we believe that open surgery for elective sacroiliac joint fusion has significant disadvantages compared to iFuse.

Due to its invasiveness, pain, long recovery time, and infrequent use, 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.

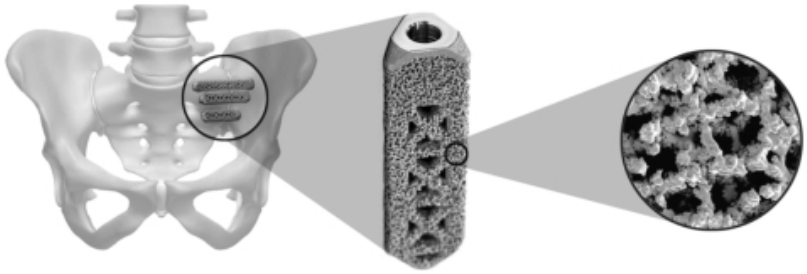
Non-Surgical Treatment of Sacroiliac Joint Disease

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 system, which includes our implants and instruments, is designed to address the shortcomings of alternative treatments, including open surgery, non-surgical management, and screw-based and other minimally invasive stabilization and fusion procedures. As shown in the graphic below, our iFuse implants are triangular, and three implants are typically used in each procedure. Our implants are made of titanium and have a porous surface. Each iFuse implant 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. 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, as shown below, 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 fusion of the sacroiliac joint, as well as other minimally invasive techniques, 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 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 iFuse. 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 iFuse and other products, as well as the substantial published clinical evidence showing the safety and effectiveness of iFuse, are the reason why a growing number of payors have recommended that iFuse be reimbursed for sacroiliac surgery to the exclusion of other technologies that are designed for the procedure.

Our implants cross the sacroiliac joint and provide immediate stability, which is why we believe pain diminishes soon after the iFuse 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 bridges across the joint from the iliac bone to the sacrum. Placing each implant requires four basic steps:

- **Pin**. The surgeon inserts a guide pin through the iliac bone, across the sacroiliac joint and into the sacrum.

- **Drill**. Surgeons drill over the guide pin, through the iliac bone, across the sacroiliac joint and just into the sacrum. This step is optional if using the sharp-tip broach.

- **Broach**. The surgeon impacts a triangular broach over the pin which prepares a triangular channel that is slightly smaller than the iFuse implant.

- **Implant**. The surgeon impacts the implant into the triangular channel thereby spanning the sacroiliac joint and docking the implant in the sacrum. The channel is slightly smaller than the implant, which produces an interference fit.

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 currently offer three custom instrument sets for surgical placement of 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 materials, such as PEEK and aluminum to improve visualization under fluoroscopy during an iFuse procedure.

In addition to our iFuse and iFuse-3D 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 intra-operatively. In March 2018, we introduced surgical pins cleared for use with the 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 mid-2019, we introduced the iFuse Bedrock technique that supplements pelvic fixation in deformity and degeneration cases, and provides enhanced initial stabilization and long-term SI-joint fusion. In late-2019, we introduced the iFuse Bone allograft for homologous use.

Our Published Studies

iFuse is the only minimally invasive product for sacroiliac joint fusion commercially available in the U.S. that, to our knowledge, is supported by substantial high-quality published evidence of safety, clinical effectiveness, durability, and economic utility. Our implants have a triangular cross section, which resists twisting of the implant within the bone in which it is implanted, helping stabilize the joint even before fixation of the bone onto the implant, or bony ingrowth, which results in fusion. Products from our competitors use screws to treat the sacroiliac joint, which do not resist twisting within the bone as well as our patented triangular implants. A study we performed showed that our iFuse implants have more than six times the rotation resistance of a screw designed for sacroiliac joint fusion. We hold issued patents on implants with cross-sections of many non-round shapes, including the triangular shape we use for iFuse. 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. Each titanium iFuse implant is at least three times the strength of a typical eight-millimeter surgical screw and the larger porous surface area of our implants allows for bony ingrowth. Three of our implants are typically used in each procedure.

The safety, durable effectiveness and cost effectiveness of iFuse are all supported by a large number of studies that have resulted in more than 80 published papers. Several of these papers publish results from three prospective multi-center studies (INSITE, SIFI, and iMIA) that we sponsored, two of which were randomized controlled clinical trials. A prospective, follow-on study called "LOIS" that we also sponsored tracks certain study participants from INSITE and SIFI for up to five years after their initial surgery. Additionally, there have been several studies showing longer-term follow-up of up to six years.

INSITE Study Design

INSITE is a randomized controlled study conducted in the U.S. Positive 24-month follow-up results were published in August 2016 in the *International Journal of Spine Surgery* showing statistically significant and clinically important reduction in pain and disability after sacroiliac joint fusion but very little response to maximal non-surgical treatment.

The INSITE clinical trial included 148 subjects treated at 19 centers in the U.S., with subjects randomized in a two-to-one ratio to either immediate sacroiliac joint fusion with iFuse or non-surgical management. The study design allowed subjects in the non-surgical management group to cross over and have surgery after six months. By 24 months after the start of the clinical trial, 89% of the non-surgical management group subjects still participating in the trial had elected to cross over to have the iFuse procedure, primarily because they derived little clinical benefit from non-surgical treatments. The study's results can be summarized as follows:

- **Reduction in Pain**. There was statistically significant and clinically important pain reduction in subjects treated with iFuse as compared to very small responses in the same measures in those treated with non-surgical management. Subjects surgically treated with iFuse had mean 52- 54- and 55-point reductions in sacroiliac joint pain at 6, 12 and 24 months, respectively, as measured by the Visual Analog Scale ("VAS"). By contrast, subjects in the non-surgical management group had only a mean 12-point reduction ($p<0.0001$) at six months. 12 points is below the commonly accepted 20-point threshold for clinically important improvement. In addition, the non-surgical management group subjects who elected after six months to cross over to have the iFuse procedure had pain reduction similar to that seen in subjects originally assigned to sacroiliac joint fusion with iFuse. At 24 months, the proportion of subjects with a reduction in VAS sacroiliac joint pain of 20 or more points due to the assigned treatment only was 83% in the iFuse group and 10% in the non-surgical management group.

- **Reduction in Disability**. There was a statistically significant and clinically important reduction in disability in subjects treated with iFuse as compared to very little response in those treated with non-surgical management. Subjects surgically treated with iFuse had a mean 27-point reduction in disability at six months, on the 0–100 Oswestry Disability Index ("ODI"), while subjects in the non-surgical management group had only a mean five-point reduction ($p<0.0001$). Five points is less than the commonly accepted 15-point threshold to denote a clinically important response. At 24 months, the iFuse group had a mean 28-point reduction in ODI. At six months, the proportion of subjects with ODI improvements of at least 15 points was 72.5% with iFuse treatment and only 13.0% in those undergoing non-surgical management ($p<0.0001$ for difference in response rate). In addition, the subjects who elected after six months to cross over to have the iFuse procedure had similar reduction in disability as the subjects originally assigned to sacroiliac joint fusion with iFuse. At 24 months, the proportion of subjects with an ODI improvement of at least 15 points with the assigned treatment only was 68.2% and 7.5% in the iFuse and non-surgical management groups, respectively ($p<0.0001$ for difference in response rate).

iMIA European Clinical Trial

iMIA is a second prospective, randomized clinical trial of sacroiliac joint fusion using iFuse compared to non-surgical management with a design very similar to that of INSITE. iMIA is a randomized controlled study conducted in Europe. Positive 24-month results were published in March 2019 in *The Journal of Bone and Joint Surgery*. Like INSITE, results from iMIA show statistically significant and clinically profound reduction in pain and disability after SI joint fusion but little improvement after non-surgical treatment.

SIFI Clinical Trial

Sacroiliac Joint Fusion with iFuse Implant System ("SIFI"), is a prospective, multicenter single-arm clinical trial. Eligibility criteria and endpoints were identical to INSITE. SIFI is a single-arm study conducted in the U.S. Positive 24-month follow-up results were published in the *International Journal of Spine Surgery* in April 2016, showing substantial and sustained reduction in pain and disability.

LOIS Clinical Trial

LOIS is a prospective follow-on study, enrolling subjects at a subset of INSITE and SIFI sites treated with iFuse. Study outcomes at four years were published in July 2018 in Medical Devices: Evidence and Research. In September 2019, we announced the publication of the 5-year results, which showed excellent durability of clinical responses and positive radiographic outcomes for SI-joint fusion using triangular titanium implants. Among 103 enrolled subjects, mean sacroiliac joint pain scores decreased 54 points from baseline prior to surgery. Disability scores decreased 26 points and quality of life improved 0.29 points, all of which are statistically significant, clinically meaningful and consistent with previously published LOIS 4-year results. The 5-year results from LOIS demonstrated that improvements in pain, patient function and quality of life demonstrated at two years in INSITE and SIFI were durable and sustained at five years. Independent radiographic analysis of CT scans at five years 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). Patient satisfaction remained high for patients treated with the iFuse Implant. There were no reported adverse events related to the study device or procedure at five years.

SALLY Clinical Trial

SALLY is a prospective single-arm multicenter trial of iFuse-3D for the treatment of sacroiliac joint dysfunction. The enrolled patient population was very similar to that of INSITE, SIFI and iMIA. Early results from SALLY show preoperative and six-month pain scores that are nearly identical to those of the three earlier prospective trials of iFuse. In addition, SALLY showed improvements in physical function tests and a larger reduction in opioid usage. A manuscript describing early SALLY results was submitted for publication in a peer-reviewed journal in February 2019.

Other Published Clinical Studies

To date, several studies, some of which we did not sponsor, have been published on the safety and effectiveness of sacroiliac joint fusion using iFuse. These are prospective or retrospective, single site or multi-site, and U.S. or Europe-based. These clinical studies demonstrate the iFuse procedure to be safe and effective. These studies demonstrate pain reduction and/or ODI improvement that is statistically significant and clinically important. These additional studies are consistent with the results of INSITE, iMIA, and SIFI, including the types and rates of adverse events observed.

A study in *Neurosurgery* published in April 2017 showed similar improvements in pain and disability in patients followed for up to six years. The study also showed a substantial reduction in the number of subjects using opioids in patients treated with iFuse at their last follow-up visit. At the last follow-up visit, 84% of patients who received non-surgical management were using opioids, while only 7% of patients treated with iFuse were using opioids.

In addition to clinical evidence, a number of economic publications we financially supported, including those in *ClinicoEconomics and Outcomes Research*, demonstrate that the iFuse procedure provides a cost savings to the healthcare system when compared to non-surgical management over time.

Coverage and Reimbursement

Coverage and reimbursement for iFuse products and related procedures vary by setting of care, payor type, and region. In the U.S., 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. These providers bill patients for any applicable deductibles or co-payments. 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.

The Medicare program is commonly used as a model for how private payors and other governmental payors develop their coverage and reimbursement policies for healthcare items and services, including iFuse procedures. Unless a national coverage policy exists for a particular technology, each of the Medicare Administrative Contractors is permitted to make its own determination of whether that item or service is covered by Medicare.

Medicare’s reimbursement rates for the iFuse procedure vary due to geographic location, the nature of facility in which the procedure is performed (i.e., hospital inpatient department, hospital outpatient department, or ambulatory surgical center) and other factors. Medicare reviews and updates its payment rates and methodologies for these settings of care annually, and rates can change from year to year. In addition, Congress can alter reimbursement rates at any time by mandating changes to Medicare’s payment methodologies.

Similarly, private payor coverage policies and reimbursement rates tend to vary across payors and settings of care. 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.

In the U.S., the American Medical Association ("AMA"), generally creates specific billing codes for surgical procedures under a coding system known as Current Procedural Terminology ("CPT"), which surgeons must use to bill and receive reimbursement for our iFuse procedure. Once a CPT code is established, the Centers for Medicare & Medicaid Services ("CMS"), typically establishes payment levels under Medicare while private payors establish rates and coverage rules independently.

Prior to our launch of iFuse, Medicare and most private insurance companies reimbursed surgeons for sacroiliac joint fusions using either an established Category I CPT code or an unlisted code. A Category I CPT code is typically assigned to procedures that are consistent with contemporary medical practice and are widely performed. Procedures with a longstanding Category I CPT code are usually reimbursed.

However, effective July 1, 2013, the AMA's CPT Editorial Panel created a new Category III CPT code for fusion of the sacroiliac joint using a minimally invasive or percutaneous approach. Category III CPT codes are used for new and emerging technologies and are reimbursed sporadically. This new code functionally redefined coding for sacroiliac joint fusions because it meant that minimally invasive or percutaneous fusion procedures should not be billed by the surgeon using the general Category I CPT code for sacroiliac fusion surgery. This coding change was accompanied by the establishment of a Medicare hospital outpatient prospective payment rate for facilities to bill for procedures with the new code.

Following the creation of the new Category III CPT code, a number of papers demonstrating the clinical success of the iFuse procedure were published. As a result of these studies, along with the support of several professional medical specialty societies and leading academic surgeons, the AMA CPT Editorial Panel established a new Category I CPT code specifically for sacroiliac joint fusion surgery using a minimally invasive or percutaneous approach. This new Category I CPT code became effective on January 1, 2015. However, the new code did not immediately lead to positive coverage decisions by payors. In many cases, the payors wanted additional published evidence before deciding to cover the procedure. As a result, positive reimbursement decisions covering the procedure have occurred over the last few years, and some payors are still in the process of making decisions based on the most recent evidence.

In March 2015, our INSITE prospective, randomized controlled multi-center clinical trial was published. In June 2015, the largest spine society in the world, the North American Spine Society ("NASS"), published a positive coverage recommendation, based on the clinical evidence, signaling to insurance companies and Medicare Administrative Contractors that sacroiliac joint fusion using a minimally invasive surgical approach should be routinely reimbursed. In March 2015, the International Society for Advancement of Spine Surgery ("ISASS"), also published a similar, updated positive coverage document signaling to insurance companies in the U.S. that evidence supports reimbursement for the procedure.

Coverage decisions for this code are made independently by each private insurance company and each of the Medicare Administrative Contractors that help manage Medicare. The process of obtaining coverage is laborious. As of June 30, 2016, because of the iFuse clinical evidence, all Medicare Administrative Contractors were covering the procedure. At the time, very few private payors were covering. As of December 31, 2018, U.S. payors covering 256.5 million lives regularly reimbursed for the iFuse procedures, a 58% increase over December 31, 2017. As of December 31, 2019, U.S. payors covering 282.7 million lives regularly reimbursed for the iFuse procedures, a 10% increase over December 31, 2018.

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 U.S. 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. An example of payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis pursuant to the pertinent statute and regulations.

Specialty benefit managers and companies which perform healthcare technology assessments have significant influence on coverage decisions. In May 2016, the ECRI Institute Health Technology Assessment Information Service published a positive review of the iFuse Implant System, citing our clinical evidence. In January 2018, the Blue Cross Blue Shield Association, the licensor to all 36 Blue Cross and Blue Shield insurers across the U.S., wrote a favorable review of the clinical evidence conferring a positive coverage recommendation for minimally invasive sacroiliac fusion, but only when performed with iFuse. In February 2018, Milliman Care Guidelines, a Hearst Company publication, also recommended coverage and in May 2018, AIM Specialty Health, owned by Anthem, established coverage for only iFuse and none of our competitors. In October 2018, eviCore recommended our iFuse system exclusively for sacroiliac joint fusion or stabilization.

Private Payors. Private payors also decide whether to cover and how much to pay on an individual basis. We target and track 65 of the largest private payors. Of the targeted and tracked payors, 52 were covering regularly, or had announced coverage for, the iFuse procedure, while the remaining private payors were reevaluating their coverage policies. As of December 31, 2019, of the private payors, 32 have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence. Further, 20 private payors are covering iFuse and other sacroiliac joint fusion products.

As of December 31, 2019, of the U.S. payors covering 282.7 million lives that reimburse for iFuse, 147.9 million lives are covered by private payors. The table below summarizes the overall covered lives by payor type as of December 31, 2019:

	Covered Lives (in millions)
Commercial, exclusive	57.6
Commercial, non-exclusive	90.3
Medicaid	55.5
Medicare	64.5
Military/Federal	14.8
	282.7

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.

In December 2019, CIGNA established a positive coverage policy for minimally invasive SI joint fusion using the iFuse Implant System. CIGNA is the fourth largest commercial health plan in the U.S. with approximately 14.6 million members. Also in December 2019, Anthem, which is the second largest commercial health plan in the U.S. with approximately 34.9 million members, published a positive coverage policy for minimally invasive SI joint fusion procedures using the iFuse Implant System for the treatment of chronic SI joint pain or functional impairment, but only subsequent to pelvic girdle trauma. The Anthem policy does not generally cover SI joint dysfunction due to degenerative sacroiliitis. There are other large and small private payors, including Aetna and Humana, that have not published positive coverage policies for the procedure. Some of these non-covering payors are reevaluating coverage given the latest data, but there can be no assurance they will reach positive coverage decisions. In most cases, the payors who are not covering are reevaluating coverage. Many payors will only review their coverage policies for a procedure on a scheduled basis, which can be every few months or as infrequently as once per year.

Prior to payor coverage, surgeons have been reluctant to get trained on a procedure for which they could not reliably be reimbursed. While we believe the increased coverage described above will have a positive effect on the number of iFuse procedures and our associated revenue in the future, the effect likely will happen with a lag time: after a positive coverage decision is made, a number of months may pass before it impacts the number of procedures and associated revenue, since the surgeons have to be made aware of the coverage decision, in some cases attend on of our training courses to learn the surgical technique, schedule re-examinations of patients who were candidates for surgery and subsequently schedule surgeries for the patients who are still candidates.

We believe that it generally takes between 6 and 24 months for a surgeon to fully incorporate iFuse 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.

Coverage Outside the U.S.

Outside the U.S., 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. Some countries will require us to gather additional clinical data before recognizing and granting broader coverage and reimbursement for our products.

Health Technology Assessment ("HTA") of medical devices is, however, becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including the United Kingdom, France, Germany, Ireland, Italy, Spain and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual products as well as their potential implications for the healthcare system. Those elements of medical devices are compared with other treatment options available on the market. The outcome of HTA regarding specific medical devices will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medical device varies between EU Member States. In addition, pursuant to Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU Member States and in pricing and reimbursement decisions and may negatively affect price in at least some EU Member States.

