

7,200,000 Shares



**Common Stock**

---

This is the initial public offering of shares of common stock of SI-BONE, Inc.

We are offering 7,200,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is \$15.00. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol “SIBN.”

We are an emerging growth company under the federal securities laws and will be subject to reduced public company reporting requirements. See “Prospectus Summary—Implications of Being an Emerging Growth Company.”

---

**Investing in our common stock involves a high degree of risk. See “[Risk Factors](#)” beginning on page 15.**

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$ 15.00	\$ 108,000,000
Underwriting discounts and commissions <sup>(1)</sup>	\$ 1.05	\$ 7,560,000
Proceeds, before expenses, to us	\$ 13.95	\$ 100,440,000

(1) See “Underwriting” for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses.

To the extent that the underwriters sell more than 7,200,000 shares of common stock, the underwriters have a 30-day option to purchase up to an additional 1,080,000 shares from us at the initial public offering price, less the underwriting discounts and commissions.

Certain of our existing stockholders or their affiliates, including entities affiliated with our directors, that had submitted indications of interest have agreed to purchase an aggregate of 1,225,000 shares of our common stock in this offering at the initial public offering price.

The underwriters expect to deliver the shares against payment in New York, New York on October 19, 2018.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

---

**Morgan Stanley**

**Canaccord Genuity**

**BofA Merrill Lynch**

**JMP Securities**

October 16, 2018

## TABLE OF CONTENTS

	<u>Page</u>		<u>Page</u>
<a href="#">Prospectus Summary</a>	1	<a href="#">Executive Compensation</a>	135
<a href="#">Risk Factors</a>	15	<a href="#">Certain Relationships and Related Party Transactions</a>	148
<a href="#">Information Regarding Forward-Looking Statements</a>	59	<a href="#">Principal Stockholders</a>	151
<a href="#">Market, Industry, and Other Data</a>	61	<a href="#">Description of Capital Stock</a>	155
<a href="#">Use of Proceeds</a>	62	<a href="#">Shares Eligible for Future Sale</a>	160
<a href="#">Dividend Policy</a>	62	<a href="#">Material U.S. Federal Income Tax Consequences to Non-U.S.</a>	
<a href="#">Capitalization</a>	63	<a href="#">Holders of our Common Stock</a>	162
<a href="#">Dilution</a>	65	<a href="#">Underwriting</a>	166
<a href="#">Selected Consolidated Financial Data</a>	67	<a href="#">Legal Matters</a>	174
<a href="#">Management's Discussion and Analysis of Financial Condition</a>		<a href="#">Experts</a>	174
<a href="#">and Results of Operations</a>	69	<a href="#">Where You Can Find Additional Information</a>	174
<a href="#">Business</a>	88	<a href="#">Index to Consolidated Financial Statements</a>	F-1
<a href="#">Management</a>	124		

---

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

**Through and including November 10, 2018 (25 days after commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.**

## TRADEMARKS

Unless the context indicates otherwise, as used in this prospectus, the terms "SI-BONE" and "iFuse Implant System" or "iFuse" and other iFuse-formative trademarks, as well as other trademarks or service marks of SI-BONE appearing in this prospectus, are the property of SI-BONE. This prospectus contains additional trade names, trademarks, and service marks of ours and of other companies. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

## KEY METRICS FOR STUDIES

Statistical significance in the studies described in this prospectus is denoted by p-values for both pain and disability analysis. The p-value is the statistical probability that the results observed are due to chance alone (i.e., a p-value <0.0001 for reduction in pain means that there is a less than a 0.01% chance that the demonstrated reduction in pain for subjects surgically treated with iFuse in relation to the non-surgical management group was purely due to chance).

The performance for subjects surgically treated with iFuse is evaluated using a number of commonly used metrics, including the following:

- **Visual analog scale, or VAS:** VAS measures a patient's pain intensity on a 0–100 scale, with zero representing no pain and 100 representing the worst pain imaginable. The VAS score is used to calculate changes in patient pain.
- **Oswestry Disability Index, or ODI:** ODI measures a patient's disability on a scale of 0–100, where zero represents no disability and scores greater than 60 represent very severe disability.

## INVESTORS OUTSIDE THE UNITED STATES

Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

## PROSPECTUS SUMMARY

*This summary highlights certain information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our common stock. You should carefully consider, among other things, our consolidated financial statements and the related notes and “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus. Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “SI-BONE,” “the company,” “we,” “us,” and “our” refer to SI-BONE, Inc.*

### **Our Business**

We are a medical device company that has 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, more than 34,000 procedures have been performed by over 1,700 surgeons, in the United States and 33 other countries. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the sacroiliac joint. We believe iFuse is currently used in the majority of minimally invasive surgical fusions of the sacroiliac joint in the United States.

The two sacroiliac joints are the largest joints in the body and connect the sacrum, near the base of the spine, to the iliac bones, the two major bones of the pelvis. The iFuse system includes a series of patented triangular implants, the instruments we have developed to enable the procedure, as well as the diagnostic and surgical techniques we have developed to enable physicians to perform the procedure. We introduced our second generation implant, the iFuse-3D, in 2017. We market our products with a direct sales force and a number of distributors in the United States, and with a combination of a direct sales force and distributors in other countries.

Our growth rate has recently increased, which we attribute in part to more widespread insurance coverage for sacroiliac fusion procedures, with many recent positive payor coverage policies exclusive to our iFuse system, as well as our efforts to educate the market regarding sacroiliac dysfunction. Since January 1, 2018, because of the strength of published clinical evidence on iFuse, 18 U.S. payors have published reimbursement policies exclusively covering the patented triangular design of our iFuse implants and excluding coverage of other products that are intended to fuse the sacroiliac joint. We believe that the full impact of each exclusive coverage decision grows over time as we continue to educate surgeons about the coverage and the medical criteria they need to follow, and train them on the diagnosis and how to perform the iFuse procedure.

In 2016 and 2017, we generated revenue of \$42.1 million and \$48.0 million, respectively, a growth rate of 14%, and incurred net losses of \$20.6 million and \$23.0 million, respectively. Our gross margins were 88% and 89% for 2016 and 2017, respectively. For the six months ended June 30, 2017 and 2018, we generated revenue of \$22.5 million and \$26.4 million, respectively, a growth rate of 17%, and incurred net losses of \$12.5 million and \$7.3 million, respectively. Our gross margins were 89% and 92% for the six months ended June 30, 2017 and 2018, respectively. The number of iFuse procedures performed in the six months ended June 30, 2017 and 2018 was 2,739 and 3,200, respectively.

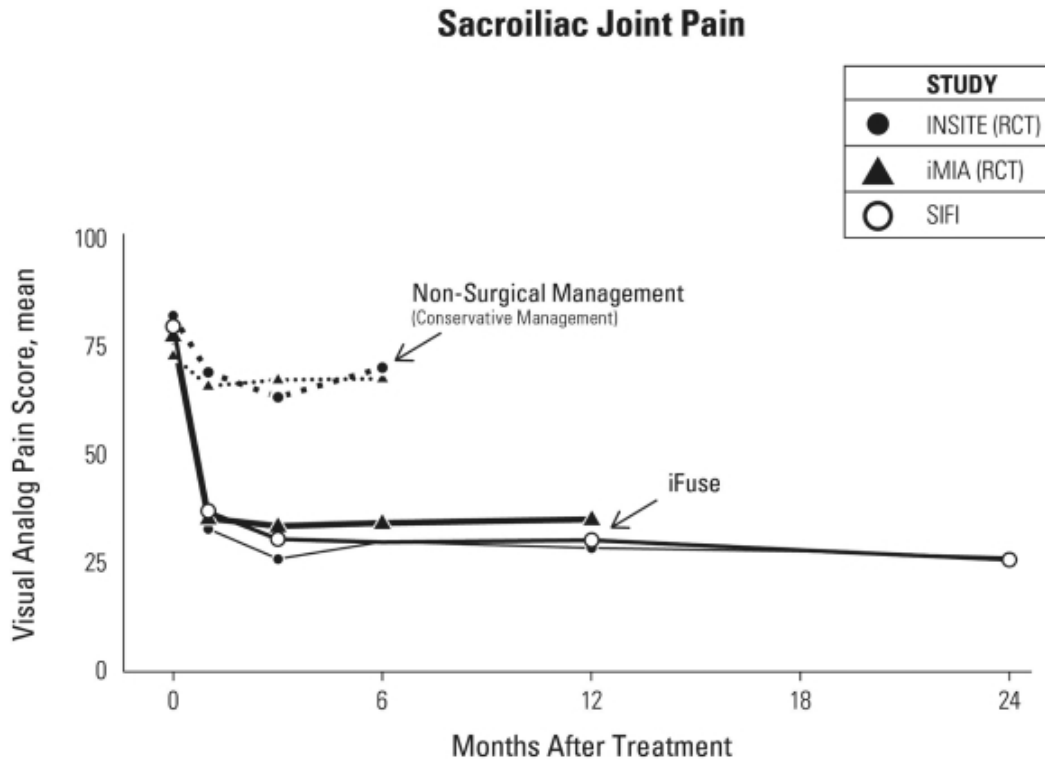
Patients with sacroiliac joint dysfunction may experience debilitating pain. We believe that the sacroiliac joint is the last major joint to be addressed by the orthopedic implant industry. Studies have shown that the disability that results from disease of the sacroiliac joint is comparable to the disability 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.

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.

**Published Clinical Evidence on iFuse**

The safety, clinical effectiveness, durability of pain relief and reduction in disability, cost effectiveness, and reduction in opioid use that result from iFuse are supported by a large number of studies that have resulted in more than 60 published papers. Several of these papers publish results from three prospective multicenter studies (INSITE, SIFI, and iMIA), two of which were randomized controlled clinical trials. These three prospective multicenter studies were summarized in a publication in *SPINE*, analyzing combined results from the three trials, as summarized in the graph below:



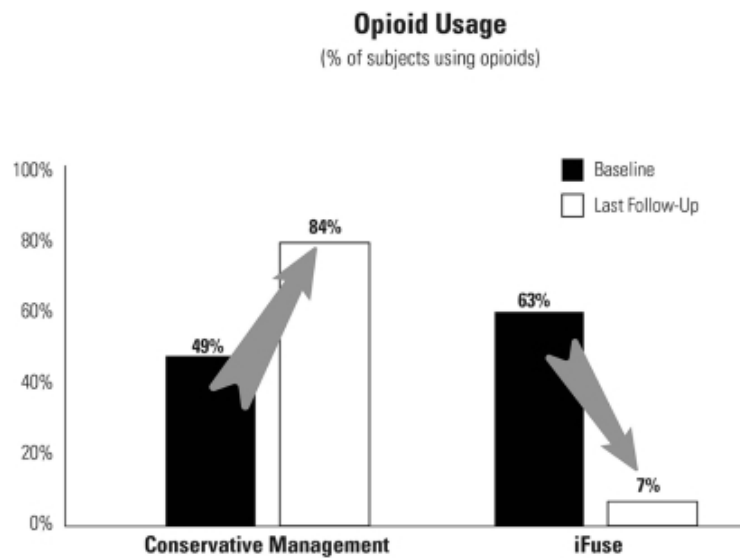
In INSITE, for example, one of the studies included in the graph above, subjects surgically treated with iFuse had mean 52-, 54-, and 55-point reductions in sacroiliac joint pain at 6, 12, and 24 months, respectively, as measured by the VAS, a standard method of assessing pain in which study subjects are asked to rate their pain from 0 (no pain) to 100 (worst imaginable pain). By contrast, subjects in the non-surgical management group had only a mean 12-point reduction at six months ( $p < 0.0001$ ), and only a small proportion of patients in the

non-surgical group had sufficient pain relief. The 12-point reduction in pain in the non-surgical management group is below a commonly accepted threshold of 20 points for clinically significant reduction in chronic back pain. 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 was 83% in the iFuse group and 10% in the non-surgical management group.

Results from the iMIA and SIFI studies were similar to INSITE.

There have been several studies showing longer-term follow-up of up to six years.

- LOIS is a prospective follow-on study, enrolling subjects at a subset of INSITE and SIFI sites treated with iFuse. Study outcomes at three years were published in April 2018 in *Medical Devices: Evidence and Research*. Amongst 103 enrolled subjects, mean sacroiliac joint pain at three years decreased from 81.5 preoperatively to 26.2 (a 56-point improvement from baseline,  $p < .0001$ ). A manuscript showing sustained improvement in pain and disability at four-year follow-up was recently accepted for publication.
- 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. As shown in the graph below, 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.



Surgical revision rate is an important measurement of a treatment’s effectiveness for patients. Studies on lumbar, or lower back, fusion, a different type of spine procedure from iFuse, have shown revision rates as approximately 12%. A study published in *Medical Devices: Evidence and Research* in November 2015 showed that the cumulative four-year revision rate with iFuse was 3.5%. A single surgeon retrospective study published in the *International Journal of Spine Surgery* in January 2017 showed that the cumulative four-year revision rate for screw-based treatment of the sacroiliac joint was five times higher than the cumulative four-year revision rate for iFuse.

See “Business—Our Published Studies” for more detail from these studies.

### **Market Opportunity**

We estimate that over 30 million American adults have chronic lower back pain. For patients whose chronic lower back pain stems from the sacroiliac joint, our experience in both clinical trials and commercial settings indicates that iFuse could be beneficial for at least 30% of patients who are properly diagnosed and screened for surgery by trained healthcare providers. Approximately 282,000 patients in the United States were estimated to have received multiple non-surgical steroid injections for sacroiliac joint pain in 2017. 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 United States could be 279,000 patients annually, for a potential annual market in the United States of approximately \$2.7 billion. While we have made significant inroads at penetrating this market, patients received only 4,319 iFuse procedures in 2017.

### **Limitations of Prior Treatment**

Patients with sacroiliac joint dysfunction or sacroiliac joint arthritis 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 very quickly decreases 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 become less common in the United States since we introduced iFuse.

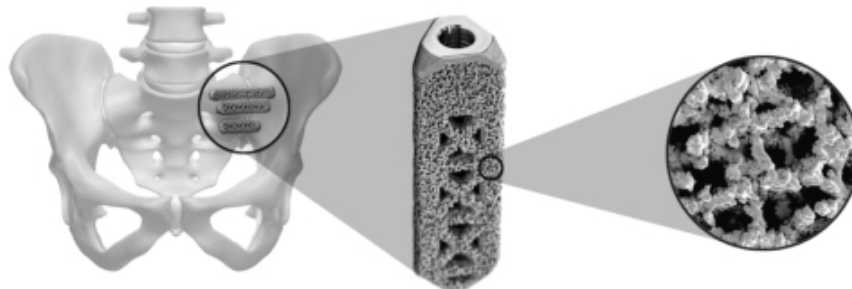
Due to its invasiveness, pain, long recovery time, and infrequent use, the open sacroiliac joint fusion procedure was rarely taught in medical school or residency programs. Prior to our launch of iFuse, most spine surgeons were unfamiliar with the sacroiliac joint and had never performed a sacroiliac 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.

Since we launched iFuse, we have made considerable investments in teaching healthcare professionals to accurately diagnose and treat sacroiliac joint disorders. We provide instruction and training on how to perform provocative maneuvers in a physician's office that can reveal the sacroiliac joint as the source of pain. If the provocative tests are positive, surgeons (or other physicians) 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.

Recently, major medical societies involved in spine surgery have begun offering sacroiliac joint diagnostic training sessions for their membership. In 2018, these societies include the North American Spine Society, or NASS, Congress of Neurologic Surgeons, or CNS, American Academy of Neurologic Surgeons, or AANS, International Society for the Advancement of Spine Surgery, or ISASS, and the Scoliosis Research Society, or SRS.

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%. 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.

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 the implants and across the joint, permanently stabilizing or fusing the joint.

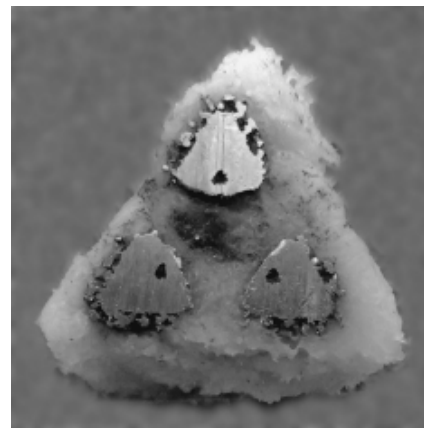
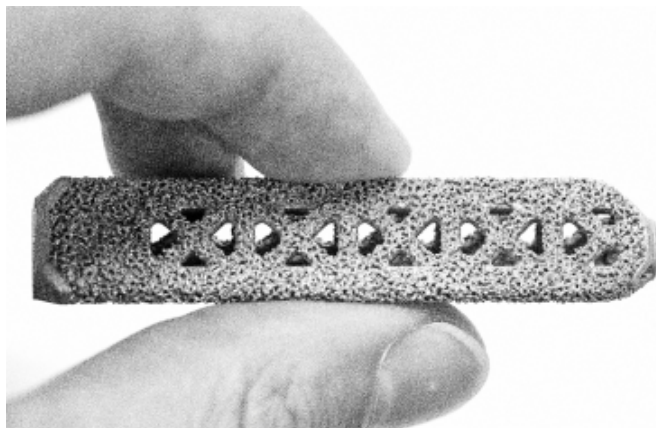


Because of the triangular shape, porous surface, strength, and other differentiating factors of our iFuse implants, we believe that our published clinical data do not apply to other minimally invasive solutions. Little published evidence of safety, clinical effectiveness, durability, or economic utility currently exists for sacroiliac fusion devices other than iFuse. We 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 Second-Generation Implant**

Our second-generation iFuse implant, iFuse-3D, shown on the left below, was cleared for marketing by the U.S. Food and Drug Administration in March 2017 and the European Union in May 2017. This patented titanium implant combines the triangular cross-section of the iFuse implant with a proprietary 3D-printed porous surface and fenestrated design. This design also allows the surgeon to fill the implant with ground-up bone before implanting it, which some surgeons believe accelerates bone through-growth. iFuse-3D implants have shown positive bony ingrowth in cell culture and animal studies, whether or not ground-up bone is used, as shown in two peer reviewed studies published in June 2017 in the *International Journal of Spine Surgery*. The image on the right below shows the cross section cut from an iFuse-3D implant removed from an animal as part of the study, and reveals robust growth of bone into the implants.



### **Coverage and Reimbursement**

As of August 31, 2018, U.S. payors covering 250 million lives reimburse for iFuse, 115 million of which are covered by private payors. There are a number of large and small private payors, including Aetna, Cigna, Humana, and Anthem, that are not yet reimbursing 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.

Prior to our launch of iFuse in 2009, Medicare and most private insurance companies reimbursed surgeons routinely for sacroiliac joint fusions, which were primarily invasive. However, effective July 1, 2013, the American Medical Association's, or AMA's, Editorial Panel effectively restricted reimbursement for minimally invasive sacroiliac joint fusion because they considered the published clinical evidence at the time to be inadequate.

Subsequently, as a result of the growing number of published clinical studies demonstrating the effectiveness and safety of iFuse, along with the support of several professional medical specialty societies and leading academic surgeons, the AMA Editorial Panel established a new reimbursement code for minimally invasive sacroiliac joint fusion surgery, effective 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.

Coverage decisions for this code are made independently by each private insurance company and each of the seven regional 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. However, as of August 31, 2018, 39 of the largest 65 private payors were covering regularly, or had announced coverage for, the iFuse procedure, while the remaining private payors were reevaluating their coverage policies. Of these, 23 private payors have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence. Seventeen of these exclusive coverage policies have published since January 1, 2018, which we believe has contributed to our accelerating sales growth in fiscal year 2018.

Prior to payor coverage, surgeons have been reluctant to get trained on a procedure for which they could not reliably be reimbursed. We believe it takes between six and 24 months for surgeons to fully incorporate iFuse into their practices after payors initiate coverage. 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. As reimbursement coverage has improved, surgeon interest in learning to diagnose the sacroiliac joint and perform iFuse procedures has been increasing.

Specialty benefit managers and companies which perform healthcare technology assessments have significant influence on coverage decisions. In 2018, four of the leading organizations, including Milliman Care Guidelines, AIM Specialty Health, Blue Cross Blue Shield Association Evidence Street, and eviCore Healthcare published positive coverage recommendations to their constituents and payor customers, of which three have recommended that iFuse be covered exclusively. Internationally, the United Kingdom's National Institute for Health and Care Excellence, or NICE, published a positive coverage recommendation for sacroiliac joint fusion in 2017. 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. Additionally, in August 2018, the public hospital system in France announced it would initiate coverage for iFuse exclusively beginning September 6, 2018.

### **Our Strategy**

Our business objective is to maintain and enhance our leadership position in the area of sacroiliac joint fusion by providing clinically proven products and procedure-related training to promote relief of pain and disability in affected patients. To accomplish this objective, we intend to:

- Continue to educate physicians and other healthcare providers, payors, and patients globally about the growing body of evidence supporting the safety, durable clinical effectiveness, economic benefit, and reduction in opioid use associated with the iFuse procedure;
- Educate and train the healthcare community on the prevalence, anatomy, diagnosis, and treatment options for the sacroiliac joint, including minimally invasive surgical fusion, and work with and support medical societies including NASS, CNS, AANS, ISASS, SRS, and the American Academy of Orthopaedic Surgeons, or AAOS, to increase their education programs teaching the diagnosis of the sacroiliac joint as part of the differential diagnosis of lower back pain;
- Increase exclusive and non-exclusive reimbursement coverage for iFuse;
- Expand our direct field organization in the United States and select European countries to help drive adoption of our iFuse products;
- Maintain our technological leadership by investing in the creation of new or improved products for sacroiliac joint surgery, and obtain domestic and international regulatory clearance or approvals to market them in the United States and additional countries; and
- Continue to grow our existing intellectual property portfolio.

## **Company History**

SI-BONE was founded in 2008 by orthopedist Mark A. Reiley, M.D., the main inventor of iFuse and member of our board of directors, as well as 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 in 2007. He also invented the INBONE total ankle replacement system, which was sold to Wright Medical Technology, Inc. in 2008.

As of June 30, 2018, we had 168 employees, including a direct field sales organization of 72 in the United States and 28 in Europe. We intend to expand our direct field organization with some of the proceeds from this offering. As of June 30, 2018, we had 40 issued patents throughout the world, of which 34 were in the United States, and 18 pending patent applications, of which 11 were in the United States. These patents and applications cover various aspects of the iFuse procedure, implants, and instruments.

## **Risks Associated with Our Business**

Our business is subject to numerous risks, as more fully described in the section “Risk Factors,” which immediately follow this prospectus summary. These risks include, among others:

- 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.
- 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.
- 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.
- If healthcare payors reverse decisions to cover minimally invasive sacroiliac joint fusion exclusively when performed with iFuse and choose to reimburse for procedures performed with competitive products, our market share could decline, adversely affecting our revenues.
- We may not be able to convince physicians that iFuse is an attractive alternative to our competitors’ products and that our procedure is an attractive alternative to existing surgical and non-surgical treatments of the sacroiliac joint.
- Surgeons and payors may not find our clinical evidence to be compelling, which could limit our sales and revenue, and on-going and future research may prove our products to be less safe and effective than initially anticipated.
- 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.
- 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.
- We currently manufacture and sell products used in a single procedure, 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.

- We, our suppliers, and our third-party manufacturers are subject to extensive governmental regulation both in the United States and abroad, and failure to comply with applicable requirements could cause our business to suffer.
- We and our sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to physician kickbacks and false claims for reimbursement, as well as equivalent foreign laws.

#### **Implications of Being an Emerging Growth Company**

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions for up to five years or until we are no longer an “emerging growth company,” whichever is earlier. In addition, the JOBS Act provides that an “emerging growth company” can delay adopting new or revised accounting standards until those standards 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.”

#### **Recent Developments**

Set forth below are certain preliminary revenue, cost of goods sold, and operating loss expectations for the three and nine months ended September 30, 2018 compared to actual unaudited financial results for the three and nine months ended September 30, 2017. We have provided a range for these preliminary results because our financial closing procedures for the three months ended September 30, 2018 are not yet complete. These preliminary results represent our estimates only based on currently available information and do not present all necessary information for an understanding of our financial condition as of September 30, 2018 or our results of operations for the three and nine months ended September 30, 2018. As we complete our quarter-end financial close process and finalize our unaudited financial statements for the three and nine months ended September 30, 2018, we will be required to make significant judgments in a number of areas, including inventory, stock-based compensation, and the liability for preferred stock warrants.

This financial information has been prepared by and is the responsibility of our management. PricewaterhouseCoopers LLP, our independent registered public accounting firm, has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial data or the accounting treatment thereof and does not express an opinion or any other form of assurance with respect thereto, nor has PricewaterhouseCoopers LLP audited or reviewed financial statements for the three and nine months ended September 30, 2017. We expect to complete our unaudited financial statements for the three and nine months ended September 30, 2018 subsequent to the completion of this offering. It is possible that we or PricewaterhouseCoopers LLP may identify items that require us to make adjustments to the financial information set forth below and those changes could be material. We do not intend to update the financial information set forth below prior to completion of our interim financial statements. Accordingly, undue reliance should not be placed on these preliminary estimates. These preliminary estimates are not necessarily indicative of any future period and should be read together with “Risk Factors,” “Information Regarding Forward-Looking Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Selected Consolidated Financial Data,” and our financial statements and related notes included elsewhere in this prospectus.

*Revenue*

We estimate that our total revenue for the three months ended September 30, 2018 was between approximately \$13.2 million and \$13.4 million as compared to \$11.7 million for the three months ended September 30, 2017. We estimate that our total revenue for the nine months ended September 30, 2018 was between approximately \$39.6 million and \$39.8 million as compared to \$34.2 million for the nine months ended September 30, 2017.

*Cost of goods sold*

We estimate that our cost of goods sold was between approximately \$1.1 million and \$1.3 million for the three months ended September 30, 2018 as compared to cost of goods sold of \$1.3 million for the three months ended September 30, 2017. We estimate that our cost of goods sold was between approximately \$3.4 million and \$3.6 million for the nine months ended September 30, 2018 as compared to cost of goods sold of \$3.9 million for the nine months ended September 30, 2017.

*Operating loss*

We estimate that our operating loss was between approximately \$2.7 million and \$3.5 million for the three months ended September 30, 2018 as compared to \$5.0 million for the three months ended September 30, 2017. We estimate that our operating loss was between \$7.4 million and \$8.2 million for the nine months ended September 30, 2018 as compared to \$15.7 million for the nine months ended September 30, 2017.

**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](http://www.si-bone.com). The information on, or that can be accessed through, our website is not part of this prospectus. We have included our website address as an inactive textual reference only.

## THE OFFERING

Shares of common stock offered by us	7,200,000 shares
Shares of common stock to be outstanding after this offering	22,995,538 shares (24,075,538 shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 30 days, to purchase up to 1,080,000 additional shares of our common stock.
Use of proceeds	<p>We estimate that the net proceeds from this offering of 7,200,000 shares of our common stock will be approximately \$98.7 million, or \$113.8 million if the underwriters exercise their option to purchase additional shares in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, at the initial public offering price of \$15.00 per share.</p> <p>We expect to use approximately \$65.0 million of the net proceeds for sales and marketing activities to support ongoing commercialization of the iFuse Implant System and the remainder, if any, for working capital and general corporate purposes, including research and development and clinical studies. We may also use a portion of our net proceeds to acquire or invest in complementary products, technologies, or businesses; however, we currently have no agreements or commitments to complete any such transactions. See “Use of Proceeds.”</p>
Risk factors	See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Nasdaq Global Market symbol	“SIBN”

Certain of our existing stockholders or their affiliates, including entities affiliated with Arboretum Ventures, Novo Holdings A/S, OrbiMed, and Skyline Venture Partners, that had submitted indications of interest have agreed to purchase an aggregate of 1,225,000 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

The number of shares of common stock to be outstanding after this offering is based on 15,795,538 shares of common stock outstanding as of June 30, 2018, and excludes:

- 2,900,842 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2018, with a weighted-average exercise price of \$4.09 per share;
- 230,066 shares of common stock, as converted, issuable upon the exercise of warrants outstanding as of June 30, 2018, with a weighted-average exercise price of \$8.69 per share;
- 26,613 additional shares of common stock reserved for future issuance under our 2008 Stock Plan, all of which ceased to be available for issuance at the time our 2018 Equity Incentive Plan became effective upon the execution of the underwriting agreement for this offering;
- 2,576,538 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan, as well as any increases in the number of shares of common stock reserved for future issuance under this plan, which became effective upon the execution of the underwriting agreement for this offering; and
- 515,307 shares of common stock reserved for future issuance under our 2018 Employee Stock Purchase Plan, as well as any increases in the number of shares of common stock reserved for future issuance under this plan, which became effective upon the execution of the underwriting agreement for this offering.

Unless otherwise indicated, all information in this prospectus assumes:

- The filing of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws upon the closing of this offering;
- A 1-for-18 reverse stock split of common stock and preferred stock effected on October 4, 2018;
- The conversion of all warrants to purchase shares of preferred stock into warrants to purchase shares of common stock immediately prior to the closing of this offering;
- The conversion of all outstanding shares of preferred stock into an aggregate of 12,066,654 shares of common stock immediately prior to the closing of this offering;
- The issuance of 21,616 shares of common stock upon the automatic net exercise of warrants, with an exercise price of \$9.10 per share, immediately prior to the closing of this offering, at the initial public offering price of \$15.00 per share.
- The reclassification of all outstanding shares of Series 1 common stock and Series 2 common stock into a single class of common stock named “common stock,” which shall have the same voting powers, preferences, rights and qualifications, limitations, and restrictions as the current Series 2 common stock, immediately prior to the closing of this offering;
- No exercise of outstanding options and warrants, other than as provided for above; and
- No exercise by the underwriters of their option to purchase up to 1,080,000 additional shares of common stock.

### SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes included within this prospectus. The consolidated statements of operations data for the years ended December 31, 2016 and 2017, are derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2017 and 2018, and the consolidated balance sheet data at June 30, 2018, are derived from our unaudited consolidated financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and our results for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the full fiscal year.

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
(in thousands, except share and per share data)				
<b>Consolidated Statements of Operations Data:</b>				
Revenue	\$ 42,101	\$ 47,983	\$ 22,531	\$ 26,375
Cost of goods sold	5,165	5,112	2,566	2,230
Gross profit	36,936	42,871	19,965	24,145
Operating expenses:				
Sales and marketing	35,215	41,646	21,130	21,285
Research and development	6,380	5,513	2,768	2,502
General and administrative	12,906	13,062	6,737	4,972
Total operating expenses	54,501	60,221	30,635	28,759
Loss from operations	(17,565)	(17,350)	(10,670)	(4,614)
Interest and other income (expense), net:				
Interest income	71	175	73	130
Interest expense	(3,308)	(6,204)	(1,920)	(2,544)
Other income (expense), net	213	340	66	(320)
Net loss	(20,589)	(23,039)	(12,451)	(7,348)
Other comprehensive income:				
Changes in foreign currency translation	67	(70)	(35)	33
Comprehensive loss	\$ (20,522)	\$ (23,109)	\$ (12,486)	\$ (7,315)
Net loss per common share, basic and diluted <sup>(1)</sup>	\$ (6.21)	\$ (6.65)	\$ (3.63)	\$ (2.04)
Weighted-average common shares used to compute basic and diluted net loss per common share <sup>(1)</sup>	3,314,198	3,467,096	3,426,963	3,603,308
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(1)</sup>		\$ (1.50)		\$ (0.45)
Pro forma weighted-average number of common shares used to compute basic and diluted net loss per share (unaudited) <sup>(1)</sup>		15,480,394		15,691,578

(1) See Note 14 to our consolidated financial statements included elsewhere in this prospectus for the method used to calculate net loss per common share, basic and diluted, and pro forma net loss per common share, basic and diluted, and weighted-average number of shares used in the computation of the per share amounts.



	As of June 30, 2018		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 16,233	\$ 16,233	\$ 114,973
Working capital	20,040	20,040	118,780
Total assets	29,913	29,913	128,653
Redeemable convertible preferred stock warrant liability	646	—	—
Total long-term borrowings	38,834	38,834	38,834
Total liabilities	47,068	46,422	46,422
Redeemable convertible preferred stock	118,548	—	—
Total stockholders' (deficit) equity	(135,703)	(16,509)	82,231

- (1) The pro forma column reflects (i) the conversion of all outstanding shares of our preferred stock into an aggregate of 12,066,654 shares of common stock immediately prior to the closing of this offering, (ii) the issuance of 21,616 shares of common stock upon the automatic net exercise of outstanding warrants, with an exercise price of \$9.10 per share, immediately prior to the closing of this offering, at the initial public offering price of \$15.00 per share, and (iii) the reclassification of our preferred stock warrant liability to additional paid-in capital immediately prior to the closing of this offering.
- (2) The pro forma as adjusted column further reflects the sale of 7,200,000 shares of common stock in this offering, at the initial public offering price of \$15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, 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 you may lose all or part of your 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 2017 and the six months ended June 30, 2018, we had net losses of \$23.0 million and \$7.3 million, respectively. As of June 30, 2018, we had an accumulated deficit of \$147.1 million. To date, we have financed our operations primarily through 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. Following this offering, 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 recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. In addition, our credit facility agreement requires us to comply with certain financial covenants, including minimum liquidity, revenue, and earnings targets. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2017, describing the existence of substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to raise sufficient capital in this offering, we may need to obtain alternative financing or significantly modify our operational plans for us to continue as a going concern. 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 Procedure Terminology, or 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, or CMS, which administers the Medicare program, as guidelines for setting their coverage and reimbursement policies. By June 30, 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 United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they chose to cover. For example, several Blue Cross Blue Shield payors have recently 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 surgery 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.

The national average Medicare payment per procedure to hospital outpatient departments increased from \$10,538 to \$14,704 effective January 1, 2017. Effective January 1, 2018, the national average Medicare payment to hospital outpatient departments is \$15,371. Effective January 1, 2018, the Medicare payment to an ambulatory surgery center for a sacroiliac joint fusion is \$12,456. 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 United States. In 2015, the national average physician payment for the new Category I CPT Code for minimally invasive sacroiliac fusion was \$574, and we believe that this payment caused adoption of the procedure to slow. Effective January 1, 2016, the national average Medicare payment for the Category I CPT code increased to \$718, and the national average payment effective January 1, 2018, is \$720. 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 view the current Medicare reimbursement amount 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 August 31, 2018, 23 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, in August 2018, the public hospital system in France announced it would initiate 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 the first six months of 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.

***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 solution 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 sacroiliac joint pain in their diagnostic work-up because they did not have an adequate surgical procedure to perform for patients diagnosed with the condition. 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 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.

***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 United States have either received premarket clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, or are exempt from premarket review. Those marketed in the European Union, or EU, have been the subject of a CE Certificate of Conformity. The 510(k) clearance process of the U.S. Food and Drug Administration, or 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, or 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 United States. 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 United States 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 pricing pressure and a reduction in the number of iFuse procedures performed.

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, or PODs, 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. The number of competitors that we are aware of marketing sacroiliac joint fusion products in the United States has grown from zero to 18 since 2008. Many 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. Our field is intensely competitive, 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.

In the United States, we believe that our primary competitors currently are Globus Medical, Inc., Medtronic plc, XTant Medical Holdings, Inc., and RTI Surgical, Inc. Our primary competitors in Europe are Globus Medical, SIGNUS Medizintechnik GmbH, and XTant Medical Holdings. 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, or 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.

## [Table of Contents](#)

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 products used in a single procedure, 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 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 June 30, 2018, our U.S. sales force consisted of 45 sales representatives directly employed by us and 30 third-party distributors. As of June 30, 2018, our international sales force consisted of 18 sales representatives and 27 exclusive third-party distributors, which together have had sales in 33 countries through June 30, 2018. 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 United States. 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.

***We have a limited operating history and may face difficulties encountered by early stage companies in new and rapidly evolving markets.***

We were formed in 2008. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, you must consider the risks and difficulties frequently encountered by early stage companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of medical devices. These risks include our inability to:

- increase coverage by third-party, private, and government payors;
- establish and increase awareness of our brand and strengthen customer loyalty;
- obtain domestic and international regulatory clearances or approvals, and CE Certificates of Conformity;
- conformity to commercialize new products and enhance our existing products;
- manage rapidly changing and expanding operations;
- grow our direct sales force and increase the number of our third-party distributors to expand sales of our products in the United States and in targeted international markets;

## [Table of Contents](#)

- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- continue to develop and enhance our products and product candidates;
- expand our presence and commence operations in international markets;
- perform clinical research and trials on our existing products and current and future product candidates; and
- attract and retain qualified personnel.

We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

### ***Our sales volumes and our operating results may fluctuate over the course of the year.***

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.

## [Table of Contents](#)

Some of the products we may seek to develop and introduce in the future will require FDA clearance or approval before commercialization in the United States, and commercialization of such products outside of the United States would likely require additional regulatory approvals, or Certificates of Conformity and import licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly 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.

***If our business strategy proves to be flawed, or if we do not successfully implement our business strategy, our business and results of operations will be adversely affected.***

Our business strategy was based on assumptions about the market that might prove wrong. We believe that various demographics and industry-specific trends will help drive growth in the market and our business, but these demographics and trends have been and will continue to be uncertain. Actual demand for our products could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments to those offered by our products gain widespread acceptance.

To implement our business strategy we need to, among other things, develop and introduce new products, find new applications for and improve our existing products, obtain new domestic and international regulatory clearances or approvals and CE Certificates of Conformity and domestic and international regulatory clearance or approval for new products and applications, and educate surgeons and payors about the clinical benefits and cost effectiveness of our products. We may not be able to successfully implement our business strategy. Also, our strategy of focusing exclusively on the sacroiliac joint market may limit our ability to grow. In addition, in order to increase our sales, we will need to commercialize additional products and expand our direct and third-party distributor sales forces in existing and new regions, all of which could result in our becoming subject to additional or different foreign and domestic regulatory requirements, with which we may not be able to comply. Moreover, we may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our products obsolete. Any failure to implement our business strategy may 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.

Although it will be subject to lock-up agreements and other restrictions on trading, a portion of the equity of our management team will not contain other contractual transfer restrictions at the time of this offering and may become tradable after the expiration of the 180-day lock-up agreement with the underwriters. This liquidity may represent material wealth to such individuals and impact retention and focus of existing key members of management.

***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 you 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 one supplier, Orchid Bio-Coat, a division of Orchid Orthopedic Solutions LLC, for our iFuse implants and one supplier, rms Company, for our second-generation iFuse-3D 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;
- 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.

## [Table of Contents](#)

In addition, most of our supply and manufacturing agreements do not have minimum manufacturing or purchase obligations. As such, we have no obligation to buy any given quantity of products, and our 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. 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, or product discontinuations. 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 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 or countries of 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;

## [Table of Contents](#)

- 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 solution 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 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, our estimates of cost savings to the economy and healthcare system as a result of the iFuse procedure are based on our internal estimates and market research and could also be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market or 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 presented in this prospectus. 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, or FCPA, and the United Kingdom Bribery Act, or UKBA, anti-boycott laws, anti-money laundering laws, and regulations relating to economic sanctions imposed by the United States, including the Office of Foreign Asset Control of the U.S. Treasury. Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

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

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



## [Table of Contents](#)

- 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;
- power losses; and
- computer systems, or Internet, telecommunications, or data network failures.

## [Table of Contents](#)

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.

#### **Risks Related to Our Legal and Regulatory Environment**

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

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory 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;

## [Table of Contents](#)

- 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 United States, with very limited exception, we must obtain either clearance under Section 510(k) of the FDCA for Class II devices or approval of a premarket approval, or 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, preclinical, 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 United States, 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

## [Table of Contents](#)

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 you 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 postmarketing studies. These studies can be very expensive and time consuming to conduct. Failure to comply with those studies in a timely manner could result in the revocation of the 510(k) clearance for a product that is subject to such a 522 Order and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States.

In the EEA, our medical devices must 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, 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.

Additionally, 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

## [Table of Contents](#)

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.

The FDA and other regulatory 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 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.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. 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, order 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 federal 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. 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, 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 Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians 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; 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; 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.

## [Table of Contents](#)

If we or our employees are found to have violated any of the above laws we may be subjected to administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties and damages, and damage to our reputation. Additional information about these laws is provided in “Business—Regulation.”

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, to the extent applicable, 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. 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 and state 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 and state 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. Actions under the federal False Claims Act may also be brought by whistleblowers under its *qui tam* provisions.

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 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 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.

There are a number of state, federal, and international laws protecting the privacy and security of health information and personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny of companies' data practices and escalating levels of enforcement and sanctions. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes certain requirements regarding the privacy, security, use, and disclosure of an individual's protected health information, or PHI, by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as "covered entities," and their "business associates," or subcontractors who provide services to covered entities that involve the creation, use, maintenance, or disclosure of PHI. ARRA included significant increases in the penalties for improper use or disclosure of an individual's PHI under HIPAA and extended enforcement authority to state attorneys general. The amendments also created notification requirements applicable to covered entities and business associates in certain cases when PHI in their control has been inappropriately accessed or disclosed. In the case of a breach of unsecured PHI, covered entities may be required to provide notification to individuals affected by the breach, federal regulators, and, in some cases, local and national media. In addition to HIPAA, most states have laws requiring notification of affected individuals and state regulators in the event of a breach of "personal information," which is a broader class of information than the PHI protected by HIPAA. Certain states also have data privacy requirements applicable to individually identifiable health information. Privacy laws in different states may contain different requirements, and such laws may not be pre-empted by HIPAA, which could complicate our efforts to comply.

In addition, even when HIPAA does not apply, according to the 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. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

Many foreign countries and governmental bodies, including the EU, Australia, and other relevant jurisdictions, have laws and regulations concerning the collection and use of personal or sensitive data obtained from their residents or by businesses operating within their jurisdiction. For example, the European Commission recently adopted the General Data Protection Regulation, or the GDPR, effective on May 25, 2018, that will supersede current EU data protection legislation, impose more stringent EU data protection requirements and provide for greater penalties for noncompliance. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use "personal data," or any information relating to an identified or identifiable natural person, in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, and substantial new obligations on services providers. Non-compliance with the GDPR can trigger steep fines of up to €20 million or 4% of total worldwide annual revenues, whichever is higher. Given the breadth and depth of changes in data protection obligations, achieving and maintaining GDPR compliance will require considerable time and resources.

We are at risk of enforcement actions taken by certain EU data protection authorities until such point in time that we may be able to ensure that all transfers of personal data to us from the European Economic Area are conducted in compliance with all applicable regulatory obligations, the guidance of data protection authorities and evolving best practices. We may find it necessary to establish systems to maintain personal data originating from the EU in the European Economic Area, which may involve substantial expense and may cause us to need to divert resources from other aspects of our business, all of which may 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 United States, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products.

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

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

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

## [Table of Contents](#)

***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, or 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 or withdrawal of CE Certificates of Conformity;
- refusal to grant export approval for our products; and
- criminal prosecution.

In addition, we may be 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.

## [Table of Contents](#)

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, or CAPA, 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 and state healthcare laws and regulations, 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 laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. In the United States, 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. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life." Moreover, iFuse is one of the few devices regulated through the class II pathway that has claims for clinical improvements. iFuse-3D, which was FDA-cleared in 2017, has a very similar indication statement but does not have the statement regarding improvement in pain, function and quality of life. In the United States, 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. However, if the FDA 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 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, we are required to report to the FDA 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 within the required timeframes, or at all, FDA 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, or 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.

Any adverse event involving our products, whether in the United States or abroad could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or 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.

***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 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.

## [Table of Contents](#)

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 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. 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.

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. Failure to receive clearance or approval 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 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 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 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. 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.

Moreover, the policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. The outcome of the 2016 election and the forthcoming 2018 mid-term elections 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. On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the EEA. These proposals are intended to strengthen the medical devices rules in the EEA. On April 5, 2017, the final text of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) were adopted by the Parliament and the Council. These regulations, which will substantially impact medical devices manufacturers, will be applicable from May 2020 for the MDR and May 2022 for the IVDR. 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;

## [Table of Contents](#)

- 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, or 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 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 and appear likely in the 115th United States 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 United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

### ***Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, imposes, among other things, an annual excise tax on any entity that manufactures or imports medical devices offered for sale in the United States. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to \$20.0 billion over the next decade. A two-year moratorium currently applies to this tax through December 2019. After that time, the tax may be repealed or modified, or the moratorium may be lifted, in which case sales of our iFuse would be subject to this excise tax. In July 2018, the U.S. House of Representatives voted to repeal this tax. The U.S. Senate is expected to vote on the matter in the fourth quarter of 2018.

### ***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 medical devices for sacroiliac joint surgery procedures. Sacroiliac joint surgery involves 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 recently passed comprehensive tax reform bill 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.

## **Risks Related to Our Intellectual Property**

### ***Our ability to protect our intellectual property and proprietary technology is uncertain.***

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 June 30, 2018, we owned 34 issued U.S. patents and had 11 pending U.S. patent applications, and we owned six issued foreign patents and had seven pending foreign patent applications. As of June 30, 2018, we have 12 registered trademarks in the United States and have filed for one more. We have sought protection for at least two 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 you 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 which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available. Since most of our issued patents are for the United States only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our products.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. We cannot assure you 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 you 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 United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make and sell our products. We have conducted a limited review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and the uncertainty of litigation increase the risk of 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 this Offering and Ownership of Our Common Stock**

#### ***The price of our common stock may be volatile, and the value of your investment could decline.***

Prior to this offering, there has been no public market for our common stock, and medical device stocks have historically experienced volatility. The trading price of our common stock following this offering may fluctuate substantially. Following the closing of this offering, the market price of our common stock may be higher or lower than the price you pay in the offering, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your 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 United States, foreign countries, or both;
- lock-up releases and sales of large blocks of our common stock;

## [Table of Contents](#)

- 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.

***Sales of substantial amounts of our common stock in the public markets, including when the "lock-up" or "market standoff" period ends, or the perception that sales might occur, could reduce the price of our common stock and may dilute your voting power and your ownership interest in us.***

Sales of a substantial number of shares of our common stock in the public market after this offering, or the perception that these sales could occur, could adversely affect the market price of our common stock, and may make it more difficult for you to sell your common stock at a time and price that you deem appropriate. Based on the total number of outstanding shares of our common stock as of June 30, 2018, upon the closing of this offering, we will have 22,995,538 shares of common stock outstanding. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any shares held by our "affiliates" as defined in Rule 144 under the Securities Act.

Subject to certain exceptions, we, our directors and officers and the holders of substantially all of our capital stock, warrants and stock options have agreed not to offer, sell or agree to sell, directly or indirectly, any shares of common stock without the permission of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated for a period of 180 days from the date of this prospectus. When the lock-up period expires, our security holders will be able to sell shares in the public market subject to any restrictions under the securities laws. In addition, Morgan Stanley and Merrill Lynch may, in their discretion, release all or some portion of the shares subject to lock-up agreements prior to the expiration of the lock-up period. See "Shares Eligible for Future Sale" for more information. Sales of a substantial number of such shares upon expiration, or the perception that such sales may occur, or early release of the lock-up, could cause our share price to fall, or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Based on shares outstanding as of June 30, 2018, the holders of 12,088,270 shares, or approximately 52.6%, of our common stock after this offering, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

We may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

***Insiders will continue to have substantial control over us after this offering, which could limit your ability to influence the outcome of key transactions, including a change of control.***

Our directors, executive officers, and each of our stockholders that own greater than 5% of our outstanding common stock, in the aggregate, will beneficially own approximately 52.5% of the outstanding shares of our

common stock after this offering, based on the number of shares outstanding as of June 30, 2018. The aggregate beneficial ownership of this group of stockholders reflects that certain entities affiliated with Arboretum Ventures, OrbiMed, and Skyline Venture Partners, each a beneficial owner of more than 5% of our capital stock, and certain other existing stockholders that had submitted indications of interest have agreed to purchase an aggregate of 1,225,000 shares of our common stock in this offering at the initial public offering price.

As a result, these stockholders will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a manner that is adverse to your interests. This concentration of ownership may have the effect of deterring, delaying, or preventing a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

***There is no existing market for our common stock, and we cannot assure you that a market will develop for our common stock or what the market price of our common stock will be.***

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the Nasdaq Global Market or otherwise or how liquid that market might become. If an active trading market does not develop, you may have difficulty selling any shares of our common stock that you purchase, and the value of such shares might be materially impaired.

In addition, we cannot predict the prices at which our common stock will trade. The initial public offering price for our common stock has been determined by negotiations between us and the representatives of the underwriters and may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell shares of our common stock at prices equal to or greater than the price you paid in this offering.

***We have broad discretion in the use of net proceeds that we receive in this offering, and if we do not use those proceeds effectively, your investment could be harmed.***

The principal purposes of this offering are to create a public market for our common stock, obtain additional working capital, and facilitate our future access to the public equity markets. We intend to use the net proceeds from this offering for general corporate purposes, including working capital, sales, and marketing activities, research initiatives including enhancement of our solution, investment in technology and development and capital expenditures. We also may use a portion of the net proceeds from this offering to acquire or invest in technologies, solutions, or businesses that complement our business, although we have no present commitments, and we have not allocated specific amounts of net proceeds, to complete any such transactions or plans. Accordingly, our management will have broad discretion in the application of the net proceeds to us from this offering. Investors in this offering will need to rely upon the judgment of our management regarding the application of the proceeds. If we do not use the net proceeds that we receive in this offering effectively, our business, results of operations, and financial condition could be harmed.

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

As of December 31, 2017, we had net operating loss, or NOL, carryforwards of \$124.9 million and \$101.7 million available to reduce future taxable income, if any, for U.S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in 2029 and 2019, 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. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including this offering, some of which may be outside of our control. If a future ownership change occurs, our ability to use our NOL tax credit carryforwards may be materially limited, which would harm our future operating results by effectively increasing our future tax obligations.

***The requirements of being a public company may strain our resources, divert our management's attention, and affect our ability to attract and retain qualified board members.***

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and will be required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming, or costly and increase demand on our systems and resources. Among other things, the Exchange Act requires that we file annual, quarterly, and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal controls over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and results of operations. Although we have already hired additional employees to comply with these requirements, we may need to hire even more employees in the future, which will increase our costs and expenses.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

***Failure to establish and maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.***

After the closing of this offering, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq Global Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing with the year ending December 31, 2019, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K for that year, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal controls within a specified period, and we are not currently in compliance with, and we cannot be certain when we will be able to implement the requirements of Section 404. As a result, we may experience difficulty in producing accurate financial statements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well

designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. In addition, in connection with the future attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, our stockholders could lose confidence in our reporting, and the market price of our stock could decline. In addition, we could be subject to sanctions or investigations by the Nasdaq Global Market, the Securities and Exchange Commission, or SEC, or other regulatory authorities.

***We are an “emerging growth company,” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company” as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and only two years of selected financial data;
- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements, and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from complying with new or revised financial accounting standards until such time as such standards are applicable to private companies.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

## [Table of Contents](#)

***Because the initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock following this offering, new investors will experience immediate and substantial dilution.***

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock immediately following this offering based on the total value of our tangible assets less our total liabilities. Therefore, if you purchase shares of our common stock in this offering, you will experience immediate dilution of \$11.43 per share, the difference between the initial public offering price of \$15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and the pro forma as adjusted net tangible book value per share of our common stock of \$3.57, immediately after giving effect to the issuance of shares of our common stock in this offering. See “Dilution.”

***If securities or industry analysts do not publish research or reports about our business, or publish unfavorable research reports about our business, our share price and trading volume could decline.***

The trading market for our common stock will, to some extent, depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us publishes unfavorable commentary about us or changes their opinion of our business prospects, our share price would likely decline. If one or more of these analysts ceases coverage of or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***We do not intend to pay dividends for the foreseeable future and, consequently, your ability to achieve a return on your investment 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, you may only receive a return on your 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 that will be in effect upon closing of this offering 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.

## [Table of Contents](#)

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 you 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 federal district courts of the United States of America will be 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. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, strategy and plans, industry environment, potential growth opportunities, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. The forward-looking statements are contained principally in “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectation that, for the foreseeable future, a significant portion of our revenues will be derived from sales of the iFuse Implant System, or iFuse;
- our ability to expand our sales and marketing capabilities to increase demand for iFuse, expand geographically, and obtain favorable coverage and reimbursement determinations from third-party payors;
- our estimates of our market opportunity;
- developments or disputes concerning our intellectual property or other proprietary rights;
- competition in the markets we serve;
- our expectations of the reliability and performance of iFuse;
- our expectations of the benefits to patients, providers, and payors of iFuse;
- our reliance on a limited number of suppliers, including sole source suppliers, which may impact the availability of replacement instruments and materials;
- the factors we believe drive demand for iFuse and our ability to sustain or increase such demand;
- our ability to develop additional revenue opportunities, including new devices;
- the scope of protection we establish and maintain for intellectual property rights covering iFuse and any other device we may develop;
- our estimates regarding our costs and risks associated with our international operations and international expansion;
- our ability to retain and recruit key personnel and expand our sales force;
- 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 forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of

## [Table of Contents](#)

factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

## **MARKET, INDUSTRY, AND OTHER DATA**

This prospectus contains estimates, projections, and other information concerning our industry, our business, and the markets for our products and product candidates, including data regarding the estimated size of those markets for our products and product candidates, their projected growth rates, the perceptions and preferences of surgeons and patients regarding certain procedures, surgeon and patient data, as well as data regarding market research, estimates, and forecasts prepared by our management. We obtained the industry, market, and other data throughout this prospectus from our own internal estimates and research, as well as from industry publications and research, surveys, and studies conducted by third parties.

Information based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. In some cases, we do not expressly refer to the sources from which this data is derived.



## USE OF PROCEEDS

We estimate that the net proceeds from this offering of 7,200,000 shares of common stock will be approximately \$98.7 million, or \$113.8 million if the underwriters exercise their option to purchase additional shares in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, at the initial public offering price of \$15.00 per share.

We expect to use the net proceeds from this offering, as follows:

- approximately \$65.0 million for sales and marketing activities to support ongoing commercialization of the iFuse Implant System, including, but not limited to, expansion of our sales force, additional medical affairs and educational efforts, and expanding our international sales presence; and
- the remainder, if any, for working capital and general corporate purposes, including research and development and clinical studies to bring new enhancements to the existing product offering.

We may also use a portion of our net proceeds to acquire or invest in complementary products, technologies, or businesses; however, we currently have no agreements or commitments to complete any such transactions.

As of the date of this prospectus, since we cannot specify with certainty all of the particular uses of the net proceeds, our management will have broad discretion over the use of the net proceeds from this offering. Pending the use of the proceeds from this offering, we intend to invest the net proceeds in short-term interest-bearing investment-grade securities, certificates of deposit or government securities.

## 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. In addition, our credit facility with Biopharma Credit Investments IV Sub LP, or Pharmakon, restricts our ability to pay dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions, and capital requirements. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2018:

- on an actual basis;
- on a pro forma basis to reflect:
  - the conversion of all outstanding shares of our preferred stock into an aggregate of 12,066,654 shares of common stock immediately prior to the closing of this offering;
  - the issuance of 21,616 shares of common stock upon the automatic net exercise of outstanding warrants, with an exercise price of \$9.10 per share, immediately prior to the closing of this offering, at the initial public offering price of \$15.00 per share;
  - the reclassification of our preferred stock warrant liability to additional paid-in capital immediately prior to the closing of this offering; and
  - the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of 7,200,000 shares of common stock in this offering at the initial public offering price of \$15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth in “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of June 30, 2018		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except for share and per share amounts)		
Cash and cash equivalents	\$ 16,233	\$ 16,233	\$ 114,973
Redeemable convertible preferred stock warrant liability	\$ 646	\$ —	\$ —
Total long-term borrowings <sup>(1)</sup>	38,834	38,834	38,834
Redeemable convertible preferred stock, \$0.0001 par value; 12,104,749 shares authorized, 11,871,578 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	118,548	—	—
Stockholders’ equity (deficit):			
Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.0001 par value; 19,333,333 shares authorized, 3,707,268 shares issued and outstanding, actual; 100,000,000 shares authorized, 15,795,538 shares issued and outstanding, pro forma; and 100,000,000 shares authorized, 22,995,538 shares issued and outstanding, pro forma as adjusted	1	2	2
Additional paid-in capital	10,933	130,126	228,866
Accumulated other comprehensive income	435	435	435
Accumulated deficit	(147,072)	(147,072)	(147,072)
Total stockholders’ (deficit) equity	(135,703)	(16,509)	82,231
Total capitalization	\$ 22,325	\$ 22,325	\$ 121,065

(1) Total borrowings consist of \$40.0 million of principal, net of discount of \$1.2 million.

The number of shares of common stock to be outstanding after this offering is based on 15,795,538 shares of common stock outstanding as of June 30, 2018, and excludes:

- 2,900,842 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2018, with a weighted-average exercise price of \$4.09 per share;
- 230,066 shares of common stock, as converted, issuable upon the exercise of warrants outstanding as of June 30, 2018, with a weighted-average exercise price of \$8.69 per share;
- 26,613 additional shares of common stock reserved for future issuance under our 2008 Stock Plan, which ceased to be available for issuance at the time our 2018 Equity Incentive Plan became effective upon the execution of the underwriting agreement for this offering;
- 2,576,538 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan, as well as any increases in the number of shares of common stock reserved for future issuance under this plan, which became effective upon the execution of the underwriting agreement for this offering; and
- 515,307 shares of common stock reserved for future issuance under our 2018 Employee Stock Purchase Plan, as well as any increases in the number of shares of common stock reserved for future issuance under this plan, which became effective upon the execution of the underwriting agreement for this offering.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Historical net tangible book value (deficit) per share represents our total tangible assets less our liabilities and preferred stock that is not included in equity divided by the total number of shares outstanding. As of June 30, 2018, our historical net tangible book value (deficit) was \$(135.7) million, or \$(36.61) per share.

Our pro forma net tangible book value (deficit) as of June 30, 2018, was \$(16.5) million, or \$(1.05) per share after giving effect to (i) the conversion of all outstanding shares of our preferred stock into an aggregate of 12,066,654 shares of common stock; (ii) the issuance of 21,616 shares of common stock upon the automatic net exercise of outstanding warrants, with an exercise price of \$9.10 per share, immediately prior to the closing of this offering, at the initial public offering price of \$15.00 per share; (iii) the reclassification of our preferred stock warrant liability to additional paid-in capital immediately prior to the closing of this offering.

After giving further effect to receipt of the net proceeds of our sale of 7,200,000 shares of common stock, at the initial public offering price of \$15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of June 30, 2018, would have been approximately \$82.2 million, or \$3.57 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$4.62 per share to our existing stockholders and an immediate dilution of \$11.43 per share to new investors participating in this offering.