As a further step in this direction, on January 31, 2018, the European Commission adopted a proposal for a regulation on HTA. This legislative proposal is intended to increase cooperation among EU Member States in assessing health technologies, including new medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The proposal would permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. The European Commission has stated that the role of the draft HTA regulation is not to influence pricing and reimbursement decisions in the individual EU Member States. However, this consequence cannot be excluded.

In April 2017, the UK's National Institute for Health and Care Excellence ("NICE"), published guidance on minimally invasive sacroiliac joint fusion, recommending that the procedure be available to properly diagnosed patients in the UK National Health System. NICE develops guidance and quality standards in health and social care and is a worldwide leader in technology evaluations. The recommendation states that the safety and efficacy of minimally invasive sacroiliac joint fusion surgery is adequate provided that standard arrangements are in place. Use with standard arrangements is the most positive recommendation that NICE can make for an interventional procedure such as minimally invasive SI joint fusion. In October 2018, NICE published medical technology guidance specific to the iFuse Implant System, recommending that it be used in the National Health System because of the evidence demonstrating that treatment with iFuse improves pain, quality of life, and disability in properly selected patients. The continued relevance of the NICE guidance following the departure of the UK from the EU on 31 January 2020 is yet to be determined. Additionally, in August 2018, the public hospital system in France announced it would initiate coverage for iFuse exclusively beginning September 6, 2018. Some countries will require us to gather additional clinical data before recognizing and granting broader coverage and reimbursement for our products. It is our intent to complete the requisite clinical studies and obtain coverage and reimbursement approval beyond what we have today in countries where it makes economic sense to do so.

Medical Affairs and Education

We have created a medical affairs team that focuses both internally and externally. Internally, specialized medical knowledge, and practical experience with iFuse are used to help train our sales, marketing, quality, reimbursement, clinical, regulatory, engineering, and product development teams. This same specialized medical knowledge and practical experience allow us to create and execute a wide variety of programs to train the relevant external medical community, to assist them in identifying and diagnosing patients with sacroiliac joint dysfunction and in performing the iFuse procedure. The medical affairs team is led by a fellowship trained orthopedic spine surgeon. As of December 31, 2019, our U.S. faculty consisted of 107 surgeons, 26 pain management physicians, 22 nurse practitioners/physician's assistants, and 103 physical therapists. These third-party consultants educate surgeons, physician's assistants, nurses, physical therapists, and other healthcare professionals regarding sacroiliac joint diagnosis and the iFuse procedure.

Our surgeon training programs are for orthopedic spine surgeons, neurosurgeons, general orthopedic surgeons, and orthopedic trauma surgeons. Since its introduction, over 2,000 surgeons have treated patients with iFuse. We grew our active surgeon base to 539 surgeons as of December 31, 2019, compared to 450 active surgeons as of December 31, 2018. We define an active surgeon to be a surgeon who has performed at least one case in the last three months. The increase in active surgeons is primarily due to training of additional surgeons throughout the year.

We also have a large number of educational programs for the broader medical community including primary care physicians and other healthcare practitioners that may manage a sacroiliac joint patient non-surgically, such as physical therapists, pain management physicians, and chiropractors. As of December 31, 2019, our medical affairs team and physical therapist consultants have educated over 7,700 physical therapists on sacroiliac joint dysfunction, its diagnosis and iFuse as a potential treatment. We also work to educate case managers, facilities where the iFuse procedure is performed such as hospitals, as well as payors and health plans. For example, as of December 31, 2019, we have trained over 1,300 case managers across the U.S. Case managers help patients navigate the healthcare system so that they receive the appropriate treatment. In addition to the continuing education program for case managers, we have created continuing education programs for physical therapists and chiropractors. As of December 31, 2019, our physical therapy continuing education programs were approved in 47 states. These programs include instruction on the diagnosis and non-surgical treatment of sacroiliac joint dysfunction due to degenerative sacroiliitis and sacroiliac joint disruptions. Our medical affairs programs focus on working with leading spine surgeons to educate other surgeons on the differential diagnosis of sacroiliac joint disorders and the use of iFuse. We also work closely with medical 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 iFuse 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 U.S. covered ten sales regions as of December 31, 2019. 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, 2019, our U.S. sales force consisted of 56 territory sales managers directly employed by us, and 37 third-party distributors.

As of December 31, 2019, we had 39 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, 2019, our international sales force consisted of 19 sales representatives directly employed by us and 27 exclusive third-party distributors, which together had sales in 35 countries through December 31, 2019. We anticipate continuing to build our operations in the major European countries while establishing distributor arrangements in smaller ones. We intend to follow a similar model in Europe to the one established in the U.S., working with internationally recognized healthcare professional experts as we expand our training and reimbursement activities. As of December 31, 2019, beyond Europe and the U.S., surgeons had performed the first iFuse procedures in Australia, Bahrain, Canada, Cayman Islands, Hong Kong, Israel, Japan, Kuwait, New Zealand, Saudia Arabia, South Africa, and Turkey.

In addition to general sales and marketing training, we provide our sales organization with comprehensive, hands-on cadaveric and dry-lab training sessions focusing on the clinical benefits of our products and how to use them. We believe our robust training and professional development programs have been an important component of our success to date and will help support our anticipated future growth. We expect to continue to increase the size of our sales organization in order to increase sales and market penetration and to provide the significant, ongoing level of customer support required by our sales and marketing strategy.

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.

Research and Development

Since our initial launch of the iFuse Implant System, we have introduced a number of new product and procedure enhancements. An example is the iFuse-3D implant, which we developed over several years and launched in 2017. The most notable instrument enhancement was the release of the revamped instrument set that included a number of radiolucent instruments.

In 2017, we also 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 intra-operatively. In March 2018, we introduced surgical pins which may be used with the 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 mid-2019, we introduced the iFuse Bedrock technique that supplements pelvic fixation in deformity and degeneration cases and provides enhanced initial stabilization and long-term SI-joint fusion. In late-2019, we introduced the iFuse Bone allograft for homologous use.

We expect to continue developing enhancements to iFuse to meet our customers’ changing needs and improve the surgery’s effectiveness. For example, we know that some surgeons use iFuse to treat trauma patients post-stabilization. We are developing products and techniques to help surgeons improve the treatment of these patients, and we will seek any additional regulatory clearances that may be required. We also design and manufacture Class I instruments for our surgeon customers based on special requests under our “Non-Standard Product” program.

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. However, all of these products are either screw-based or allograft products. 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. We also expect there to be a continued push for non-surgical alternatives.

In the U.S., 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 customers 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 regulated by the FDA differently from implantable medical devices made of metallic or other non-tissue based materials, unless these customers include specific claims about their intended use which exceed a homologous use, or use consistent with the original function of the donor tissue.

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 U.S. Our triangular titanium implant is differentiated from other screw-based technologies on the market. iFuse is the only minimally invasive product for sacroiliac joint fusion commercially available in the U.S. 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 80 published papers. We have received exclusive reimbursement coverage in the U.S. 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, 2019, we had been issued 40 patents in the U.S., and 10 patents outside of U.S. Also, as of December 31, 2019, we have 19 pending patent applications in the U.S. and 5 pending patent applications outside of the U.S. We have focused the majority of our foreign patent efforts in China, Europe, and Japan. Our current U.S. patents on iFuse, including the triangular shape, expire in August 2024. Our current U.S. patents on iFuse 3D, including the fenestrated design, expire in September 2035. Our foreign patents will expire between August 2025 and October 2031.

We have 14 registered trademarks in the U.S. and have filed for 4 more. In other countries, we have focused on registering three primary trademarks: “iFuse Implant System,” “SI-BONE,” and the SI-BONE logo. As of December 31, 2019, we have sought protection for at least 2 of these trademarks in 60 countries including the 28 European member countries of the Madrid Protocol.

We 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 employment.

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 U.S., 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 U.S. and other countries. Most notably, all of our products sold in the U.S. are subject to the Federal Food, Drug, and Cosmetic Act ("FDCA") as implemented and enforced by the FDA. 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 U.S. 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 manufacture 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.

PMA Approval

A PMA must be submitted to the FDA for any device that is classified in Class III or otherwise cannot be cleared through the 510(k) process (although the FDA has discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process). PMA applications must be supported by, among other things, valid scientific evidence demonstrating the safety and effectiveness of the device, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, once the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will formally accept the application for review. The FDA, by statute and by regulation, has 180 days to review an "accepted" PMA application, although the review of an application more often occurs over a significantly longer period of time, and can take up to several years. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation.

In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSR. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. In approving a PMA the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of a PMA-approved device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the de novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

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"), for 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 U.S. 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.

The FDA inspected our facilities in May 2014. As a result, we received a Form 483 with three observations that have been since been corrected following a corrective and preventative action plan. We responded to the Agency in writing and the matter was closed as of October 2014. To date, the FDA has not taken any further actions with respect to the May 2014 inspection or its findings. The FDA inspected our facilities again in December 2016. As a result, no findings were noted.

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, 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 Essential Requirements concerning medical devices that are imposed by the Medical Device Directive (Council Directive 93/42/EEC) and the related national implementing legislation of individual EU member states as well as related guidance. Demonstration of compliance with these requirements entitles us to affix the CE mark to our medical devices, without which they cannot be commercialized in the EEA.

To demonstrate compliance with the Essential Requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by the competent authorities of a EEA country to conduct conformity assessments. The Notified Body typically audits and examines products' Technical File and the quality system for the manufacture, clinical evaluation report, design and final inspection of our devices before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements. Following the issuance of this CE Certificate of Conformity, we can draw up an EC Declaration of Conformity and affix the CE mark to the products covered by this CE Certificate of Conformity and the EC Declaration of Conformity. We have successfully completed several Notified Body audits since our original certification in November 2010. Following these audits, our Notified Body issued International Standards Organization Certificates and CE Certificates of Conformity allowing us to draw up an EC Declaration of Conformity and affix the CE mark to certain of our devices.

After the product has been CE marked and placed on the market in the EEA, we must comply with a number of regulatory requirements relating to:

- registration of medical devices in individual EEA countries;
- pricing and reimbursement of medical devices;
- establishment of post-marketing surveillance and adverse event reporting procedures;
- Field Safety Corrective Actions, including product recalls and withdrawals; and
- interactions with physicians.

Failure to comply with these requirements may result in enforcement measures being taken against us by the competent authorities of the EEA countries. These can include fines, administrative penalties, compulsory product withdraws, injunctions, and criminal prosecution. Such enforcement measures would have an adverse effect on our capacity to market our products in the EEA and, consequently, on our business and financial position.

In May 2017, the Medical Device Regulation (Regulation 2017/745) was adopted. From May 26, 2020, the Medical Device Regulation will repeal and replace the Medical Device Directive and the Active Implantable Medical Device Directive. Unlike directives, which must be implemented into the national laws of the EU Member States, the Medical Device Regulation will be directly applicable in the EU Member States and, on the basis of the EEA agreement, in 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. Once applicable, the Medical Device Regulation will, among other things:

- strengthen the rules on placing medical devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthen 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. Among others, 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 in that jurisdiction are in place and on sponsors and investigators the obligation to ensure they make use of these systems.

Once applicable, the Medical Device Regulation will impose increased compliance obligations which we must respect if we wish to continue to access the EU market. This includes the up-classification of some of our devices. Moreover, the scrutiny imposed by Notified Bodies for the technical documentation related these devices will increase considerably.

Further, the advertising and promotion of our products in the EEA is currently subject to the provisions of the Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, Directive 2005/29/EC on unfair commercial practices, and from 26 May 2020, 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 U.S., the iFuse Implant System is intended for sacroiliac fusion for conditions, including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis. This includes conditions where symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months. The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. In the future, we plan to pursue additional 510(k) clearances for new products and changes to the current indication for iFuse.

In November 2010, we obtained a CE Certificate of Conformity and affixed a CE mark to our iFuse Implant System to allow commercialization of iFuse in the EEA. In the EEA and Switzerland, iFuse is intended for sacroiliac joint fusion. 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. Current delays in the revisions to the current bilateral agreement between the EU and Switzerland necessary to ensure the on-going supply of our CE marked medical devices in Switzerland following entry into application of the Medical Device Regulation may, however, affect this plan.

Since July 2013, we have obtained approval for iFuse in regions beyond the U.S. 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.

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 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) 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. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided (beginning in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

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

If we or our employees are found to have violated any of the above laws we may be subject to administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal 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 physician kickbacks and false claims for reimbursement, as well as equivalent foreign laws"*** 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.

Violations of these federal and state fraud and abuse laws can subject us to administrative, civil, and criminal penalties, including imprisonment, substantial fines, penalties, damages, and exclusion from participation in federal healthcare programs, including Medicare and Medicaid.

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 U.S.

HIPAA 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 civil monetary penalties up to $58,490 per violation, not to exceed $1.755 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or 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 suppliers for implants are rms Company ("RMS") for iFuse-3D, which represents the majority of our implant sales, and Orchid MPS Holdings, LLC ("Orchid") for iFuse. To mitigate supply risk, we hold four to six months 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 U.S.

We entered into a non-exclusive Manufacturing, Quality and Supply Agreement with RMS in February 2017, which was amended in July 2017. Pursuant to such 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. In the initial three-year term of the agreement, 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. After the initial term, 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. With respect to our first generation iFuse implant, the parts manufactured by RMS needs to be coated by Orchid to finish the goods. RMS is currently our only supplier of iFuse-3D implants.

Our iFuse implants are provided by Orchid Bio-Coat, a division of Orchid Orthopedic Solutions LLC. In April 2016, we entered into a Quality and Manufacturing Agreement with Orchid, which agreement was amended in March 2017, April 2019 and June 2019. Pursuant to such agreement, Orchid manufactures certain of our implants in accordance with our specifications. 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. In the first year of the agreement, the prices we paid for products were fixed as specified in the agreement. On an annual basis thereafter, we meet with Orchid to review changes in direct costs beyond certain thresholds and may negotiate changes to prices based on such changes in costs. In addition, the prices we pay for product may be increased with our consent to the extent such products are ordered with delivery timeline shorter than agreed upon order timeline. The initial agreement had a term of five years, and pursuant to subsequent amendments it is now automatically renewing for successive 30-day periods; provided, however, the agreement may be terminated by either party with 30 days' notice, as specified in the agreement.

Aside from quality agreements, we do not currently have any significant manufacturing agreements with our other manufacturers and orders are primarily controlled through purchase orders.

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 U.S., 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.

Employees

As of December 31, 2019, we had 262 employees, including sales and marketing, product development, general administrative and accounting, both domestically and internationally. As of December 31, 2019, we had a direct field sales organization of 107 in the U.S. and 19 in Europe. Our ability to recruit, develop and retain highly skilled talent is a significant determinant of our success. We continue to emphasize employee development and training, and we embrace diversity and inclusion. We also have policies setting forth our expectations for nondiscrimination and a harassment-free work environment. None of our employees is subject to a collective bargaining agreement, and we consider our relationship with our employees to be good.

Emerging Growth Company Status

We qualify as an “emerging growth company” as defined in Section 101 of the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). We will continue to be an emerging growth company until December 31, 2023, unless one of the following occurs: (i) if our total annual gross revenues are $1.07 billion or more; or (ii) if we issued more than $1.0 billion in non-convertible debt in the past three years; or (iii) if we become a "large accelerated filer," as defined in Rule 12b-2 of the Exchange Act.

As an emerging growth company under the JOBS Act, we can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

As an emerging growth company, we are also exempt from Section 404(b) of the Sarbanes-Oxley Act of 2002 and Section 14A(a) and (b) of the Exchange Act. Section 404(b) of the Sarbanes-Oxley Act of 2002 requires a public company’s auditor to attest to, and report on, management’s assessment of its internal controls. Sections 14A(a) and (b) of the Exchange Act, implemented by Section 951 of the Dodd-Frank Act, require companies to hold shareholder advisory votes on executive compensation and golden parachute compensation. As long as we qualify as an emerging growth company, we will not be required to comply with the requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 and Section 14A(a) and (b) of the Exchange Act.

Smaller Reporting Company Status

We qualify as a “smaller reporting company” as defined under Rule 12b-2 of the Exchange Act. We will continue to qualify as a smaller reporting company if: (i) our public float is less than $250.0 million; or (ii) our annual revenues is less than $100.0 million and our public float is less than $700.0 million. As per guidance, we determine whether we qualify as a smaller reporting company annually as of the last business day of our second fiscal quarter. As a smaller reporting company, we may use the smaller reporting company scaled disclosure accommodations of Regulation S-K and S-X in our filings, including among others:

- two years of income statements rather than three years as required by Rule 8-02 of Regulation S-X;
- two-year management discussions and analysis comparison rather than three-year comparison as required by Item 303 of Regulation S-K;
- no requirement to provide selected financial data table required by Item 301 of Regulation S-K;
- no requirement to provide market risk disclosures required by Item 305 of Regulation S-K;
- no requirement to provide supplemental financial information required by Item 302 of Regulation S-K; and
- less extensive narrative disclosure than required of other reporting companies, particularly in the description of executive compensation as required by Item 402 of Regulation S-K.

Company History

SI-BONE was founded in 2008 by the main inventor of iFuse, orthopedist Mark A. Reiley, M.D., our President, Chief Executive Officer, and Chairman, 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, 2019 and 2018, we had net losses of $38.4 million and $17.5 million, respectively. As of December 31, 2019, we had an accumulated deficit of $195.6 million. We have financed our operations primarily through the net proceeds of our public offerings of our common stock, private placements of equity securities, certain debt-related financing arrangements, and from sales of our products. We have devoted substantially all of our resources to research and development of our products, sales and marketing activities, investments in training and educating surgeons and other healthcare providers, and clinical and regulatory matters for our products. There can be no assurances that we will be able to generate sufficient revenue from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flows. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance, and commercialize our existing and new products and incur additional operational and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives.

Our expected future capital requirements may depend on many factors including expanding our surgeon base, the expansion of our sales force, and the timing and extent of spending on the development of our technology to increase our product offerings. We may need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations.

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

Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Hospitals, surgeons, and other healthcare providers that purchase or use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices.

Adequate coverage and reimbursement for procedures performed with our products is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage, continue to deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. For example, our sales decreased significantly after minimally invasive sacroiliac joint fusion was assigned to a Category III Current Procedural Terminology ("CPT") code effective July 1, 2013. After implementation of this Category III CPT Code, surgeons were no longer able to consistently obtain reimbursement for procedures performed using our products. However, effective January 1, 2015, minimally invasive sacroiliac joint fusion was assigned to a Category I CPT Code.