The following table illustrates this dilution to new investors on a per share basis:

Initial public offering price per share	\$15.00
Historical net tangible book value (deficit) per share as of June 30, 2018	\$(36.61)
Pro forma increase in net tangible book value (deficit) per share attributable to the conversion of our preferred stock and preferred stock warrants	<u>35.56</u>
Pro forma net tangible book value per share as of June 30, 2018	(1.05)
Increase in net tangible book value per share attributable to new investors purchasing shares in this offering	<u>4.62</u>
Pro forma as adjusted net tangible book value per share after this offering	<u>3.57</u>
Dilution per share to new investors participating in this offering	<u>\$11.43</u>

If the underwriters' option to purchase additional shares in this offering is exercised in full, the pro forma as adjusted net tangible book value would be \$4.04 per share, the increase in the pro forma as adjusted net tangible book value per share for existing stockholders would be \$5.09 per share and the dilution to new investors participating in this offering would be \$10.96 per share.

## [Table of Contents](#)

The table below summarizes, as of June 30, 2018, on the pro forma basis described above, the number of shares of our common stock, the total consideration, and the average price per share (1) paid to us by our existing stockholders and (2) to be paid by new investors participating in this offering at the initial public offering price of \$15.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount (in thousands)	Percent	
Existing stockholders	15,795,538	68.7%	\$123,319,207	53.3%	\$ 7.81
New investors	7,200,000	31.3	108,000,000	46.7%	15.00
Total	<u>22,995,538</u>	<u>100.0%</u>	<u>\$231,319,207</u>	<u>100.0%</u>	

In addition, if the underwriters' option to purchase additional shares is exercised in full, the number of shares held by existing stockholders will be reduced to 65.6% of the total number of shares of common stock to be outstanding upon closing of this offering, and the number of shares of common stock held by new investors participating in this offering will be further increased to 34.4% of the total number of shares of common stock to be outstanding upon closing of the offering.

The number of shares of common stock to be outstanding after this offering excludes:

- 2,900,842 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2018, with a weighted-average exercise price of \$4.09 per share;
- 230,066 shares of common stock, as converted, issuable upon the exercise of warrants outstanding as of June 30, 2018, with a weighted-average exercise price of \$8.69 per share;
- 26,613 additional shares of common stock reserved for future issuance under our 2008 Stock Plan, which ceased to be available for issuance at the time our 2018 Equity Incentive Plan became effective upon the execution of the underwriting agreement for this offering;
- 2,576,538 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan, as well as any increases in the number of shares of common stock reserved for future issuance under this plan, which became effective upon the execution of the underwriting agreement for this offering; and
- 515,307 shares of common stock reserved for future issuance under our 2018 Employee Stock Purchase Plan, as well as any increases in the number of shares of common stock reserved for future issuance under this plan, which became effective upon the execution of the underwriting agreement for this offering.

To the extent that any outstanding stock options or warrants are exercised, new options are issued under our stock-based compensation plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. If all outstanding options under our 2008 Stock Plan as of June 30, 2018 and all outstanding warrants as of June 30, 2018 (other than warrants that will be automatically net exercised immediately prior to the closing of this offering) were exercised for cash, then our existing stockholders, including the holders of these options and warrants, would own 72.4% and our new investors would own 27.6% of the total number of shares of our common stock outstanding upon the closing of this offering, respectively. In such event, the total consideration paid by our existing stockholders, including the holders of these options and warrants, would be \$137.1 million, or 55.9%, the total consideration paid by our new investors would be \$108.0 million, or 44.1%, the weighted-average price per share paid by our existing stockholders would be \$7.25 and the price per share paid by our new investors would be \$15.00.

## SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes included within this prospectus. The consolidated statements of operations data for the years ended December 31, 2016 and 2017, and the consolidated balance sheet data at December 31, 2016 and 2017, are derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2017 and 2018, and the consolidated balance sheet data at June 30, 2018, are derived from our unaudited consolidated financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and our results for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the full fiscal year.

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
(in thousands, except share and per share data)				
<b>Consolidated Statements of Operations Data:</b>				
Revenue	\$ 42,101	\$ 47,983	\$ 22,531	\$ 26,375
Cost of goods sold	5,165	5,112	2,566	2,230
Gross profit	<u>36,936</u>	<u>42,871</u>	<u>19,965</u>	<u>24,145</u>
Operating expenses:				
Sales and marketing	35,215	41,646	21,130	21,285
Research and development	6,380	5,513	2,768	2,502
General and administrative	12,906	13,062	6,737	4,972
Total operating expenses	<u>54,501</u>	<u>60,221</u>	<u>30,635</u>	<u>28,759</u>
Loss from operations	(17,565)	(17,350)	(10,670)	(4,614)
Interest and other income (expense), net:				
Interest income	71	175	73	130
Interest expense	(3,308)	(6,204)	(1,920)	(2,544)
Other income (expense), net	213	340	66	(320)
Net loss	<u>(20,589)</u>	<u>(23,039)</u>	<u>(12,451)</u>	<u>(7,348)</u>
Other comprehensive income:				
Changes in foreign currency translation	67	(70)	(35)	33
Comprehensive loss	<u>\$ (20,522)</u>	<u>\$ (23,109)</u>	<u>\$ (12,486)</u>	<u>\$ (7,315)</u>
Net loss per common share, basic and diluted <sup>(1)</sup>	<u>\$ (6.21)</u>	<u>\$ (6.65)</u>	<u>\$ (3.63)</u>	<u>\$ (2.04)</u>
Weighted-average common shares used to compute basic and diluted net loss per common share <sup>(1)</sup>	<u>3,314,198</u>	<u>3,467,096</u>	<u>3,426,963</u>	<u>3,603,308</u>
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (1.50)</u>		<u>\$ (0.45)</u>
Pro forma weighted-average number of common shares used to compute basic and diluted net loss per share (unaudited) <sup>(1)</sup>		<u>15,480,394</u>		<u>15,691,578</u>

(1) See Note 14 to our consolidated financial statements included elsewhere in this prospectus for the method used to calculate net loss per common share, basic and diluted, and pro forma net loss per common share, basic and diluted, and weighted-average number of shares used in the computation of the per share amounts.

[Table of Contents](#)

	As of December 31,		As of June 30,
	2016	2017	2018
(in thousands)			
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 27,900	\$ 22,408	\$ 16,233
Working capital	22,938	26,091	20,040
Total assets	39,436	35,834	29,913
Redeemable convertible preferred stock warrant liability	588	422	646
Total long-term borrowings	29,310	38,704	38,834
Total liabilities	35,048	46,664	47,068
Redeemable convertible preferred stock	113,121	118,548	118,548
Total stockholders' deficit	(108,733)	(129,378)	(135,703)

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks, uncertainties, and assumptions, such as our plans, objectives, expectations, intentions, and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Some of the numbers included herein have been rounded for convenience of presentation. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section "Risk Factors" included elsewhere in this prospectus.*

### Overview

We are a medical device company that has 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, more than 34,000 procedures have been performed by over 1,700 surgeons, in the United States and 33 other countries. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the sacroiliac joint. We believe iFuse is currently used in the majority of minimally invasive surgical fusions of the sacroiliac joint in the United States.

The two sacroiliac joints are the largest joints in the body and connect the sacrum, near the base of the spine, to the iliac bones, the two major bones of the pelvis. The iFuse system includes a series of patented triangular implants, the instruments we have developed to enable the procedure, as well as the diagnostic and surgical techniques we have developed to enable physicians to perform the procedure. We introduced our second generation implant, the iFuse-3D, in 2017. We market our products with a direct sales force and a number of distributors in the United States, and with a combination of a direct sales force and distributors in other countries.

We have incurred net losses since our inception in 2008. During 2016 and 2017 and for the six months ended 2018 we had net losses of \$20.6 million, \$23.0 million, and \$7.3 million, respectively. As of June 30, 2018, we had an accumulated deficit of \$147.1 million. To date, we have financed our operations primarily through private placements of equity securities, certain debt-related financing arrangements, and sales of our products. We have devoted substantially all of our resources to research and development of our products, reimbursement-related initiatives, sales and marketing activities, and clinical, quality assurance, and regulatory matters for our products.

### Factors Affecting Results of Operations

#### *Coverage and Reimbursement*

As of August 31, 2018, U.S. payors covering 250 million lives reimburse for iFuse, 115 million of which are covered by private payors. There are a number of large and small private payors, including Aetna, Cigna, Humana, and Anthem, that are not yet reimbursing 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.

Prior to our launch of iFuse in 2009, Medicare and most private insurance companies reimbursed surgeons routinely for sacroiliac joint fusions, which were primarily invasive. However, effective July 1, 2013, the AMA's Editorial Panel effectively restricted reimbursement for minimally invasive sacroiliac joint fusion because they considered the published clinical evidence at the time to be inadequate.

Subsequently, as a result of the growing number of published clinical studies demonstrating the effectiveness and safety of iFuse, along with the support of several professional medical specialty societies and



leading academic surgeons, the AMA Editorial Panel established a new reimbursement code for minimally invasive sacroiliac joint fusion surgery, effective 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.

Coverage decisions for this code are made independently by each private insurance company and each of the seven regional 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, 2016, U.S. payors covering approximately 133 million lives regularly reimbursed for the iFuse procedure, and as of December 31, 2017, U.S. payors covering approximately 162 million lives regularly reimbursed for the iFuse procedure. However, as of August 31, 2018, 39 of the largest 65 private payors were covering regularly, or had announced coverage for, the iFuse procedure, while the remaining private payors were reevaluating their coverage policies. Of these, 23 private payors have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence. Seventeen of these exclusive coverage policies have published since January 1, 2018, which we believe has contributed to our accelerating sales growth in our fiscal year 2018.

### ***Our Sales Force***

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

Our direct sales organization in the United States is comprised of seven sales regions. Each region is comprised of a number of territory sales managers who 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. As of June 30, 2018, our territory sales managers were led by seven regional sales managers who reported to our Vice President of U.S. Sales. The Vice President of U.S. Sales reports to our Chief Commercial Officer. As of June 30, 2018, our U.S. sales force consisted of 45 sales representatives directly employed by us and 30 third-party distributors.

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.

As of June 30, 2018, we had 28 employees working in our European operations, and have established operations in Italy (2010), Germany (2014), and the United Kingdom (2015). As of June 30, 2018, our international sales force consisted of 18 sales representatives directly employed by us and 27 exclusive third-party distributors, which together had sales in 33 countries through June 30, 2018. 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 United States, working with internationally recognized healthcare professional experts as we expand our training and reimbursement activities. As of June 30, 2018, beyond Europe and the United States, surgeons had performed the first iFuse procedures in Australia, Cayman Islands, Hong Kong, Israel, Japan, Kuwait, New Zealand, Taiwan, Turkey, and Saudi Arabia.

We have in the past and expect in the future to enter into different compensation arrangements with our sales professionals, which include minimum guaranteed commissions. This has impacted our compensation expenses in the past and we expect it will in the future.

## **Components of Results of Operations**

### ***Revenue***

We derive substantially all 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, and the number of implants used for a particular patient. Similar to other orthopedic companies, our revenue can also fluctuate from quarter to quarter due to a variety of factors, including reimbursement, sales force changes, physician activities, and seasonality. Our revenue from international sales may also be significantly 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 the iFuse implants and instrument sets. Cost of goods sold consists primarily of costs of the components of iFuse implants and instruments, 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 in absolute dollars as case levels increase.

In accordance with the Patient Protection and Affordable Care Act, effective January 1, 2013, we began to incur an excise tax on sales of medical devices in the United States. Effective December 2015, the Act was amended to include a provision to suspend the tax on medical devices through 2017. In January 2018, the suspension on the tax on medical devices was further extended through 2019. In July 2018, the U.S. House of Representatives voted to repeal this tax. The U.S. Senate is expected to vote on the matter in the fourth quarter of 2018. Our gross margins have been and will continue to be affected by a variety of factors, including the cost to have our products manufactured for us, pricing pressure from increasing competition, and the factors described above impacting our revenue. 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 gross margin.

### ***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 in absolute dollars, as we continue to invest and grow our business, but decrease as a percentage of revenue. In September 2017, we implemented cost-saving measures, which reduced our operational expenses through headcount reductions, reduced project spending, and more targeted marketing and surgeon training activities.

### ***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, and professional education departments. In addition, our sales and marketing expenses include commissions and bonuses, generally based on a percentage of sales, to our sales managers and directors, direct sales representatives and third-party distributors. We expect our sales and marketing expenses to increase in absolute dollars 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

## [Table of Contents](#)

commitments among them and increasing the number of our direct sales representatives, especially with increased reimbursement and adoption in the United States. 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 sales representatives 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 in absolute dollars 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 compensation, stock-based compensation expense, and other costs for finance, accounting, legal, compliance, reimbursement, and administrative matters. We expect our general and administrative expenses to increase in absolute dollars 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 will be traded; additional insurance expenses; investor relations activities; and other administrative and professional services. While we expect the general and administrative expenses to increase in absolute dollars, we anticipate that it will decrease as a percentage of revenue over time.

### *Interest Expense*

Interest expense is related to borrowings and includes the amortization of debt discounts derived from the issuance of warrants.

### *Other Income (Expense), Net*

Other income (expense), net consists primarily of the changes in fair value of our preferred stock warrant liability and net gain (loss) on foreign currency transactions. In connection with this initial public offering, we expect that our preferred stock warrant liability will be settled.

## Results of Operations

The following table sets forth our results of operations for the period presented:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
(in thousands)				
<b>Consolidated Statements of Operations Data:</b>				
Revenue	\$ 42,101	\$ 47,983	\$ 22,531	\$ 26,375
Cost of goods sold	5,165	5,112	2,566	2,230
Gross profit	36,936	42,871	19,965	24,145
Operating expenses:				
Sales and marketing	35,215	41,646	21,130	21,285
Research and development	6,380	5,513	2,768	2,502
General and administrative	12,906	13,062	6,737	4,972
Total operating expenses	54,501	60,221	30,635	28,759
Loss from operations	(17,565)	(17,350)	(10,670)	(4,614)
Interest and other income (expense), net:				
Interest income	71	175	73	130
Interest expense	(3,308)	(6,204)	(1,920)	(2,544)
Other income (expense), net	213	340	66	(320)
Net loss	<u>\$ (20,589)</u>	<u>\$ (23,039)</u>	<u>\$ (12,451)</u>	<u>\$ (7,348)</u>

The following table sets forth our results of operations as a percentage of revenue:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
<b>Consolidated Statements of Operations Data:</b>				
Revenue	100%	100%	100%	100%
Cost of goods sold	12	11	11	8
Gross profit	88	89	89	92
Operating expenses:				
Sales and marketing	84	87	94	81
Research and development	15	11	12	9
General and administrative	31	27	30	19
Total operating expenses	130	125	136	109
Loss from operations	(42)	(36)	(47)	(17)
Interest and other income (expense), net:				
Interest income	—	—	—	—
Interest expense	(8)	(13)	(8)	(10)
Other income (expense), net	1	1	0	(1)
Net loss	<u>(49)%</u>	<u>(48)%</u>	<u>(55)%</u>	<u>(28)%</u>

## [Table of Contents](#)

The following table sets forth our United States and international revenue:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
	(in thousands)			
United States	\$ 38,791	\$ 43,351	\$ 20,385	\$ 23,456
International	3,310	4,632	2,146	2,919
	<u>\$ 42,101</u>	<u>\$ 47,983</u>	<u>\$ 22,531</u>	<u>\$ 26,375</u>

The following table sets forth our United States and international revenue as a percentage of our total revenue:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
United States	92%	90%	90%	89%
International	8	10	10	11
	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

### Comparison of the Six Months Ended June 30, 2017 and 2018

#### *Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin*

	Six Months Ended June 30,		\$ Change	% Change
	2017	2018		
	(in thousands, except for percentages)			
Revenue	\$ 22,531	\$ 26,375	\$ 3,844	17%
Cost of goods sold	2,566	2,230	(336)	(13)%
Gross profit	<u>\$ 19,965</u>	<u>\$ 24,145</u>	<u>\$ 4,180</u>	21%
Gross margin				
				89%                      92%

*Revenue.* Revenue increased \$3.8 million, or 17%, for the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The majority of the increase is due to \$3.0 million of growth from domestic sales as a result of higher sales force productivity and improved U.S. reimbursement coverage. In addition, international revenue increased \$0.8 million as a result of an expanded international direct sales force and improving reimbursement coverage in Europe.

*Cost of Goods Sold, Gross Profit, and Gross Margin.* Total cost of goods sold decreased \$0.3 million, or 13%, for the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The decrease in cost of goods sold is primarily due to \$0.5 million of cost control measures related to reduced headcount in operations that more than offset the increase in direct product costs from higher case volumes. Gross profit increased \$4.2 million, or 21%, to \$24.1 million due to higher revenue and lower cost of goods sold.

### Operating Expenses

	<u>Six Months Ended June 30,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2017</u>	<u>2018</u>		
	(in thousands, except for percentages)			
Sales and marketing	\$ 21,130	\$ 21,285	\$ 155	1%
Research and development	2,768	2,502	(266)	(10)%
General and administrative	6,737	4,972	(1,765)	(26)%
Total operating expenses	<u>\$ 30,635</u>	<u>\$ 28,759</u>	<u>\$ (1,876)</u>	

*Sales and Marketing Expenses.* Sales and marketing expenses increased \$0.2 million, or 1%, for the six months ended June 30, 2018, compared to the six months ended June 30, 2017. The increase was primarily due to \$0.9 million in increased salaries, commissions, and related expenses due to an increase in the number of sales representatives hired late in the first quarter of 2017 to support the growth of our business. This increase was largely offset by a \$0.5 million decrease in the level of spending on general marketing costs related to a shift in marketing effort from print media to less expensive digital media, as well as other cost control measures that were put in place at the end of the third quarter of 2017. The increased compensation costs were also offset by a \$0.3 million decrease in surgeon training costs, including training facilities and consulting surgeon costs due to continued focus on maximizing class sizes to more fully leverage training events.

*Research and Development Expenses.* Research and development expenses decreased \$0.3 million, or 10%, for the six months ended June 30, 2018, compared to the six months ended June 30, 2017. The decrease was primarily due to a \$0.3 million reduction in compensation expense related to cost control measures put in place at the end of the third quarter 2017.

*General and Administrative Expenses.* General and administrative expenses decreased \$1.8 million, or 26%, for the six months ended June 30, 2018, compared to the six months ended June 30, 2017. The decrease was primarily due to a decrease of \$0.5 million in compensation expense due to the write-off of principal and interest due on a promissory note from our Chief Executive Officer in the first half of 2017, with no similar write-offs in the six months ended June 30, 2018. In addition, there were decreases of \$0.4 million in legal costs for patent and general corporate matters, \$0.3 million in audit and accounting fees, \$0.2 million in compensation expense as a result of a decrease in headcount, \$0.1 million in travel expense, and \$0.2 million of recoveries of accounts receivable previously written off during the six months ended June 30, 2017.

### Interest and Other Income (Expense), Net

	<u>Six Months Ended June 30,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2017</u>	<u>2018</u>		
	(in thousands except for percentages)			
Interest income	\$ 73	\$ 130	\$ 57	78%
Interest expense	(1,920)	(2,544)	(624)	33
Other income (expense), net	66	(320)	(386)	NM

*Interest Income.* Interest income increased \$0.1 million, or 78%, for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 due to investment of excess cash in money market funds.

*Interest Expense.* Interest expense increased \$0.6 million, or 33%, for the six months ended June 30, 2018, compared to the six months ended June 30, 2017, primarily due to a \$10.0 million increase in the level of borrowings associated with closing a new debt arrangement in October 2017.

*Other Income (Expense), Net.* Other income (expense), net, decreased \$0.4 million for the six months ended June 30, 2018, compared to the six months ended June 30, 2017 primarily due to losses related to the change in the fair value of our preferred stock warrants outstanding, which are accounted for as a liability and revalued at each reporting period, and foreign currency exchange losses.

## Comparison of the Years Ended December 31, 2016 and 2017

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

	Years Ended December 31,		\$ Change	% Change
	2016	2017		
	(in thousands except for percentages)			
Revenue	\$ 42,101	\$ 47,983	\$ 5,882	14%
Cost of goods sold	5,165	5,112	(53)	(1)%
Gross profit	<u>\$ 36,936</u>	<u>\$ 42,871</u>	<u>\$ 5,935</u>	16%
Gross margin	88%	89%		

**Revenue.** Revenue increased \$5.9 million, or 14%, from 2016 to 2017. The increase of \$5.9 million was primarily due to an increase of \$4.6 million from growth of domestic revenue from additional hiring of sales personnel and improved U.S. reimbursement coverage. In addition, we had \$1.3 million from growth of international revenue from our branch in the United Kingdom, increased sales force productivity in Germany, and new business in Australia and Taiwan.

**Cost of Goods Sold, Gross Profit, and Gross Margin.** Total cost of goods sold decreased \$0.1 million, or 1%, from 2016 to 2017. This is primarily due to the reduction in inventory write-offs from improved inventory level management, offset by the increase in direct product costs from higher case volumes. Gross profit increased \$5.9 million, or 16%, to \$42.9 million from 2016 to 2017 due to higher revenue and relatively flat cost of goods sold.

### Operating Expenses

	Years Ended December 31,		\$ Change	% Change
	2016	2017		
	(in thousands except for percentages)			
Sales and marketing	\$ 35,215	\$ 41,646	\$ 6,431	18%
Research and development	6,380	5,513	(867)	(14)%
General and administrative	12,906	13,062	156	1%
Total operating expenses	<u>\$ 54,501</u>	<u>\$ 60,221</u>	<u>\$ 5,720</u>	

**Sales and Marketing Expenses.** Sales and marketing expenses increased \$6.4 million, or 18%, from 2016 to 2017 from increased efforts to support higher revenues. The increase was primarily due to \$4.7 million in increased salaries, guaranteed minimum commissions, and related expenses from higher headcount, \$0.9 million in increased commissions due to higher revenues, \$0.7 million in increased general marketing expenses, and \$0.2 million in surgeon training programs.

**Research and Development Expenses.** Research and development expenses decreased \$0.9 million, or 14%, from 2016 to 2017. The decrease was partially due to a \$0.4 million reduction in salaries and related expenditures, from lower headcount, a \$0.3 million reduction in clinical trial expense as the INSITE and SIFI studies mature, and a decrease of \$0.2 million in reduced consulting expense from lower engineering project spending.

**General and Administrative Expenses.** General and administrative expenses increased \$0.2 million, or 1%, from 2016 to 2017. The increase was primarily due to an increase of \$0.9 million in salaries and employee related costs, including the forgiveness of a loan to the Chief Executive Officer for \$0.5 million. This increase was offset by a decrease of \$0.3 million in external professional fees related to reimbursement related activities

## [Table of Contents](#)

and a decrease of \$0.3 million in accounting fees. Included in general administrative expenses is \$1.5 million and \$1.3 million in public offering costs previously recorded on the consolidated balance sheet, which were written off in 2016 and 2017, respectively, as a result of delays in the public offering process.

### *Interest and Other Income (Expense), Net*

	Years Ended December 31,		\$ Change	% Change
	2016	2017		
		(in thousands except for percentages)		
Interest income	\$ 71	\$ 175	\$ 104	146%
Interest expense	(3,308)	(6,204)	(2,896)	88%
Other income (expense), net	213	340	127	60%

*Interest Income.* Interest income increased \$0.1 million, or 146%, from 2016 to 2017 due to investment of excess cash in money market funds.

*Interest Expense.* Interest expense increased \$2.9 million, or 88%, from 2016 to 2017 primarily due to the extinguishment of a credit facility with Silicon Valley Bank, or SVB, and Oxford Finance LLC, or Oxford, in October 2017. The extinguishment resulted in \$1.5 million in early termination fees and we expensed an additional \$0.7 million of unamortized debt discounts. In conjunction with the extinguishment, we entered into a new term loan with Pharmakon, or the New Term Loan, with an increased principal balance from \$30.6 million to \$40.0 million resulting in an increase in interest of approximately \$0.2 million. In December 2016, we also had drawn an additional \$4.0 million in debt, resulting in \$0.4 million of higher interest expense in 2017.

*Other Income (Expense), Net.* Other income (expense), net, increased \$0.1 million or 60%, from 2016 to 2017, as a result in losses related to the change in the fair value of outstanding preferred stock warrants, which are accounted for as a liability and revalued at each reporting period.

### **Liquidity and Capital Resources**

As of June 30, 2018, we had cash and cash equivalents of \$16.2 million. Since inception, we have financed our operations through private placements of preferred stock, debt financing arrangements, and the sale of our products. As of June 30, 2018, we had \$38.8 million principal amount of outstanding debt, net of debt discounts.

As of June 30, 2018, we had an accumulated deficit of \$147.1 million. During 2017 and the six months ended June 30, 2018 we incurred net losses of \$23.0 million and \$7.3 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date. We evaluated our current cash position, historical results, forecasted cashflows, and plans in regards to liquidity. We further considered the debt covenants associated with our current debt agreement. These covenants require us to maintain a minimum cash balance of \$5.0 million and revenue targets. Beginning with the three months ended March 31, 2019, we are required to meet either revenue or earnings targets. If we do not comply with these covenants, the debt will immediately become due. Considering all of these factors, we believe, absent this offering, that there is substantial doubt about our ability to continue as a going concern for the next 12 months.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date of this offering. 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.



## [Table of Contents](#)

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***

In October 2015, we entered into a term loan facility and a revolving line of credit with SVB and Oxford, or Term Loan, for \$35.2 million. The first tranche of the Term Loan closed in October 2015 for \$16.2 million, the proceeds of which were used to pay off previous loans with SVB of \$15.5 million and final fees of \$0.7 million related to the previous loans. Prepayment fees on the then existing debt facilities were waived. We drew the second tranche of \$10.0 million in November 2015 and the third tranche of \$4.0 million in December 2016. The maturity date of the Term Loan was December 1, 2019, and it carried an interest rate equal to the greater of 11% or the WSJ Prime rate plus 7.75%.

In connection with this agreement, we also issued to SVB and Oxford warrants to purchase, in the aggregate, 63,622 shares of our Series 6 preferred stock, with an exercise price of \$16.47 per share. Subsequently, in August 2016, we amended the agreement to extend the draw period of the fourth tranche for an additional three months. In conjunction with the additional draw of the Term Loan, we issued an additional 9,712 warrants for the purchase of Series 7 preferred stock at an exercise price of \$10.03 per share in December 2016. In February 2017, we amended the agreement to extend the interest only period by six months to October 2017 and extended the draw period of the fourth tranche through January 2018.

In October 2017, we extinguished the Term Loan and revolving line of credit facility with SVB and Oxford and concurrently, entered into the New Term Loan with Pharmakon for \$40.0 million. The New Term Loan includes an interest-only period for 35 months through September 2020 and is then repaid for 25 months of equal principal payments plus interest through December 2022. The New 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 New 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 New Term Loan requires us to maintain a minimum cash balance of \$5.0 million and revenue targets. Beginning with the three months ended March 31, 2019, we are required to meet either revenue or earnings targets. Under the New Term Loan, we also have a second tranche of \$10.0 million available through January 2019, contingent upon the achievement of certain revenue milestones. The New Term Loan is collateralized by all of our assets, including intellectual property.

As of December 31, 2017 and June 30, 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, 2017:

	Payments Due By Period				More than 5 years
	Total	Less than 1 year	1-3 years (in thousands)	4-5 years	
Principal obligations on the debt arrangements <sup>(1)</sup>	\$40,000	\$ —	\$ 4,444	\$35,556	\$ —
Interest obligations on the debt arrangements <sup>(1)</sup>	18,658	4,664	9,341	4,653	—
Operating leases <sup>(2)</sup>	967	721	169	77	—
Purchase obligations	146	146	—	—	—
<b>Total</b>	<b>\$59,771</b>	<b>\$ 5,531</b>	<b>\$13,954</b>	<b>\$40,286</b>	<b>\$ —</b>

(1) For further discussion, see Note 6 to our consolidated financial statements.

(2) Operating lease obligations consist primarily of lease payments for our San Jose, California facility and Europe facilities.

In February 2018, we entered into a new seven-year lease for our Santa Clara, California facility. The total commitment is \$5.1 million.

### Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

	Six Months Ended June 30,		\$ Change	% Change
	2017	2018		
(in thousands, except for percentages)				
Net cash (used in) provided by:				
Operating activities	\$(9,520)	\$(5,673)	\$ 3,847	(40)%
Investing activities	(274)	(715)	(441)	161%
Financing activities	5,218	208	(5,010)	(96)%
Effects of exchange rate changes on cash and cash equivalents	27	5	(22)	(82)%
Net decrease in cash and cash equivalents	<u>\$(4,549)</u>	<u>\$(6,175)</u>	<u>\$ (1,626)</u>	

	Years Ended December 31,		\$ Change	% Change
	2016	2017		
(in thousands, except for percentages)				
Net cash (used in) provided by:				
Operating activities	\$(16,753)	\$(17,530)	\$ (777)	5%
Investing activities	(441)	(478)	(37)	(8)%
Financing activities	24,755	12,862	(11,893)	(48)%
Effects of exchange rate changes on cash and cash equivalents	67	(346)	(413)	(617)%
Net increase (decrease) in cash and cash equivalents	<u>\$ 7,628</u>	<u>\$(5,492)</u>	<u>\$(13,120)</u>	

#### Cash Used in Operating Activities

Net cash used in operating activities decreased \$3.8 million, or 40%, from the six months ended June 30, 2017 to the six months ended June 30, 2018. The decrease in the net cash used in operating activities was primarily due to a decrease of \$5.1 million in our net loss, offset by a decrease of \$1.3 million in accounts payable related to the timing of payments made.