Many private payors refer to coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare program, as guidelines for setting their coverage and reimbursement policies. By December 31, 2016, all Medicare Administrative Contractors were regularly reimbursing for minimally invasive sacroiliac joint fusion. Private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures performed with our products. Private commercial payors have been slower to adopt positive coverage policies for minimally invasive sacroiliac joint fusion, and many private payors still have policies that treat the procedure as experimental or investigational and do not regularly reimburse for the procedure. Future action by CMS or third-party payors may further reduce the availability of payments to physicians, outpatient surgery centers, and/or hospitals for procedures using our products.

The healthcare industry in the U.S. has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they chose to cover. For example, several Blue Cross Blue Shield payors have adopted policies that treat 3D-printed orthopedic implants that come in standard sizes, rather than customized to the patient's anatomy, such as our iFuse-3D implant, as experimental and investigational and therefore not eligible for reimbursement. There can be no guarantee that we will be able to provide the scientific and clinical data necessary to overcome these policies. Such policies may contribute to a decrease in sales of our iFuse-3D implants. Payors may adopt policies in the future restricting access to medical technologies like ours and/or the procedures performed using such technologies. Therefore, we cannot be certain that the procedures performed with each of our products will be reimbursed. There can be no guarantee that, should we introduce additional products in the future, payors will cover those products or the procedures in which they are used.

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

If the reimbursement provided by third-party payors to hospitals, surgeons, and other healthcare providers for procedures performed using our products is insufficient, adoption and use of our products and the prices paid for our implants may decline.

When an iFuse procedure is performed, both the surgeon and the healthcare facility, either a hospital or ambulatory surgical center, submit claims for reimbursement to the healthcare payor. Generally, the facility obtains a lump sum payment, or facility fee, for minimally invasive sacroiliac joint fusions. Our products are purchased by the facility, along with other supplies used in the procedure. The facility must also pay for its own fixed costs of operation, including certain operating room personnel involved in the procedure. If these costs exceed the facility fee reimbursement, the facility's managers may discourage or restrict surgeons from performing the procedure in the facility or using certain technologies, such as our iFuse implants, to perform the procedure.

Effective January 1, 2020, the national average Medicare payment to hospital outpatient departments is $15,944 and the Medicare payment to an ambulatory surgical center for a sacroiliac joint fusion is $12,981. We believe that payments to facilities are generally adequate for these facilities to offer the iFuse procedure. However, there can be no guarantee that these facility fee payments will not decline in the future. The number of iFuse procedures performed and the prices paid for our implants may in the future decline if payments to facilities for minimally invasive sacroiliac joint fusions decline.

Surgeons are reimbursed separately for their professional time and effort to perform a surgical procedure. Prior to reassignment of minimally invasive sacroiliac joint fusion to a Category III CPT Code, the national average Medicare physician fee schedule payment to surgeons for CPT codes commonly used to submit claims for reimbursement for the iFuse procedure was approximately $1,000 and the procedure was commonly covered by both government and private commercial payors in the U.S. Effective January 1, 2020, the average Medicare payment for the Category I CPT code is $915. Many private payors set their payment amounts with reference to the Medicare payment, often approximately 10% to 33% higher than the Medicare payment for a procedure. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all.

We believe that some surgeons may continue to view the Medicare and commercial reimbursement amounts as insufficient for the procedure, given the work effort involved with the procedure, including the time to diagnose the patient and obtain prior authorization from the patient's health insurer if necessary. Many private payors require extensive documentation of a multi-step diagnosis before authorizing minimally invasive sacroiliac joint fusion for a patient. We believe that some private payors apply their own coverage policies and criteria inconsistently, and surgeons may not be able to consistently have minimally invasive sacroiliac fusions approved and covered. The perception by physicians that the reimbursement for minimally invasive sacroiliac joint fusion is insufficient to compensate them for the work required, including diagnosis, documentation, obtaining payor approval for the procedure, and burden on their office staff, may negatively affect the number of procedures performed and may therefore impede the growth of our revenues or cause them to 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.

As of December 31, 2019, 32 of the largest 65 U.S. private payors that we track and target have issued positive coverage policies covering the patented triangular design of our iFuse implants and excluding coverage of other products that are intended to fuse the sacroiliac joint because of the clinical evidence supporting the use of iFuse and the lack of clinical evidence supporting the use of other products. Additionally, the public hospital system in France initiated coverage for iFuse exclusively beginning September 6, 2018. We believe that payors have adopted these exclusive coverage decisions due to the strength of our clinical evidence and in part due to recommendations of specialty benefit managers and healthcare technology assessment organizations. In 2018, AIM Specialty Health, Blue Cross Blue Shield Association Evidence Street, and eviCore Healthcare published positive coverage recommendations to their constituents and payor customers, recommending that iFuse be covered exclusively. Clinical trials of the type and size necessary to offer evidence of the safety and efficacy of competing products could be performed and could show that other products for sacroiliac joint fusion are as effective as, or more effective than, iFuse. Payors could also abandon their decisions to cover iFuse exclusively for other reasons. If healthcare payors covering a significant number of covered lives reverse their policies of covering minimally invasive sacroiliac joint fusion exclusively when performed with the iFuse system, sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

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

Surgeons play the primary role in determining the course of treatment in consultation with their patients and, ultimately, the product that will be used to treat a patient. In order for us to sell our iFuse system successfully, we must convince surgeons through education and training that treatment with iFuse is beneficial, safe, and cost-effective for patients as compared to our competitors' products. If we are not successful in convincing surgeons of the merits of iFuse, they may not use our product, and we will be unable to increase our sales and achieve or grow profitability.

Historically, most spine surgeons did not include an evaluation of the sacroiliac joint in their diagnostic work-up because they did not have an adequate surgical procedure to perform for patients diagnosed with sacroiliac joint dysfunction. As a result, some patients with lower back pain resulting from sacroiliac joint dysfunction are misdiagnosed. We believe that educating surgeons and other healthcare professionals about the clinical merits and patient benefits of iFuse is an important element of our growth. 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 the benefits of using our products. 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. These pain physicians often offer a variety of non-surgical and surgical interventions to sacroiliac joint dysfunction patients, including, but not limited to, steroid injections, radiofrequency ablation of the nerves serving the sacroiliac joint and implantation of neurostimulation devices and other products intended to treat the sacroiliac joint. Our professional education program seeks to teach pain physicians, and other health care providers, about the benefits of iFuse, in order to prompt these providers to refer their patients with sacroiliac joint dysfunction to surgeons who have been trained to perform the iFuse procedure. These providers may, however, prefer to continue to treat these patients with the interventions they offer. If we are unable to convince potential referring health care providers of the comparative benefits of iFuse, and we are therefore unable to prompt sufficient numbers of these providers to refer their patients with sacroiliac joint dysfunction for treatment by surgeons trained to perform the iFuse procedure, sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition.

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

The products we currently market in the U.S. have either received premarket clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act ("FDCA"), or are exempt from premarket review. Those marketed in the European Union ("EU"), have been the subject of a CE Certificate of Conformity. The 510(k) clearance process of the U.S. Food and Drug Administration ("FDA") requires us to document that our product is "substantially equivalent" to another 510(k)-cleared products. The 510(k) process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes, such as a premarket approval, ("PMA"), and does not usually require pre-clinical or clinical studies. Additionally, to date, we have not been required to complete clinical studies in connection with the sale of our products outside the U.S. As a result, while there are a number of published studies relating to iFuse and minimally invasive sacroiliac joint surgery that support the safety and effectiveness of our products and the benefits they offer, our clinical studies may lack the size and scope of randomized controlled clinical trials required to support approval of a PMA. For these reasons, surgeons may be slow to adopt our products, third-party payors may be slow to provide coverage, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by surgeons, significantly reduce our ability to achieve expected sales, and could prevent us from achieving profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension, or withdrawal of FDA clearance, and suspension, variation, or withdrawal of our CE Certificates of Conformity, significant legal liability or harm to our business reputation, which could have a material adverse effect on our results or operations and financial condition. Similar risks apply to product approvals and registrations in other countries outside the U.S. and the EU as well.

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

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

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

We are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our products will be justified and incorporated into the overall cost of the procedure. In addition, to the extent there is a shift from inpatient setting to outpatient settings, we may experience increased pricing pressure.

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

Physician-owned distributorships ("POD"), are medical device distributors that are owned, directly or indirectly, by physicians. These physicians profit from selling or arranging the sale of medical devices for use in procedures they perform on their own patients at hospitals that purchase the devices from the POD. We currently do not engage with PODs. The proliferation of PODs could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.

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 negatively affected and we may not grow.

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

The number of competitors that we are aware of marketing sacroiliac joint fusion products in the U.S. has grown from zero to 23 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 as at a disadvantage.

In the U.S., we believe that our primary competitors currently are Medtronic plc and Globus Medical, Inc. Our primary competitors in Europe are Globus Medical, Inc. and SIGNUS Medizintechnik GmbH. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of the sacroiliac joint that compete directly or indirectly with our products. 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.

Some of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies. These competitors may enjoy several competitive advantages over us, including:

- greater financial, human, and other resources for product research and development, sales and marketing, and legal matters;
- significantly greater name recognition;
- established relationships with surgeons, hospitals, and other healthcare providers;
- large and established sales and marketing and distribution networks;
- greater experience in obtaining and maintaining domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater ability to cross-sell their products or to incentivize hospitals or surgeons to use their products.

New participants have increasingly entered the medical device industry. Many of these new competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our products or that are alternatives to our existing or planned 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 sales or margins could decrease, thereby harming our business.

We currently manufacture and sell a single family of products focused on procedures, the goal of which is to stabilize and fuse the sacroiliac joint, which could negatively affect our operations and financial condition.

We do not sell any product other than iFuse and related tools and instruments. Therefore, we are solely dependent on widespread market adoption of iFuse and we will continue to be dependent on the success of this single product for the foreseeable future. There can be no assurance that iFuse will gain a substantial degree of market acceptance among surgeons, patients or healthcare providers. Our failure to successfully increase sales of iFuse or any other event impeding our ability to sell iFuse, would result in a material adverse effect on our results of operations, financial condition and continuing operations.

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

In November 2018, we introduced our iFuse Bedrock technique, in which spine surgeons place iFuse implants across the sacroiliac joint using a different surgical approach to treat sacroiliac joint dysfunction at the same time they are fusing multiple levels of the spine above and affixing those spinal fusion devices to the pelvis. In April 2019, the FDA cleared promotion of iFuse Bedrock for a broader and more general purpose, to provide additional stability and immobilization of the sacroiliac joint in connection with a thoracolumbar fusion procedure. To date, clinical experience with the iFuse Bedrock technique is limited and we have yet to complete a clinical trial to evaluate the iFuse Bedrock technique. Surgeons do not know if the addition of iFuse implants to the implants used to fuse multiple levels of the lumbar spine will result in patient benefit. If surgeons' clinical experience with iFuse Bedrock is not positive, or if our clinical trials do not show meaningful benefits to the patients undergoing this procedure, sale of our iFuse implants for this indication could be adversely impacted, which could negatively affect our operations and financial condition.

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

As of December 31, 2019, our U.S. sales force consisted of 56 territory sales managers directly employed by us and 37 third-party distributors. As of December 31, 2019, our international sales force consisted of 19 sales representatives directly employed by us and 27 exclusive third-party distributors, which together have had sales in 35 countries through December 31, 2019. Our operating results are directly dependent upon the sales and marketing efforts of both our direct sales force and of our third-party distributors.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and third-party distributors with significant technical knowledge in various areas, such as spine health and treatment. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. Our intention is for our direct sales representatives and third-party distributors to develop long-lasting relationships with the surgeons they serve. If our direct sales representatives or third-party distributors fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. Some of our international third-party distributors account for a significant portion of our international sales volume, and if any such third-party distributor were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative third-party distributors or increase our reliance on our direct sales representatives, which may not prevent our sales from being adversely affected. If a direct sales representative or third-party distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified third-party distributors or to hire additional direct sales representatives to work with us. Furthermore, we may not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or third-party distributors would prevent us from expanding our business and generating sales.

In addition, distribution arrangements are complex and time consuming to negotiate and document, especially outside the U.S. We may not be able to negotiate distribution arrangements on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our products, delay their potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our products or bring them to market and generate revenue.

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

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

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

Our products may have undesirable side effects which may require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

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

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

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

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

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

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

- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk;
- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;
- 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 of such products.

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

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

We generally use a small number of suppliers for our instruments and 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 and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- we may experience delays in delivery by our third-party manufacturers and suppliers due to changes in demand from us or their other customers;
- fluctuations in demand for products that our third-party manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our third-party manufacturers and suppliers may wish to discontinue supplying components or services to us for risk management reasons;
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our third-party manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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

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

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

In addition, each of our third-party suppliers operates at a facility in a single location and substantially all of our inventory of component supplies and finished goods is held at these locations. We, and our suppliers, take precautions to safeguard facilities, including acquiring insurance, employing back-up generators, adopting health and safety protocols, and utilizing off-site storage of computer data. However, vandalism, terrorism, or a natural or other disaster, such as an earthquake, fire, or flood, could damage or destroy equipment or our inventory of component supplies or finished products, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our suppliers' facilities could harm our business, financial condition, and operating results.

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

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

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

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

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

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

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

If we do not develop and obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. 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 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 customized to the patient's needs. In order to market our products effectively, we often maintain and provide surgeons and hospitals with back-up products and products of different sizes. For each surgery, fewer than all of the components of the set are used, and therefore certain portions of the set may become obsolete before they can be used. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

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

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

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

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

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

- exposure to different legal and regulatory standards;
- lack of stringent protection of intellectual property;
- obstacles to obtaining domestic and foreign export, import, and other governmental approvals, permits, and licenses and compliance with foreign laws;
- potentially adverse tax consequences and the complexities of foreign value-added tax systems;
- adverse changes in tariffs and trade restrictions;
- limitations on the repatriation of earnings;
- difficulties in staffing and managing foreign operations;
- transportation delays and difficulties of managing international distribution channels;
- longer collection periods and difficulties in collecting receivables from foreign entities;
- increased financing costs;
- currency risks; and
- political, social, and economic instability and increased security concerns.

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

Our goal of a successful international expansion 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 medical and changes through the development and introduction of new products. Product development involves a high degree of risk and there can be no assurance that our new product development efforts will result in any commercially successful products.

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

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

- sales and marketing, accounting, and financial functions;
- inventory management;

- engineering and product development tasks; and
- our research and development data.

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

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

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

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

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

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

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

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

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

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

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

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

Epidemic diseases, or the perception of their effects, could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Outbreaks of epidemic, pandemic, or contagious diseases, such as COVID-19, the recent novel coronavirus or, historically, the Ebola virus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome, or the H1N1 virus, could divert medical resources and priorities towards the treatment of that disease. An outbreak of a contagious disease, or continued escalation of the outbreak of the COVID-19, could also negatively affect hospital admission rates and the decision by patients to undergo elective surgery, which could decrease demand for procedures using our iFuse implants and cause other disruptions to our business. Business disruptions could include disruptions or restrictions on our ability to travel or to distribute our products, 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 epidemic, pandemic, or contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products. Any of these events could negatively impact the number of procedures using our iFuse implants that are performed and have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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 users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

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

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

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

In the EEA, our medical devices must currently comply with the Essential Requirements set forth in Annex I to the EU Medical Devices Directive (Council Directive 93/42/EEC), or Essential Requirements. Compliance with these requirements is a prerequisite to be able to affix the CE mark to our medical devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a third-party organization designated by the competent authorities of a EEA country to conduct conformity assessments, known as a Notified Body. The Notified Body would typically audit and examine the medical device's Technical File including the clinical evaluation, the quality system for the manufacture, design and conduct a final inspection of our medical devices before issuing a CE Certificate of Conformity demonstrating compliance with the Essential Requirements or the QSR of the Medical Devices Directive.

As part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices to verify that they comply with the relevant Essential Requirements covering safety and performance. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions/ warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from (i) clinical studies conducted on the devices being assessed; (ii) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated; or (iii) both clinical studies and scientific literature. With respect to implantable devices, or devices classified as Class III in the EU, the manufacturer must conduct clinical studies to obtain the required clinical data, unless the relying on existing clinical data from similar devices can be justified. As part of the conformity assessment procedure, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation for the medical device. The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time consuming.

In May 2017, the EU Medical Device Regulation, (Regulation 2017/745) was adopted, as described in "Item 1. Business - Regulation - International Regulation of Our Products".

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

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

- warning letters;
- fines;
- injunctions;
- civil penalties;

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

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

We and our sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to physician kickbacks and false claims for reimbursement, as well as equivalent foreign laws.

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

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

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

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

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

In certain cases, federal, state and foreign authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved, or "off-label" uses of their products. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for "off-label" uses. We market our products and provide promotional materials and training programs to surgeons regarding the use of our products. If it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, criminal penalty, and damage to our reputation. Federal, state and foreign authorities also pursue actions for false claims based upon improper billing and coding advice or recommendations, as well as decisions related to the medical necessity of procedures, including the site-of-service where procedures are performed.

Various state and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. The Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal Anti- Kickback Statute. To enforce compliance with the federal laws, the U.S. Department of Justice has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare company settles an investigation with the Department of Justice or other law enforcement agencies, it may need to agree to additional onerous compliance and reporting requirements as part of a consent decree, deferred or non-prosecution agreement, or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

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

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

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

In June 2018, California enacted the California Consumer Privacy Act ("CCPA"). The CCPA, which became effective on January 1, 2020, requires a broad range of businesses to honor the requests of California residents to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used and shared. The CCPA provides for civil penalties of up to $7,500 for intentional violations, and a private right of action for data breaches that allows private plaintiffs to seek the greater of actual damages or statutory damages of up to $750 per consumer per data breach. These remedies are expected to increase data breach litigation. The California Attorney General, who is charged with interpreting and enforcing the law, has not yet promulgated final implementing regulations, and considerable uncertainty as to how the law will be implemented and enforced remains. Although the CCPA includes exemptions for certain clinical trials data, and protected health information governed by HIPAA, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end-customers, and other affected individuals, and the imposition of integrity obligations and agency oversight, damage to our reputation, and loss of goodwill, any of which could harm on our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the European Union, the U.S., and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products.

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

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

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

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

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

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

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

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

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

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

The FDA inspected our facilities in May 2014. As a result, we received a Notice of Inspectional Observations, or Form 483, with three observations that have since been addressed with a corrective and preventative action plan. We responded to the Agency in writing and the matter was closed as of October 2014 through the issuance of an Establishment Inspection Report. To date, the FDA has not taken any further action with respect to the May 2014 inspection or its findings. The FDA inspected our facilities again in December 2016 and no findings were noted.