## [Table of Contents](#)

Net cash used in operating activities increased \$0.8 million, or 5%, from 2016 to 2017. The increase in the net cash used in operating activities was primarily due to an increase of \$2.5 million in our net loss, an increase of \$1.2 million in accounts receivable, an increase of \$2.2 million in inventory, and an increase in prepaid and other assets of \$0.1 million. These uses of cash were partially offset by an increase of \$2.3 million in accounts payable, and an increase of \$1.8 million in accrued liabilities, as well as non-cash adjustments for the write-off of a debt discount of \$0.7 million and the forgiveness of a note receivable of \$0.4 million.

### *Cash Used in Investing Activities*

Net cash used in investing activities increased \$0.4 million, or 161%, from the six months ended June 30, 2017 to the six months ended June 30, 2018. Cash used in investing activities for the six months ended June 30, 2018 primarily consisted of leasehold improvements related to the new building lease entered into in February 2018 of \$0.6 million. Cash used in investing activities for the six months ended June 30, 2017 primarily consisted of instrument set purchases of \$0.3 million. The instrument sets are carried by our sales representatives and used during iFuse procedures.

Net cash used in investing activities was relatively constant from 2016 to 2017 and consisted primarily of instrument set purchases.

### *Cash Provided by Financing Activities*

Cash provided by financing activities decreased \$5.0 million, or 96%, from the six months ended June 30, 2017 to the six months ended June 30, 2018. Cash provided by financing activities for the six months ended June 30, 2017 consisted primarily of net proceeds of \$5.4 million from the issuance of Series 7 preferred stock from February through March 2017, offset by payments for public offering costs of \$0.3 million. Cash provided by financing activities for the six months ended June 30, 2018 consisted of proceeds from exercises of common stock options of \$0.2 million.

Cash provided by financing activities decreased \$11.9 million, or 48%, from 2016 to 2017. Cash provided by financing activities during 2016 consisted of net proceeds of \$20.3 million from the issuance of Series 7 preferred stock from June through August 2016 and proceeds from additional debt financing of \$4.0 million in December 2016. Cash provided by financing activities during 2017 consisted of net proceeds of \$5.4 million from the issuance of Series 7 preferred stock from February through March 2017 and proceeds of \$40 million from debt financing, offset by \$29.1 million in extinguishment of debt financing, \$1.1 million in repayment of debt financing, payments of debt issuance costs of \$1.5 million, and payments of public offering costs of \$1.3 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 U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated, and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. 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 detail on our critical accounting policies, see Note 2 to our consolidated financial statements appearing elsewhere in this prospectus.

## **Revenue Recognition**

Our revenue is derived from the sale of our products to medical groups and hospitals through our direct sales force and distributors throughout the United States and Europe.

In accordance with ASC Topic 605, Revenue Recognition, we recognize 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. For the majority of product sales where our sales representative delivers the product at the point of implantation at hospitals or other medical facilities, we recognize revenue related to product sales upon completion of the procedure and authorization by the customer. Revenue is recognized upon receipt of a purchase agreement or agreement on pricing terms with the customer and when all other revenue recognition criteria are met. For the remaining sales, which include distributor and hospital sales where the product is ordered in advance of a procedure and a valid purchase order has been received, we recognize revenue based on shipping or delivery, which represents the point in time when the customer has taken ownership and assumed risk of loss and the required revenue recognition criteria are met. Such customers are obligated to pay within specified terms regardless of when or if they ever sell or use the products, and we have no post-delivery obligations.

## **Stock-Based Compensation**

We measure our stock-based awards made to employees based on the estimated fair value of the awards as of the grant date using the Black-Scholes option pricing model. Stock-based compensation cost 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 ultimately expected to vest.

Equity instruments issued to nonemployees are recorded at their fair value on the measurement date and are subject to periodic adjustment 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. Stock-based compensation related to stock options granted to nonemployees is recognized as the stock options are earned.

In July 2016, we modified the terms of 575,742 vested and unvested stock option awards by reducing their exercise price to the fair value of our common stock on the date of modification which resulted in an incremental value of \$0.4 million being allocated to the options. In December 2017, we modified the terms of 394,656 unvested stock option awards by reducing their exercise price to the fair value of our common stock on the date of modification and removing the vesting performance conditions for the awards which resulted in a fair value expense of \$0.8 million for the options.

We recorded total non-cash stock-based compensation expense of \$1.4 million during both 2016 and 2017. At June 30, 2018, we had \$2.2 million of total unrecognized employee stock-based compensation expense, net of estimated forfeitures, related to stock option grants. This amount will be recognized as expense over a weighted-average period of 2.5 years. We expect to continue to grant stock options in the future, and, to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

The intrinsic value of all outstanding options as of June 30, 2018 was \$31.7 million based on the initial public offering price of \$15.00 per share, of which \$27.0 million related to vested options and \$4.7 million related to unvested options.

### ***Determining Fair Value of Stock Options***

We recognize compensation costs related to stock-based awards granted to employees and directors, including stock options, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

## [Table of Contents](#)

The Black-Scholes option-pricing model requires the use of subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Expected Term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.
- *Expected Volatility*—Since we have been privately held and do not have any trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, or area of specialty.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- *Expected Dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Our board of directors intends all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. 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, developed these valuations using significant judgment and taking 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 that a company will generate. These future cash flows are discounted to their present values using a discount rate based on the capital rates of return for venture-backed early stage companies and is adjusted to reflect the risks inherent in our 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. From the comparable companies, a representative market value multiple is determined and then applied to the subject company's financial results to estimate the value of the subject company.

The enterprise values derived from the approaches discussed above were then allocated to each of our classes of stock using a hybrid methodology, which included both the Option Pricing Method, or OPM, and the Probability Weighted Expected Return Method, or PWERM. The allocation of these enterprise values to each part of our capital structure, including our common stock, was done based on the OPM. OPM treats the rights of the holders of preferred and common shares as equivalent to call options on any value of the enterprise above certain breakpoints of value based upon the liquidation preferences of the holders of preferred shares, as well as their rights to participation and conversion. Thus, the estimated value of the common stock can be determined by estimating the value of its portion of each of these call option rights. The OPM is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts. The OPM backsolve method derives the implied enterprise value of a company from a recent transaction involving our own securities issued on an arms-length basis. Under the PWERM the value is estimated based upon analysis of future values for the enterprise under varying scenarios, probabilities are ascribed to these scenarios based on expected future outcomes. PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM include an initial public offering scenarios.

After the equity value is determined and allocated to the various classes of shares, a discount for lack of marketability, or DLOM, is applied to arrive at the fair value of common stock. A DLOM is applied based on the

## [Table of Contents](#)

theory that as an owner of a private company stock, the stockholder has limited opportunities to sell this stock and any such sale would involve significant transaction costs, thereby reducing overall fair market value.

Following the closing of this offering, the fair value of our common stock will be determined based on the closing price of our common stock on the Nasdaq Global Market.

### **Preferred Stock Warrant Liability**

We have issued freestanding warrants to purchase shares of common and preferred stock in connection with our prior debt facilities. We account for these warrants as a liability in our consolidated financial statements because the underlying instrument into which the warrants are exercisable contains deemed liquidation provisions that are outside our control.

The warrants were recorded at fair value using the Black-Scholes option pricing model. The warrants are re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net in the consolidated statements of operations. We will continue to adjust the liability for changes in fair value until the earlier of (i) exercise or expiration of the warrants, or (ii) the closing of an initial public offering, at which time certain preferred stock warrants will be converted into warrants to purchase common stock and the liability will be reclassified to additional paid-in capital, if they qualify for equity classification.

### **Common Stock Warrants**

We account 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. We determined that the warrants for shares of common stock issued in connection with our prior debt facilities. We estimate the fair value of our warrants for shares of common stock by using the Black-Scholes option pricing model. 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 after the issuance of the warrants.

### **Income Taxes**

We account for income taxes under the 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. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

As of December 31, 2017, we had net operating loss carryforwards of \$124.9 million and \$101.7 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. If not utilized, our federal and state net operating loss carryforwards begin to expire in 2029 and 2019, respectively, and valuation allowances have been established, where necessary. We also have research credit carryforwards of approximately \$1.6 million and \$1.7 million available to reduce future taxable income, if any, for both federal and California state income tax purposes, respectively. The federal credits begin to expire in 2030, and the California credits have no expiration date. Realization of these net operating loss and research credit carryforwards could expire unused and be unavailable to reduce future income tax liabilities, which could materially and adversely affect our results of operations.

We did not record a provision or benefit for income taxes during the six months ended June 30, 2017 or 2018. We continue to maintain a full valuation allowance against our net deferred tax assets.

## [Table of Contents](#)

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 or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the positions sustainability 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.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. We have determined that we experienced Section 382 ownership changes in 2010 and \$1.4 million of our NOL carryforwards are subject to limitation.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act, or the Tax Act, was enacted into law and the new legislation contains several key tax provisions that affected us, including a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and liabilities as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We consider the accounting of the deferred tax re-measurements to be complete. However, ongoing guidance and accounting interpretation are expected in the near term and we expect to complete our analysis relating to this guidance and interpretation within the measurement period in accordance with SAB 118.

### **Off-Balance Sheet Arrangements**

During 2016 and 2017 and for the six months ended June 30, 2018, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

### **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, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

### **Quantitative and Qualitative Disclosures about Market Risk**

#### ***Interest Rate Risk***

We are exposed to interest rate risks related to our cash and cash equivalents. We had cash and cash equivalents of \$22.4 million and \$16.2 million as of December 31, 2017 and June 30, 2018, respectively, which

consist of bank deposits and money market funds. Our cash balance consisted of bank deposits and money market funds in 2017. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

We had outstanding debt of \$38.7 million and \$38.8 million as of December 31, 2017 and June 30, 2018, which accrues interest at a fixed rate of 11.5%. In the ordinary course of business, we may enter into contractual arrangements to reduce our exposure to interest rate risks. We do not believe that a 10% change in interest rates would have a significant impact on our consolidated financial statements.

#### **Foreign Currency Exchange Risk**

We operate in countries other than the United States, and, therefore, we are exposed to foreign currency risks. We bill most direct sales outside of the United States in local currencies, which are mostly comprised of the Euro and the British Pound. Operating expenses related to these sales are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. We do not believe that a 10% change in foreign currency exchange rates would have a significant impact on our net income. We do not currently hedge our exposure to foreign currency exchange rate fluctuations; however, we may choose to hedge our exposure in the future.

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, which required 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. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. 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, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies the implementation guidance on principal versus agent considerations in ASU 2014-09. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, 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. These standards have the same effective date and transition date as ASU 2014-09. Our management is undergoing its assessment of the new standard, which includes the review of contracts and revenue channels, and will adopt the standard for the fiscal year ending December 31, 2019.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. ASU 2015-11 simplifies the guidance on the subsequent measurement of inventory, excluding inventory measured using last-in, first out or the retail inventory method. Under the new standard, in scope inventory should be measured at the lower of cost and net realizable value. The new standard will become effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2016, for public companies. For all other entities, the new standard is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017, with early adoption permitted. We have adopted this standard for the fiscal year ended December 31, 2017, which did not have a material impact on our consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. ASU 2015-17 specifies that deferred tax assets and liabilities shall be classified as noncurrent, or long-term, in a



classified statement of financial position. The new standard is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. For private entities, the new standard is effective for fiscal years beginning after December 15, 2017, and interim periods within fiscal years beginning after December 15, 2018. Earlier application is permitted for all entities as of the beginning of an interim or an annual reporting period. We have early adopted this standard for the fiscal year ended December 31, 2017, which did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued its new lease accounting guidance. Under the new guidance, ASU 2016-02, *Leases (Topic 842)*, lessor accounting is largely unchanged. The new lease guidance simplifies the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Under the new guidance, lessees will be required to recognize a lease liability, which is a lessor's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which 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. The new guidance is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018 for public companies and beginning after December 15, 2019 for private companies. Early adoption is permitted for any interim or annual financial statements not yet issued. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing and operating leases) must apply a modified retrospective approach for all leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. We are currently evaluating the impact of this standard on our consolidated financial statements, and anticipate adopting the standard for the fiscal year ending December 31, 2020.

In March 2016, the FASB issued ASU 2016-09, which simplified several aspects of accounting for stock-based compensation transactions. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new guidance is effective for public entities for fiscal years beginning after December 15, 2016 and interim periods within those years. Other entities must apply the new guidance in fiscal years beginning after December 15, 2017 and in interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. We early adopted this standard in the first quarter of 2017 by recording the cumulative impact of applying this guidance to retained earnings, which was not material. We elected to continue to estimate the number of awards that are expected to vest.

In August 2016, the FASB issued ASU 2016-15 *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 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. Current GAAP does not include specific guidance on these eight cash flow classification issues. The amendments of this ASU are effective for reporting periods beginning after December 15, 2017 for public companies, and reporting periods beginning after December 15, 2018 and interim periods with fiscal years beginning after December 15, 2019 for private companies, with early adoption permitted. We are currently evaluating the impact of adopting ASU 2016-15 on our consolidated financial statements, and anticipate adopting the standard for the fiscal year ending December 31, 2019.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of

## [Table of Contents](#)

the change in terms or conditions. The standard is effective for all entities for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. We have adopted this standard for the fiscal year ending December 31, 2018, which did not have a material impact on our consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II*. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public business entities, the amendments in Part I of this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update 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 for all entities, including adoption in an interim period. We are currently evaluating the impact that the adoption of this standard will have on our consolidated financial statements, and anticipate adopting the standard for the fiscal year ending December 31, 2020.

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, or the 2017 Tax 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. We are currently evaluating the impact that the adoption of this standard will have on our consolidated financial statements, and anticipate adopting the standard for the fiscal year ending December 31, 2019.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of *Topic 718, Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees 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*. We are evaluating the impact that the adoption of this standard will have on our consolidated financial statements, and anticipate adopting the standard for the fiscal year ending December 31, 2020.

## BUSINESS

### Overview

We are a medical device company that has 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, more than 34,000 procedures have been performed by over 1,700 surgeons, in the United States and 33 other countries. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the sacroiliac joint. We believe iFuse is currently used in the majority of minimally invasive surgical fusions of the sacroiliac joint in the United States.

The two sacroiliac joints are the largest joints in the body and connect the sacrum, near the base of the spine, to the iliac bones, the two major bones of the pelvis. The iFuse system includes a series of patented triangular implants, the instruments we have developed to enable the procedure, as well as the diagnostic and surgical techniques we have developed to enable physicians to perform the procedure. We introduced our second generation implant, the iFuse-3D, in 2017. We market our products with a direct sales force and a number of distributors in the United States, and with a combination of a direct sales force and distributors in other countries.

Our growth rate has recently increased, which we attribute in part to more widespread insurance coverage for sacroiliac fusion procedures, with many recent positive payor coverage policies exclusive to our iFuse system, as well as our efforts to educate the market regarding sacroiliac dysfunction. Since January 1, 2018, because of the strength of published clinical evidence on iFuse, 18 U.S. payors have published reimbursement policies exclusively covering the patented triangular design of our iFuse implants and excluding coverage of other products that are intended to fuse the sacroiliac joint. We believe that the full impact of each exclusive coverage decision grows over time as we continue to educate surgeons about the coverage and the medical criteria they need to follow, and train them on the diagnosis and how to perform the iFuse procedure.

In 2016 and 2017, we generated revenue of \$42.1 million and \$48.0 million, respectively, a growth rate of 14%, and incurred net losses of \$20.6 million and \$23.0 million, respectively. Our gross margins were 88% and 89% for 2016 and 2017, respectively. For the six months ended June 30, 2017 and 2018, we generated revenue of \$22.5 million and \$26.4 million, respectively, a growth rate of 17%, and incurred net losses of \$12.5 million and \$7.3 million, respectively. Our gross margins were 89% and 92% for the six months ended June 30, 2017 and 2018, respectively. The number of iFuse procedures performed in the six months ended June 30, 2017 and 2018 was 2,739 and 3,200, respectively.

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, clinical effectiveness, durability of pain relief and reduction in disability, cost effectiveness, and reduction in opioid use that result from iFuse are supported by a large number of studies that have resulted in more than 60 published papers. Several of these papers publish results from three prospective multicenter studies (INSITE, SIFI, and iMIA), two of which were randomized controlled clinical trials. Additionally, there have been several studies showing longer-term follow-up of up to six years.

- INSITE is a randomized controlled study conducted in the United States. 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. In April 2015, INSITE was awarded the “Best Overall Paper” out of approximately 450 submitted clinical study papers at the International Society for Advancement of Spine Surgery, or ISASS, conference.

- iMIA is a randomized controlled study conducted in Europe. Positive six-month follow-up results were published in *European Spine Journal* in May 2016, and the 12 follow-up results were published in August 2017 in *Pain Physician*. 24-month results are currently under review at an orthopedic journal. 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 is a single-arm study conducted in the United States. 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 is a prospective follow-on study, enrolling subjects at a subset of INSITE and SIFI sites treated with iFuse. Study outcomes at three years were published in April 2018 in *Medical Devices: Evidence and Research*. Amongst 103 enrolled subjects, mean sacroiliac joint pain at three years decreased from 81.5 preoperatively to 26.2 (a 56-point improvement from baseline,  $p < .0001$ ). A manuscript showing sustained improvement in pain and disability at four-year follow-up was recently accepted for publication.
- 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.

The INSITE clinical trial included 148 subjects treated at 19 centers in the United States, 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 a statistically significant and clinically important pain reduction in subjects treated with iFuse as compared to very small responses 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 VAS. By contrast, subjects in the non-surgical management group had only a mean 12-point reduction ( $p < .0001$ ) 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, or ODI, while subjects in the non-surgical management group had only a mean five-point reduction ( $p < .0001$ ). 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

## [Table of Contents](#)

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). These are very large differences.

Patients from certain sites participating in the INSITE study will be followed for up to five years as part of LOIS, a separate long-term study.

Surgical revision rate is an important measurement of a treatment's effectiveness for patients. Studies on lumbar, or lower back, fusion, a different type of spine procedure from iFuse, have shown revision rates as approximately 12%. A study published in *Medical Devices: Evidence and Research* in November 2015 showed that the cumulative four-year revision rate with iFuse was 3.5%. A single surgeon retrospective study published in the *International Journal of Spine Surgery* in January 2017 showed that the cumulative four-year revision rate for screw-based treatment of the sacroiliac joint was five times higher than the cumulative four-year revision rate for iFuse.

### **Market Opportunity**

We estimate that over 30 million American adults have chronic lower back pain. For patients whose chronic lower back pain stems from the sacroiliac joint, our experience in both clinical trials and commercial settings indicates that iFuse could be beneficial for at least 30% of patients who are properly diagnosed and screened for surgery by trained healthcare providers. Approximately 282,000 patients in the United States were estimated to have received multiple non-surgical steroid injections for sacroiliac joint pain in 2017. 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 United States could be 279,000 patients annually, for a potential annual market in the United States of approximately \$2.7 billion. While we have made significant inroads at penetrating this market, patients received only 4,319 iFuse procedures in 2017.

Patients with sacroiliac joint dysfunction may experience debilitating pain. We believe that the sacroiliac joint is the last major joint to be addressed by the orthopedic implant industry. Studies have 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.

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 United States, 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. In all other countries where iFuse is available commercially, the system is indicated for sacroiliac joint 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 or sacroiliac joint arthritis 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 very quickly decreases 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 become less common in the United States since we introduced 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.

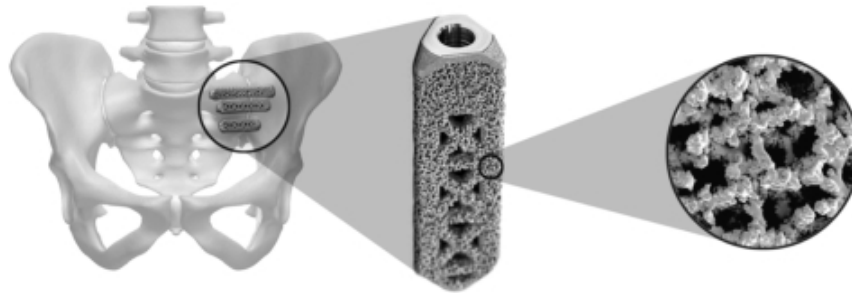
### **Non-Surgical Treatment of Sacroiliac Joint Disease**

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 the INSITE study. 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 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 fixation 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 the implants and across the joint, permanently stabilizing or fusing the joint.

By contrast, open fusion of the sacroiliac joint, as well as the minimally invasive solutions offered by other companies, typically use screws and/or plates for fixation. When placed across the sacroiliac joint, standard orthopedic screws, which lack features to encourage biologic fixation, have an exhibited propensity 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 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.



## [Table of Contents](#)

- **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 across the orthopedic implant industry, 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 is comprised of 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 is comprised of instruments made with more radiolucent materials, such as PEEK and aluminum to improve visualization under fluoroscopy during an iFuse procedure. We also have instrument sets which have been cleared for use with Medtronic's surgical navigation system and with the Mazor surgical robot.

### **Our Strategy**

Our business objective is to maintain and enhance our leadership position in the area of sacroiliac joint fusion by providing clinically proven products and procedure-related training to promote pain and disability relief in affected patients. To accomplish this objective, we intend to:

- Continue to educate physicians, payors, and patients globally about the growing body of evidence supporting the safety, durable clinical effectiveness, economic benefit, and reduction in opioid use associated with the iFuse procedure;
- Educate and train the healthcare community on the prevalence, anatomy, diagnosis, and treatment options for the sacroiliac joint, including minimally invasive surgical fusion, and work with and support medical societies including NASS, CNS, AANS, ISASS, SRS, and AAOS to increase their education programs teaching the diagnosis of the sacroiliac joint as part of the differential diagnosis of lower back pain;
- Increase exclusive and non-exclusive reimbursement coverage for iFuse;
- Expand our direct field organization in the United States and select European countries to help drive adoption of our iFuse products;
- Maintain our technological leadership by investing in the creation of new or improved products for sacroiliac joint surgery, and obtain domestic and international regulatory clearance or approvals to market them in the United States and additional countries; and
- Continue to grow our existing intellectual property portfolio.

### **Our Published Studies**

iFuse is the only minimally invasive product for sacroiliac joint fusion commercially available in the United States that, to our knowledge, is supported by substantial high-quality published evidence of safety, clinical effectiveness, durability, and economic utility.

These benefits are supported by more than 60 published papers (46 of which we financially supported), including a prospective, randomized controlled multi-center clinical trial referred to as "INSITE" and a



prospective multi-center clinical study referred to as “SIFI.” INSITE 24-month follow-up results were published in August 2016 in *International Journal of Spine Surgery*. 6-month and 1-year summaries were also published in reputable journals. Published results demonstrate clinically important and statistically significant improvement for sacroiliac joint pain, disability due to lower back pain, quality of life, and patient satisfaction. Moreover, the level of published evidence supporting the safety and effectiveness of sacroiliac joint fusion using iFuse is high.

In the United States, the iFuse Implant System is FDA-cleared with the following indication statement: The iFuse Implant System® is intended for sacroiliac 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. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life.

iFuse-3D, which was FDA-cleared in 2017, has a very similar indication statement but does not have the statement regarding improvement in pain, function, and quality of life. In the United States, 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.

### ***INSITE Study Design***

INSITE is a prospective multicenter randomized controlled trial conducted in the US. This section describes INSITE in more detail.

INSITE enrollment took place between January 2013 and May 2014 at 19 sites in the United States. Adults between 21 and 70 years old were eligible to participate if they had a confirmed diagnosis of sacroiliac dysfunction due to degenerative sacroiliitis and/or sacroiliac joint disruption. Diagnosis was based on the subject’s history, provocative tests performed in the surgeon’s office, and at least a 50% decrease in sacroiliac joint pain 30 to 60 minutes after local anesthetic was injected into the joint under image guidance. Eligibility required a sacroiliac VAS pain score of at least 50, where zero represents no pain and 100 represents the worst pain imaginable, as well as a baseline ODI score of at least 30, which has a scale of 0-100, where zero represents no disability and scores greater than 60 represent very severe disability.

Exclusion criteria included inability to diagnose pain related to the sacroiliac joint, sacroiliac joint pain due to inflammatory conditions, severe back pain deemed to be due primarily to other causes, history of recent major trauma to the pelvis, metabolic bone disease, or any condition that made treatment with the study devices infeasible or interfered with the ability to participate in physical therapy. Subjects involved in litigation, on disability leave, or receiving workers’ compensation related to their back or sacroiliac joint pain were also excluded. Subjects were randomly assigned to sacroiliac joint fusion or non-surgical management in a two to one ratio. After six months of follow-up, subjects could elect to receive sacroiliac joint fusion surgery using iFuse. All of the subjects who were randomized to non-surgical management completed at least six months of follow-up before electing to cross over to surgery. There was no early crossover.

Subjects assigned to non-surgical management began immediately with treatment consisting of one or more of the following: 1) management of pain with medication, including narcotics; 2) physical therapy; 3) steroid injections in the sacroiliac joint; and 4) radiofrequency ablation of local nerves. Physical therapy followed American Physical Therapy Association, or APTA, guidelines. Not all non-surgical management interventions were provided to all non-surgical management subjects. Non-surgical management interventions were provided serially, typically in order of increasing invasiveness, according to individual needs.

Baseline assessments included medical history and physical examination. Subjects were scheduled for follow-up at 1, 3, 6, 12, 18, and 24 months after enrollment. At each follow-up, the subjects evaluated their pain and disability by completing questionnaires to assess pain and disability.

## [Table of Contents](#)

A high-resolution pelvic CT scan was performed at the 24-month follow-up for those subjects randomized to and treated with iFuse. The primary purpose of the CT scan is to judge the adherence of bone onto the implants on both the sacral and iliac sides of the sacroiliac joint and to determine whether there is bone bridging across the joint. Other radiographic endpoints were assessed as well.

The study required that subjects receive only the assigned treatment to month six. After six months, the study allowed subjects assigned to non-surgical treatment to cross over to surgery. Crossover was allowed because the anticipated success rate for non-surgical management was low, and many subjects would not have participated without the ability to cross over to surgical care within the study. One-hundred percent of subjects who crossed over to surgical treatment in the study did so shortly after their six-month visit was complete in compliance with the design of the study. Nearly 90% of non-surgical management subjects still participating at month six crossed over to surgical care. All subjects who crossed over had sacroiliac joint fusion using iFuse and were subsequently evaluated with follow-up visits. No early crossover occurred.

The primary endpoint was a composite success or failure endpoint. Success was defined as reduction from baseline VAS sacroiliac joint pain by at least 20 points, absence of device-related serious adverse events, absence of neurological worsening related to the sacral spine, and absence of surgical re-intervention (removal, revision, reoperation, or supplemental fixation) for sacroiliac joint pain. Secondary endpoints included improvement from baseline in VAS, ODI, as well as treatment satisfaction and other criteria. Other important measures included quality of life assessments.

In the study, 442 subjects at 19 centers were screened for participation, of which 148 were enrolled and treated. Mean subject age was 51 years and 18 (12%) were 65 years of age or older. Most subjects (94.6%) were Caucasian and approximately two-thirds were female.

Enrolled subjects were highly debilitated by sacroiliac joint pain as indicated by high baseline VAS scores (mean 82.3) and ODI scores (mean 56.8). Nineteen percent were not working due to chronic pain. The duration of pain prior to enrollment averaged 6.4 years (range 0.5 to 40.7 years), and 87.2% had had pain for more than one year and 73.6% had pain for more than two years.

Trial subjects had previously undergone sacroiliac-specific physical therapy (72.3% of subjects), sacroiliac steroid injections (85.8%) and radiofrequency ablation of the sacroiliac joint (16.2%). Approximately two-thirds were taking opioid pain medications at baseline and all reported that multiple activities commonly caused or worsened their sacroiliac joint pain.

Follow-up was excellent with 96% of non-surgical subjects having 6-month follow-up and 87% of sacroiliac joint fusion patients having 24-month follow-up.

All subjects assigned to sacroiliac joint fusion underwent the procedure. Of the subjects assigned to surgery, 76 had the iFuse procedure on one sacroiliac joint, while 26 underwent the procedure on both sacroiliac joints. Mean procedure time was 45 minutes (range 14 to 140 minutes). Mean estimated blood loss was 33 ml (range 0.5 to 250 ml). Three implants were used in 91.2% of cases and most implants were seven millimeters in diameter. The hospital length of stay ranged from zero to seven days, and 97.1% were discharged in two days or less.