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

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

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

Our promotional materials and training methods must comply with FDA and other applicable national and foreign laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA and equivalent third country authorities do not restrict or regulate a physician's choice of treatment within the practice of medicine. In the U.S., the full indication for the iFuse Implant System is: "The iFuse Implant System is intended for sacroiliac joint fusion for conditions including 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 six months. The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion" 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.

Further, under the FDA's medical device reporting, regulations, and equivalent rules of other countries, we are required to report to the FDA or a similar authority in such other country, any information that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. If we fail to report these events to the FDA or applicable authority in another country within the required timeframes, or at all, FDA, or the applicable authority in the other country, could take enforcement action against us. Any such adverse event involving our products or repeated product malfunctions may result in a voluntary or involuntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations, and financial condition.

In the EEA, we must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the Member States of the EEA, and manufacturers are required to take Field Safety Corrective Actions ("FSCAs"), to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. The entry into application in May 2020 of the Medical Device Regulation will increase the obligation that we must fulfill in relation to vigilance and post-market surveillance obligations.

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

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

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

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

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

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

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make and document this determination in the first instance. A manufacturer may determine that a modification could not significantly affect safety or effectiveness and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. FDA may review any manufacturer's decision and may not agree with our decisions regarding whether new clearances or approvals are necessary. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified until clearance or approvals can be obtained, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

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, and we may be subject to significant enforcement action, regulatory fines, or penalties.

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 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.

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 harm our future growth.

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 ability to grow our business.

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 to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products or our Notified Body may not issue CE Certificate of Conformity for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products, new intended uses, or modifications to existing products and our Notified Body may refuse to issue new CE Certificates of Conformity. Failure to receive clearance, approval, or Certificates of Conformity for our new products would have an adverse effect on our ability to expand our business.

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

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

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

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

Initiating and completing clinical trials necessary to support a PMA application for our future products and additional safety and effectiveness data beyond that typically required for a 510(k) clearance for iFuse, as well as other possible future product candidates, and to support a conformity assessment procedure to support a new CE Certificate of Conformity would be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product, or new indication for use, we advance into clinical trials may not have favorable results in later clinical trials.

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

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

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

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

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

From time to time, Congress introduces legislation that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Moreover, the new Medical Device Regulation will enter into application on May 26, 2020. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

In December 2016, the 21st Century Cures Act was enacted, with a number of provisions impacting medical device regulation. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market, and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Leadership, personnel and structural changes within the FDA as well as recent and impending federal election outcomes, including the 2020 presidential election, could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Another example can be found in the EEA. The Medical Devices Regulation became effective on May 25, 2017. Following its entry into application on May 26, 2020, the Medical Devices Regulation will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EEA. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the Medical Devices Regulation repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA Member States, regulations are directly applicable, i.e., without the need for adoption of national legislation in EEA Member States implementing them. The purpose of regulations is to eliminate current differences in regulation of medical devices among EEA Member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices to ensure a high level of safety and health while supporting innovation. These regulations will substantially impact medical devices manufacturers. Examples of the changes which will be introduced by these regulations include the following:

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

The Medical Device Regulation substantially amplifies the provisions of the Medical Device Directive governing clinical investigations of medical devices. Among others, 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 on sponsors and investigators the obligation to ensure they make use of these make use of these systems.

Transition from the regulation of our products under the current Medical Device Directive, and implementing legislation in each EU Member State, to regulation under the Medical Devices Regulation may require a substantial transition effort by us. In addition, detail as to how certain aspects of the Medical Devices Regulation will be applied remains unclear. Failure to update our quality system and regulatory documentation could delay our transition to compliance with the Medical Devices Regulation and delay or prevent us from obtaining new CE Certificates of Conformity under the Regulation. Transition from compliance with the Medical Device Directive to the Medical Devices Regulation could result in disruption to our business in the EEA which could adversely affect our business, results of operation and financial condition. In addition, any changes to the membership of the European Union, such as the departure of the United Kingdom from the EU, may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations, and other healthcare-related organizations. Recent political, economic, and regulatory influences are subjecting the healthcare industry to fundamental changes that can impact coverage and reimbursement from third-party payors. For example, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, among other things, reduced and/or limited Medicare reimbursement to certain providers. Legislative changes to the Patient Protection and Affordable Care Act remain possible in the 116th U.S. Congress and under the Trump Administration. We expect that the Patient Protection and Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products. Other federal laws further reduce Medicare's payments to providers by two percent through 2024. These reductions reduce reimbursement for our products, which could potentially negatively impact our revenue, and may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

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

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

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

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

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

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

The comprehensive tax reform bill adopted in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses arising after 2017 to 80% of current year taxable income and elimination of carrybacks of such net operating losses, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modification or repeal of many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax

reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

The UK's withdrawal from the EU and uncertainty regarding tariffs affecting U.S. imports and exports may have a negative effect on global economic conditions, financial markets and our business.

On January 31, 2020, the UK withdrew from the EU. Brexit has created significant uncertainty concerning the future relationship between the UK and the EU. In light of the fact that a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product in the UK or the EU. Any changes in our manufacturing or commercialization activities as a result of Brexit, could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the euro with respect to each other and to the U.S. dollar have already been, and may continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

We do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to membership in the EU will impact our business, particularly our ability to conduct international business from a base of operations in the UK. The UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, possibly resulting in increased trade barriers, which could make doing business in Europe more difficult and/or costly. Moreover, in the U.S., tariffs on certain U.S. imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, these tariffs and other trade restrictions, whether resulting from the UK's withdrawal from the EU or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

Risks Related to Our Intellectual Property

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

We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and non- disclosure agreements and other methods, to protect our proprietary technologies and know-how. As of December 31, 2019, we owned 40 issued U.S. patents and had 19 pending U.S. patent applications, and we owned 10 issued foreign patents and had 5 pending foreign patent applications. We have focused the majority of our foreign patent efforts in China, Europe, and Japan. Our current U.S. patents on iFuse, including the triangular shape, expire in August 2024. Our current U.S. patents on iFuse 3D, including the fenestrated design, expire in September 2035. Our foreign patents will expire between August 2025 and October 2031. Competitors may market similar triangular shaped devices upon the expiration of the patents in 2024. We will continue to have patent protection of our 3D-printed fenestrated implants through 2035.

As of December 31, 2019, we have 14 registered trademarks in the U.S. and have filed for 4 more. We have sought protection for at least 2 of these trademarks in 60 countries including the 28 European member countries of the Madrid Protocol.

We have applied for patent protection relating to certain existing and proposed products and processes. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented 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 continue, 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 business assets and management's attention being diverted to patent litigation. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. Further, as the number of participants in the medical device industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, including treble, or triple, damages if an infringement is found to be willful, and/or royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations, and financial condition. If passed into law, patent reform legislation currently pending in the U.S. Congress could significantly change the risks associated with bringing or defending a patent infringement lawsuit. For example, fee shifting legislation could require a non-prevailing party to pay the attorney fees of the prevailing party in some circumstances.

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

Risks Related to Ownership of Our Common Stock

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

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

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

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

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

- payor coverage and reimbursement;
- the number of products sold in the quarter and our ability to drive increased sales of our products;
- our ability to establish and maintain an effective and dedicated sales force;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- 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 net operating loss carryforwards to reduce our income taxes.

As of December 31, 2019, we had net operating loss ("NOL") carryforwards of $164.4 million and $129.6 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in 2028 and 2020, respectively. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which generally occurs if the percentage of the corporation’s stock owned by 5% stockholders increases by more than 50% over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have determined that we have experienced Section 382 ownership changes in 2010 and $1.4 million of our NOL and tax credit carryforwards are subject to limitation. We also updated our Section 382 ownership change analysis through June 30, 2019, considering the recent changes in ownership following our IPO in October 2018. Based on the result of the analysis, we concluded that we did not undergo ownership change that would require for any additional limitations on our NOL carryforwards. We further concluded that the equity shift between June 30, 2019 to December 31, 2019 was not material, considering the changes in the outstanding number of shares at each respective periods. 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.

We do not intend to pay dividends for the foreseeable future and, consequently, our stockholders' ability to achieve a return on investment in our common stock will depend on appreciation in the price of our common stock.

We have never declared or paid any dividends on our common stock. We intend to retain any earnings to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the future. As a result, our stockholders may only receive a return on an investment in our common stock if the market price of our common stock increases. In addition, our loan and security agreements contain restrictions on our ability to pay dividends.

Our credit facility contains covenants that may restrict our business and financing activities.

Borrowings under our credit facility are secured by substantially all of our assets. Our credit facility also restricts our ability to, among other things:

- dispose of or sell assets;
- make material changes in our business or management;
- consolidate or merge with or acquire other entities;
- incur additional indebtedness;
- incur liens on our assets;
- pay dividends or make distributions on our capital stock;
- make certain investments;
- enter into transactions with our affiliates;
- make any payment in respect of any subordinated indebtedness; and
- waive or amend any of our current intellectual property agreements or material contracts.

These restrictions are subject to certain exceptions. In addition, our loan and security agreement requires us to maintain a minimum cash balance and revenue targets. Beginning with the three months ended March 31, 2019, we are required to meet either revenue or earnings targets.

The covenants in our credit facility, 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 credit facility agreement to become immediately due and payable and terminate all commitments to extend further credit.

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

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

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

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

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

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

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

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

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

Our amended and restated certificate of incorporation also provides that the U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, in light of a Delaware Chancery Court opinion issued in December 2018, we announced that we currently do not intend to enforce this aspect of our forum selection clause.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our leased headquarters in Santa Clara, California, comprises approximately 21,848 square feet. 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 office spaces in Gallarate, Italy, Mannheim, Germany and Knaresborough, United Kingdom to accommodate our European sales and marketing team.

Item 3. Legal Proceedings

On February 6, 2019, a putative class action captioned Eric B. Fromer Chiropractic, Inc. ("Plaintiff") v. SI-BONE, Inc. (Civil Action No. 5:19-cv-633-SVK), was filed in the U.S. District Court, Northern District of California. The complaint alleges violations of the Telephone Consumer Protection Act (the “TCPA”) on behalf of an individual and a putative class of persons alleged to be similarly situated. The complaint alleges that we sent invitations to an educational dinner event to health care providers by way of facsimile transmission. The TCPA prohibits using a fax machine to send unsolicited advertisements not including proper opt-out instructions or to send unsolicited advertisements to persons with whom the sender did not have an established business relationship. The plaintiff sought various forms of relief, including statutory damages of $500 for each violation of the TCPA or, in the alternative, treble damages of up to $1,500 for each knowing and willful violation of the TCPA and a permanent injunction prohibiting us from sending or having sent advertisements by way of facsimile transmission. On December 23, 2019 the parties filed a joint stipulation of dismissal of the case in the District Court in the Northern District of California and on January 14, 2020, the parties executed a definitive settlement agreement (the "Settlement Agreement"), pursuant to which, we agreed to settle all disputes regarding the advertising faxes to the settlement class.

As this lawsuit is being resolved through a negotiated settlement and class resolution process, we believe that we will incur a loss associated with resolution of the claims against us. We accrued a litigation expense of $3.2 million during the year ended December 31, 2019 within general and administrative expenses in the consolidated financial statements. The accrual reflects the estimable and probable costs that we may incur based on estimated claims submitted by members of the settlement class, as defined in the Settlement Agreement. The final disposition of the lawsuit may result in a loss in excess of the aggregate recorded amount.

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 March 6, 2020, we had 209 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.

Recent Sales of Unregistered Securities

There were no sales of unregistered equity securities during the three months ended December 31, 2019.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of shares or equity securities during the three months ended December 31, 2019.

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, 2019, approximately $39.5 million of the net proceeds had been used for general corporate purposes including cash used in operations and capital expenditures.

Item 6. Selected Financial Data.

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

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 focused on the development of implantable devices used in the surgical treatment of the sacropelvic anatomy. We have pioneered a proprietary minimally invasive surgical implant system, which we call iFuse, to fuse the sacroiliac joint to treat sacroiliac joint dysfunction, which often causes severe lower back pain. Since we introduced iFuse in 2009, as of December 31, 2019, more than 44,000 procedures have been performed by over 2,000 surgeons, in the U.S. and 35 other countries.

We introduced our second-generation implant, the iFuse-3D, in 2017. This patented titanium implant combines the triangular cross-section of our first-generation iFuse Implant with a proprietary 3D-printed porous surface and fenestrated design.

In April 2019, we received clearance from the U.S. Food and Drug Administration ("FDA"), to promote the use of our iFuse system with the iFuse Bedrock technique for fusion of the sacroiliac joint in conjunction with multi-level spinal fusion procedures to provide further stabilization and immobilization of the sacroiliac joint. We received CE marking and began marketing our iFuse system for the same indication in Europe in December 2019.

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") by issuing 8,280,000 shares of common stock, at an offering price of $15.00 per share, for net proceeds of $113.4 million after deducting underwriting discounts and commissions and offering expenses payable by us. In January 2020, we received $50.3 million of net proceeds, after deducting the underwriting discounts and commissions but before offering expenses, from our public offering of 4,300,000 shares of our common stock, of which 2,490,053 shares were offered and sold by us. Further, in February 2020, the underwriters fully exercised its option to purchase 645,000 shares of our common stock at a public offering price of $21.50 per share for an additional net proceeds of $13.0 million to us, after deducting the underwriting discounts and commissions. For more information regarding this subsequent public offering, refer to Item 8. Financial Statements and Supplementary Data, "Note 14 - Subsequent Events" in the accompanying Notes to Consolidated Financial Statements.

Factors Affecting Results of Operations and Key Performance Indicators

We monitor certain key performance indicators that we believe provides 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 others, our key performance indicators including our ability to expand our sales force, increase surgeon activity, engage key opinion leaders and influence coverage and reimbursements.

Expanding our sales force

We made significant investments in our sales force. As of December 31, 2019, our U.S. sales force consisted of 56 territory sales managers directly employed by us and 37 third-party distributors, compared to 45 territory sales managers directly employed by us and 30 third-party distributors as of December 31, 2018. As of December 31, 2019, our international sales force consisted of 19 sales representatives directly employed by us and 27 exclusive third-party distributors, compared to 14 sales representatives directly employed by us and 23 exclusive third-party distributors as of December 31, 2018. We anticipate continuing to build our operations in the major European countries while establishing distributor arrangements in smaller ones. We believe that our expanded field organization allows us to reach more surgeons, educating them to include the sacroiliac joint in their differential diagnosis of lower back pain and to regularly perform the iFuse procedure for patients for whom the procedure is indicated.

Increasing surgeon activity

We grew our active surgeon base to 539 surgeons as of December 31, 2019, compared to 450 active surgeons as of December 31, 2018. We define an active surgeon to be a surgeon who has performed at least one case in the last three months. The increase in active surgeons is primarily due to training of additional surgeons throughout the year. We have several surgeon trainer consultants who train new surgeons, focusing on diagnosis and treatment. As of December 31, 2019, approximately 1,400 surgeons in the U.S. 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. for training in the future.

Engaging key opinion leaders

We conduct training courses in several academic centers in the U.S. We are seeing interest from key opinion leaders at academic centers in our Bedrock technique. We introduced this technique in June 2019 for use in the fusion of the sacroiliac joints in conjunction with a multi-segment spinal fusion, or long construct, procedure. The Bedrock technique is based on our proprietary implants and is used to increase stability at the base of a long construct. Biomechanical data shows that placing iFuse implants with the Bedrock technique reduces sacroiliac joint motion by approximately 30% in conjunction with a long construct. Interest in the Bedrock technique has enabled our field sales representatives to access leading spine surgeons at important academic medical centers in the U.S. Our representatives are often then able to train a broader group of spine surgeons, including residents and fellows in training at the centers, on both the Bedrock technique and minimally invasive sacroiliac fusion. We recently received CE mark clearance for the promotion of the Bedrock technique in Europe and we are now in the process of launching the promotion of this technique in select European markets. We believe that acceptance of the sacroiliac joint as a pain generator by leading spine surgeons may result in more widespread awareness of sacroiliac joint dysfunction and its role in causing certain types of chronic low back pain.

Influencing coverage and reimbursement

We made progress in 2019 in both the number of covered lives and the Medicare physician fee for surgeons performing minimally invasive sacroiliac fusion in the U.S.

- ***Covered lives*** - As of December 31, 2019, of the U.S. payors covering 282.7 million lives that reimburse for iFuse, 147.9 million lives are covered by private payors, compared to 256.2 million covered lives, of which 121.7 million were covered by private payors as of December 31, 2018. We track the number of U.S. covered lives, or individuals whose healthcare is paid for by a private commercial or governmental payor that routinely reimburses for minimally invasive sacroiliac fusion, as a proxy for availability of the procedure within the U.S. healthcare payment system. As of December 31, 2019, 32 private payors have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence, compared to 26 exclusive coverage policies as of December 31, 2018. These payors have based their exclusive coverage decisions on the quality of our data. Further, as of December 31, 2019 and 2018, 20 and 19, respectively, private payors are covering iFuse and other products for sacroiliac joint fusion. We believe that the full impact of each coverage decision grows over time as surgeons gain confidence that they will receive reimbursement for the majority of their diagnosed patients.

- ***Surgeon payment*** - The Center for Medicare & Medicaid Services ("CMS") announced in November 2019 that the U.S. national average physician fee reimbursement for minimally invasive sacroiliac joint fusion increased from $720, effective January 1, 2019 to $915, effective January 1, 2020. Many private payors set their payment amounts with reference to the Medicare payment, often approximately 10% to 33% higher than the Medicare payment for a procedure. We believe that expanded coverage for minimally invasive sacroiliac fusion and the increase in physician reimbursement for the procedure may enable surgeons to treat more patients diagnosed with sacroiliac joint dysfunction with iFuse.

Components of Results of Operations

Revenue

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

Cost of Goods Sold, Gross Profit, and Gross Margin

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

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

Operating Expenses

Our operating expenses consist of sales and marketing, research and development, and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consist of salaries, sales commissions and other cash and stock-based compensation related expenses. We expect operating expenses to increase as we continue to invest and grow our business.