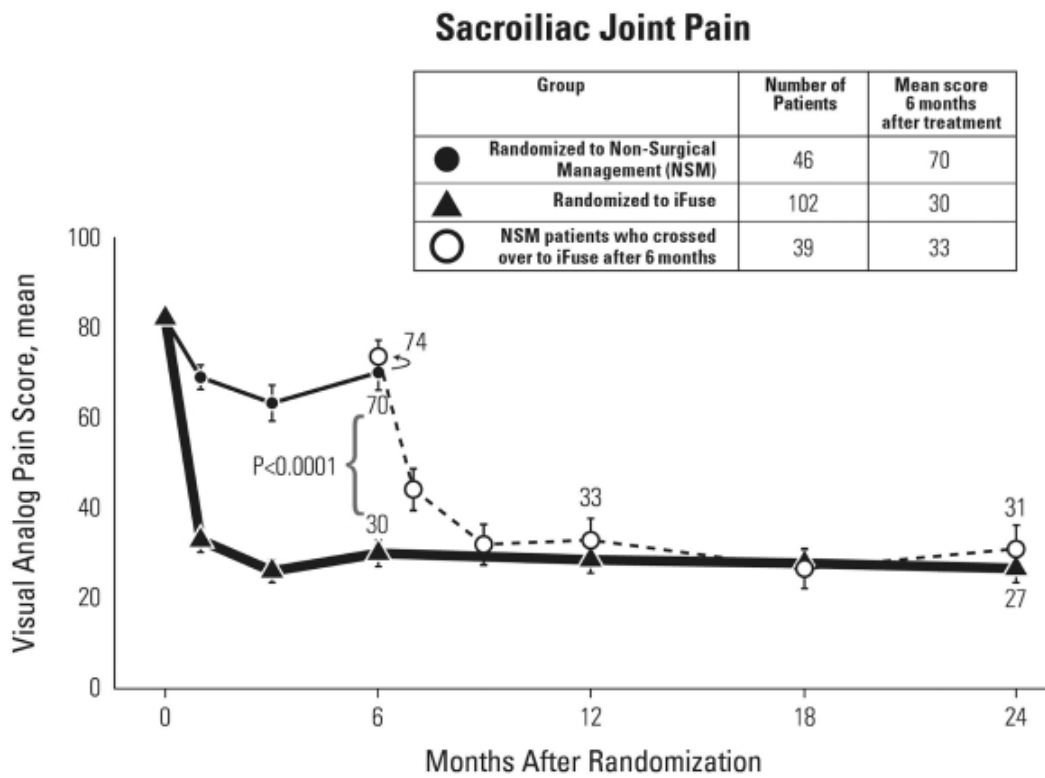
Of the 46 subjects assigned to non-surgical management:

- All but one received physical therapy during the six months after treatment assignment;
- 73.9% underwent at least one steroid injection;
- 45.7% underwent radiofrequency ablation of the sacroiliac joint; and
- 87.0% underwent at least two types of non-surgical management treatments in addition to pain medications.

The above data suggests that the intensity of non-surgical management interventions was high and representative of that provided in standard clinical practice.

INSITE clinical outcomes can be summarized as follows.

- Reduction in Pain.** There was a statistically significant and clinically important reduction in pain among subjects treated with iFuse as compared to non-surgical management. As shown in the graph below, subjects surgically treated with iFuse had a mean 52-point VAS reduction in sacroiliac joint pain at six months. The reduction in pain was sustained with a mean 54- and 55-point reduction in sacroiliac joint pain observed at 12 and 24 months, respectively. By contrast, subjects in the non-surgical management group had only a mean 12-point reduction ( $p < 0.0001$ ) at six months. 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 was 83% in the iFuse group and 10% in the non-surgical management group.

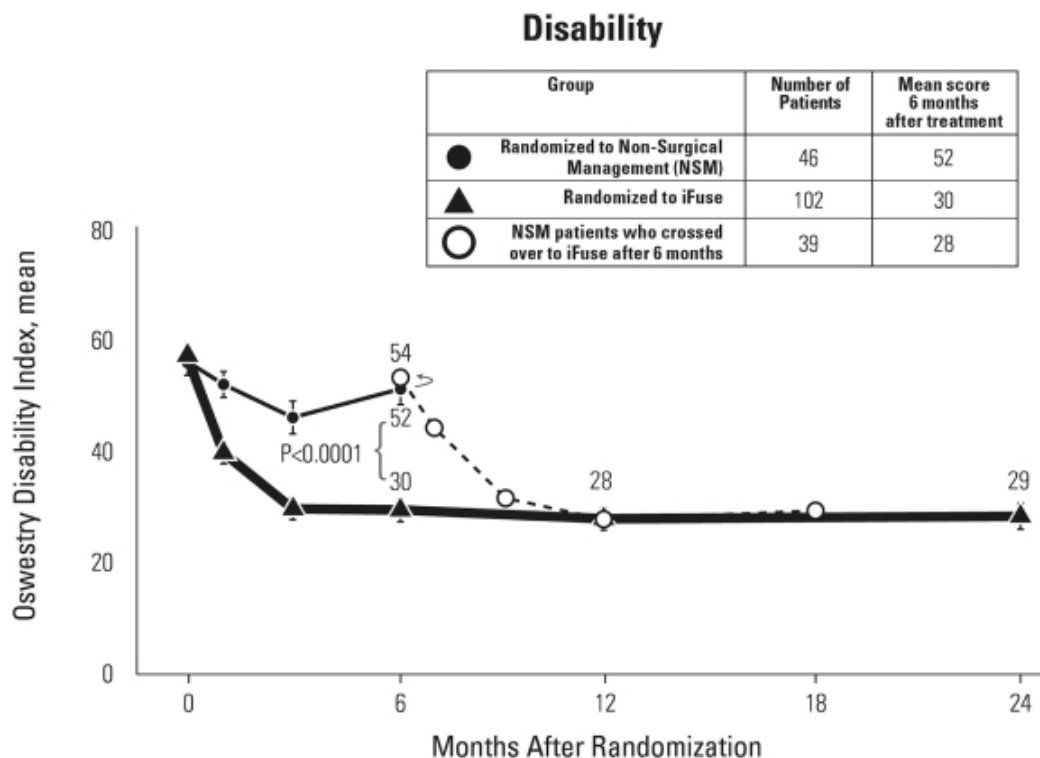


Subjects who elected not to cross over to surgery had reduced pain at six months, but their pain worsened somewhat over time. In contrast, the non-surgical management group subjects who elected to cross over to have the iFuse procedure had pain reduction similar to that seen in subjects originally assigned to sacroiliac joint fusion with iFuse. These clinically important differences show the effectiveness of sacroiliac joint fusion with iFuse.

- Reduction in Disability.** There was a statistically significant reduction in disability with iFuse as compared to non-surgical management. As shown in the graph below, subjects surgically treated with

iFuse had a mean 27-point ODI reduction in disability at six months, while subjects in the non-surgical management group had only a mean 4.6-point decrease ( $p < 0.0001$ ). At 12 and 24 months, the iFuse group had a mean 29- and 28-point reduction in disability, respectively. At six months, the proportion of subjects with ODI improvements of at least 15 points was 72.5% and 13.0% in the iFuse and non-surgical management groups, respectively. At 24 months, the proportion of subjects with an improvement of at least 15 points due to the assigned treatment was 68.2% and 7.5% in the iFuse and non-surgical management groups, respectively ( $p < 0.0001$ ).

As shown in the figure below, 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. These clinically important differences show the effectiveness of sacroiliac joint fusion with iFuse.



**Patient Satisfaction**

Patient satisfaction was assessed by asking subjects whether they were very satisfied, somewhat satisfied, somewhat dissatisfied or very dissatisfied with the treatment received. At six months, 79.0% of subjects who had received the iFuse procedure were very satisfied, compared with 27.3% of subjects in the non-surgical management group. At six months, 81.0% of surgery subjects said they would definitely have the procedure again. At 24 months, satisfaction rates were high, with 73.3% reporting being very satisfied with surgical treatment of the sacroiliac joint, and 71.1% indicated they would have the procedure again. These results are consistent with the satisfaction results from other studies, covering approximately 500 subjects.

**Adverse Events**

During the first six months, the mean number of adverse events per subject was slightly but not statistically significantly higher in the surgery group (1.3 events) as compared to the non-surgical management group (1.1

## Table of Contents

events,  $p=0.3063$ ). The most common adverse event related to our implant was leg pain resulting from misplacement of the implant, resulting in impingement of the implant on a lumbar spine nerve root. The most common adverse event for our implant procedure has been minor wound infections. None of these adverse events required surgical treatment. The following table shows the number and percentages of subjects who had adverse events related to the iFuse device and the iFuse procedure.

Category	Non-Surgical Management	Sacroiliac Joint Fusion
	(n=46) N (%)	(n=102) N (%)
Related to iFuse implant		
Definitely related	—	2 (2.0%)
Probably related	—	1 (1.0%)
Total	—	3 (2.9%)
Related to non-surgical management or iFuse procedure**	3 (6.5%)	6 (5.9%)
Definitely related	1 (2.2%)	10 (9.8%)
Probably related	4 (8.7%)	16 (15.7%)
Total		

\* Percent reported as number of events divided by number assigned to treatment.

\*\* Events from first 180 days shown.

In summary, we believe the INSITE study, a prospective, randomized controlled multi-center clinical trial, provides substantial evidence of clinically important and statistically significant efficacy supporting the superiority of sacroiliac joint fusion using iFuse as compared to non-surgical management. Further, the fact that subjects who crossed over responded, as well as those who were originally assigned to the iFuse group, adds significantly to the trial's validity and importance.

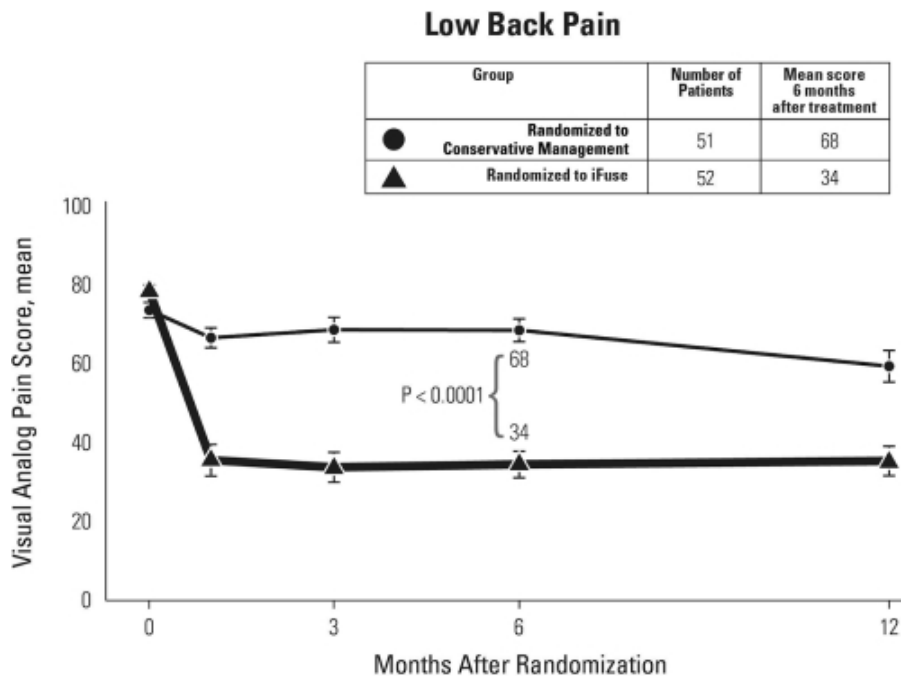
### *iMIA European Clinical Trial*

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 enrolled and treated 103 subjects at nine sites in four European countries. The trial's six-month results were published in *European Spine Journal* in May 2016 and 12-month results were published in August 2017 in *Pain Physician*.

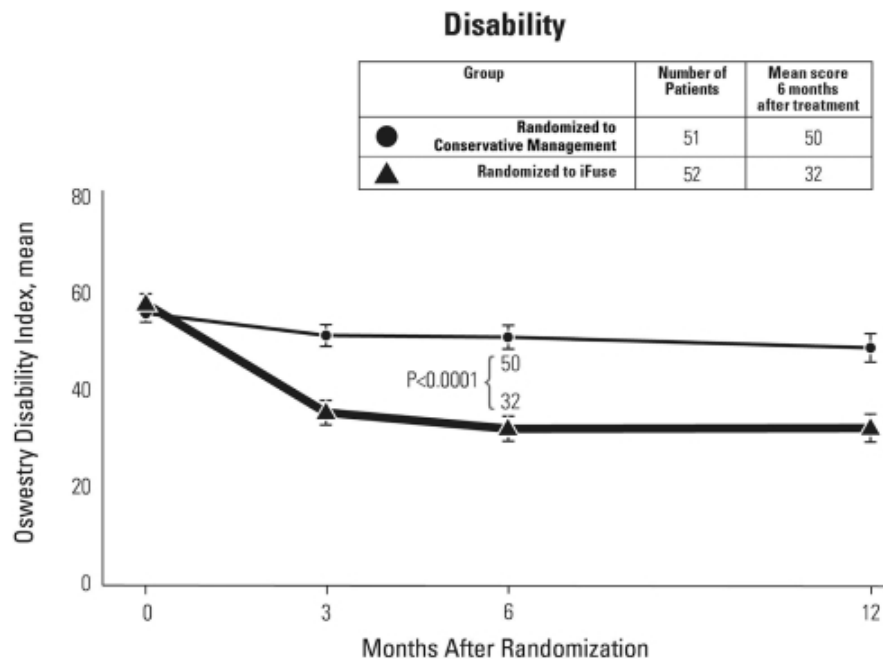
In iMIA, 103 adults with chronic sacroiliac joint pain at nine sites in four European countries were randomly assigned in a one-to-one ratio to either immediate sacroiliac joint fusion with iFuse or conservative management. Conservative management was performed according to the European guidelines for the diagnosis and management of pelvic girdle pain and consisted of optimization of medical therapy, individualized physical therapy and adequate information and reassurance as part of a multifactorial treatment.

At 12 months, low back pain in the surgically treated group improved by 42 points and ODI improved by 25 points ( $p<.0001$  from baseline). Adverse events occurred at a low rate and the frequency of adverse events did not differ between groups. One case of postoperative nerve impingement occurred in the surgical group, which was resolved by repositioning the implant.

The figure below shows mean VAS pain scores at baseline and throughout follow-up. The results show clinically profound, rapid and sustained reduction in pain following treatment with iFuse, in contrast with conservative management.



The figure below shows mean ODI scores at baseline and throughout follow-up. The results show clinically profound, rapid and sustained reduction in disability following treatment with iFuse, in contrast with conservative management.



A manuscript describing 24-month results is currently under review at a medical journal. Study data show that improvements in pain, disability and quality of life were sustained at 24 months and satisfaction rates remained high.

**SIFI Clinical Trial**

Sacroiliac Joint Fusion with iFuse Implant System, or SIFI, is a prospective, multicenter single-arm clinical trial. Eligibility criteria and endpoints were identical to INSITE. A manuscript summarizing 24-month results was published in *International Journal of Spine Surgery* in April 2016.

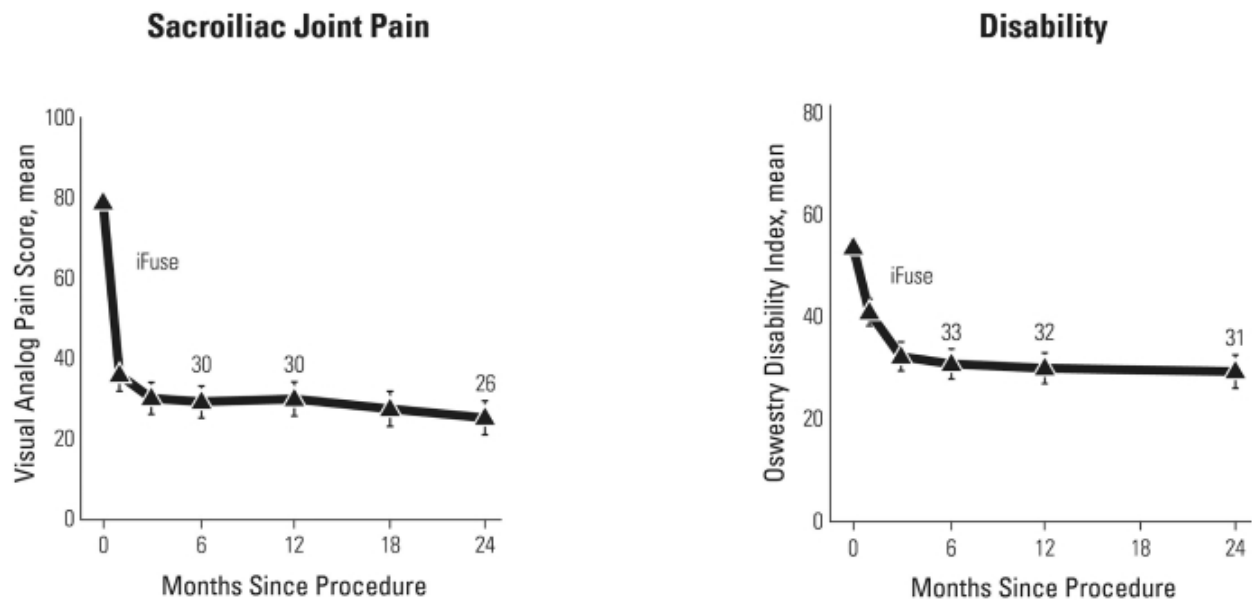
Each of the 172 enrolled subjects received the iFuse procedure at one of 26 participating sites between August 2012 and December 2013. Mean subject age was 51 years and 96.5% subjects were Caucasian and approximately 70% were female. Follow-up rates at month 6, 12, and 24 were 97%, 91%, and 87%, respectively.

Baseline sacroiliac pain and disability scores were high. The mean baseline VAS score was 79.8, while the mean baseline ODI score was 55.2. The mean duration of pain prior to enrollment was five years (range 0.4 to 41 years), and 84.3% had had pain for more than one year and 64.5% had had pain for more than two years.

Seventy-six percent were taking opioid pain medications at baseline and all reported that multiple activities commonly caused their sacroiliac joint pain. Many subjects (44.2%) had a history of prior lumbar fusion, and concomitant spine disease was common. Sacroiliac joint pain persisted despite prior treatments with physical therapy (64.5% of subjects), sacroiliac joint steroid injections (94.2%), and prior radiofrequency ablation of the joint (15.7%).

Hospital length of stay ranged from zero to seven days, and 95.3% were discharged in two days or less. Prolonged hospital stays were related to subject comorbidities, not procedure-related adverse events.

The figure on the left below shows mean VAS pain scores at baseline and throughout follow-up. The figure on the right shows mean ODI scores at baseline and throughout follow-up. The results for both VAS pain and ODI scores each show clinically important and sustained reduction in disability across the subject population and follow-up period, consistent with the results observed in the surgical group in INSITE.



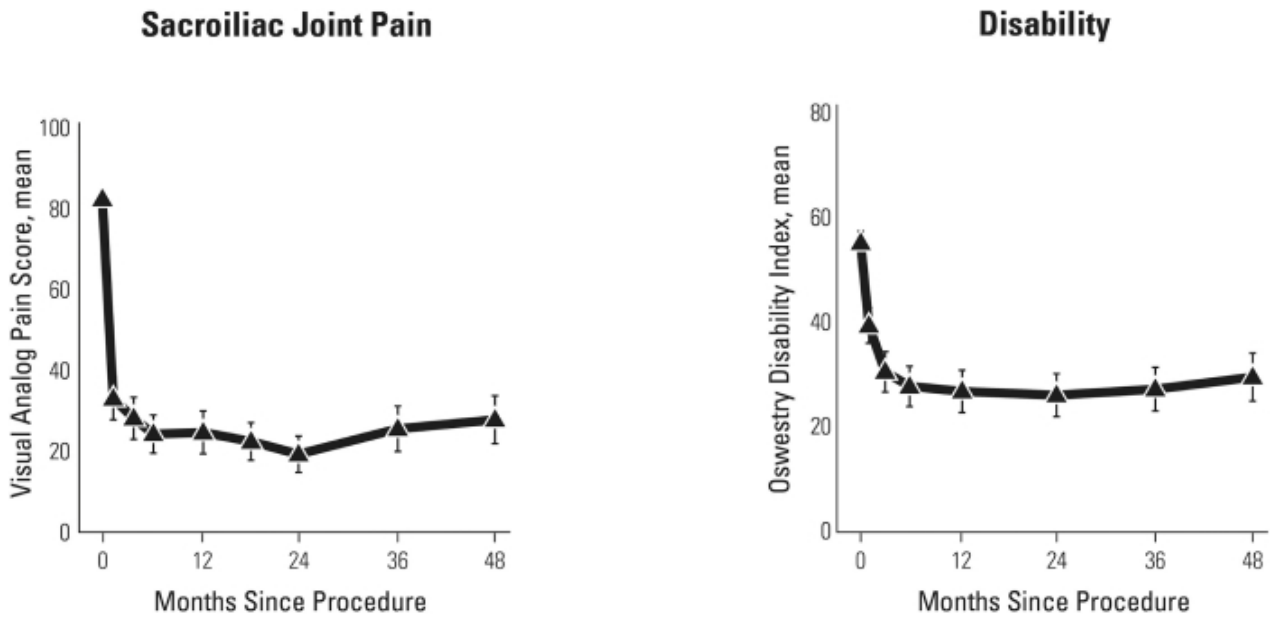
Satisfaction rates were high, with 78.1% reporting being very satisfied with sacroiliac joint treatment by month 24 and 93.8% being very or somewhat satisfied. 74.7% indicated they would definitely have the procedure again; 88.4% indicated they would probably or definitely have the procedure again.

Four adverse events (2.4% of all subjects) were rated by the investigator to be definitely device-related and three (1.8%) were probably device-related. Pain related to implant impingement on sacral nerve roots occurred in three cases (including one non-study-related side), all of which resolved with immediate repositioning of implants. In four cases, sacroiliac joint or hip pain was attributed to the presence of an implant or bone growth around the implant. Twenty-six events were rated as probably or definitely related to the placement procedure. The most common events were wound infection, irritation or drainage, sacroiliac joint pain related to implant malposition (described above), and recurrent sacroiliac joint pain related to inadequate device placement. One subject had a deep wound infection that required surgical debridement.



**LOIS Clinical Trial**

LOIS is a prospective follow-on study, enrolling subjects at a subset of INSITE and SIFI sites who underwent sacroiliac joint fusion. Enrolled subjects will be followed out to five years following surgery. Study outcomes at three years were published in April 2018 in *Medical Devices: Evidence and Research*. Among 103 enrolled subjects, mean sacroiliac joint pain at three years decreased from 81.5 preoperatively to 26.2 (a 56-point improvement from baseline,  $p < .0001$ ), as shown in the graph below on the left. A manuscript with results at four years of follow-up was recently accepted for publication. Study data show continued improvements in pain, disability and quality of life sustained at 48 months.



Subjects in the LOIS study experienced similar improvements in disability and quality of life. As shown in the graph above on the right, average disability prior to treatment as measured on the ODI scale was 56.3 and fell to an average of 28.2 by 36 months following treatment. Average quality of life as measured by the EuroQol-5D prior to treatment was 0.45 and had improved to 0.75 by 36 months following treatment with iFuse.

**Additional Published Clinical Studies**

We have demonstrated the long-term durability of pain relief resulting from treatment with iFuse in several other published studies. A study published in the *Open Orthopedics Journal* in 2014, which we financially supported, showed that significant clinical pain relief observed at 12 months was maintained for five years. Similar results with four and one-half year follow-up were published in the *Journal of Spine* in 2014. A retrospective multicenter analysis of three-year outcomes after sacroiliac joint fusion with iFuse showed similar responses.

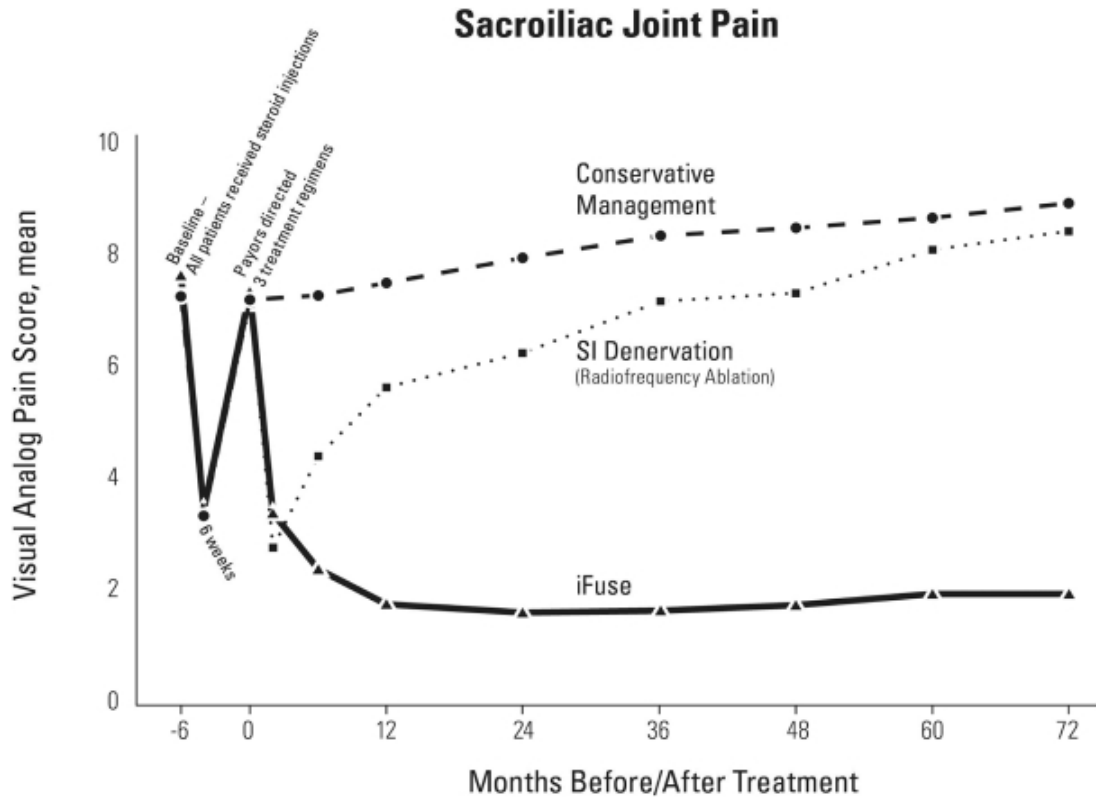
Of more than 500 patients treated with iFuse in 10 studies we have sponsored or followed in which satisfaction was measured, 91% were satisfied or very satisfied with the result. All of the iFuse studies published as of June 2018 report sacroiliac joint pain using the VAS pain scale are in the graph below. We financially supported nine of these thirteen 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-

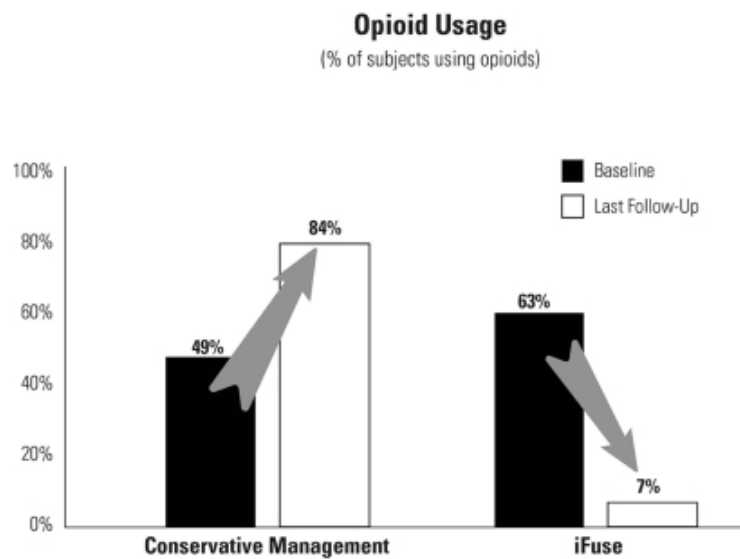
site, and U.S.- or Europe-based. These clinical studies demonstrate the iFuse procedure to be safe and effective. These studies demonstrate pain reduction and/or ODI improvement that is statistically significant and clinically important. The type and rate of reported adverse events were similar to those reported in INSITE, iMIA, and SIFI. These additional studies are consistent with the results of INSITE, iMIA, and SIFI.

A study published in April 2017 in *Neurosurgery* shows the impact of non-coverage of sacroiliac joint fusion by the healthcare system. In this study, a Spanish neurosurgeon reports the clinical experience of 423 patients seen in his clinic for sacroiliac joint pain. While many patients' pain resolved without intervention, 152 of the patients (36%) had continued sacroiliac joint pain. Of these patients, 74 did not have access to the procedure due to their insurers' denial of coverage and instead were only able to pursue continued non-surgical treatment. Of the remaining 78 patients, 51 underwent radiofrequency ablation of lateral branches of sacral nerve roots and 27 underwent sacroiliac joint fusion with iFuse.

The group treated non-surgically had poor outcomes, including increased pain, disability, and opioid use, as well as worsened work status. By contrast, patients who were able to undergo the iFuse procedure had very large improvements in pain and disability, improved work status, and a decreased incidence of opioid use. The differences in all outcomes (pain, disability, work status, and opioid use) were both statistically significant and clinically profound. The graph below shows the pain scores of the three treatment cohorts followed in this study.



The graph below shows the changes in the percentage of subjects using opioids among the iFuse and conservative care groups in the study. Forty-nine percent of subjects who were not able to access treatment with iFuse were using opioids at the beginning of the study, whereas 80% of them were using opioids at the time of their final follow-up. In contrast, 63% of the subjects who were able to obtain treatment with iFuse were using opioids prior to treatment, whereas only 7% were using opioids at their final follow-up visit.



There are several important aspects to this study:

- It can be considered a “pseudorandomized trial” in that insurance denials (which dictated which treatment the patient could receive) was not clearly related to any important predictor of clinical outcomes. This enhances the comparability of groups.
- It is the longest reported cohort of non-surgical treatment of sacroiliac joint pain published to date.
- Non-surgical treatment was clearly associated with poor outcomes, consistent with our experience in the US, in which patients receive repeated, and sometimes expensive, non-surgical treatments but do not derive significant benefit.