Sales and Marketing Expenses

Sales and marketing expenses primarily consist of salaries, stock-based compensation expense, and other compensation related costs, for personnel employed in sales, marketing, medical affairs, reimbursement and professional education departments. In addition, our sales and marketing expenses include commissions and bonuses, generally based on a percentage of sales, to our senior sales management, direct territory sales managers, territory associate representatives and third-party distributors. We expect our sales and marketing expenses to increase with the continued commercialization of our current and future products and continued investment in our global sales organization, including broadening our relationships with third-party distributors, expanding exclusivity commitments among them and increasing the number of our direct sales representatives, especially with increased reimbursement and adoption in the U.S. Our sales and marketing expenses may fluctuate from period to period due to the seasonality of our business and as we continue to add direct territory sales managers in new territories.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, clinical and regulatory expenses (including clinical study expenses), and consulting services, outside prototyping services, outside research activities, materials, depreciation, and other costs associated with development of our products. Research and development expenses also include related personnel and consultants' compensation and stock-based compensation expense. We expense research and development costs as they are incurred. We expect research and development expense to increase as we develop new products, add research and development personnel, and undergo clinical activities, including more clinical studies to gain additional regulatory clearances and wider surgeon adoption.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, stock-based compensation expense, and other costs for finance, accounting, legal, compliance, and administrative matters. We expect our general and administrative expenses to increase to support the growth of our business. We also expect to incur additional general and administrative expenses as a result of operating as a public company, including but not limited to: expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and those of the Nasdaq Global Market on which our securities are traded; additional insurance expenses; investor relations activities; and other administrative and professional services.

Interest Income

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

Interest Expense

Interest expense is primarily related to borrowings and amortization of debt issuance costs. Prior to our initial public offering, interest expense also included the amortization of debt discounts derived from the issuance of warrants.

Other Income (Expense), Net

Other income (expense), net consists primarily of net foreign exchange gains (losses) on foreign transactions. Prior to our initial public offering, other income (expense), net included changes in fair value of our preferred stock warrant liability. In connection with our IPO, our preferred stock warrant liability was reclassified to equity upon conversion of preferred stock warrants to common stock warrants.

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, 2019		Year ended December 31, 2018	
	Amount	%	Amount	%
	(in thousands, except for percentages)			
Consolidated Statements of Operations Data:				
Revenue	$ 67,301	100 %	$ 55,380	100 %
Cost of goods sold	6,790	10 %	4,833	9 %
Gross profit	60,511	90 %	50,547	91 %
Operating expenses:				
Sales and marketing	68,251	101 %	44,497	80 %
Research and development	7,279	11 %	5,376	10 %
General and administrative	20,984	31 %	12,639	23 %
Total operating expenses	96,514	143 %	62,512	113 %
Loss from operations	(36,003)	(53)%	(11,965)	(22)%
Interest and other income (expense), net:				
Interest income	2,551	4 %	769	2 %
Interest expense	(4,949)	(7)%	(5,108)	(9)%
Other expense, net	(2)	— %	(1,149)	(2)%
Net loss	$ (38,403)	(56)%	$ (17,453)	(31)%

We derive the majority of our revenue from sales to customers in the U.S. Revenue by geography is based on billing address of the customer. No single country outside the U.S. accounts for more than 10% of the total revenue during the periods presented. The table below summarizes our revenue by geography:

	Year ended December 31, 2019		Year ended December 31, 2018	
	Amount	%	Amount	%
	(in thousands except for percentages)			
United States	$ 61,843	92%	$ 50,137	91%
International	5,458	8%	5,243	9%
	$ 67,301	100%	$ 55,380	100%

Comparison of the years ended December 31, 2019 and 2018

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

	Year ended December 31,			
	2019	2018	$ Change	% Change
	(in thousands except for percentages)			
Revenue	$ 67,301	$ 55,380	$ 11,921	22%
Cost of goods sold	6,790	4,833	1,957	40%
Gross profit	$ 60,511	$ 50,547	$ 9,964	20%
Gross margin	90%	91%		

Revenue. Revenue increased $11.9 million, or 22%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. This is primarily due to an increase of $11.7 million from growth of U.S. revenue due to the hiring of more sales force and training of new surgeons resulting to increased case volumes. Our international sales also increased $0.2 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 mainly due to increased case volumes.

Cost of Goods Sold, Gross Profit, and Gross Margin. Total cost of goods sold increased $2.0 million, or 40%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The increase was primarily due to higher sales volumes. Higher net revenue resulted in increased gross profit of $10.0 million, or 20%. Gross margin decreased to 90% for the year ended December 31, 2019 as compared to 91% the year ended December 31, 2018 due to an increase in personnel in operations to support the growth of the business.

Operating Expenses:

	Year ended December 31,			
	2019	2018	$ Change	% Change
	(in thousands, except for percentages)			
Sales and marketing	$ 68,251	$ 44,497	$ 23,754	53%
Research and development	7,279	5,376	1,903	35%
General and administrative	20,984	12,639	8,345	66%
Total operating expenses	$ 96,514	$ 62,512	$ 34,002	

Sales and Marketing Expenses. Sales and marketing expenses increased $23.8 million, or 53%, for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase was primarily due to an increase of $8.6 million in salaries and other employee related costs, $2.5 million in travel expense, and $1.8 million in facilities and other related expenses as a result of an increase in headcount, $5.5 million in commissions due to increased sales, $2.7 million in stock-based compensation expense due to increase in headcount and issuance of stock grants with higher market value, and $2.7 million in training, advertising and marketing costs due to continued commercialization of our current and future products and continued investment in our global sales organization.

Research and Development Expenses. Research and development expenses increased $1.9 million, or 35%, for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase was primarily due to an increase of $0.9 million in salaries and other employee related costs, $0.4 million in stock-based compensation expense, and $0.6 million in facilities and other related expenses from increased research and development activities as well as higher headcount.

General and Administrative Expenses. General and administrative expenses increased $8.3 million, or 66%, for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase was primarily due to $3.2 million of accrued litigation expense in 2019, and increases of $0.8 million in salaries and employee related costs due to increases in headcount, $2.0 million in stock-based compensation from an increase in headcount and issuance of stock grants with higher market value, $1.3 million in consulting and professional services due to additional regulatory and other compliance services required for a public company, and $1.0 million in facilities and other expenses due to expansion of our general and administrative department.

Interest and Other Income (Expense), Net:

	Year ended December 31,			
	2019	2018	$ Change	% Change
	(in thousands, except for percentages)			
Interest income	$ 2,551	$ 769	$ 1,782	232 %
Interest expense	(4,949)	(5,108)	159	(3)%
Other expense, net	(2)	(1,149)	1,147	(100)%
Total interest and other expense, net	$ (2,400)	$ (5,488)	$ 3,088	(56)%

Interest Income. Interest income increased $1.8 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018, mainly as a result of full year investments in marketable securities during the year ended December 31, 2019 compared to partial year investments in marketable securities during the year ended December 31, 2018, following the IPO.

Interest Expense. Interest expense remained relatively unchanged for the year ended December 31, 2019 as compared to the year ended December 31, 2018.

Other Expense, Net. Other expense, net, decreased by $1.1 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018, primarily due to the change in fair value of preferred stock warrant liability of $0.8 million recognized in the year ended December 31, 2018, and lower foreign currency exchange losses.

Liquidity and Capital Resources

As of December 31, 2019, we had cash and marketable securities of $93.1 million compared to $122.2 million as of December 31, 2018. Since inception, we have financed our operations through our initial public offering, private placements of preferred stock, debt financing arrangements, and the sale of our products. In January and February 2020, we received a total of $63.4 million of net proceeds after deducting underwriting discounts and commissions but before offering expenses, from a follow-on public offering of our common stock, including the underwriters' full exercise its option to purchase additional shares of our common stock. For more information regarding subsequent public offering, refer to Item 8. Financial Statements and Supplementary Data, “Note 14 - Subsequent Events” in the accompanying Notes to Consolidated Financial Statements.

As of December 31, 2019, we had an accumulated deficit of $195.6 million. During the years ended December 31, 2019 and 2018, we incurred a net loss of $38.4 million and $17.5 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date. As of December 31, 2019 and 2018, we had $39.2 million and $39.0 million, respectively, principal amount of outstanding debt, net of debt issuance costs. The debt covenants associated with our current debt agreement require us to maintain a minimum cash balance and meet either minimum net sales or trailing 12-month consolidated earnings before interest, taxes, depreciation, and amortization ("EBITDA") targets as discussed in detail below. If we do not comply with these covenants, the debt will immediately become due.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. We continue to face challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to: (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory 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.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our sales and marketing efforts, research and development activities, or other operations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we are unable to raise capital, we will need to delay, reduce, or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

Borrowings

Our outstanding debt is related to a term loan we entered with Biopharma Credit Investments IV Sub LP, or Pharmakon, in October 2017 for total loan proceeds of $40.0 million. The term loan includes an interest-only period for 35 months through September 2020 and is then repaid in equal principal payments plus interest through December 2022. The term loan carries a fixed interest rate of 11.5% and a closing fee of 1.5% of the funded amount, or $0.6 million. The term loan includes a pre-payment fee of the remaining interest payable for the first 30 months of the agreement if it is prepaid within the first 30 months, a 2% prepayment penalty for months 31-48, and a 1% penalty for months 49-60. The term loan is collateralized by all of our assets, including intellectual property. The term loan requires us to maintain a minimum cash balance of $5.0 million.

Beginning in the first quarter of 2019, we are required to meet either minimum net sales or trailing 12-month consolidated EBITDA targets. We need to meet one or the other, but not both. If we do not meet either the minimum net sales or trailing 12-month consolidated EBITDA targets, the debt will immediately become due. The remaining minimum net sales and trailing 12-month consolidated EBITDA targets are as follows:

Twelve Months Ending	Minimum Net Sales		Trailing 12-Month Consolidated EBITDA
	(in thousands)		
March 31, 2020	$57,500	or	$1,000
June 30, 2020	$58,500	or	$2,000
thereafter, as applicable	$60,000	or	$3,000

As of December 31, 2019 and 2018, we were in compliance with all of our debt obligations and covenants.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019:

		Payments Due By Period			
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
		(in thousands)			
Principal obligations on the debt arrangements	$ 40,000	$ 4,444	$ 35,556	$ —	$ —
Interest obligations on the debt arrangements	9,331	4,677	4,654	—	—
Operating leases	5,128	1,102	1,932	1,729	365
Purchase obligations	403	403	—	—	—
Total	$ 54,862	$ 10,626	$ 42,142	$ 1,729	$ 365

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,			
	2019	2018	$ Change	% Change
	(in thousands, except for percentages)			
Net cash provided by (used in):				
Operating activities	$ (31,627)	$ (14,519)	$ (17,108)	118 %
Investing activities	13,491	(97,825)	111,316	(114)%
Financing activities	3,488	115,150	(111,662)	(97)%
Effects of exchange rate changes on cash and cash equivalents	(37)	(94)	57	(61)%
Net (decrease) increase in cash and cash equivalents	$ (14,685)	$ 2,712	$ (17,397)	

Cash Used in Operating Activities

Net cash used in operating activities increased by $17.1 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. Net cash used in operating activities for the year ended December 31, 2019 of $31.6 million resulted from cash outflows due to a net loss of $38.4 million, adjusted for $7.3 million of non-cash items, and cash outflows from changes in operating assets and liabilities of $0.5 million. Net cash used in operating activities for the year ended December 31, 2018 of $14.5 million resulted from cash outflows due to a net loss of $17.5 million, adjusted for $4.0 million of non-cash items, and cash outflows from changes in operating assets and liabilities of $1.0 million. The increase in net loss, net of non-cash items for the year ended December 31, 2019 compared to the year ended December 31, 2018 was mainly due to higher operating expenses from expansion of the business, partially offset by higher revenue. Cash outflows from changes in operating assets and liabilities for the years ended December 31, 2019 and 2018 were primarily due to increases in inventories and accounts receivable as a result of increased case volumes and growth of the business, partially offset by increases in accounts payable, accrued expenses and other liabilities due to timing of payments and accrual of litigation expense.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities in the year ended December 31, 2019 was $13.5 million compared to net cash used in investing activities of $97.8 million in the year ended December 31, 2018. Cash provided by investing activities for the year ended December 31, 2019 consisted of maturities of our marketable securities of $159.8 million, partially offset by purchases of marketable securities of $143.9 million and purchases of property and equipment of $2.4 million. Net cash used in investing activities for the year ended December 31, 2018 primarily consisted of purchases of marketable securities of $96.9 million, which was mainly from the net proceeds from our IPO, and purchases of property and equipment of $0.9 million.

Cash Provided by Financing Activities

Cash provided by financing activities in the year ended December 31, 2019 was $3.5 million compared to $115.2 million in the year ended December 31, 2018. Cash provided by financing activities for the year ended December 31, 2019 consisted of proceeds received from stock option exercises of $1.5 million and proceeds received from issuance of shares of common stock under our employee stock purchase plan of $2.2 million, partially offset by payments due to additional accrual of public offering costs of $0.2 million. Cash provided by financing activities for the year ended December 31, 2018 consisted of proceeds from our IPO, net of underwriting discounts and commissions of $115.5 million, and proceeds from exercise of stock options of $1.6 million, partially offset by payments of public offering costs of $1.9 million and repurchases of common stock of $0.1 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 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 policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates. 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. We believe the following critical accounting policies reflect significant judgments and estimates used in the preparation of our consolidated financial statements:

- revenue recognition;
- stock-based compensation; and
- income taxes

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. Through the year ended December 31, 2018, in accordance with ASC Topic 605, Revenue Recognition ("ASC 605"), we recognized revenue when persuasive evidence of an arrangement exists, title and risk of loss has transferred to the customer, the sales price is fixed or determinable, and collectability is reasonably assured.

As a result of the adoption of the new revenue standard in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606") effective for the fiscal year ended December 31, 2019, we now 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. Under the new revenue recognition standard, 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. There had been no material differences in our revenue recognition accounted for under ASC 605 and ASC 606. The adoption of the new revenue standard did not result to a material impact on our consolidated financial statements. For more comprehensive discussion of our adoption to the new revenue standards, refer to "*Adoption of New Revenue Recognition Standard"* in “Note 2 - Summary of Significant Account Policies” in the accompanying Notes to Consolidated Financial Statements in Item 8 of this Form 10-K. As it relates to product sales where our sales representative delivers the product at the point of implantation at hospital or other medical facilities, we continue to recognize the revenue upon completion of the procedure and authorization by the customer, net of rebates and price discounts. This represents majority of our consolidated revenue. 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 consists 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.

Stock-Based Compensation

We apply the fair value recognition provisions of stock-based compensation. We recognize stock-based compensation expense 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, we reduce our stock-based compensation for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that we expect to vest. To the extent actual forfeitures differ from the estimates, we record the difference as a cumulative adjustment in the period that the estimates are revised.

We estimate the grant date fair value of stock options using the Black-Scholes option valuation model. The model requires us 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 we expect the share-based awards to be outstanding. We use the simplified method to determine the expected term as permitted by the guidance since we have 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* - Since we became public in October 2018 and have no sufficient trading history, we use stock price volatility using the average historical volatilities of publicly traded companies within our industry that we consider comparable to our business over a period approximately equal to the expected term of our stock options.

- *Risk-Free Interest Rate* - We base the risk-free interest rate 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* - We have not paid any dividends and we have no current plans to pay dividends on our common stock. As such, we use expected dividend yield of zero.

We base the fair value of the restricted stock unit ("RSU") grant on the market price of our common stock on the date of grant.

Prior to IPO, the fair value of the shares of our common stock has historically been determined by our Board of Directors since there were no public market information available for our common stock. The estimated fair value of our 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*. Our Board of Directors, with the assistance of management and independent third-party valuation experts, developed these valuations and took into account numerous factors, including developments at our company, market conditions, and contemporaneous independent third-party valuations. In valuing our common stock, the fair value of our business, or enterprise value, was determined using both the income approach and market approach. The income approach estimates value based on the expectation of future cash flows. The market approach estimates value based on a comparison of the subject company to comparable public companies in a similar line of business. The assumptions used in determining the fair value of our common stock involved management's best estimates and judgments at the time the valuation was performed. Subsequent to our IPO, we now use the market closing price our common stock as reported on the Nasdaq Global Market on the date of grant.

We record equity instruments issued to non-employees at their fair value on the measurement date which are subject to periodic adjustments as the underlying equity instruments vest. We believe that the estimated fair value of the stock options is more readily measurable than the fair value of the services received. We recognize stock-based compensation related to stock options granted to non-employees as the stock options are earned.

In the event we modify the underlying terms of stock options on which stock-based compensation was granted, we recognize additional expense for any modification that increases the total fair value of the share-based payment arrangement at the modification date.

Income Taxes

We account for income taxes under the liability method, whereby we determine deferred tax assets and liabilities 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 we expect the differences to affect taxable income.

We recognize uncertain tax positions when it meets a more-likely-than-not threshold. We recognize potential accrued interest and penalties related to unrecognized tax benefits as income tax expense. We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment. Assessing an uncertain tax position begins with the initial determination of the sustainability of the position and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit may change as new information becomes available.

We record a valuation allowance to reduce deferred tax assets when management cannot conclude that it is more-likely-than-not that the net deferred tax asset will be recovered. The valuation allowance is determined by assessing both positive and negative evidence to determine whether it is more-likely-than-not that deferred tax assets are recoverable; such assessment is required on a jurisdiction-by-jurisdiction basis. There is judgment required in determining whether we should record the valuation allowance against deferred tax assets. We continue to maintain a full valuation allowance against our deferred tax assets due to the uncertainty surrounding realization of these assets. The realization of net deferred tax assets is dependent on our ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets.

Off-Balance Sheet Arrangements

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

Seasonality

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

JOBS Act Accounting Election

In April 2012, the JOBS Act was enacted. Section 107(b) of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, are not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

See Note 2 of Notes to 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

As a "smaller reporting company," we are not required to provide the information 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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SI-BONE, Inc. and its subsidiaries (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of changes in redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements 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 of these consolidated financial statements 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers LLP
San Jose, California
March 11, 2020

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, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,435	$ 25,120
Short-term investments	81,345	97,103
Accounts receivable, net of allowance for doubtful accounts of $238 and $263, respectively	11,720	8,486
Inventory	5,452	3,343
Prepaid expenses and other current assets	2,510	1,990
Total current assets	111,462	136,042
Long-term investments	1,278	—
Property and equipment, net	3,954	2,154
Other non-current assets	315	325
TOTAL ASSETS	$ 117,009	$ 138,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,811	$ 2,146
Accrued liabilities and other	11,605	6,860
Current portion of long-term borrowings	4,358	—
Total current liabilities	18,774	9,006
Long-term borrowings	34,865	38,963
Other long-term liabilities	362	360
TOTAL LIABILITIES	54,001	48,329
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; 25,163,803 and 24,450,757 shares issued and outstanding, respectively	3	3
Additional paid-in capital	258,121	246,927
Accumulated other comprehensive income	464	439
Accumulated deficit	(195,580)	(157,177)
TOTAL STOCKHOLDERS' EQUITY	63,008	90,192
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 117,009	$ 138,521

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,	
	2019	**2018**
Revenue	$ 67,301	$ 55,380
Cost of goods sold	6,790	4,833
Gross profit	60,511	50,547
Operating expenses:		
Sales and marketing	68,251	44,497
Research and development	7,279	5,376
General and administrative	20,984	12,639
Total operating expenses	96,514	62,512
Loss from operations	(36,003)	(11,965)
Interest and other income (expense), net:		
Interest income	2,551	769
Interest expense	(4,949)	(5,108)
Other expense, net	(2)	(1,149)
Net loss	(38,403)	(17,453)
Other comprehensive income (loss):		
Unrealized gain of marketable securities	44	10
Changes in foreign currency translation	(19)	27
Comprehensive loss	$ (38,378)	$ (17,416)
Net loss per share, basic and diluted	$ (1.55)	$ (2.20)
Weighted-average number of common shares used to compute basic and diluted net loss per share	24,705,980	7,950,284

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

SI-BONE, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2017	11,871,578	$ 118,548	3,603,140	$ 1	$ 9,943	$ 402	$ (139,724)	$ (129,378)
Issuance of common stock upon exercise of stock options, net of shares withheld	—	—	289,077	—	1,136	—	—	1,136
Issuance of common stock upon exercise of unvested stock options	—	—	106,028	—	—	—	—	—
Conversion from preferred stock to common stock	(11,871,578)	(118,548)	12,066,654	1	118,547	—	—	118,548
Conversion from preferred stock warrants to common stock warrants	—	—	—	—	1,248	—	—	1,248
Issuance of common stock from warrants exercise	—	—	121,486	—	—	—	—	—
Issuance of common stock from IPO proceeds, net	—	—	8,280,000	1	113,602	—	—	113,603
Repurchase of unvested early exercised stock options	—	—	(15,628)	—	—	—	—	—
Stock-based compensation	—	—	—	—	2,312	—	—	2,312
Vesting of early exercised stock options	—	—	—	—	139	—	—	139
Foreign currency translation	—	—	—	—	—	27	—	27
Unrealized gain of marketable securities	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	(17,453)	(17,453)
Balances as of December 31, 2018	—	—	24,450,757	3	246,927	439	(157,177)	90,192
Issuance of common stock upon exercise of stock options, net of shares withheld	—	—	444,788	—	1,490	—	—	1,490
Issuance of common stock related to employee stock purchase plan	—	—	168,457	—	2,203	—	—	2,203
Issuance of common stock upon vesting of restricted stock units	—	—	108,631	—	—	—	—	—
Repurchase of unvested early exercised stock options	—	—	(8,830)	—	—	—	—	—
Stock-based compensation	—	—	—	—	7,464	—	—	7,464
Vesting of early exercised stock options	—	—	—	—	197	—	—	197
Additional accrual of IPO related costs	—	—	—	—	(160)	—	—	(160)
Foreign currency translation	—	—	—	—	—	(19)	—	(19)
Unrealized gain on marketable securities	—	—	—	—	—	44	—	44
Net loss	—	—	—	—	—	—	(38,403)	(38,403)
Balances as of December 31, 2019	—	$ —	25,163,803	$ 3	$ 258,121	$ 464	$ (195,580)	$ 63,008

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,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (38,403)	$ (17,453)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	7,464	2,312
Depreciation and amortization	774	722
Accretion on marketable securities	(1,413)	(209)
Amortization of debt issuance costs	259	259
Change in fair value of redeemable convertible preferred stock warrants	—	826
Loss on sale and disposal of property and equipment	171	52
Changes in operating assets and liabilities		
Accounts receivable	(3,236)	(1,028)
Inventory	(2,105)	(759)
Prepaid expenses and other assets	(515)	(752)
Accounts payable	383	251
Accrued liabilities and other	4,994	1,260
Net cash used in operating activities	(31,627)	(14,519)
Cash flows from investing activities		
Maturities of marketable securities	159,800	—
Purchases of marketable securities	(143,864)	(96,883)
Purchases of property and equipment	(2,445)	(942)
Net cash provided by (used in) investing activities	13,491	(97,825)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discounts and commissions	—	115,506
Proceeds from the exercise of common stock options	1,490	1,614
Proceeds from issuance of common stock under employee stock purchase plan	2,203	—
Repurchase of unvested early exercised stock options	(38)	(73)
Payments of public offering costs	(167)	(1,897)
Net cash provided by financing activities	3,488	115,150
Effect of exchange rate changes on cash and cash equivalents	(37)	(94)
Net (decrease) increase in cash and cash equivalents	(14,685)	2,712
Cash and cash equivalents at		
Beginning of year	25,120	22,408
End of year	$ 10,435	$ 25,120
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 4,949	$ 5,500
Supplemental disclosure of non-cash information		
Conversion of redeemable convertible preferred stock to common stock	—	118,547
Conversion of preferred stock warrants to common stock warrants	—	1,248
Vesting of early exercised stock options	197	139
Purchases of property and equipment included in accounts payable and accrued liabilities	375	82
Public offering costs included in accounts payable	—	7

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 the most common types of sacroiliac joint disorders that cause lower back pain. The Company introduced its primary product, the iFuse Implant System, or iFuse, in 2009 in the U.S., in 2010 in certain countries in the European Union, and in 2015 in certain countries in the rest of the world.

Reverse Stock Split

In October 2018, the Company's board of directors and stockholders approved a 1-for-18 reverse stock split of the Company's common stock and redeemable convertible preferred stock, which was effected on October 4, 2018. The par value of the common stock and redeemable convertible preferred stock was not adjusted as a result of the reverse split. All issued and outstanding share and per share amounts of common stock, redeemable convertible preferred stock, stock options, and warrants included in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all periods presented.

Initial Public Offering

On October 16, 2018, the Company’s Registration Statement on Form S-1 (File No. 333-227445) relating to the initial public offering ("IPO") of its common stock was declared effective by the Securities and Exchange Commission ("SEC"). Pursuant to such Registration Statement, the Company sold 8,280,000 shares at an initial public offering price of $15.00 per share for net proceeds of $113.4 million to the Company, net of underwriting discounts and commissions and offering costs. Upon the closing of the IPO, all of the Company's outstanding shares of redeemable convertible preferred stock were automatically converted into an aggregate of 12,066,654 shares of common stock and the Company's outstanding warrants to purchase 156,550 shares of redeemable convertible preferred stock were automatically converted into warrants to purchase an aggregate of 160,657 shares of common stock, resulting in reclassification of the related redeemable convertible preferred stock warrant liability of $1.2 million to additional paid-in-capital.

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 include: fair value of assets and liabilities; analysis of the allowance for doubtful accounts; inventory valuation; valuation of deferred tax assets, including related valuation allowances; fair value of common stock and redeemable convertible preferred stock warrants; stock-based compensation; and useful lives of long-lived assets. Estimates are based on historical experience, where applicable and other assumptions believed to be reasonable by the management. Actual results could differ from those estimates.

JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company has elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies. Those standards apply to companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. The Company continues to be an emerging growth company until December 31, 2023, unless one of the following occurs: (i) if the Company's total annual gross revenues are $1.07 billion or more; or (ii) the Company has issued more than $1.0 billion in non-convertible debt in the past three years; or (iii) the Company becomes a "large accelerated filer," as defined in Rule 12b-2 of the Exchange Act.

Segments

Operating segments are based on components of the Company that engage in business activities that earn revenue and incur expenses and (a) whose operating results are regularly reviewed by the Company's chief operating decision maker ("CODM"), to make decisions about resource allocation and performance and (b) for which discrete financial information is available. The CODM for the Company are the Chief Executive Officer ("CEO") and Chief Operating Officer & Chief Financial Officer ("COO/CFO"). The CEO and the COO/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. No single country outside the U.S. accounts for more than 10% of the total revenue during the periods presented. Long-lived assets held outside the U.S. are immaterial. Following table summarizes the Company's revenue by geography:

	Year ended December 31,	
	2019	2018
	(in thousands)	
United States	$ 61,843	$ 50,137
International	5,458	5,243
	$ 67,301	$ 55,380

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.

Other Risks and Uncertainties

The Company is subject to risks common to medical device companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, the ability to obtain adequate coverage and reimbursement from third-party payors and uncertainty of market acceptance of products.

The Company is dependent on third-party manufacturers and suppliers, in some cases single source suppliers. The Company currently has limited long term contracts with its key suppliers and is subject to risks such as manufacturing failures, non-compliance with regulatory requirements, price fluctuations, inability to properly meet demand and third-party supplier discontinuation of operations.

Liquidity

As of December 31, 2019, the Company had cash and marketable securities of $93.1 million compared to $122.2 million as of December 31, 2018. Since inception, the Company financed its operations through its initial public offering, private placements of preferred stock, debt financing arrangements, and the sale of products. As of December 31, 2019, the Company's accumulated deficit was $195.6 million. During the years ended December 31, 2019 and 2018, the Company incurred a net loss of $38.4 million and $17.5 million, respectively.

The Company also has certain debt covenants associated with its current debt agreement. These covenants include a $5.0 million minimum cash balance and revenue targets, which if not met would result in the debt becoming immediately due. The Company is required to meet either minimum net sales or trailing 12-month consolidated earnings before interest, taxes, depreciation, and amortization ("EBITDA") targets. The Company was in compliance with all debt covenants as of December 31, 2019 and 2018.

Based upon the Company's current operating plan, the Company believes that its existing cash and marketable securities will enable the Company to fund its operating expenses and capital expenditure requirements through at least the next 12 months. The Company continues to face challenges and uncertainties and, as a result, its available capital resources may be consumed more rapidly than currently expected due to: (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes that the Company may make to the business that affect ongoing operating expenses; (c) changes that the Company may make in its business strategy; (d) regulatory developments affecting the Company's existing products; (e) changes that the Company may make in its research and development spending plans; and (f) other items affecting the Company's forecasted level of expenditures and use of cash resources.

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. Unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive income (loss) ("OCI") on the consolidated balance sheets. The Company evaluates its investments to assess whether those in unrealized loss positions are other-than-temporarily impaired. The Company considers impairments to be other-than-temporary if they are related to deterioration in credit risk or if it is likely the Company will sell the securities before the recovery of their cost basis. Realized gains and losses and declines in value judged to be other-than-temporary are determined based on the specific identification method and are reported in other income (expense), net on the consolidated statements of operations.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company generally does not require collateral or other security in support of accounts receivable. Allowances are provided for individual accounts receivable when the Company becomes aware of a customer's inability to meet its financial obligations, such as in the case of bankruptcy, deterioration in the customer's operating results or change in financial position. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. The Company also considers broad factors in evaluating the sufficiency of its allowance for doubtful accounts, including the length of time receivables are past due, significant one-time events, creditworthiness of customers and historical experience. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote.

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, 2019 and 2018, the Company has not experienced impairment losses on its long-lived assets.

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. Through the year ended December 31, 2018, in accordance with ASC Topic 605, Revenue Recognition ("ASC 605"), the Company recognized revenue when persuasive evidence of an arrangement exists, title and risk of loss has transferred to the customer, the sales price is fixed or determinable, and collectability is reasonably assured.

As a result of the adoption of the new revenue standard in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606") effective for the fiscal year ended December 31, 2019, the Company now recognizes the revenue when control is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for the goods or services. Under the new 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. There had been no material differences in the Company's revenue recognition accounted for under ASC 605 and ASC 606. 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 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, agreed price list, or purchase order, 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 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. 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 is generally based on the surgeries performed. The Company applied the practical expedient that permits an entity to expense the cost to obtain a contract as incurred when the expected amortization is one year or less. 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, 2019 and 2018.

Medical Device Excise Tax

In accordance with the Patient Protection and Affordable Care Act, effective January 1, 2013, the Company began to incur an excise tax on sales of medical devices in the U.S. The Company recorded the medical device excise tax within the cost of goods sold in the consolidated statements of operations and comprehensive loss when incurred. Effective January 1, 2016, the Consolidated Appropriations Act of 2016, which was signed into law in December 2015, included a two-year suspension on the medical device excise tax. In January 2018, the suspension on the tax on medical devices was further extended through January 1, 2020. In December 2019, the U.S. Senate passed a bipartisan legislation to permanently repeal the medical device excise tax.

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 (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 $0.4 million and $0.7 million for the year ended December 31, 2019 and 2018, 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* - Since the Company became public in October 2018 and has no sufficient trading history, the Company uses stock price volatility using the average historical volatilities of publicly traded companies within its industry that the Company considers to be comparable to its business over a period approximately equal to the expected term for its stock options.
- *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 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*. The Company's Board of Directors, with the assistance of management and independent third-party valuations, developed these valuations and took into account numerous factors, including developments of the Company, market conditions, and contemporaneous independent third-party valuations. In valuing the Company's common stock, the fair value of its business, or enterprise value, was determined using both the income approach and market approach. The income approach estimates value based on the expectation of future cash flows. The market approach estimates value based on a comparison of the subject company to comparable public companies in a similar line of business. The assumptions used in determining the fair value of the Company's common stock involved management's best estimates and judgments at the time the valuation was performed. 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 series of redeemable convertible preferred stock and 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 redeemable convertible preferred stock and early exercised stock options as the holders of redeemable convertible preferred stock and early exercised stock options 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, redeemable convertible preferred stock and common stock options and warrants are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, redeemable convertible preferred stock and 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 (deficit) 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.

Public Offering Costs

Specific incremental costs (i.e. consisting of legal, accounting and other fees and costs) directly attributable to a proposed or actual offering of securities may properly be deferred and charged against the gross proceeds of the offering. In the event a planned offering of securities does not occur or is significantly delayed, all of the costs will be expensed. Upon completion of the IPO on October 16, 2018, the previously deferred and capitalized public offering costs incurred which were recorded within prepaid expenses and other current assets were charged against the gross proceeds of the offering. No public offering cost was deferred as of December 31, 2018.

On November 13, 2019, the Company filed a Shelf Registration Statement on Form S-3 with the SEC that was declared effective by the SEC on November 25, 2019, registering a proposed maximum aggregate primary offering of $200.0 million of unspecified number of shares of common stock; shares of preferred stock; debt securities; or warrants to purchase shares of common stock that the Company may offer in one or more offerings on terms to be determined at the time of sale (the "Prior Registration Statement"). On December 27, 2019, the Company filed a Shelf Registration Statement on Form S-3 with the SEC that was declared effective by the SEC on January 2, 2020, registering the unsold maximum aggregate primary offering under the Prior Registration Statement and additional 2,000,000 shares of the Company's common stock held by the selling stockholders to be named in a prospectus supplement, that may, from time to time, offer or sell in a secondary offering. The incremental costs incurred directly attributable to the shelf filing of $0.1 million were deferred within prepaid expenses and other current assets as of December 31, 2019. See “Note 14 - Subsequent Events” in the accompanying Notes to Consolidated Financial Statements for discussions regarding the subsequent public offering.

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’ deficit 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.

In connection with the IPO, all of the Company's redeemable convertible preferred stock warrants were automatically converted into common stock warrants. The redeemable convertible preferred stock warrants were classified as liabilities on the consolidated balance sheet at their estimated fair value because the shares underlying the warrants required the Company to transfer assets to the holders at a future date. The redeemable convertible preferred stock warrants were measured at fair value and were subjected to re-measurement at each balance sheet date. The change in fair value were recognized in other income (expense), net on the consolidated statements of operations. The Company estimated the fair value of these liabilities using option pricing models and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Adoption of New Revenue Recognition Standard

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard is effective for fiscal years beginning after December 15, 2017 for public companies, and for fiscal years beginning after December 15, 2018, and interim periods beginning after December 15, 2019, for private companies. Early application is permitted. The standard permits the use of either the retrospective or cumulative effect transition method. In March 2016, the FASB issued ASU 2016-08, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, which relates to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. In November 2018, the FASB issued ASU 2018-18, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB’s new revenue standard.

The Company adopted this standard using the modified retrospective method effective for the year ended December 31, 2019.This approach was applied to all contracts that were not completed as of January 1, 2019. As an emerging growth company that elected to take advantage of the JOBS Act accounting election, the Company was not required to adopt the new revenue standard in the interim reporting periods on the year of adoption and is not required, and intends not, to revise its 2019 interim periods which were reported under ASC 605. The adoption of the new revenue standard did not result to a material impact on the Company's consolidated financial statements and no adjustment was made to the opening balance of accumulated deficit at January 1, 2019. The comparative 2018 period has not been adjusted and continued to be reported under ASC 605. ASC 606's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. As it relates to product sales where the Company's sales representative delivers the product at the point of implantation at hospital or medical facilities, which represents majority of the Company's revenue, the Company continues to recognize the revenue upon completion of the procedure and authorization by the customer, net of rebates and price discounts. As it relates to sale of products through distributors and hospitals where product is ordered in advance of the procedure, the Company expects to continue to recognize the revenue upon shipments to the customers, net of rebates and price discounts. Additionally, the new standard requires the capitalization of costs to obtain a contract, primarily sales commissions, and amortization of these costs over the contract period or estimated customer life. The Company's sales commissions paid to its sales representatives is generally based on the surgeries performed. The Company applied the practical expedient that permits an entity to expense the cost to obtain a contract as incurred when the expected amortization is one year or less. As such, the Company recognize sales commission as expense when incurred.

The Company disaggregates revenues from contracts with customers into geographical regions. The Company determined that disaggregating revenue into these categories depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by regional economic factors. For information revenue by geography, refer to *Segments* in "Note 2 - Summary of Significant Accounting Policies" in the accompanying Notes to Consolidated Financial Statements.

Other Recently Adopted Accounting Standards

In July 2019, the FASB issued ASU 2019-07, Codification Updates to SEC Sections - Amendments to SEC Paragraphs Pursuant to SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization, and Miscellaneous Updates. This update clarifies or improves the disclosure and presentation requirements of a variety of codification topics by aligning them with the SEC's regulations, thereby eliminating redundancies and making the codification easier to apply. This update is effective upon issuance. The Company does not expect the disclosure and presentation amendments included in this update, which are to be applied prospectively, to have a material impact on its consolidated financial statements and related disclosures.