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. One of these studies used data from INSITE to calculate the incremental cost-effectiveness of the iFuse procedure and found it to be similar to that of hip and knee arthroplasty, commonly known as total joint replacement. The two latter procedures are generally accepted as being safe, effective, and highly cost-effective. The incremental cost effectiveness ratio, or ICER, of a procedure or therapy is a common way of quantifying its cost-effectiveness and represents the incremental cost to the healthcare system of providing one additional quality adjusted life-year, obtained by dividing the average cost of the therapy by the average increase in quality-adjusted life years that it achieves. Therapies with ICERs below \$50,000 are considered cost-effective and generally gain acceptance. For example, studies have shown that the ICER of total joint replacement surgery for knees is approximately \$12,000 and that for hip replacements is approximately \$10,000. One study showed the ICER of the iFuse procedure to be \$13,000, nearly as cost-effective as knee and hip surgeries, which are both common and well-accepted procedures. The ICER of iFuse derived from data from the INSITE trial is significantly better than the published ICERs of other common spine surgeries derived from one of the few other randomized controlled clinical trials

## [Table of Contents](#)

of spine surgeries. Published analyses of the data from this trial showed the ICER of discectomy to be approximately \$21,000, the ICER of standard decompressive laminectomy to be approximately \$64,000, and the ICER of posterior decompressive laminectomy to be approximately \$59,000. Each of these is a commonly performed spine surgery.

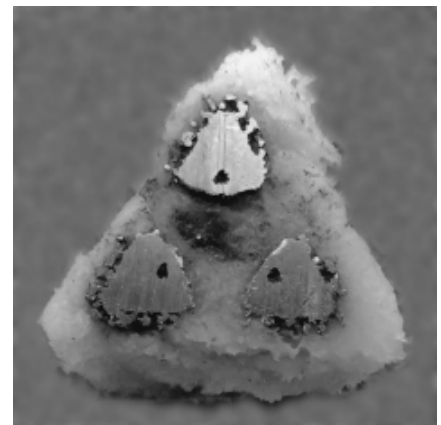
A second study detailed a health economics model examining the cost impact of failing to consider the sacroiliac joint in the diagnosis of patients with low back pain in patients seeking surgery. Taking into account both the prevalence of sacroiliac joint dysfunction and the costs of diagnostic workup and surgical treatment, if a surgeon evaluating a patient with chronic low back pain fails to consider the sacroiliac joint, on average \$3,100 more healthcare expenditures will ensue. The study concluded that taking the sacroiliac joint into account can save healthcare systems substantial amounts due primarily to reduction in misdiagnosis and its attendant costs.

A third study used data from our two prospective trials conducted in the United States to examine the impact of sacroiliac joint fusion on worker productivity. Results suggest that sacroiliac joint fusion can increase the productivity of affected workers by an average of \$6,900 compared to continued non-surgical care.

A fourth health economic study currently under review for publication examined healthcare costs for low back pain before and after sacroiliac joint fusion in patients in a commercial insurance database. Analysis showed reductions in median low back pain-related healthcare costs after sacroiliac joint fusion compared to before. A break-even analysis for health plan reimbursements for patients undergoing minimally invasive sacroiliac joint fusion on an outpatient basis showed similar cumulative claims for patients not undergoing the procedure within approximately 2.5 years. Following the procedure, per patient costs related to sacroiliac joint pain decrease to approximately \$250 per quarter among the group who underwent sacroiliac joint fusion.

### **Our Second-Generation Implant**

Our second-generation iFuse implant, iFuse-3D, shown on the left below, was cleared for marketing by the U.S. Food and Drug Administration in March 2017 and the European Union in May 2017. This patented titanium implant combines the triangular cross-section of the iFuse implant with a proprietary 3D-printed porous surface and fenestrated design. This design also allows the surgeon to fill the implant with ground-up bone before implanting it, which some surgeons believe accelerates bone through-growth. iFuse-3D implants have shown positive bony ingrowth in cell culture and animal studies, whether or not ground-up bone is used, as shown in two peer reviewed studies published in June 2017 in the *International Journal of Spine Surgery*. The image on the right below shows the cross section cut from an iFuse-3D implant removed from an animal as part of the study, and reveals robust growth of bone into the implant.



## Coverage and Reimbursement

Coverage and reimbursement for iFuse products and related procedures vary by setting of care, payor type, and region. In the United States, healthcare providers that purchase iFuse products look to various third-party payors, such as Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, accountable care organization, or ACOs, 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.

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 seven regional 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 United States, the American Medical Association, or AMA, generally creates specific billing codes for surgical procedures under a coding system known as Current Procedure Terminology, or CPT, which surgeons must use to bill and receive reimbursement for our iFuse procedure. Once the CPT code is established, the Centers for Medicare & Medicaid Services, or CMS, establishes payment levels and coverage rules 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 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 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.

## [Table of Contents](#)

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, or NASS, published a positive coverage recommendation, based on the clinical evidence, advocating 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, or ISASS, also published a similar, updated positive advocacy document intended to encourage insurance companies in the United States to reimburse for the procedure.

Coverage decisions for this code are made independently by each private insurance company and each of the seven regional 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, 2016, U.S. payors covering approximately 133 million lives regularly reimbursed for the iFuse procedure, and as of December 31, 2017, U.S. payors covering approximately 162 million lives regularly reimbursed for the iFuse procedure. However, by August 31, 2018, 39 of the largest 65 private payors that we track had positive coverage policies for the procedure, were consistently covering the procedure, or had announced coming future coverage.

Third-party payors, whether governmental or commercial, are also developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. 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 new 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 also from time to time 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 using a prescribed statutory formula.

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 franchisor to all 36 Blue Cross and Blue Shield insurers across the United States, wrote 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 July 2018, eviCore published its draft guidelines to be published in final form in October 2018, recommending 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 that cover over 200 million lives in the United States as of December 31, 2017. As of August 31, 2018, 39 of the largest 65 private payors were covering regularly, or had announced coverage for, the iFuse procedure, while the remaining private payors were reevaluating their coverage policies. Of these, 23 private payors have issued positive coverage policies exclusive to iFuse for sacroiliac joint fusion because of the clinical evidence. Seventeen of these exclusive coverage policies have

## [Table of Contents](#)

published since January 1, 2018, which we believe has contributed to our accelerating sales growth in fiscal year 2018. The private payors covering iFuse exclusively are:

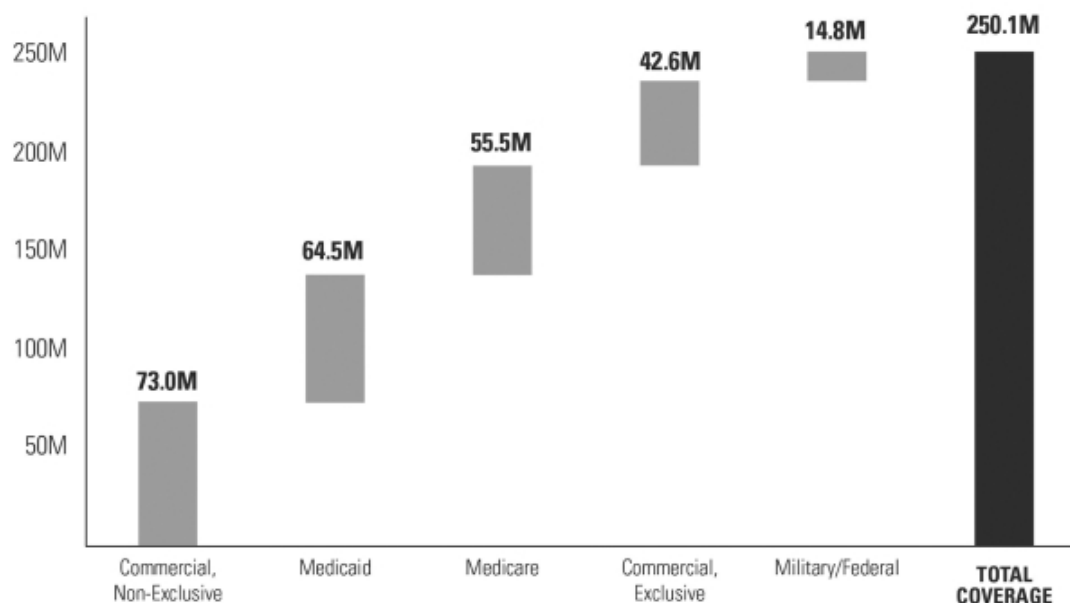
- BCBS Florida
- BCBS-Illinois (HCSC)
- BCBS-New Mexico (HCSC)
- BCBS-Oklahoma (HCSC)
- BCBS-Texas (HCSC)
- BCBS- Montana (HCSC)
- BCBS-Idaho
- BCBS-Kansas City
- BCBS-Kansas
- BCBS-Louisiana
- BCBS-Massachusetts
- BCBS-Minnesota
- BCBS-Mississippi
- BCBS-New Jersey (Horizon)
- BCBS-NY (HealthNow)
- BCBS-Capital Blue (Pennsylvania)
- BCBS-Independence
- BCBS-Regence
- BCBS-South Carolina
- BCBS-Tennessee
- BCBS-Wyoming
- BCBS-Capital Health (Florida)
- Select Health

The private payors covering iFuse and other sacroiliac joint fusion products are:

- BCBS-Highmark
- BCBS-Michigan
- BCBS-Nebraska
- BCBS-North Dakota
- BCBS-Vermont
- Emblem Health
- Geisinger Health Plan
- Harvard Pilgrim
- Health New England
- Kaiser California
- Kaiser Northwest
- Kern Health Systems
- Network Health
- Priority Health
- United Healthcare
- Utah Public Employee Health Plan

As of August 31, 2018, U.S. payors covering 250 million lives reimburse for iFuse, 115 million of which are covered by private payors. The chart below shows the overall coverage as of August 31, 2018:

### iFuse Covered Lives by Payor Type



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.

There are a number of large and small private payors, including Aetna, Cigna, Humana, and Anthem, that are not yet reimbursing 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, schedule re-examinations of patients who were candidates for surgery and subsequently schedule surgeries for the patients who are still candidates. We believe it takes between 6 and 24 months for surgeons to fully incorporate iFuse into their practices after payors initiate coverage. 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 United States**

Outside the United States, reimbursement levels vary significantly by country, and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Some countries will require us to gather additional clinical data before recognizing and granting broader coverage and reimbursement for our products.

In April 2017, the UK's National Institute for Health and Care Excellence, or 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 MIS 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. 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 board-certified fellowship trained orthopedic spine surgeon. As of June 30, 2018, our U.S. faculty consisted of 80 surgeons, 19 pain management physicians, 11 nurse practitioners/physician's assistants, and 83 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, approximately 1,700 surgeons have treated patients with iFuse. 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 June 30, 2018, our medical affairs team and physical therapist consultants have educated over 3,600 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 June 30, 2018, we have trained over 1,200 case managers across the United States. 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 June 30, 2018, our physical therapy continuing education programs were approved in 43 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 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 United States is comprised of seven sales regions. Each region is comprised of a number of territory sales managers who 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. As of June 30, 2018, our territory sales managers were led by seven regional sales managers who reported to our Vice President of U.S. Sales. The Vice President of U.S. Sales reports to our Chief Commercial Officer. As of June 30, 2018, our U.S. sales force consisted of 45 sales representatives directly employed by us and 30 third-party distributors.

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.

As of June 30, 2018, we had 28 employees working in our European operations, and have established operations in Italy (2010), Germany (2014), and the United Kingdom (2015). As of June 30, 2018, our international sales force consisted of 18 sales representatives directly employed by us and 27 exclusive third-party distributors, which together had sales in 33 countries through June 30, 2018. 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 United States, working with internationally recognized healthcare professional experts as we expand our training and reimbursement activities. As of June 30, 2018, beyond Europe and the United States, surgeons had performed the first iFuse procedures in Australia, Cayman Islands, Hong Kong, Israel, Japan, Kuwait, New Zealand, Taiwan, Turkey, and Saudi Arabia.

## **Research and Development**

Since our initial launch of the iFuse system, we have introduced a number of new instrument enhancements, product enhancements 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 instruments set which included a number of radiolucent instruments. We also design and manufacture, Class I instruments for our surgeon customers based on special request under our “Non-Standard Product” program.

In 2017, we introduced an instrument set which is cleared for use with Medtronic’s surgical navigation system, allowing the surgeon to visualize the 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. 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 SI joint dysfunction in patients in whom the surgeon is also implanting other devices to treat other spine conditions. We are developing products and techniques to help surgeons improve the treatment of these patients, and we will seek any additional regulatory clearances which may be required. Our research and development expense for 2016 and 2017 and for the six months ended June 30, 2017 and June 30, 2018 was \$6.4 million, \$5.5 million, \$2.8 million, and \$2.5 million, respectively.

## **Competition**

We believe 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 increase the 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 United States, we believe that our primary competitors currently are Globus Medical, Inc., Medtronic plc, XTant Medical Holdings, Inc., and RTI Surgical, Inc. Our primary competitors in Europe are Globus Medical, SIGNUS Medizintechnik GmbH, and XTant Medical Holdings. However, they 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 are comprised of human cells or tissues and are regulated by the FDA differently from implantable medical devices made of metallic or other non-tissue based materials.

Based on our commercial experience and market research, we believe iFuse is currently used in the majority of minimally invasive surgical fusions of the sacroiliac joint in the United States. iFuse is the only minimally invasive product for sacroiliac joint fusion commercially available in the United States that, to our knowledge, is supported by published clinical evidence including randomized controlled studies that demonstrate the safety, clinical effectiveness, durability, and economic utility. These benefits are supported by more than 60 published papers.

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 June 30, 2018, we had been issued 34 patents in the United States, five patents in Japan and one in China. Also, as of June 30, 2018, we have 11 pending patent applications in the United States and seven pending patent applications outside of United States. We have focused the majority of our foreign patent efforts in China, Europe, and Japan.

Generally, our current U.S. patents are expected to expire between August 2024 to September 2035, and our Japanese patents are expected to expire between August 2025 and October 2031.

We have 12 registered trademarks in the United States and have filed for one more. In other countries, we have focused on registering three primary trademarks: “iFuse Implant System,” “SI-BONE,” and the SI-BONE logo. As of June 30, 2018, we have sought protection for at least two 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 United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. There can be no assurance that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents but which 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 unknown to us, which applications may later result in issued patents that our existing or future products or proprietary technologies may be alleged and/or found to infringe.

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

## **Regulation**

### ***Domestic Regulation of Our Products and Business***

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the 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, development, and manufacture;
- product safety, testing, labeling, and storage;
- record keeping procedures;
- product marketing, sales, distribution and export; 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;
- 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.

We have registered our facility with the FDA as a medical device manufacturer. The FDA has broad post-market and regulatory enforcement powers. We and our third-party manufacturers 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 our suppliers.

#### ***FDA Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k), clearance or approval of a 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. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the

device in accordance with the “de novo” process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. All of our currently marketed products are Class II devices, subject to 510(k) clearance.

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, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device’s safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a “letter to file” in which the manufacturer documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

### ***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, or 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, or 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 institutional review board, or IRB, could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high- risk devices, by the ministry of health in the applicable country.

### ***Pervasive and Continuing Regulation***

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

- Product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or 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;

## [Table of Contents](#)

- 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.

The FDA has broad post-market and regulatory enforcement powers. We are subject to 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 EEA our devices are required to comply with the Essential Requirements concerning medical devices. 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, 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.

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

### ***Regulatory Status***

In November 2008, we received 510(k) clearance to market our first generation iFuse implant from the FDA. Since 2008, we have received additional FDA 510(k) clearances for new instruments, additional implant sizes and labeling changes. In the United States, 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. Clinical Studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life. 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 European.

Since July 2013, we have obtained approval for iFuse in regions beyond the United States and the EEA, including Australia, Canada, Hong Kong, Israel, Malaysia, New Zealand, Singapore, and Saudi Arabia. Additional product applications are under review in Mexico, India, South Korea, and Taiwan. We are currently collecting information to determine our regulatory strategy in China and 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 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 reimbursed under Medicare, Medicaid, or other federally funded healthcare programs. Descriptions of some of the laws and regulations that may affect our ability to operate follows.

The federal Anti-Kickback Statute prohibits, among other things, persons from 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, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare 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 Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly, and there is no exception or safe harbor for many common business activities. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs, as well as by any third-party payors, including commercial payors.

The civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim 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 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. *Qui tam* actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Most private citizen actions are declined by the Department of Justice or

## [Table of Contents](#)

dismissed by federal courts. However, the investigation costs for a company can be significant and material even if the allegations are without merit. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government.

False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of \$11,181 to \$22,363 per claim (adjusted annually for inflation). Because of the potential for large monetary exposure, healthcare companies often resolve allegations without admissions of liability for significant and sometimes material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Moreover, to avoid the risk of exclusion from federal healthcare programs as a result of a False Claims Act settlement, companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance.

In addition, HIPAA created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement 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, 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 CMS information related to payments or other "transfers of value" made to physicians 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.

Certain states also mandate implementation of corporate compliance programs, impose restrictions on device manufacturer marketing practices, and/or require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities.

The FCPA and similar anti-bribery laws in other countries, such as the 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 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 HIPAA, as amended by HITECH, in the United States.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we could be required to report the improper use or disclosure to the U.S. Department of Health and Human Services, or HHS, which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to \$55,910 per violation, not to exceed \$1.68 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.

## [Table of Contents](#)

In addition, even when HIPAA does not apply, according to the 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. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In the European Union, we may be 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 and certain individuals who may be affiliated with our customers, including physician users of our products. 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 national laws implementing each of them. 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 new EU-wide GDPR became applicable on May 25, 2018, replacing the data protection laws previously issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU Member State, resulting 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 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 EUR 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.

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 that they have sufficient technical and organizational security measures in place. 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 instruments and implants. The majority of our instruments have secondary manufacturing suppliers and we continually work with additional manufacturers to establish secondary suppliers. Our iFuse implants are currently provided by a single source, Orchid Bio-Coat, a division of Orchid Orthopedic Solutions LLC. In April 2016, we entered into a Quality and Manufacturing Agreement with Orchid MPS Holdings, LLC, or Orchid, which agreement was amended in March 2017, pursuant to which Orchid manufactures certain of our implants in accordance with our specifications. We purchase product under the agreement pursuant to purchase orders we are required to deliver against a blanket purchase order we provide

## [Table of Contents](#)

based on our product forecast. However, while we are required to purchase the amounts forecast in the blanket purchase order, we are not required to purchase product in excess of a specified amount of inventory based on our original forecast. During the first year of the agreement, the prices we pay for products are fixed under the agreement; provided that on an annual basis thereafter we will 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 timelines shorter than agreed upon order timelines. The initial term of the agreement is three years; provided, however, the agreement may be terminated immediately by (a)(i) either party as the result of the other party's bankruptcy or insolvency, (ii) in the case of Orchid, our failure to make payments for products purchased under the agreement if such failure continues for a specified period after notice from Orchid, or (iii) either party as the result of a material breach of the agreement and such breaching party fails to cure such breach within a specified period after notice from the non-breaching party, (b) us in the event Orchid fails to remedy any deficiencies we may identify pursuant to our right to inspect Orchid's facilities under the agreement, and (c) either party with prior written notice as provided under the agreement. To mitigate supply risk, we carry a minimum of two months of reserve stock based on current sales estimates and typically place implant orders with Orchid prior to estimated demand.

We have also added a second source supplier for machine parts. On February 1, 2017, we entered into a non-exclusive Manufacturing, Quality and Supply Agreement with rms Company, or RMS, pursuant to which 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. We amended this agreement on July 7, 2017 to provide for our purchase of product pursuant to purchase orders we must deliver against a blanket purchase order we provide based on our product forecast. While we are required to purchase the amounts forecast in the blanket purchase order, we are not required to purchase product in excess of a specified amount of inventory based on our original forecast. During 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 in the event of a material breach of the agreement by the other party or by the insolvency of the other party. We may terminate the agreement at any time in the event (i) RMS fails to ship conforming product and such failure results in delays as specified in the agreement, (ii) RMS changes its manufacturing site without our prior approval, (iii) of a change of control of RMS, or (iv) RMS breaches a non-solicit covenant with respect to our employees or consultants. With respect to our first generation iFuse implant, the parts manufactured by RMS need to be coated by Orchid to finish the goods. RMS is currently our only supplier of iFuse-3D implants.

Aside from quality agreements, we do not currently have manufacturing agreements with any of our other manufacturers and orders are 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 worldwide are subject to regulation and periodic planned and unannounced inspection by the FDA and other domestic and international regulatory agencies.

In the United States, products we sell are required to be manufactured in compliance with the FDA's QSR, 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. We have obtained the following international certifications: Quality Management System ISO13485, Full Quality Assurance Certification for the design and manufacture of iFuse, and a Design Examination certificate for iFuse.

## [Table of Contents](#)

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.

### **Legal Proceedings**

We are, and from time to time may be, party to litigation and subject to claims incident to the ordinary course of business. As our growth continues, we may become party to an increasing number of litigation matters and claims. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect our future results of operations, cash flow or financial position. We are not presently party to any legal proceedings that in the opinion of management, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition, or cash flow.

### **Employees**

As of June 30, 2018, we had 168 employees, including sales and marketing, product development, general administrative and accounting, both domestically and internationally. As of June 30, 2018, we had a direct field sales organization of 72 in the United States and 28 in Europe. In the United States, we sell primarily through our direct field organization, and we have a small number of third-party distributors. None of our employees is subject to a collective bargaining agreement, and we consider our relationship with our employees to be good.

### **Company History**

SI-BONE was founded in 2008 by the main inventor of iFuse and member of our board of directors, 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. He also invented the INBONE total ankle replacement system, which was sold to Wright Medical Technology, Inc. in 2008.

**Facilities**

Our leased headquarters in Santa Clara, California, is comprised of 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.

## MANAGEMENT

### Executive Officers, Key Employees, and Directors

The following table sets forth information regarding our executive officers, key employees, and directors, as of September 30, 2018:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b>Executive Officers</b>		
Jeffrey W. Dunn	64	President, Chief Executive Officer and Chairman
Laura A. Francis	51	Chief Financial Officer
Michael A. Pisetsky	40	General Counsel and Chief Compliance Officer
W. Carlton Reckling, M.D.	56	Chief Medical Officer and Vice President, Medical Affairs
Anthony J. Recupero	60	Chief Commercial Officer
Scott A. Yerby, Ph.D.	50	Chief Technology Officer
<b>Key Employees</b>		
Daniel J. Cher, M.D.	54	Vice President, Clinical Affairs
Roxanne J. Dubois	53	Vice President, Regulatory
Nikolas F. Kerr	47	Vice President, Product Marketing
Andrea Mercanti	55	Vice President, EMEA Operations
Joseph W. Powers	59	Vice President, Marketing
<b>Non-Employee Directors</b>		
David P. Bonita, M.D.(2)	43	Director
Timothy E. Davis, Jr.(1)(2)	48	Director
John G. Freund, M.D.(3)	64	Director
Gregory K. Hinckley(1)	71	Director
Karen A. Licitra(2)	59	Director
Timothy B. Petersen(1)	54	Director
Mark A. Reiley, M.D.	68	Director
Keith C. Valentine(3)	51	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

### Executive Officers

**Jeffrey W. Dunn** has served as our President and Chief Executive Officer and as the Chairman of our board of directors since our inception in April 2008. Prior to joining us, Mr. Dunn served as Chief Executive Officer of INBONE Technologies, Inc., an ankle replacement and small bone fusion medical device company, from December 2006 to April 2008, until its sale to Wright Medical Technology, Inc. in April 2008. From August 2000 to June 2006, Mr. Dunn was the Chief Executive Officer of Active Decisions, Inc., a software as a service business, until its sale to Knova Software, Inc. From December 1999 to June 2000, Mr. Dunn was the Chief Executive Officer of Velogic, Inc., an internet performance testing software company, until its sale to Keynote Systems Inc. From June 1999 to December 1999, Mr. Dunn was the Chief Executive Officer of EnterpriseLink

Inc., a provider of enterprise Internet enablement software, until its sale to Merant, Inc. From November 1994 to June 1998, Mr. Dunn was Chief Executive Officer of AccelGraphics Inc., a 3D graphics system supplier, until its sale to Evans and Sutherland Computer Corporation. As well, during his career, Mr. Dunn held executive positions with Evans and Sutherland, Cygnet Systems, Inc., Avnet, Inc. and Xerox Corporation. Mr. Dunn received a B.A. from Colgate University and an M.B.A. from Babson College. We believe Mr. Dunn's experience in the industry, his role as our President and Chief Executive Officer, and his knowledge of our company enable him to make valuable contributions to our board of directors.

**Laura A. Francis** has served as our Chief Financial Officer since May 2015. Prior to joining us, Ms. Francis was the Chief Financial Officer for Auxogyn, Inc., a women's health company, from December 2012 to September 2014. From September 2004 to December 2012, Ms. Francis served as Vice President of Finance, Chief Financial Officer and Treasurer for Promega Corporation, a life science reagent company. From March 2002 to September 2004, Ms. Francis served as the Chief Financial Officer of Bruker BioSciences Corporation, a public life science instrumentation company. From May 2001 to March 2002, Ms. Francis served as Chief Operating Officer and Chief Financial Officer of Nutra-Park Inc., an agricultural biotechnology company. From April 1999 to May 2001, Ms. Francis was Chief Financial Officer of Hypercosm, Inc., a software company. From October 1995 to April 1999, Ms. Francis was an engagement manager with McKinsey & Company, a consulting firm. Early in her career, Ms. Francis was an audit manager with Coopers & Lybrand, an accounting firm. Ms. Francis received a B.B.A. from the University of Wisconsin and an M.B.A. from Stanford University. She is a Certified Public Accountant (inactive) in the State of California.

**Michael A. Pisetsky** has served as our General Counsel and Chief Compliance Officer since August 2016. Mr. Pisetsky joined us in March 2015 as our Director of Legal. From August 2011 to March 2015, Mr. Pisetsky practiced law privately, serving as General Counsel to New Wave Surgical Corp. and Mark Properties, Inc. a large operator of shopping centers in the Southeast, among a number of other companies in the medical technology and healthcare services space. From August 2008 to July 2011, Mr. Pisetsky was an Associate in the Business Department at Cooley LLP in Palo Alto, representing a portfolio of medical technology, biotech, healthcare services and general technology clients, from inception to public offering and eventual sale. Mr. Pisetsky received his B.A. with Honors from Harvard College. Mr. Pisetsky received his J.D. (magna cum laude) and M.B.A., including a certificate in Health Sector Management, concurrently from Duke University.

**W. Carlton Reckling, M.D.** has served as our Vice President, Medical Affairs since April 2012 and our Chief Medical Officer since February 2017. From July 1994 to April 2012, Dr. Reckling was a spine surgeon at the Spine Center in Loveland, Colorado, Rocky Mountain Orthopedic Specialists in Cheyenne, Wyoming, the Center for Spine & Orthopedic Surgery in Cheyenne, Wyoming, Associates in Orthopedic Surgery in Cheyenne, Wyoming, and Ramsey Hospital and Clinics in St. Paul, Minnesota. Dr. Reckling received a B.S. in Chemical Engineering from Northwestern University, an M.D. from Creighton University, and an M.B.A. from the University of Wyoming. He completed his internship and his residency in orthopedic surgery at the University of Minnesota. While in the Minnesota program, he spent time at the Twin Cities Scoliosis Center. He completed his fellowship in spine surgery at Queen's University Medical Centre in Nottingham, England. Dr. Reckling also underwent additional training in general surgery at the University of Minnesota Hospitals and Clinics in Minneapolis, Minnesota. Dr. Reckling is a board-certified orthopedic spine surgeon.

**Anthony J. Recupero** has served as our Chief Commercial Officer since July 2016. Prior to joining us, Mr. Recupero was the President of Catalyst Performance Advisors, LLC, where he advised leading medical device companies on commercial strategy from June 2013 to July 2016. In July 2008, Mr. Recupero joined Baxano, Inc., a medical device company with minimally invasive products to treat degenerative conditions of the spine affecting the lumbar region, initially as Vice President of Sales and Marketing and was promoted in February 2009 to President and Chief Executive Officer until its acquisition by TranS1 in June 2013. From January 2005 to July 2008, Mr. Recupero was President of Recupero Consulting Group, LLC, where he advised leading medical device companies on commercial strategy. From October 1999 to December 2004, Mr. Recupero was the Vice President of Sales for Kyphon. Early in his career, Mr. Recupero progressed to senior sales



management roles at United States Surgical Corporation and Sulzer Spine-Tech, Inc. Mr. Recupero received a B.A. in Communications from State University of New York at Albany.

**Scott A. Yerby, Ph.D.** has served as our Chief Technology Officer since January 2011. Prior to joining us, Dr. Yerby served as Vice President, Research and Development for ProMed, Inc., a medical supply company, from June 2009 to January 2011. From May 2007 to June 2009, Dr. Yerby sat on the board of several non-profit organizations. From June 2000 to May 2007, Dr. Yerby served as Vice President of Research and Development for St. Francis Medical Technologies, Inc., a spinal manufacturing company, until its acquisition by Kyphon, Inc. From June 1997 to June 2000, Dr. Yerby served as Director of Experimental Biomechanics at the Palo Alto VA Hospital. Early in his career, Dr. Yerby held appointments as Consulting Assistant Professor at Stanford University in the Department of Mechanical Engineering, Division of Biomechanical Engineering, and the Department of Functional Restoration, Division of Orthopedic Surgery. Dr. Yerby received B.S. and M.S. degrees in Mechanical Engineering and a Ph.D. in Biomedical Engineering, all from the University of California, Davis.