In February 2018, the FASB issued ASU 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220). This update provides companies with the option to reclassify stranded tax effects caused by the 2017 Tax Cuts and Jobs Act from accumulated other comprehensive income to retained earnings. This standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company has adopted this standard effective January 1, 2019, and the adoption did not have any material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), which provides guidance on the following eight specific cash flow classification issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. This update is effective for reporting periods beginning after December 15, 2017 for public companies, and fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019 for private companies, with early adoption permitted. The Company has adopted this standard effective January 1, 2019, and the adoption did not have any material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards Not Yet Effective

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires that lessee's recognize a right-of-use asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. A lease liability is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset is an asset that represents the lessee's right to use, or control use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the adoption date. In July 2018, the FASB issued ASU 2018-10 and ASU 2018-11, which provides clarification on the narrow aspects of the guidance and provide an additional transition method to adopt the new leases standard. The new transition method allows an entity to recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. The new leases standard must be adopted using a modified retrospective transition method and allows for the application of the new guidance at the beginning of the earliest comparative period presented or at the adoption date. In November 2019, the FASB issued ASU 2019-10, which revised the mandatory effective dates of the new lease standard. For public companies, the new guidance remained effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the new guidance is now effective for fiscal years beginning after December 15, 2020 and interim periods within fiscal years beginning after December 15, 2021. Early adoption is still permitted for any interim or annual financial statements not yet issued.

As an emerging growth company, the new lease standard is now effective for the Company for the fiscal year ending December 31, 2021 and interim periods within fiscal year ending December 31, 2022. The Company is currently evaluating the impact of this standard on its consolidated financial statements including the timing of its adoption. The Company anticipates electing several practical expedients that permit the Company not to reassess (1) whether a contract is or contains a lease, (2) the classification of existing leases, and (3) whether previously capitalized initial direct costs would qualify for capitalization under ASC 842. The Company expects that the adoption of this new standard will have a material impact on its balance sheet. The most significant impact would be the recognition of operating lease right-of-use assets and liability. The standard is not expected to have a material impact to the Company's consolidated statements of income and cash flows.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. FASB issued ASU 2019-05 in May 2019 and ASU 2019-08 in November 2019 for codification improvements of Topic 326. The new standard revises the accounting requirements related to the measurement of credit losses and will require organizations to measure all expected credit losses for financial assets based on historical experience, current conditions and reasonable and supportable forecasts about collectability. Assets must be presented in the financial statements at the net amount expected to be collected. In November 2019, the FASB issued ASU 2019-10, which defers the effective date of ASU 2016-13 for public companies that are eligible to be smaller reporting companies and all other companies, to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. In February 2020, the FASB issued ASU 2020-02, which provides guidance regarding methodologies, documentation, and internal controls related to expected credit losses. The Company is currently evaluating the impact of this standard on its consolidated financial statements, but do not expect the standard will have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Improvements to Non-employee Share-Based Payment Accounting. ASU 2018-07 expands the scope of Topic 718, Compensation-Stock Compensation, to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, Equity-Equity-Based Payments to Non-Employees. For public business entities, the amendments are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. The Company is currently evaluating the impact that the adoption of this standard will have on the consolidated financial statements and anticipates adopting the standard for the fiscal year ending December 31, 2020.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurements, which eliminates, adds or modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. This update is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year, with early adoption permitted to adopt either the entire standard or only the provisions that eliminate or modify the requirements. The Company is currently evaluating the impact that the adoption of this standard will have on the consolidated financial statements and anticipates adopting the standard for the fiscal year ending December 31, 2020.

3. Marketable Securities

The table below summarizes the marketable securities:

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 3,068	$ —	$ —	$ 3,068
Commercial paper	2,495	—	—	2,495
Cash equivalents	5,563	—	—	5,563
U.S. treasury securities	67,051	34	(2)	67,083
Corporate bonds	9,075	24	(2)	9,097
Commercial paper	5,165	—	—	5,165
Short-term investments	81,291	58	(4)	81,345
Corporate bonds	1,278	—	—	1,278
Long-term investments	1,278	—	—	1,278
Total marketable securities	$ 88,132	$ 58	$ (4)	$ 88,186

The long-term investments outstanding as of December 31, 2019 mature in April 2021.

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Money market funds	$ 15,223	$ —	$ —	$ 15,223
U.S. treasury securities	1,000	—	—	1,000
Commercial paper	6,635	—	—	6,635
Cash equivalents	22,858	—	—	22,858
U.S. treasury securities	65,491	2	(4)	65,489
Corporate bonds	19,708	15	(3)	19,720
Commercial paper	11,894	—	—	11,894
Short-term investments	97,093	17	(7)	97,103
Total marketable securities	$ 119,951	$ 17	$ (7)	$ 119,961

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, 2019			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 3,068	$ —	$ —	$ 3,068
U.S. treasury securities	67,083	—	—	67,083
Corporate bonds	—	10,375	—	10,375
Commercial paper	—	7,660	—	7,660
Total marketable securities	$ 70,151	$ 18,035	$ —	$ 88,186

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Marketable securities				
Money market funds	$ 15,223	$ —	$ —	$ 15,223
U.S. treasury securities	66,489	—	—	66,489
Corporate bonds	—	19,720	—	19,720
Commercial paper	—	18,529	—	18,529
Total marketable securities	$ 81,712	$ 38,249	$ —	$ 119,961

5. Balance Sheet Components

Inventory

As of December 31, 2019 and 2018, inventory consisted entirely of finished goods.

Property and Equipment, net:

	December 31, 2019	December 31, 2018
	(in thousands)	
Machinery and equipment	$ 4,613	$ 3,785
Construction in progress	1,854	730
Computer and office equipment	598	407
Leasehold improvements	497	448
Furniture and fixtures	187	148
	7,749	5,518
Less: Accumulated depreciation and amortization	(3,795)	(3,364)
	$ 3,954	$ 2,154

Depreciation expense was $0.8 million and $0.7 million for the years ended December 31, 2019 and 2018, respectively.

Accrued Liabilities and Other:

	December 31, 2019	December 31, 2018
	(in thousands)	
Accrued compensation and related expenses	$ 7,274	$ 5,425
Accrued litigation expense	3,200	—
Accrued professional services	392	583
Sales tax payable	370	388
Liability for early exercise of unvested stock options	97	331
Others	272	133
	$ 11,605	$ 6,860

6. Commitments and Contingencies

Operating Leases

The Company has an existing seven-year non-cancelable operating lease for an office building space of approximately 21,848 square feet, located in Santa Clara, California which lease commenced in April 2018. The Company also have non-cancelable operating leases for its office building spaces in Gallarate, Italy and Mannheim, Germany which both expire in November 2024 and in Knaresborough, United Kingdom, which expires in December 2026. Further, the Company also leases vehicles under operating lease arrangements for certain of its sales personnel in Europe which expire various times in 2020 to 2022.

Rent expense is recorded over the lease terms on a straight-line basis. Rent expense charged to operations under operating leases totaled approximately $1.2 million and $1.2 million for the years ended December 31, 2019 and 2018, respectively.

The aggregate future minimum lease payments under all leases as of December 31, 2019 are as follows:

Year Ending December 31,	(in thousands)
2020	$ 1,102
2021	1,003
2022	929
2023	860
2024	869
Thereafter	365
	$ 5,128

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. These outstanding commitments amounted to $0.4 million and $0.2 million as of December 31, 2019 and 2018, respectively. In addition, the Company also has other obligations for goods and services entered into in the normal course of business. These obligations, however, are either not enforceable or legally binding or are subject to change based on the Company's business decisions.

Legal Proceedings

On February 6, 2019, a putative class action captioned Eric B. Fromer Chiropractic, Inc. ("Plaintiff") v. SI-BONE, Inc. (Civil Action No. 5:19-cv-633-SVK), was filed in the U.S. District Court, Northern District of California. The complaint alleges violations of the Telephone Consumer Protection Act (the "TCPA") on behalf of an individual and a putative class of persons alleged to be similarly situated. The complaint alleges that the Company sent invitations to an educational dinner event to health care providers by way of facsimile transmission. The TCPA prohibits using a fax machine to send unsolicited advertisements not including proper opt-out instructions or to send unsolicited advertisements to persons with whom the sender did not have an established business relationship. The plaintiff sought various forms of relief, including statutory damages of $500 for each violation of the TCPA or, in the alternative, treble damages of up to $1,500 for each knowing and willful violation of the TCPA and a permanent injunction prohibiting the Company from sending or having sent advertisements by way of facsimile transmission. On December 23, 2019 the parties filed a joint stipulation of dismissal of the case in the District Court in the Northern District of California and on January 14, 2020, the parties executed a definitive settlement agreement (the "Settlement Agreement"), pursuant to which, the Company agreed to settle all disputes regarding the advertising faxes to the settlement class.

As this lawsuit is being resolved through a negotiated settlement and class resolution process, the Company believes that it will incur a loss associated with resolution of the claims against it. The Company has accrued litigation expense of $3.2 million during the year ended December 31, 2019 within general and administrative expenses in the consolidated financial statements. The accrual reflects the estimable and probable costs that the Company may incur based on estimated claims submitted by members of the settlement class, as defined in the Settlement Agreement. The final disposition of the lawsuit may result in a loss in excess of the aggregate recorded amount.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future but have not yet been made.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. No liability associated with such indemnifications has been recorded to date.

7. Borrowings

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

	December 31, 2019	December 31, 2018
	(in thousands)	
Principal outstanding	$ 40,000	$ 40,000
Less: unamortized debt issuance costs	(777)	(1,037)
Outstanding debt, net of debt issuance costs	$ 39,223	$ 38,963
Classified as:		
Current portion of long-term borrowings	$ 4,358	$ —
Long-term borrowings	$ 34,865	$ 38,963

The outstanding debt is related to a term loan entered by the Company with Biopharma Credit Investments IV Sub LP, or Pharmakon, in October 2017 for total loan proceeds of $40.0 million. The total debt issuance costs of $1.3 million were recorded as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet and are being amortized over the period of the term loan using the effective interest method to interest expense in the consolidated statement of operations. The term loan includes an interest-only period for 35 months through September 2020 and is then repaid in equal quarterly principal payments plus interest through December 2022. The New Term Loan is collateralized by all of the Company's assets, including intellectual property. The term loan carries a fixed interest rate of 11.5% and a closing fee of 1.5% of the funded amount, or $0.6 million. The term loan includes a pre-payment fee equal to the interest due for the first 30 months of the agreement if it is prepaid within the first 30 months, a 2% prepayment penalty for months 31-48, and a 1% penalty for months 49-60. The loan is a senior obligation secured with a blanket first lien on the assets of the Company. The effective interest rate for the year ended December 31, 2019 and 2018 was 12.3% and 12.3%, respectively.

The table below summarizes annual future minimum principal payments under the loan agreement as of December 31, 2019:

Year ending December 31,	**(in thousands)**
2020	$ 4,444
2021	17,778
2022	17,778
Total minimum principal payments	$ 40,000

The term loan requires the Company to maintain a minimum cash balance of $5.0 million and to achieve certain revenue targets. Beginning with the first quart of 2019, the Company is required to meet either minimum net sales or trailing 12-month consolidated EBITDA targets. The Company needs to meet one or the other, but not both. If the Company does not meet either the minimum net sales or trailing 12-month consolidated EBITDA targets, the debt will immediately become due. The remaining minimum net sales and trailing 12-month consolidated EBITDA targets are as follows:

Twelve Months Ending	**Minimum Net Sales**		**Trailing 12-Month Consolidated EBITDA**
	(in thousands)		
March 31, 2020	$57,500	or	$1,000
June 30, 2020	$58,500	or	$2,000
thereafter, as applicable	$60,000	or	$3,000

The Company was in compliance with all debt covenants as of December 31, 2019 and 2018.

8. Warrants

The table below summarizes common stock warrants issued and outstanding at both December 31, 2019 and 2018:

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, 2019 and 2018 were 25,163,803 shares and 24,450,757 shares, respectively. As of December 31, 2019 and 2018, there was no preferred stock issued and outstanding. See “Note 14 - Subsequent Events” in the accompanying Notes to Consolidated Financial Statements for discussions regarding issuance of additional common stock through a subsequent public offering.

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. On January 1, 2019, the total number of shares of common stock reserved for issuance increased by 1,222,538 shares. The Company filed a Registration Statement on Form S-8 on March 22, 2019 to register these additional shares reserved for issuance under the 2018 EIP. As of December 31, 2019, a total of 2,567,295 shares of common stock are available for future grants under the 2018 EIP. On January 1, 2020, the total number of shares of common stock reserved for issuance under the 2018 EIP automatically increased by 1,258,190 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 shares issued under the Plan are exercisable immediately, but subject to a right of repurchase by the Company of any unvested shares. RSUs granted under the 2018 Equity Incentive Plan 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, 2019 and 2018:

	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, 2017	3,001,929	$4.15		
Granted	100,080	$8.88		
Exercised	(395,117)	$4.08		
Canceled and forfeited	(65,694)	$4.81		
Outstanding as of December 31, 2018	2,641,198	$4.27		
Granted	638,983	$20.89		
Exercised	(444,924)	$3.36		
Canceled and forfeited	(116,286)	$11.30		
Outstanding as of December 31, 2019	2,718,971	$8.02	6.83	$ 36,872
Options vested and exercisable as of December 31, 2019	2,126,781	$5.32	6.27	$ 34,463
Options vested and expected to vest as of December 31, 2019	2,652,883	$7.80	6.76	$ 36,540

The aggregate intrinsic value of options exercised during the years ended December 31, 2019 and 2018 amounted to $6.8 million and $3.6 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 fair value of the Company's common stock prior to the IPO was based on the third-party valuations as determined by the Company's Board of Directors. Subsequent to IPO, the Company uses market price at for its common stock as reported on the Nasdaq Global Market. The aggregate intrinsic values of options outstanding, options vested and exercisable, and options vested and expected to vest as of December 31, 2019 represents the difference between the weighted average 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, 2019 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
$0.84 - $2.11	87,394	1.52	$1.56	87,394	$1.52
$3.24 - $3.98	564,938	4.35	$3.47	564,938	$3.50
$4.32 - $5.94	1,409,650	7.11	$4.63	1,306,033	$4.61
$6.84 - $7.92	39,844	7.96	$7.32	20,298	$7.20
$17.72 - $18.96	154,189	9.37	$17.85	51,110	$17.82
$19.02 - $22.00	462,956	9.05	$21.91	97,008	$21.94
	2,718,971	6.83	$8.02	2,126,781	$5.32

The weighted average grant date fair value of all options granted were $9.78 per share and $3.98 per share for the years ended December 31, 2019 and 2018, respectively. The table below summarizes the assumptions used to estimate the grant date fair value of the stock options granted during the respective periods using the Black-Scholes option-pricing model:

	Year ended December 31,					
	2019			2018		
Expected term (years)	5.0	to	7.0	5.0	to	7.0
Expected volatility	41.7%	to	47.3%	42.0%	to	47.0%
Risk-free interest rate	1.3%	to	2.6%	2.4%	to	3.0%
Dividend yield	—%			—%		

As of December 31, 2019, there was $5.5 million of unrecognized compensation cost related to stock options granted. These costs are expected to be recognized over a period of approximately 2.6 years.

Early Exercise of Unvested Stock Options

Early exercises of stock options 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 (deficit) as the options vest. As of December 31, 2019 and 2018, the Company had a total of 21,404 and 74,019 shares of common stock, respectively, subject to repurchase under the Plan and $0.1 million and $0.3 million, respectively, of associated liabilities for the repurchase.

Restricted Stock Units

The following table summarizes restricted stock units activity for the years ended December 31, 2019 and 2018:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2017	**—**	**$—**
Granted	54,036	$11.79
Canceled and forfeited	(600)	$20.60
Outstanding as of December 31, 2018	53,436	$11.69
Granted	639,726	$20.14
Vested	(108,631)	$19.10
Canceled and forfeited	(41,490)	$18.48
Outstanding as of December 31, 2019	543,041	$19.72

As of December 31, 2019, there was a total unrecognized compensation cost of $8.6 million. These costs are expected to be recognized over a period of approximately 3.1 years.

Employee Stock Purchase Plan

Under the Company's 2018 Employee Stock Purchase Plan (the "ESPP") adopted in October 2018, the Company 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. There were 515,307 shares of common stock originally reserved for issuance under the ESPP. Under the ESPP, the number of shares reserved for issuance under the ESPP automatically increases on January 1st of each year, starting on January 1, 2019, and continuing through January 1, 2029, by an amount equal to (i) the lesser of 1% of the total number of shares of the Registrant's common stock outstanding on December 31st of the preceding calendar year, and (ii) 555,555 shares of common stock. On March 22, 2019, the Company filed a Registration Statement on Form S-8 to register 244,507 additional shares of common stock for issuance under the ESPP. As of December 31, 2019, a total of 591,357 shares of common stock are available for future grants under the 2018 EIP. On January 1, 2020, the total number of shares of common stock reserved for issuance under the ESPP Plan increased by 251,638 shares.

As of December 31, 2019 and 2018, total accumulated ESPP related employee payroll deductions amounted to $0.2 million and $0.4 million, respectively, which were included within accrued compensation and related expenses in the consolidated balance sheets. For the year ended December 31, 2019 and 2018, the Company recognized $0.8 million and $0.2 million, respectively, of stock-based compensation expense related to ESPP. As of December 31, 2019, the unrecognized compensation cost for the ESPP was $0.3 million.

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

	Year ended December 31,	
	2019	2018
Expected term (years)	0.5	0.5
Expected volatility	38.3% to 58.4%	44.0%
Risk-free interest rate	1.6% to 2.4%	2.5%
Dividend yield	—%	—%

Stock-Based Compensation

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

	Year ended December 31,	
	2019	2018
	(in thousands)	
Cost of goods sold	$ 185	$ 34
Sales and marketing	3,335	651
Research and development	516	156
General and administrative	3,428	1,471
	$ 7,464	$ 2,312

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. The Company has made no contributions to the 401(k) plan since its inception up to December 31, 2018. 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 from January 2, 2019 through December 31, 2019. For the year ended December 31, 2019, the Company made $0.1 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,	
	2019	2018
	(in thousands, except share and per share data)	
Net loss	$ (38,403)	$ (17,453)
Weighted-average shares used to compute basic and diluted net loss per share	24,705,980	7,950,284 *
Net loss per share, basic and diluted	$ (1.55)	$ (2.20)

* Calculated based on the 1-for-18 reverse stock split effected October 4, 2018.

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,	
	2019	2018
Stock options	2,718,971	2,641,198
Restricted stock units	543,041	53,436
Shares subject to repurchase	21,404	74,019
ESPP purchase rights	65,442	89,606
Common stock warrants	118,122	118,122
	3,466,980	2,976,381

13. Income Taxes

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

	Year ended December 31,	
	2019	2018
	(in thousands)	
Domestic	$ (37,709)	$ (16,835)
Foreign	(694)	(618)
Loss before income taxes	$ (38,403)	$ (17,453)

There was no provision for income taxes recorded for the years ended December 31, 2019 and 2018. 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.

On December 22, 2017, the U.S. enacted a law commonly known as the Tax Cuts and Jobs Act (the “Act”) which makes widespread changes to the Internal Revenue Code, including a reduction in the federal corporate tax rate from 35.0% to 21.0%, and move from a worldwide tax system to territorial system. As a result of the enactment of the Act, during the year ended December 31, 2018, the Company recognized a reduction to its deferred tax assets of approximately $15.8 million. The reduction to Company's deferred tax assets did not result in the recognition of provision for income taxes as the Company maintains full valuation allowance on its net deferred tax assets.

The components of deferred income taxes are as follows:

	Year ended December 31,	
	2019	2018
	(in thousands)	
Federal	$ 8,523	$ 3,555
State	1,569	822
Foreign	(200)	200
Total deferred income taxes	9,892	4,577
Change in deferred tax valuation allowance	(9,892)	(4,577)
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,	
	2019	2018
Tax at statutory federal rate	(21.0)%	(21.0)%
State tax, net of federal benefit	(4.1)%	(5.3)%
Tax credits	(0.7)%	(0.7)%
Change in deferred tax valuation allowance	25.8 %	26.2 %
Other	— %	0.8 %
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,	
	2019	2018
	(in thousands)	
Net operating loss carryforwards	$ 42,032	$ 35,067
Research and development credits	2,428	2,255
Accruals and reserves	4,222	2,059
Stock compensation	1,512	899
Depreciation and amortization	110	132
Total deferred tax assets	50,304	40,412
Less: Valuation allowance	(50,304)	(40,412)
Total deferred tax asset, net of valuation allowance	$ —	$ —

The following table summarizes changes in the valuation allowance for the year ended December 31, 2019 and 2018:

	Year ended December 31,	
	2019	2018
	(in thousands)	
Beginning balance	$ 40,412	$ 35,835
Additions during the period	9,892	4,577
Ending balance	$ 50,304	$ 40,412

As of December 31, 2019, the Company had net operating loss (“NOL”) carryforwards of approximately $164.4 million and $129.6 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. If not utilized, the Company’s federal NOL carryforward begins to expire in 2028, and the state NOL carryforward begins to expire in 2020.

As of December 31, 2019, the Company had credit carryforwards of approximately $2.1 million and $2.2 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 Tax Reform Act of 1986 limits the use of NOL and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In general, if the Company experiences a greater than 50% aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code (California has similar laws). The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company has not utilized any NOL carryovers through December 31, 2019. In addition, the Company's deferred tax assets are subject to full valuation allowance, and thus no benefit for deferred tax assets have been recorded. The Company has determined that it experienced Section 382 ownership changes in 2010 and $1.4 million of its NOL carryforwards are limited. The Company also updated its Section 382 ownership change analysis through June 30, 2019, considering the recent changes in ownership following its IPO in October 2018. Based on the result of the analysis, the Company concluded that it did not undergo ownership change that would require additional limitations on its NOL carryforwards. The Company further concluded that the equity shift between June 30, 2019 to December 31, 2019 was not material, considering the changes in the outstanding number of shares at each respective period. 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 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, 2019 and 2018 consisted of the following:

	Year ended December 31,	
	2019	2018
	(in thousands)	
Balance at beginning of the year	$ 1,084	$ 993
Increases related to current year's tax positions	203	91
Balance at end of the year	$ 1,287	$ 1,084

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, 2019 and 2018. None of the Company's unrecognized tax benefits that, if recognized, would affect its effective tax rates for the years ended December 31, 2019 and 2018. 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 or state 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. Subsequent Events

Public Offering of Common Stock

Pursuant to the Shelf Registration Statement on Form S-3 which was declared effective by the SEC on January 2, 2020 and the Final Prospectus Supplement dated January 22, 2020, on January 27, 2020, the Company sold 2,490,053 shares at a follow-on public offering price of $21.50 per share for a net proceeds of $50.3 million to the Company, after deducting the underwriting discounts and commissions but before offering expenses. Upon completion of the offering and issuance of common stock, the Company had 27,708,111 shares of common stock outstanding. The Company also granted the underwriters an option for a period of 30 days from the date of filing the prospectus supplement to purchase up to 645,000 additional shares of the Company's common stock at a public offering price of $21.50 per share. On February 24, 2020, the underwriters fully exercised its option to purchase additional shares of the Company's common stock for an additional net proceeds of $13.0 million to the Company, after deducting the underwriting discounts and commissions. The Company intends to use the net proceeds from this offering to support the continued commercial expansion of its iFuse system, sales and marketing, surgeon training and clinical studies, as well as working capital and general corporate purposes. The Company may also use a portion of the net proceeds to acquire or invest in complementary products, technologies, or businesses; however, the Company currently has no agreements or commitments to complete any such transactions.

In addition to the shares sold by the Company in the public offering, on January 27, 2020, the selling stockholders sold 1,809,947 shares of the Company’s common stock previously held by the selling shareholders at a price to the public of $21.50 per share. The Company did not receive any proceeds from the sales by the selling shareholders. In conjunction with the sales by the selling shareholders, the Company incurred offering costs associated with the selling of shares by the selling shareholders, which will be recognized as transaction costs within general and administrative expenses on consolidated statement of operations in the first quarter of 2020.

Settlement Agreement

On January 14, 2020, the Company entered into a definitive settlement agreement related to an outstanding legal proceeding. For information regarding this legal proceeding, refer to *Legal Proceedings* in “Note 6 - Commitments and Contingencies” in the accompanying Notes to Consolidated Financial Statements.

Joint Development Agreement with a Related Party

On February 24, 2020, the Company entered into a joint development agreement (the "Development Agreement") with SeaSpine Orthopedics Corporation ("SeaSpine") to develop a next generation device for sacropelvic fixation. Mr. Keith Valentine, who serves as the President, Chief Executive Officer and a member of the board of directors of SeaSpine, also serves as a member of the Company's Board of Directors since August 2015.

Pursuant to the development Plan, SeaSpine shall use reasonable efforts to assist in the develop 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 of approximately $10,000 to SeaSpine to reimburse for full time resources employed by SeaSpine responsible to conduct the development activities. 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 parties, in situations defined in the Development Agreement.

Supplementary Data

Selected Quarterly Consolidated Financial Data (Unaudited)

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

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 principal executive officer and principal financial officer, 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, 2019, our management, with the participation of our Chief Executive Officer ("CEO") and our Chief Operating Officer & Chief Financial Officer ("COO/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 COO/CFO have concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, our management used the criteria set forth in the Internal Control -Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management's assessment, management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm because as an "emerging growth company" we are exempt from Section 404(b) of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the fourth quarter of the year ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 2020 Annual Meeting of Stockholders, or the 2020 Proxy Statement, which will be filed not later than 120 days after the end of our fiscal year ended December 31, 2019, 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 2020 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 2020 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 2020 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 2020 Proxy Statement.

PART IV

Item 15. Exhibits, 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				
10.1+	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 April 27, 2015, between the Registrant and Laura Francis.	S-1	333-227445	10.10	9/20/2018

10.12+	Severance and Change in Control Agreement dated March 15, 2016, between the Registrant and Laura Francis.	S-1	333-227445	10.11	9/20/2018
10.13+	Amended and Restated Letter Agreement, dated March 1, 2017, between the Registrant and Laura Francis.	S-1	333-227445	10.12	9/20/2018
10.14+	Offer Letter Agreement, dated February 7, 2012, between the Registrant and W. Carlton Reckling.	S-1	333-227445	10.13	9/20/2018
10.15+	Severance and Change in Control Agreement, dated March 15, 2016, between the Registrant and W. Carlton Reckling.	S-1	333-227445	10.14	9/20/2018
10.16+	Letter Agreement, dated January 18, 2017, between the Registrant and W. Carlton Reckling.	S-1	333-227445	10.15	9/20/2018
10.17+	Offer Letter Agreement, dated December 16, 2010, between the Registrant and Scott A. Yerby.	S-1	333-227445	10.16	9/20/2018
10.18+	Severance and Change in Control Agreement dated March 15, 2016, between the Registrant and Scott A. Yerby.	S-1	333-227445	10.17	9/20/2018
10.19+	Offer Letter Agreement, dated June 19, 2016, between the Registrant and Anthony J. Recupero.	S-1	333-227445	10.18	9/20/2018
10.20	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
10.21	Loan Agreement, dated October 13, 2017, between the Registrant and Biopharma Credit Investments IV Sub LP, as amended on June 15, 2018.	S-1	333-227445	10.20	9/20/2018
10.22	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
10.23	Form of Warrant to Purchase Common Stock issued to Westriver Mezzanine Loans, LLC.	S-1	333-227445	10.22	9/20/2018
10.24	Form of Warrant to Purchase Common Stock issued to Silicon Valley Bank.	S-1	333-227445	10.23	9/20/2018
10.25	Warrant to Purchase Series 5 Preferred Stock issued to Silicon Valley Bank dated July 17, 2013.	S-1	333-227445	10.24	9/20/2018
10.26	Warrant to Purchase Series 6 Preferred Stock issued to Silicon Valley Bank dated November 26, 2014.	S-1	333-227445	10.25	9/20/2018
10.27	Form of Warrant to Purchase Series 6 Preferred Stock issued to Silicon Valley Bank.	S-1	333-227445	10.26	9/20/2018
10.28	Form of Warrant to Purchase Series 6 Preferred Stock issued to Oxford Finance, LLC.	S-1	333-227445	10.27	9/20/2018
10.29	Warrant to Purchase Series 7 Preferred Stock issued to Oxford Finance, LLC dated December 22, 2016.	S-1	333-227445	10.28	9/20/2018
10.30	Warrant to Purchase Series 7 Preferred Stock issued to Silicon Valley Bank dated December 22, 2016.	S-1	333-227445	10.29	9/20/2018
10.31+	Form of Restricted Stock Unit Grant Notice and Award Agreement.	S-1	333-227445	10.30	9/20/2018
10.32+	Changes to Chief Operating Officer & Chief Financial Officer Compensation	8-K	001-38701	Item 5.02	8/6/2019
10.33+	Amendment to Restricted Stock Units of Chief Operating Officer & Chief Financial Officer	10-Q	001-38701	10.2	11/12/2019

10.34+	Changes to Chief Executive Officer, Chief Operating Officer & Chief Financial Officer, and Chief Commercial Officer Compensation	8-K	001-38701	Item 5.02	1/3/2020
10.35+	2019 U.S. Bonus Plan	8-K	001-38701	Item 5.02	1/22/2019
10.36+*	2019 Non-Employee Directors' Compensation Policy				
21.1*	List of Subsidiaries of Registrant				
23.1*	Consent of PricewaterhouseCoopers, Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (contained in the signature page of this report)				
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* 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, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Santa Clara, California, on March 11, 2020.

SI-BONE, Inc.

By: /s/ Jeffrey W. Dunn
Jeffrey W. Dunn
President and Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

SI-BONE, Inc.

By: /s/ Laura A. Francis
Laura A. Francis
Chief Operating Officer & 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 in and about the premises, 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, as amended, 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/ Jeffrey W. Dunn Jeffrey W. Dunn	President and Chief Executive Officer (Principal Executive Officer) and Director	March 11, 2020
/s/ Laura A. Francis Laura A. Francis	Chief Operating Officer & Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2020
/s/ Timothy E. Davis, Jr. Timothy E. Davis, Jr.	Lead Independent Director, Director	March 11, 2020
/s/ Mark J. Foley Mark J. Foley	Director	March 11, 2020
/s/John G. Freund, M.D. John G. Freund, M.D.	Director	March 11, 2020
/s/ Jeryl L. Hilleman Jeryl L. Hilleman	Director	March 11, 2020
/s/ Gregory K. Hinckley Gregory K. Hinckley	Director	March 11, 2020
/s/ Karen A. Licitra Karen A. Licitra	Director	March 11, 2020
/s/ Keith C. Valentine Keith C. Valentine	Director	March 11, 2020

Exhibit 4.3

DESCRIPTION OF SI-BONE, INC. COMMON STOCK

Our authorized capital stock consists of 100,000,000 shares of common stock, $0.0001 par value per share, and 5,000,000 shares of preferred stock, $0.0001 par value per share. A description of our common stock and the material terms and provisions of our certificate of incorporation and bylaws affecting the rights of holders of our common stock is set forth below. The description is intended as a summary, and is qualified in its entirety by reference to our certificate of incorporation and the bylaws.

Common Stock

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption, or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders are distributable ratably among the holders of our common stock, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Anti-takeover Effects of Provisions of our Certificate of Incorporation and Bylaws and Delaware Law

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. This section prevents some Delaware corporations from engaging, under some circumstances, in a business combination, which includes a merger or sale of at least 10% of the corporation's assets with any interested stockholder, meaning a stockholder who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of the corporation's outstanding voting stock, unless:

- the transaction is approved by the board of directors prior to the time that the interested stockholder became an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- subsequent to such time that the stockholder became an interested stockholder the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or amended and restated bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Certificate of Incorporation and Bylaws Provisions

Our amended and restated certificate of incorporation and our amended and restated bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control of our management team, including the following:

- *Board of Directors Vacancies*. Our amended and restated certificate of incorporation and amended and restated bylaws authorize our board of directors to fill vacant directorships, including newly-created seats. In addition, the number of directors constituting our board of directors is set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

- *Classified Board*. Our amended and restated certificate of incorporation and amended and restated bylaws provide that our board of directors is classified into three classes of directors, each of whom will hold office for a three-year term. In addition, directors may only be removed from the board of directors for cause and only by the approval of a majority of our then-outstanding shares of our common stock. The existence of a classified board could delay a successful tender offeror from obtaining majority control of our board of directors, and the prospect of that delay might deter a potential offeror.

- *Stockholder Action; Special Meeting of Stockholders*. Our amended and restated certificate of incorporation provides that stockholders are not able to take action by written consent, and are only be able to take action at annual or special meetings of our stockholders. Stockholders are not be permitted to cumulate their votes for the election of directors. Our amended and restated bylaws further provide that special meetings of our 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.

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at any meeting of stockholders. Our amended and restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.

- *Issuance of Undesignated Preferred Stock*. Our board of directors have the authority, without further action by the holders of common stock, to issue up to 5,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by the board of directors. The existence of authorized but unissued shares of preferred stock enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise.

Choice of Forum

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 fiduciary duty by any director, officer, or other employee to us or our stockholders; 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 or any director or officer or other employee that is governed by the internal affairs doctrine. The provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We do not currently intend to enforce the federal forum selection provision unless a recent Delaware Chancery Court decision invalidating such a clause is appealed and the Delaware Supreme Court reverses the decision.

Exhibit 10.36

SI-BONE, Inc.

2019 Non-Employee Directors' Compensation Policy
Approved by the Board of Directors
June 13, 2019

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

Annual Cash Compensation

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

1. Annual Board Service Retainer:
    a. Eligible Directors: $40,000

2. Annual Committee Member / Chair Service Retainer:
    a. Member / Chairperson of the Audit Committee: $9,000 / $20,000
    b. Member / Chairperson of the Compensation Committee: $6,000 / $15,000
    c. Member / Chairperson of the N&CG Committee: $5,000 / $10,000

3. Annual Lead Independent Director Service Retainer:
    a. Lead Independent Director: $27,500

Equity Compensation

The equity compensation set forth below will be granted under the SI-BONE, Inc. 2018 Equity Incentive Plan (the "***Plan***"), and will be documented on the applicable form of equity award agreement most recently approved for use by the Board (or a duly authorized committee thereof) for Eligible Directors. All stock options granted under the Director Compensation Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Option Grant: Upon first election to the Board, each Eligible Director will be granted, upon approval by the Board or Compensation Committee of the Board, a stock option to purchase **26,236** shares of Common Stock (the "***Initial Option Grant***"). The Initial Option Grant will vest monthly over three years, such that the Initial Option Grant will be fully vested on the third anniversary of the Eligible Director's first election to the Board, subject to the Eligible Director's Continuous Service on each applicable vesting date. In addition, in the event of a Change in Control or a Corporate Transaction, any unvested portion of the Initial Option Grant will fully vest and become exercisable as of immediately prior to the effective time of such Change in Control or Corporate Transaction, subject to the Eligible Director's Continuous Service on the effective date of such transaction.

2. Additional Option Grants: The Compensation Committee may review and approve additional equity grants to Eligible Directors on the date of each subsequent annual meeting. Each Eligible Director shall receive an annual option grant of **15,741** shares of Common Stock which will vest monthly over one year from the grant date (the "***Annual Option Grant***"), such that the Annual Option Grant will be fully vested on the first anniversary of the date of grant, subject to the Eligible Director's Continuous Service on each applicable vesting date. In addition, in the event of a Change in Control or a Corporate Transaction, any unvested portion of the Annual Option Grant will fully vest and become exercisable as of immediately prior to the effective time of such Change in Control or Corporate Transaction, subject to the Eligible Director's Continuous Service on the effective date of such transaction.

Philosophy

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

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

Exhibit 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 and 333-230473) of SI-BONE, Inc. of our report dated March 11, 2020 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 11, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeffrey W. Dunn, certify that:

1. I have reviewed this Form 10-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:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Jeffrey W. Dunn

Date: March 11, 2020

Jeffrey W. Dunn
President and Chief Executive Officer

Exhibit 31.2

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

I, Laura A. Francis, certify that:

1. I have reviewed this Form 10-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:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Laura A. Francis

Date: March 11, 2020

Laura A. Francis
Chief Operating Officer & Chief Financial Officer

Exhibit 32.1

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, Jeffrey W. Dunn, President and Chief Executive Officer of SI-Bone, Inc. (the "Company"), and Laura A. Francis, Chief Operating Officer & 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, 2019, 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/ Jeffrey W. Dunn

Date: March 11, 2020

Jeffrey W. Dunn
President and Chief Executive Officer

/s/ Laura A. Francis

Date: March 11, 2020

Laura A. Francis
Chief Operating Officer & Chief Financial 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.