#### **Key Employees**

**Daniel J. Cher, M.D.** has served as our Vice President, Clinical Affairs since January 2012. From May 2008 to December 2011, Dr. Cher served as Vice President of Clinical and Regulatory Affairs at Chestnut Medical Technologies, Inc., a company developing new minimally invasive therapies for interventional neuroradiology. From March 2007 to January 2008, Dr. Cher served as Vice President of Clinical and Regulatory Affairs at Pulmonx Inc., a medical device company developing products for patients with emphysema. From October 2004 to March 2007, Dr. Cher was Medical Director and Vice President of Clinical Research at Kyphon. From October 2003 to September 2004, Dr. Cher was Medical Director for Cardima, Inc., a medical device company developing products for cardiac ablation. Prior to Cardima, Dr. Cher was a statistician at Conceptus Inc., a manufacturer and developer of medical devices aimed at permanent female sterilization. During the last 17 years, Dr. Cher has provided clinical and regulatory strategic consulting services to medical device companies in the San Francisco Bay Area and beyond. Dr. Cher received a B.S. in Biology from Stanford University and an M.D. from Yale University. Dr. Cher completed his residency in internal medicine at the University of Wisconsin, Madison, and at California Pacific Medical Center in San Francisco. He completed additional training in general internal medicine and research methods at Stanford University and the Palo Alto VA Hospital.

**Roxanne J. Dubois** has served as our Vice President, Regulatory since February 2014. Previously, Ms. Dubois served as our Senior Director, Regulatory from December 2012 to February 2014 and as a consultant for us from February 2012 to December 2012. From February 2009 to February 2014, Ms. Dubois was Vice President, Regulatory as an employee and consultant with Tenaxis Medical Inc., a medical device company. From January 2006 to December 2008, Ms. Dubois served as Vice President, Regulatory and Quality at Carbylan BioSurgery, Inc., a medical device company. From February 2005 to January 2006, Ms. Dubois served as Director, Regulatory at Kyphon. Previously, Ms. Dubois held various regulatory roles at Angiotech BioMaterials Corporation, ReGen Biologic, Inc., and Collagen Corporation. Ms. Dubois received a B.S. in Biochemistry from California Polytechnic State University, San Luis Obispo.

**Nikolas F. Kerr** has served as our Vice President, Product Marketing since August 2016. Prior to joining us, Mr. Kerr was President of Kerr Consulting Group where he advised leading medical device companies on product strategy. Previously, Mr. Kerr was Senior Director of Marketing for Benvenue Medical from December 2013 to June 2014. From August 2011 to December 2013, Mr. Kerr was Senior Director of Marketing for Baxano. From August 2006 to August 2011, Mr. Kerr served in various marketing roles at Medtronic's Spinal & Biologics Group including the Director of Global Marketing for the Kyphon division. And from August 1998 to August 2006, Mr. Kerr served in various sales, marketing, and business development roles for Milliken & Company. Mr. Kerr started his career with Credit Suisse as an Analyst for Debt Capital Markets. Mr. Kerr received a B.S. in Finance and Economics and Master of International Business Economics from the Darla Moore School of Business, University of South Carolina.

**Andrea Mercanti** has served as our Vice President, EMEA Operations since May 2013, and he previously served as our Vice President, European Operations from September 2010 to April 2013. Prior to joining us, Mr. Mercanti was General Director for Italy of MBA Incorporated, an orthopedic, spine and biomaterials distributor, from April 2009 to August 2010. From January 2008 to March 2009, Mr. Mercanti was Vice President, Sales Europe for Europe for Orthofix International N.V., a spinal care solutions company. From December 2006 to December 2007, Mr. Mercanti was Business Unit Director for Italy, Regional Director South Europe, and Director of South Europe and German speaking countries at Kyphon. From December 2005 to November 2006, he served as Regional Director for South Europe for Kyphon. From January 1987 to December 2004, Mr. Mercanti held positions in strategic sales in different divisions of Medtronic, including 12 years in the Neurological Business Unit with spinal cord stimulation treatment for pain and, in the last four years, as Director of Spine Business. Mr. Mercanti received a degree in economics from the Technical and Economics School at the Instituto Milano in Milan, Italy.

**Joseph W. Powers** has served as our Vice President, Marketing since August 2012. Previously, Mr. Powers served as our Senior Director, Business Development from January 2012 to July 2012 and as our Western Area Sales Director from December 2009 to December 2011. Prior to joining us, Mr. Powers served as Vice President, Clinical/Marketing at Benvenue Medical, Inc., a medical device company that makes minimally invasive systems for spine repair, from March 2007 to April 2009. From January 2004 to March 2007, Mr. Powers served as a Spine Consultant at Kyphon, and from December 2002 to December 2004, Mr. Powers served as Director, Product Marketing at Kyphon. Previously, Mr. Powers held positions in marketing management and project management at Target Therapeutics Inc., a medical device company. Mr. Powers received a B.S. in Biology and Chemical Engineering from Arizona State University.

#### **Non-Employee Directors**

**David P. Bonita, M.D.** has served as a member of our board of directors since April 2014. Since June 2013, Dr. Bonita has also served as a Private Equity Partner at OrbiMed Advisors LLC, an investment company focused on the healthcare industry. From June 2004 to June 2013, Dr. Bonita held various positions at OrbiMed. Prior to OrbiMed, Dr. Bonita was a corporate finance analyst in the healthcare investment banking group of Morgan Stanley from February 1998 to July 1999. From August 1997 to February 1998, Dr. Bonita served as a corporate finance analyst in the healthcare investment banking group of UBS AG, a global financial service firm. Dr. Bonita has served and continues to serve on the board of directors of numerous private and public companies, including Clementia Pharmaceuticals, Inc., a drug developer focusing on bone disorders and other diseases, from June 2013 to present; Tricida, Inc., a drug developer focusing on kidney disease, from January 2014 to present; Loxo Oncology, Inc., a developer of oncological drugs, from October 2013 to December 2017; ViewRay Inc., a designer and manufacturer of radiation therapy and imaging technologies, from January 2008 to June 2018; and Ambit Biosciences Corporation, a drug developer focusing on oncology, autoimmune, and inflammatory diseases from October 2012 to November 2014. Dr. Bonita received a B.A. in Biological Sciences from Harvard University and a joint M.D./M.B.A. from Columbia University. We believe Dr. Bonita's extensive investment experience in the healthcare industry and his experience as a public company director enable him to make valuable contributions to our board of directors.

**Timothy E. Davis, Jr.** has served as a member of our board of directors since our inception in April 2008. Mr. Davis has served as President and Chief Executive Officer of Active Implants, LLC, a company that provides orthopedic implant solutions, since February 2017. From January 2014 through September 2015, Mr. Davis served as Chief Executive Officer of MicroPort Orthopedics, Inc., a multinational producer of orthopedic products, following the purchase of Wright Medical Group's OrthoRecon Business in January 2014. From December 2006 to January 2014, Mr. Davis served in a number of executive positions for Wright Medical Technology, Inc., a subsidiary of Wright Medical Group, Inc., including President of the OrthoRecon business. From 2004 to 2006, Mr. Davis was a Partner with MB Venture Partners, LLC, a medical technology and life sciences venture capital firm. From 1997 to 2004, Mr. Davis held various positions, ultimately serving as Vice President, with Vector Fund Management, a healthcare and life sciences focused venture capital fund. Early in

his career, Mr. Davis worked in the healthcare management consulting and pharmaceutical industries. Mr. Davis received a B.E. degree in Biomedical Engineering from Vanderbilt University and an M.B.A. from the J.L. Kellogg Graduate School of Management at Northwestern University. We believe Mr. Davis' experience in the industry and his knowledge of our company enable him to make valuable contributions to our board of directors.

**John G. Freund, M.D.** has served as a member of our board of directors since January 2013. Dr. Freund founded Skyline Ventures, a venture capital firm, in October 1997 and has served as a Managing Director of Skyline since then. Prior to joining Skyline, Dr. Freund served as Managing Director in the private equity group of Chancellor Capital Management, a private capital investment firm. In November 1995, Dr. Freund co-founded Intuitive Surgical, Inc., a medical device company, and served on its board of directors until March 2000. From 1988 to 1994, he held various positions at Acuson Corporation, a maker of ultrasound equipment that is now part of Siemens, most recently as Executive Vice President. Prior to joining Acuson, Dr. Freund was a general partner of Morgan Stanley Venture Partners from 1987 to 1988. From 1982 to 1988, Dr. Freund was at Morgan Stanley & Co., an investment banking company, where he co-founded the Healthcare Group in the Corporate Finance Department in 1983. Dr. Freund has served on the board of directors of Collegium Pharmaceuticals, Inc., a biotechnology company, since 2014, Tetrphase Pharmaceuticals, Inc. since 2012, and Proteon Therapeutics, Inc., a biotechnology company, since 2014, and Sutro Biopharma, Inc., a biotechnology company, since 2014. Dr. Freund also serves on the board of directors of six U.S. registered investment funds managed by affiliates of the Capital Group, Inc. He also previously served on the board of directors of four publicly traded companies, Map Pharmaceuticals, Inc., a biopharmaceutical company, MAKO Surgical Corp., a medical device company, Concert Pharmaceuticals, Inc., a biopharmaceutical company and was Chairman of XenoPort, Inc., a biopharmaceutical company. Dr. Freund is a member of the Advisory Board for the Harvard Business School Healthcare Initiative. Dr. Freund received a B.A. in History from Harvard College, an M.D. from Harvard Medical School, and an M.B.A. from Harvard Business School, where he was a Baker Scholar. We believe Dr. Freund's experience with medical device companies, his role in the venture capital industry, and his knowledge of our company enable him to make valuable contributions to our board of directors.

**Gregory K. Hinckley** has served as a member of our board of directors since January 2011. Mr. Hinckley served as President of Mentor Graphics Corporation, an electronic design automation company, from January 1999 until his retirement in July 2017, and served on the board of directors from January 1999 to June 2016. From January 1997 to January 1999, he served as Executive Vice President. He has also served as the Chief Financial Officer of Mentor Graphics, first from January 1997 to July 2007 and again from December 2008 to July 2017. Previously, he served on the board of directors of Super Micro Computer, Inc., a manufacturer of servers, from January 2009 to February 2015 and Intermec, Inc., a developer of automated identification and data collection solutions, from July 2004 to September 2013. From August 1992 to January 1997, Mr. Hinckley served as Senior Vice President, Finance of VLSI Technology, Inc., a designer and manufacturer of custom and semi-custom integrated circuits. From January 1989 to November 1991, he served as Senior Vice President and Chief Financial Officer of Crowley Maritime Corporation, a marine solutions, transportation, and logistics company. From February 1983 to January 1989, Mr. Hinckley served as Vice President and Chief Financial Officer, and since April 2017, Mr. Hinckley has served on the board of directors of Bio-Rad Laboratories, a manufacturer and supplier of products and systems for the life science research and healthcare markets. Previously, Mr. Hinckley held a number of senior officer positions with Raychem Corporation, a developer of products and services for the aerospace, automotive and telecommunications industries. Hinckley received a B.A. in Physics from Claremont McKenna College and was a Fulbright Scholar in applied mathematics at Nottingham University. He received an M.S. in Applied Physics from the University of California, San Diego and an M.B.A. from Harvard Business School. We believe Mr. Hinckley's financial experience, his familiarity of serving on the boards of public companies, and his knowledge of our company enable him to make valuable contributions to our board of directors.

**Karen A. Licitra** has served as a member of our board of directors since August 2015. From January 2014 through August 2015, Ms. Licitra served as Corporate Vice President, Worldwide Government Affairs & Policy at Johnson & Johnson, a medical devices, pharmaceutical, and consumer packaged goods manufacturer. From

December 2011 to December 2013, Ms. Licitra served as the Worldwide Chairman, Global Medical Solutions at Johnson & Johnson. From July 2002 to November 2011, she served as the Company Group Chairman and Worldwide Franchise Chairman at Ethicon Endo-Surgery, Inc., a Johnson & Johnson medical device company. From January 2001 to June 2002, she served as the President of Ethicon Endo-Surgery. Ms. Licitra currently serves on the board of directors of Novadaq Technologies Inc., a provider of proven comprehensive fluorescence imaging solutions. Ms. Licitra received a B.S. in Commerce from Rider College. We believe Ms. Licitra's experience working for medical device companies and her knowledge of our company enable her to make valuable contributions to our board of directors.

**Timothy B. Petersen** has served as a member of our board of directors since June 2016. Since April 2002, Mr. Petersen has been employed by Arboretum Ventures, Inc. As a Managing Director of the firm, his investments primarily target capital-efficient medical device, health IT and services companies. Mr. Petersen has led investments and held board seats for Arboretum in more than fifteen companies, including HealthMedia (acquired by Johnson & Johnson), Accuri Cytometers Inc. (acquired by Becton Dickinson), IntelliCyt Corporation (acquired by Sartorius AG) and Inogen. Mr. Petersen currently serves on the boards of several private companies in addition to our Company. Mr. Petersen holds a B.A. in Economics from Williams College, an M.S. in Economics from the University of Wisconsin-Madison, and an M.B.A. from the Ross School of Business at the University of Michigan. We believe Mr. Petersen's extensive investment experience in the healthcare industry and his experience as a public company director enable him to make valuable contributions to our board of directors.

**Mark A. Reiley, M.D.** has served as a member of our board of directors since our inception in April 2008 and as our Chief Medical Officer from inception to September 2016. Dr. Reiley has also served as Chief Medical Officer of Reiley Pharmaceuticals, Inc., a pharmaceutical company, since April 2014. Previously, Dr. Reiley was Chief Medical officer of Fixes-4-Kids, Inc. from March 2009 to October 2010. Prior to joining us, Dr. Reiley was the Chief Medical Officer of INBONE Technologies from December 2004 to April 2008, until its sale to Wright Medical Technology, Inc. in April 2008. From October 1990 to May 2007, Dr. Reiley was Chief Medical Officer of Kyphon Inc., a medical device company focused on the treatment of vertebral compression fractures of the spine, until its sale to Medtronic, Inc. (now Medtronic plc). During that period, from October 2001 to March 2005, Dr. Reiley was Chief Medical officer of Archus Orthopedics Inc., a total facet replacement medical device company. Dr. Reiley was also a founding member of Berkeley Orthopedics Surgical group, where he practiced for over 25 years and trained the students and faculty at the University of California at Berkeley. He has founded and served on the boards of various private companies. Dr. Reiley received a B.A. from Claremont Men's College and an M.D. from George Washington University School of Medicine, and he completed both his orthopedic residency and fellowship at the University of California at San Francisco. We believe Dr. Reiley's experience in the industry, his role as our former Chief Medical Officer, and his knowledge of our company enable him to make valuable contributions to our board of directors.

**Keith C. Valentine** has served as a member of our board of directors since August 2015. Since June 2015, Mr. Valentine has also served as President, Chief Executive Officer and a member of the board of directors of SeaSpine Holdings Corporation. From January 2007 to January 2015, he served as President and Chief Operating Officer of NuVasive, Inc., a medical device company. From December 2004 to January 2007, he served as President of NuVasive. From January 2001 to December 2004, he held various senior executive roles in marketing, development and operations at NuVasive. Previously, Mr. Valentine served as Vice President of Marketing at ORATEC Interventions, Inc., a medical device company acquired by Smith & Nephew PLC, and spent eight years in various roles with Medtronic including Vice President of Marketing for the Thoracolumbar Division and Group Director for the BMP Biologics program, Interbody Sales Development, and International Sales and Marketing. Mr. Valentine received a B.B.A. in Management and Biomedical Sciences from Western Michigan University. We believe Mr. Valentine's experience working for medical device companies and his knowledge of our company enable him to make valuable contributions to our board of directors.

### **Family Relationships**

There are no family relationships among any of our directors or executive officers.

### **Director Independence**

Our common stock has been approved for listing on the Nasdaq Global Market. The listing rules of this stock exchange generally require that a majority of the members of a listed company's board of directors be independent within 12 months following the closing of an initial public offering. Our board of directors has determined that Dr. Bonita, Mr. Davis, Dr. Freund, Mr. Hinckley, Ms. Licitra, Mr. Petersen, and Mr. Valentine do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the Nasdaq Global Market. Mr. Dunn is not independent given his position as our President and Chief Executive Officer, and Dr. Reiley is not independent given his status as the Chief Medical Officer of Reiley Pharmaceuticals, Inc., where Mr. Dunn is a member of the board of directors. Accordingly, a majority of our directors are independent, as required under applicable Nasdaq listing rules. The independent members of our board of directors will hold separate regularly scheduled executive session meetings at which only independent directors are present.

Audit committee members must also satisfy the independence rules in Securities and Exchange Commission, or SEC, Rule 10A-3 adopted under the Securities Exchange Act of 1934, as amended. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a public company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or be an affiliated person of the listed company or any of its subsidiaries. Each of Messrs. Davis, Hinckley and Petersen qualify as an independent director pursuant to Rule 10A-3. We also intend to satisfy the audit committee independence requirement of the Nasdaq Global Market.

### **Board Composition**

Our board of directors currently consists of nine members, who were elected pursuant to the provision of a voting agreement and the related provisions of our amended and restated certificate of incorporation. Under the terms of this voting agreement, the stockholders who are party to the voting agreement have agreed to vote their respective shares to elect: (1) two directors designated by the holders of a majority of the then outstanding shares of Series 2 common, one of which will be our chief executive officer, currently Mr. Dunn and Dr. Reiley; (2) one director designated by Skyline Venture Partners Qualified Purchaser Fund V, L.P., currently Dr. Freund; (3) one director designated by Montreux Equity Partners IV, LP which is currently vacant; (4) four directors approved by a majority of the members of our board of directors and at least one of whom has relevant industry experience relating to our business, currently Mr. Hinckley, Mr. Davis, Ms. Licitra, and Mr. Valentine; (5) one director designated by OrbiMed Advisors LLC or OrbiMed Private Investments V, LP, currently Dr. Bonita; and (6) one director designated by Arboretum IV, LP, currently Mr. Petersen.

The provisions of this voting agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or appointed, or the earlier of their death, resignation, or removal.

Immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Dr. Bonita, Mr. Davis, and Dr. Reiley their term will expire at the annual meeting of stockholders to be held in 2019;

## Table of Contents

- the Class II directors will be Mr. Dunn, Dr. Freund, and Mr. Hinckley their terms will expire at the annual meeting of stockholders to be held in 2020; and
- the Class III directors will be Mr. Petersen, Ms. Licitra, and Mr. Valentine their terms will expire at the annual meeting of stockholders to be held in 2021.

Directors in a particular class will be elected for three-year terms at the annual meeting of stockholders in the year in which their terms expire. As a result, 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. Each director's term continues until the election and qualification of his or her successor, or the earlier of his or her death, resignation, or removal.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering provide that only our board of directors can fill vacant directorships, including newly-created seats. Any additional directorships resulting from an increase in the authorized number of directors would be distributed among the three classes so that, as nearly as possible, each class would consist of one-third of the authorized number of directors.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See "Description of Capital Stock—Anti-Takeover Provisions—Certificate of Incorporation and Bylaws Provisions."

### **Board Oversight of Risk**

One of the key functions of our board of directors is informed oversight of our risk management process. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its oversight function directly as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. For example, our audit committee is responsible for overseeing the management of risks associated with our financial reporting, accounting and auditing matters; our compensation committee oversees the management of risks associated with our compensation policies and programs; and our nominating and corporate governance committee oversees the management of risks associated with director independence, conflicts of interest, composition and organization of our board of directors, director succession planning, and oversight of healthcare, regulatory, and fraud and abuse compliance.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. Our board of directors and its committees set schedules for meeting throughout the year and can also hold special meetings and act by written consent from time to time, as appropriate. Our board of directors has delegated various responsibilities and authority to its committees as generally described below. The committees will regularly report on their activities and actions to the full board of directors. Each member of each committee of our board of directors qualifies as an independent director in accordance with the listing standards of the Nasdaq Global Market. Each committee of our board of directors has a written charter approved by our board of directors. Upon the closing of this offering, copies of each charter will be posted on our website at [www.si-bone.com](http://www.si-bone.com) under the Investor Relations section. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

### ***Audit Committee***

Our audit committee consists of Messrs. Davis, Hinckley, and Petersen, each of whom satisfies the independence requirements under the Nasdaq Global Market listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chairman of our audit committee is Mr. Hinckley. Our board of directors has determined that each of Messrs. Davis, Hinckley, and Petersen is an “audit committee financial expert” within the meaning of SEC regulations. Our board of directors has also determined that each member of our audit committee has the requisite financial expertise required under the applicable requirements of the Nasdaq Global Market. In arriving at this determination, the board of directors has examined each audit committee member’s scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our accounting, financial, and other reporting and internal control practices and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit service to be performed by the independent registered public accounting firm.

### ***Compensation Committee***

Our compensation committee consists of Dr. Bonita, Mr. Davis, and Ms. Licitra, each of whom our board of directors has determined to be independent under the Nasdaq Global Market listing standards and the rules and regulations of the SEC, a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. The chairman of our compensation committee is Mr. Davis.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors to oversee our compensation policies, plans, and programs and to review and determine the compensation to be paid to our executive officers, directors, and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;



## [Table of Contents](#)

- administering our stock and equity incentive plans;
- selecting independent compensation consultants and assessing whether there are any conflicts of interest with any of the committee's compensation advisors;
- reviewing and approving, or recommending that our board of directors approve, incentive compensation and equity plans, severance agreements, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management, as appropriate;
- reviewing and establishing general policies relating to compensation and benefits of our employees; and
- reviewing our overall compensation philosophy.

### ***Nominating and Corporate Governance Committee***

Our nominating and corporate governance committee consists of Dr. Freund and Mr. Valentine, each of whom our board of directors has determined to be independent under the Nasdaq Global Market listing standards. The chairman of our nominating and corporate governance committee is Mr. Valentine.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying, evaluating, and selecting, or recommending that our board of directors approve, nominees for election to our board of directors;
- evaluating the performance of our board of directors and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- reviewing management succession plans;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters, and
- overseeing administration of our healthcare compliance program.

### **Code of Conduct**

Our board of directors has adopted a code of conduct. The code of conduct applies to all of our employees, officers, directors, contractors, consultants, suppliers, and agents. Upon the closing of this offering, the full text of our code of conduct will be posted on our website at [www.si-bone.com](http://www.si-bone.com) under the Investor Relations section. We intend to disclose future amendments to, or waivers of, our code of conduct, as and to the extent required by SEC regulations, at the same location on our website identified above and in public filings. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

### **Compensation Committee Interlocks and Insider Participation**

As noted above, the compensation committee of our board of directors consists of Dr. Bonita, Mr. Davis, and Ms. Licitra. During 2017, our compensation committee consisted of Dr. Bonita, Mr. Davis, and Ms. Licitra. None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. Mr. Dunn serves as a member of the board of directors and as a member of the compensation committee of the board of directors of Reiley Pharmaceuticals, Inc., where Dr. Reiley, a member of our board of directors, serves as Chief Medical Officer.



**Non-Employee Director Compensation**

Currently, we pay our non-employee directors who are not representatives of our stockholders a fee of \$2,000 per month as compensation for their service on our board of directors. We also have a policy of reimbursing all of our non-employee directors for their reasonable out-of-pocket expenses in connection with attending board of directors and committee meetings. From time to time we have granted stock options to certain of our non-employee directors.

**2017 Non-Employee Director Compensation Table**

The following table sets forth information regarding the compensation paid to our non-employee directors during 2017.

<b>Name</b>	<b>Fees Earned or Paid in Cash</b>	<b>Option Awards(1)(2)</b>	<b>Total</b>
David P. Bonita, M.D.	\$ —	\$ —	\$ —
Timothy E. Davis, Jr.	24,000	—	24,000
John G. Freund, M.D.	—	—	—
Gregory K. Hinckley	24,000	—	24,000
Karen A. Licitra	24,000	—	24,000
Timothy B. Petersen	—	—	—
Mark A. Reiley, M.D.	—	—	—
Keith C. Valentine	24,000	—	24,000

- (1) In March 2017, we granted options to purchase 22,222 shares to each of our non-employee directors, excluding Dr. Reiley, with an exercise price of \$5.94 per share, vesting in equal monthly installments over three years commencing upon the closing of an initial public offering, subject to the non-employee director’s continued service with us through each relevant vesting date, and are early exercisable upon the closing of an initial public offering. The shares subject to the options will fully vest immediately prior to the effective time of a change in control, subject to the non-employee director’s continued service with us on the effective date of such change in control.
- (2) In accordance with SEC rules, this column does not include the value of option awards granted to the directors in March 2017, as more fully described in footnote (1) above. These option awards are subject to certain liquidity events and time-based vesting components. As of the grant date and June 30, 2018, the liquidity events were considered not “probable” of occurring. As a result, the grant date fair value of each of these option awards, for purposes of this table, is \$0. Assuming that all of the vesting conditions to the option awards were met, the estimated value of each of these option awards as of the grant date would be \$69,154. The table below lists the aggregate number of shares subject to outstanding stock options held by each of our non-employee directors as of December 31, 2017.

<b>Name</b>	<b>Number of Shares Subject to Outstanding Options as of December 31, 2017</b>
David P. Bonita, M.D.	22,222
Timothy E. Davis, Jr.	55,397
John G. Freund, M.D.	22,222
Gregory K. Hinckley	22,222
Karen A. Licitra	43,630
Timothy B. Petersen	22,222
Mark A. Reiley, M.D.	148,059
Keith C. Valentine	43,630

**EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table sets forth information regarding the compensation of our chief executive officer and our two other most highly compensated executive officers during the year ended December 31, 2017. We refer to these individuals as our “named executive officers.”

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u>	<u>Bonus(1)</u>	<u>Option Awards(2)</u>	<u>All Other Compensation(3)</u>	<u>Total</u>
Jeffrey W. Dunn <i>President and Chief Executive Officer</i>	2017	\$437,750	\$249,518	\$ 251,618	\$ 239,889(4)	\$1,178,775
Laura A. Francis <i>Chief Financial Officer</i>	2017	302,315	120,624	77,073	18,458	518,470
Anthony J. Recupero <i>Chief Commercial Officer</i>	2017	315,000	142,924	107,503	18,468	583,895

- (1) Represents payments upon the achievement of 2017 corporate goals as well as individual objectives, which were paid in January 2018. Our corporate goals included revenue growth, cash flow, expense, profitability management, reimbursement progress and clinical milestones.
- (2) Represents the aggregate grant date fair value of option awards granted to the officer in 2017 and the incremental fair value of stock options repriced in December 2017, computed in accordance with FASB ASC Topic 718. For a discussion of the assumptions made in determining the grant date fair value of our equity awards, see Note 10 to our audited consolidated financial statements included elsewhere in this prospectus.
- (3) Amounts reported include medical and life insurance premiums paid by us on behalf of our named executive officers.
- (4) Amount includes \$231,914 of principal and interest forgiven by us in March 2017, in connection with a loan we made to Mr. Dunn in February 2014. The remaining balance of the loan was forgiven by us in January 2018. For a more detailed description of this loan, see “Certain Relationships and Related Party Transactions—Loans.”

**Emerging Growth Company Status**

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including, but not limited to, the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

**Outstanding Equity Awards as of December 31, 2017**

The following table sets forth information regarding each unexercised stock option and all unvested stock held by each of our named executive officers as of December 31, 2017. Unless otherwise indicated below, all of these awards were made pursuant to our 2008 Stock Plan.

All of the options granted to our named executive officers are immediately exercisable with respect to all of the option shares, subject to our repurchase right in the event the officer’s service terminates prior to vesting in

## [Table of Contents](#)

the shares. We refer to option shares that are subject to our right of repurchase as “unvested shares” and those that are no longer subject to our right of repurchase as “vested” shares.

Name	Option Awards					
	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Vested (#)	Number of Securities Underlying Unexercised Options Unvested (#)(1)(2)	Option Exercise Price (\$)	Option Expiration Date
Jeffrey W. Dunn	07/21/14	07/21/14	232,977	39,776	3.42	07/20/24
	05/26/15	04/15/15	67,626	33,814	4.32 <sup>(3)</sup>	05/25/25
	07/26/16	06/02/16	43,088	71,813	4.32	07/25/26
	03/01/17	09/06/17	7,891	118,369	4.68 <sup>(4)</sup>	03/01/27
Laura A. Francis	05/26/15	05/26/15	12,626	—	4.32 <sup>(3)</sup>	05/25/25
	05/26/15	05/26/15	110,394	67,463	4.32 <sup>(3)</sup>	05/25/25
	07/26/16	06/02/16	8,206	13,677	4.32	07/25/26
	03/01/17	09/06/17	2,418	36,257	4.68 <sup>(4)</sup>	03/01/27
Anthony J. Recupero.	07/26/16	07/05/16	44,479	81,111	4.32	07/25/26
	03/01/17	09/06/17	3,372	50,572	4.68 <sup>(4)</sup>	03/01/27

- (1) Shares subject to the option vests in equal monthly installments over four years commencing on the vesting commencement date specified above, subject to the continued service with us through each relevant vesting date.
- (2) The unvested shares subject to these options are subject to accelerated vesting as described in “Equity Acceleration” below.
- (3) This stock option was repriced in July 2016.
- (4) This stock option was repriced in December 2017.

### **Pension Benefits**

Our named executive officers did not participate in, or otherwise, receive any benefits under, any pension or retirement plan sponsored by us in 2017.

### **Nonqualified Deferred Compensation**

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us in 2017.

### **Employment Arrangements**

We have entered into employment agreements with each of our named executive officers setting forth the initial terms of the officer’s employment with us and providing that the officer’s employment will be “at will” and may be terminated at any time. The severance benefits for our named executive officers are described in “Severance and Change in Control Agreement” below.

#### ***Employment Agreements***

##### ***Jeffrey W. Dunn***

In December 2009, we entered into an offer letter with Jeffrey W. Dunn, our President and Chief Executive Officer. Mr. Dunn’s annual base salary as of January 1, 2017 was \$437,750 and Mr. Dunn was eligible for annual variable compensation up to 50% of his base salary. As of April 1, 2018, Mr. Dunn’s annual base salary was increased to \$451,320. Upon the closing of this offering, Mr. Dunn’s annual base salary will be increased to \$540,000 and Mr. Dunn will be eligible for annual variable compensation up to 75% of his base salary.

## [Table of Contents](#)

Under the terms of Mr. Dunn's offer letter, if he is subject to an "involuntary termination," then we will continue to pay his base salary and reimburse his COBRA premiums for up to 12 months. An involuntary termination occurs if Mr. Dunn's employment is terminated by us without "cause" at any time or if he resigns for "good reason" within 12 months after a "change in control" (as such terms are defined in the offer letter). These severance benefits are contingent on Mr. Dunn's return of all of our property, execution of a release of claims, and resignation from our board of directors, if applicable.

In March 2017, Mr. Dunn was granted an option to purchase 126,260 shares of common stock with an exercise price of \$5.94 per share vesting in equal monthly installments over four years commencing upon the closing of an initial public offering, subject to Mr. Dunn's continued service with us through each relevant vesting date. In the event a change in control occurs prior to the closing of an initial public offering, this option will terminate immediately prior to the effective time of the change in control. In December 2017, this option was repriced with an exercise price of \$4.68 per share and the vesting commencement date was set at September 6, 2017.

In August 2018, Mr. Dunn was granted 33,333 restricted stock units, 50% of which will vest on the first day of the first open trading window (as determined under our insider trading policy) that occurs after the one-year anniversary of the closing of an initial public offering, and 50% of which will vest on the first day of the first open trading window (as determined under our insider trading policy) that occurs after the two-year anniversary of the closing of an initial public offering, subject to Mr. Dunn's continued service with us through each relevant vesting date. In the event a change in control occurs prior to the closing of an initial public offering, these RSUs will vest in full immediately prior to the consummation of such change in control, provided that Mr. Dunn agrees to provide service as a full-time employee or consultant for the acquirer or the surviving entity for a period not to exceed 6 months (unless otherwise agreed to by us, Mr. Dunn and the acquirer or surviving entity).

### *Laura A. Francis*

In April 2015, we entered into an offer letter with Laura A. Francis, our Chief Financial Officer. Ms. Francis' annual base salary as of January 1, 2017 was \$302,315 and Ms. Francis was eligible for annual variable compensation up to 35% of her base salary. As of April 1, 2018, Ms. Francis' annual base salary was increased to \$314,106. Upon the closing of this offering, Ms. Francis's annual base salary will be increased to \$350,000 and Ms. Francis will be eligible for annual variable compensation up to 45% of her base salary.

Under the terms of her offer letter, Ms. Francis was granted an option to purchase a number of shares of common stock equal to 1.25% of the fully-diluted capitalization as of her first day of employment, or 190,483 shares, with an exercise price of \$7.92 per share. The shares subject to this option vest as to 25% on the 12-month anniversary of May 26, 2015 and 1/36<sup>th</sup> of the balance of the shares vest each month thereafter, subject to Ms. Francis' continued service with us through each relevant vesting date. Ms. Francis' offer letter provides that she will vest in 50% of the unvested option shares if (a) we are subject to a change in control (as defined in the offer letter) before her service with us terminates and (b) she is subject to an involuntary termination (as defined in the offer letter) within 12 months after the change in control. In addition, in the event of Ms. Francis' termination for any reason other than for cause (as defined in the offer letter) we will make a lump sum payment to her equal to three months of her then-current base salary. These severance benefits are contingent on Ms. Francis' return of all of our property and execution of a release of claims.

In March 2017, we entered into an amended and restated letter agreement with Ms. Francis that provides that she will be eligible to receive a bonus of \$200,000 if we complete a qualified IPO (as defined in the letter agreement) and she remains an employee in good standing through the date that is 30 trading days after such qualified IPO, which will be paid 60 days thereafter.

In March 2017, Ms. Francis was granted an option to purchase 38,675 shares of common stock with an exercise price of \$5.94 per share vesting in equal monthly installments over four years commencing upon the

## Table of Contents

closing of an initial public offering, subject to Ms. Francis' continued service with us through each relevant vesting date. In the event a change in control occurs prior to the closing of an initial public offering, this option will terminate immediately prior to the effective time of the change in control. In December 2017, this option was repriced with an exercise price of \$4.68 per share and the vesting commencement date was set at September 6, 2017.

In August 2018, Ms. Francis was granted 3,703 restricted stock units, 50% of which will vest on the first day of the first open trading window (as determined under our insider trading policy) that occurs after the one-year anniversary of the closing of an initial public offering, and 50% of which will vest on the first day of the first open trading window (as determined under our insider trading policy) that occurs after the two-year anniversary of the closing of an initial public offering, subject to Ms. Francis' continued service with us through each relevant vesting date. In the event (a) a change in control occurs prior to the closing of an initial public offering, and (b) within three months prior to or 12 months following such change of control we terminate Ms. Francis' service with us other than for cause (as defined in Ms. Francis' RSU agreement), or Ms. Francis terminates her service for good reason (as defined in Ms. Francis' RSU agreement), these RSUs will vest in full as of the date of termination of Ms. Francis' service.

### *Anthony J. Recupero*

In June 2016, we entered into an offer letter with Anthony J. Recupero, our Chief Commercial Officer. Mr. Recupero's annual base salary as of January 1, 2017 was \$315,000 and Mr. Recupero was eligible for annual variable compensation up to 40% of his base salary. As of April 1, 2018, Mr. Recupero's annual base salary was increased to \$325,710. Upon the closing of this offering, Mr. Recupero's annual base salary will be increased to \$330,000 and Mr. Recupero will be eligible for annual variable compensation up to 45% of his base salary.

Under the terms of his offer letter, Mr. Recupero was granted an option to purchase a number of shares of common stock equal to 0.7% of the fully-diluted capitalization as of his first day of employment, or 125,590 shares, with an exercise price of \$4.32 per share. The shares subject to this option vest as to 25% on the 12-month anniversary of July 5, 2016 and 1/36<sup>th</sup> of the balance of the shares vest each month thereafter, subject to Mr. Recupero's continued service with us through each relevant vesting date. Mr. Recupero's offer letter provides that in the event we terminate him for any reason other than for cause (as defined in the letter agreement), we will provide him with the following benefits within 60 calendar days of his termination date:

- A lump sum payment equal to three months of his then-current base salary; and
- A lump sum payment in the amount of \$4,000.

Mr. Recupero's offer letter further provides that in the event we terminate him for any reason other than for cause or if he resigns for good reason (as defined in the letter agreement) either three months prior to or 12 months following the consummation of a change in control (as defined in the letter agreement), we will provide him with the following benefits within 60 calendar days of his termination date:

- A lump sum payment equal to six months of his then-current base salary;
- A lump sum payment in the amount of \$8,000;
- Accelerated vesting of any unvested option shares such that 100% of the unvested option shares shall vest as of his termination date; and
- A lump sum equal to his target annual bonus, prorated for partial months of service prior to his termination date.

These severance benefits are contingent on Mr. Recupero returning all of our property, continued adherence to the terms and condition of the proprietary information and inventions agreement between us and Mr. Recupero, resignation from our board of directors, if applicable, and execution and non-revocation of a release of claims.

## [Table of Contents](#)

In March 2017, Mr. Recupero was granted an option to purchase for 53,944 shares of common stock with an exercise price of \$5.94 per share vesting in equal monthly installments over four years commencing upon the closing of an initial public offering, subject to Mr. Recupero's continued service with us through each relevant vesting date. In the event a change in control occurs prior to the closing of an initial public offering, this option will terminate immediately prior to the effective time of the change in control. In December 2017, this option was repriced with an exercise price of \$4.68 per share and the vesting commencement date was set at September 6, 2017.

### ***Severance and Change in Control Agreement***

In March 2016, we entered into a severance letter agreement with Ms. Francis. This agreement provides that in the event we terminate her for any reason other than for cause (as defined in the letter agreement), we will provide her the following benefits within 60 calendar days of her termination date:

- A lump sum payment equal to three months of her then-current base salary; and
- A lump sum payment in the amount of \$5,700.

This agreement further provides that in the event we terminate Ms. Francis for any reason other than for cause or if she resigns for good reason (as defined in the letter agreement) either three months prior to or 12 months following the consummation of a change in control (as defined in the letter agreement), we will provide her the following benefits within 60 calendar days of her termination date:

- A lump sum payment equal to six months of her then-current base salary;
- A lump sum payment in the amount of \$11,300;
- Accelerated vesting of any unvested option shares such that 100% of the unvested option shares shall vest as of her termination date; and
- A lump sum equal to her target annual bonus, prorated for partial months of service prior to her termination date.

These severance benefits are contingent on Ms. Francis returning all of our property, continued adherence to the terms and condition of the proprietary information and inventions agreement between us and Ms. Francis, resigning from our board of directors, if applicable, and executing and not revoking a release of claims. The severance letter agreement for Ms. Francis supersedes the acceleration provisions set forth in her offer letter.

### ***Equity Acceleration***

Mr. Dunn's options to purchase 114,901 shares granted in July 2016 and 126,260 shares granted in March 2017 will fully vest if we are subject to a change in control before Mr. Dunn's service terminates, provided he agrees to provide services to the acquiring company for a period not to exceed six months. Mr. Dunn's option for 101,440 shares granted in May 2015, will vest as to 50% of the option shares if we are subject to a change in control.

In the case of all the options granted to Ms. Francis and Mr. Recupero, the accelerated vesting of any unvested option shares will occur as set forth above in "Employment Agreements" and "Severance and Change in Control Agreement."

### **Equity Plans**

The principal features of our equity plans are summarized below. These summaries are qualified in their entirety by reference to the actual verbiage of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

### **2018 Equity Incentive Plan**

Our board of directors adopted our 2018 Equity Incentive Plan, or the 2018 Plan, in July 2018, and our stockholders subsequently approved the 2018 Plan in October 2018. The 2018 Plan became effective immediately upon the execution of the underwriting agreement related to this offering. As a result, we will not grant any additional awards under our 2008 Stock Plan, which is described below.

Our 2018 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code of 1986, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation to our employees, directors, and consultants. Additionally, our 2018 Plan provides for the grant of performance cash awards to our employees, directors and consultants.

*Share Reserve.* The maximum number of shares of our common stock that may be issued under our 2018 Plan is 2,576,538. The number of shares of our common stock reserved for issuance under our 2018 Plan will automatically increase on January 1 of each year, beginning on January 1, 2019, and continuing through and including January 1, 2028, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2018 Plan is three times the share reserve.

Shares issued under our 2018 Plan will be authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under our 2018 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2018 Plan. Additionally, shares issued pursuant to stock awards under our 2018 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award, will become available for future grant under our 2018 Plan.

*Plan Administration.* Our board of directors, or a duly authorized committee of our board of directors, will administer our 2018 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified stock awards, and (2) determine the number of shares subject to such stock awards. Subject to the terms of our 2018 Plan, the board of directors has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2018 Plan.

Our board of directors has the power to modify outstanding awards under our 2018 Plan. Our board of directors has the authority to reprice any outstanding option or stock appreciation right, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

*Stock Options.* Incentive stock options and nonstatutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2018 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2018 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

*Restricted Stock Unit Awards.* Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Restricted Stock Awards.* Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft, or money order, past services to us or any other form of legal consideration (including future services) that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ceases for any reason, we may receive through a forfeiture condition or a repurchase right any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us.

*Stock Appreciation Rights.* Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2018 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

*Performance Awards.* Our 2018 Plan permits the grant of performance-based stock and cash awards. Our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period.

Our compensation committee may establish performance goals by selecting from one or more of the following performance criteria: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) total stockholder return; (5) return on equity or average stockholder's equity; (6) return on assets, investment, or capital employed; (7) stock price; (8) margin (including gross margin); (9) income (before or after taxes); (10) operating income; (11) operating income after taxes; (12) pre-tax profit; (13) operating cash flow; (14) sales or revenue targets; (15) increases in revenue or product revenue; (16) expenses and cost reduction goals; (17) improvement in or attainment of working capital levels; (18) economic value added (or an equivalent metric); (19) market share; (20) cash flow; (21) cash flow per share; (22) share price performance; (23) debt reduction; (24) customer satisfaction; (25) stockholders' equity; (26) capital expenditures; (27) debt levels; (28) operating profit or net operating profit; (29) workforce diversity; (30) growth of net income or operating income; (31) billings; (32) pre-clinical development related compound goals; (33) financing; (34) regulatory milestones, including approval of a compound; (35) stockholder liquidity; (36) corporate governance and compliance; (37) product commercialization; (38) intellectual property; (39) personnel matters; (40) progress of internal research or clinical programs; (41) progress of partnered programs; (42) partner satisfaction; (43) budget management; (44) clinical achievements; (45) completing phases of a clinical study (including the treatment phase); (46) announcing or presenting preliminary or final data from clinical studies; in each case, whether on particular timelines or generally; (47) timely completion of clinical trials; (48) submission of INDs and NDAs and other regulatory achievements; (49) partner or collaborator achievements; (50) internal controls, including those related to the Sarbanes-Oxley Act of 2002; (51) research progress, including the development of programs; (52) investor relations, analysts and communication; (53) manufacturing achievements (including obtaining particular yields from manufacturing runs and other measurable objectives related to process development



## [Table of Contents](#)

activities); (54) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; (55) establishing relationships with commercial entities with respect to the marketing, distribution, and sale of the Company's products (including with group purchasing organizations, distributors, and other vendors); (56) supply chain achievements (including establishing relationships with manufacturers or suppliers of active pharmaceutical ingredients and other component materials and manufacturers of the Company's products); (57) co-development, co-marketing, profit sharing, joint venture or other similar arrangements; and (58) other measures of performance selected by our board.

Our compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (1) in the award agreement at the time the award is granted or (2) in such other document setting forth the performance goals at the time the goals are established, our compensation committee will appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (a) to exclude restructuring and/or other nonrecurring charges; (b) to exclude exchange rate effects; (c) to exclude the effects of changes to generally accepted accounting principles; (d) to exclude the effects of any statutory adjustments to corporate tax rates; and (e) to exclude the effects of any items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (f) to exclude the dilutive effects of acquisitions or joint ventures; (g) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (h) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination, or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (i) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (j) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (k) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (l) to exclude the effect of any other unusual, non-recurring item of gain or loss.

*Other Stock Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2018 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options, and (4) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* Our 2018 Plan provides that in the event of certain specified significant corporate transactions including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transaction and (4) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding prior to such transaction are converted or exchanged into other property by virtue of the transaction, each outstanding award will be treated as the plan administrator determines unless otherwise provided in an award agreement or other written agreement between us and the award holder. The administrator will take one of the following actions with respect to such awards (1) arrange for the assumption, continuation or substitution of a stock award by a successor corporation; (2) arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation; (3) accelerate the vesting, in whole or in part, of the stock award and provide for its termination prior to the transaction; (4) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us; or (6) cancel or arrange for

the cancellation of the stock award in exchange for a payment, in the form determined by the board, equal to the excess, if any, of the per share amount (or value of property per share) payable to holders of our common stock in connection with the transaction over any exercise price payable by the participant in connection with the exercise, multiplied by the number of shares subject to the stock award. Such payment may be subject to vesting based on the participant's continuing service, provided that the vesting schedule shall be no less favorable to the holder than the schedule under which the stock award would have become vested and/or exercisable. Any escrow, holdback, earnout, or similar provisions in the definitive agreement for the transaction may apply to such payment to the holder of a stock award to the same extent and in the same manner as such provisions apply to holders of our common stock. The plan administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner.

In the event of a change in control, awards granted under the 2018 Plan will not receive automatic acceleration of vesting and/or exercisability, although this treatment may be provided for in an award agreement. Under the 2018 Plan, a change in control generally will be deemed to occur in the event: (i) a person, entity, or group acquires, directly or indirectly, our securities representing more than 50% of the combined voting power of our then outstanding securities, other than by virtue of a merger, consolidation, or similar transaction; (ii) there is consummated a merger, consolidation, or similar transaction and, immediately after the consummation of such transaction, our stockholders immediately prior thereto do not own, directly or indirectly, more than 50% of the combined outstanding voting power of the surviving entity or the parent of the surviving entity in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; (iii) there is consummated a sale or other disposition of all or substantially all of our consolidated assets, other than a sale or other disposition to an entity in which more than 50% of the entity's combined voting power is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such sale or other disposition; or (iv) a majority of our Board becomes comprised of individuals whose nomination, appointment, or election was not approved by a majority of the Board members or their approved successors.

*Transferability.* A participant may not transfer stock awards under our 2018 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2018 Plan.

*Plan Amendment or Termination.* Our board of directors has the authority to amend, suspend, or terminate our 2018 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2018 Plan. No stock awards may be granted under our 2018 Plan while it is suspended or after it is terminated.

#### **2018 Employee Stock Purchase Plan**

Our board of directors adopted our 2018 Employee Stock Purchase Plan, or the ESPP, in July 2018, and our stockholders subsequently approved the ESPP in October 2018. The ESPP became effective immediately upon the execution of the underwriting agreement related to this offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

*Share Reserve.* The maximum aggregate number of shares of our common stock that may be issued pursuant to the exercise of purchase rights under our ESPP that are granted to our employees or to employees of any of our designated affiliates is 515,307 shares. Additionally, the number of shares of our common stock reserved for issuance under our ESPP will increase automatically each year, beginning on January 1, 2019, and continuing through and including January 1, 2028, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (2) 555,555 shares or (3) a lesser number of shares as determined by our board of directors. Shares subject to purchase rights granted under our ESPP that

terminate without having been exercised in full will not reduce the number of shares available for issuance under our ESPP.

*Administration.* Our board of directors, or a duly authorized committee thereof, will administer our ESPP. Our board of directors has delegated concurrent authority to administer our ESPP to our compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase. For the initial offering, which will commence upon the execution and delivery of the underwriting agreement relating to this offering, the fair market value on the first day of the initial offering will be the price at which shares are first sold to the public.

*Limitations.* Our employees, including executive officers, or any of our designated affiliates may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (1) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year, or (2) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. An employee may not be granted rights to purchase stock under our ESPP if such employee (1) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of our common stock, or (2) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year that the purchase rights remain outstanding.

*Changes to Capital Structure.* In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights, and (4) the number of shares that are subject to purchase limits under an offering.

*Corporate Transactions.* In the event of certain significant corporate transactions including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transaction and (4) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately after such purchase.

*ESPP Amendments, Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

### **2008 Stock Plan**

*General.* Our board of directors adopted the 2008 Stock Plan in April 2008, and it was approved by our stockholders in February 2009. We have subsequently amended the 2008 Stock Plan, with the most recent amendment occurring in March 2017, the purpose of which was to increase the number of shares available for issuance under the 2008 Stock Plan. No further awards will be made under the 2008 Stock Plan following this offering; however, awards outstanding under the 2008 Stock Plan will continue in full effect in accordance with their existing terms.

*Share Reserve.* As of June 30, 2018, we have reserved 5,350,080 shares of our common stock for issuance under the 2008 Stock Plan. As of June 30, 2018, options to purchase 2,900,842 shares of common stock, at exercise prices ranging from \$0.27 to \$9.72 per share, or a weighted-average exercise price of \$4.09 per share, were outstanding under the 2008 Stock Plan, and 26,613 shares of common stock remained available for future issuance under the 2008 Stock Plan. Unissued shares subject to awards that expire or are cancelled, award shares reacquired by us and shares withheld in payment of the purchase price or exercise price of an award or in satisfaction of withholding taxes will again become available for issuance under the 2008 Stock Plan until the expiration date of the 2008 Stock Plan, as described above.

*Administration.* Our board of directors has administered the 2008 Stock Plan since its adoption, however, following this offering, the compensation committee of our board of directors will generally administer the 2008 Stock Plan. The administrator has complete discretion to make all decisions relating to the 2008 Stock Plan and the outstanding awards, including the authority to accept the cancellation of outstanding options (whether granted by us or another issuer) in return for the grant of new options for the same or a different number of shares and at the same or a different exercise price.

*Types of Awards.* The 2008 Stock Plan provides for both the direct grant or sale of shares of our common stock and for the grant of options to purchase shares of our common stock. The 2008 Stock Plan allows for the grant of both incentive and nonstatutory stock options.

*Eligibility.* Employees, non-employee members of our board of directors and consultants are eligible to participate in the 2008 Stock Plan. However, only employees are eligible to receive incentive stock options.

*Options.* The exercise price of options granted under the 2008 Stock Plan may not be less than 100% of the fair market value of our common stock on the grant date. Options expire at the time determined by the administrator, but in no event more than 10 years after they are granted, and generally expire earlier if the optionee's service terminates.

*Corporate Transactions.* In the event that we are a party to a merger or consolidation, shares acquired under the 2008 Stock Plan will be subject to the agreement of merger or consolidation, which agreement need not treat all options in an identical manner. Such agreement will provide for one or more of the following with respect to outstanding options:

- The continuation, assumption, or substitution of the option by the surviving entity or its parent;
- Full vesting and exercisability of the option, followed by cancellation of the option if not exercised prior to the transaction; or
- Cancellation of the option in exchange for a payment equal to the excess, if any, of the fair market value of the shares subject to the option over the exercise price per share of the option. Such payment

## [Table of Contents](#)

may be subject to vesting based on the optionee's continuing service, generally in accordance with the original vesting schedule applicable to the option.

*Changes in Capitalization.* In the event of certain specified changes in the capital structure of our common stock, such as a stock split, reverse stock split, stock dividend, reclassification, or any other increase or decrease in the number of issued shares of stock effective without receipt of consideration by us, proportionate adjustments will automatically be made in each of (i) the number of shares available for future grants under the 2008 Stock Plan, (ii) the number of shares covered by each outstanding option, and (iii) the exercise price per share subject to each outstanding option. In the event of an extraordinary cash dividend that has a material effect on the fair market value of our common stock, a recapitalization, spin-off, or other similar occurrence, the administrator at its sole discretion may make appropriate adjustments to one or more of the foregoing.

*Amendments or Termination.* The administrator may at any time amend, suspend or terminate the 2008 Stock Plan, subject to stockholder approval in the case of certain amendments. The 2008 Stock Plan will terminate upon the closing of this offering.

### **401(k) Plan**

We maintain a 401(k) plan for employees. The 401(k) is intended to be qualified under Section 401(k) of the Code (as defined below), with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan by eligible U.S. employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn, and so that contributions by us, if any, will be deductible by us when made. Employees may elect to reduce their current compensation by up to the statutorily prescribed annual limits and to have the amount of such reduction contributed to the 401(k) plan. The 401(k) plan permits us to make contributions up to the limits allowed by law on behalf of all eligible employees. We have not made any company contributions to the 401(k) plan to date.

### **Health and Welfare Benefits**

All our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision insurance plan, in each case on the same basis as all of our other employees.

### **Limitation on Liability and Indemnification of Directors and Officers**

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former executive officers and directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability:

- for any transaction from which the director derives an improper personal benefit;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (unlawful payment of dividends or redemption of shares); or
- for any breach of a director's duty of loyalty to the corporation or its stockholders.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies, such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we are required to indemnify our executive officers and directors to the fullest extent permitted by Delaware

## [Table of Contents](#)

law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we shall advance expenses incurred by an executive officer and director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our other officers, employees and other agents when determined appropriate by the board. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines, and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers, or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2015 to which we have been a party in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors, promoters, or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described in “Management—Non-Employee Director Compensation” and “Executive Compensation.”

### Sale of Series 6 Preferred Stock

In April and June 2015, we issued and sold an aggregate of 1,315,856 shares of Series 6 preferred stock at a purchase price of \$16.47 per share for an aggregate purchase price of \$21,674,741.

The following table summarizes purchases of shares of Series 6 preferred stock by our executive officers, directors and holders of more than 5% of our capital stock.

<u>Purchaser</u>	<u>Number of Shares</u>	<u>Aggregate Consideration</u>
Redline Capital Management S.A.	789,227	\$ 12,999,999
Skyline Venture Partners V, L.P.(1)	105,959	1,745,335
Montreux IV Associates, L.L.C.	5,778	95,190
OrbiMed Private Investments V, LP(2)	25,937	427,244
Gregory K. Hinckley(3)	12,141	200,000
Total	<u>939,042</u>	<u>\$ 15,467,768</u>

(1) John G. Freund, M.D., a member of our board of directors, is a Managing Director at Skyline Venture Partners.

(2) David P. Bonita, M.D., a member of our board of directors, is a Private Equity Partner at OrbiMed Advisors LLC.

(3) Mr. Hinckley is a member of our board of directors.

### Sale of Series 7 Preferred Stock

In June and July 2016, we issued and sold an aggregate of 2,039,530 shares of Series 7 preferred stock at a purchase price of \$10.03 per share for an aggregate purchase price of \$20,463,102. In February and March 2017, we issued and sold an aggregate of 540,874 shares of Series 7 preferred stock at a purchase price of \$10.03 per share for an aggregate purchase price of \$5,426,717.

The following table summarizes purchases of shares of Series 7 preferred stock by our executive officers, directors, and holders of more than 5% of our capital stock.

<u>Purchaser</u>	<u>Shares of Series 7 Preferred Stock</u>	
	<u>Number of Shares</u>	<u>Aggregate Gross Consideration</u>
Arboretum Ventures IV, LP(1)	1,495,036	\$ 15,000,000
Skyline Venture Partners V, L.P.(2)	398,676	4,000,000
Entities affiliated with Montreux Equity Partners(3)	199,338	2,000,000
OrbiMed Private Investments V, LP(4)	179,404	1,800,000
Redline Capital Management S.A.	106,636	1,100,000
Gregory K. Hinckley(5)	44,851	450,000
Keith C. Valentine(6)	9,966	100,000
Total	<u>2,433,907</u>	<u>\$ 24,450,000</u>

- (1) Timothy B. Petersen, a member of our board of directors, is a Managing Director at Arboretum Ventures, Inc.
- (2) John G. Freund, M.D., a member of our board of directors, is a Managing Director at Skyline Venture Partners.
- (3) Includes (a) 27,409 shares of Series 7 preferred stock held by Montreux Equity Partners IV, L.P. and (b) 171,929 shares of Series 7 preferred stock held by Montreux IV Associates IV, L.L.C.
- (4) David P. Bonita, M.D., a member of our board of directors, is a Private Equity Partner at OrbiMed Advisors LLC.
- (5) Represents shares held by Gregory K. Hinckley and Mary C. Hinckley As Community Property with the Right of Survivorship. Mr. Hinckley is a member of our board of directors.
- (6) Mr. Valentine is a member of our board of directors.

#### **Loans**

In March 2013, we loaned Daniel P. Murray, our then current Chief Financial Officer, \$200,000 in connection with the exercise of options to purchase 152,106 shares of our common stock, or the Murray Purchased Shares. The loan was evidenced by a full recourse promissory note, accrued interest on the outstanding principal amount at the rate of 1.09% per annum and was secured by a pledge of the Murray Purchased Shares and Mr. Murray's personal assets. In November 2016, the loan amount was partially repaid in the amount of \$116,000 (including principal of \$113,000 and interest of \$3,000). The remainder of the principal balance of this loan, together with all interest accrued, was fully paid in December 2017.

In February 2014, we loaned Jeffrey W. Dunn, \$437,000 in connection with the exercise of options to purchase 174,110 shares of our common stock, or the 2014 Exercised Options. The loan was evidenced by a full recourse promissory note, accrued interest on the outstanding principal amount at the rate of 1.97% per annum and was secured by a pledge of the 2014 Exercised Options and Mr. Dunn's personal assets. On March 1, 2017, we forgave \$231,914 (including principal of \$218,500 and interest of \$13,414) of this loan. As of December 31, 2017, the outstanding balance of this loan was \$231,914, including principal of \$219,500, which was forgiven on January 1, 2018.

#### **Amended and Restated Investors' Rights Agreement**

We are party to an investor rights agreement that provides holders of our preferred stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The investor rights agreement also provides for a right of first refusal in favor of certain holders of our stock with regard to certain issuances of our capital stock. The rights of first refusal will not apply to, and will terminate upon, closing of this offering. For a more detailed description of these registration rights, see "Description of Capital Stock—Registration Rights."

#### **Employment Arrangements**

We have entered into offer letters and severance and change in control agreements with our executive officers. For more information regarding these arrangements, see "Executive Compensation—Employment Arrangements."

#### **Equity Grants**

We have granted stock options to our executive officers and members of our board of directors. For a description of these stock options, see "Executive Compensation" and "Management—Non-Employee Director Compensation."



### **Indemnification Agreements**

Our amended and restated certificate of incorporation, which will be effective upon the closing of this offering, will contain provisions limiting the liability of directors, and our amended and restated bylaws, which will be effective upon the closing of this offering, will provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by our board of directors.

We intend to enter into indemnification agreements with each of our directors and executive officers and certain other key employees. The indemnification agreements will provide that we will indemnify each of our directors, executive officers, and such other key employees against any and all expenses incurred by that director, executive officer, or other key employee because of his or her status as one of our directors, executive officers, or other key employees, to the fullest extent permitted by Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws. In addition, the indemnification agreements will provide that, to the fullest extent permitted by Delaware law, we will advance all expenses incurred by our directors, executive officers, and other key employees in connection with a legal proceeding involving his or her status as a director, executive officer, or employee.

### **Policies and Procedures for Related Party Transactions**

Our audit committee has the primary responsibility for the review, approval, and oversight of any “related party transaction,” which is any transaction, arrangement, or relationship (or series of similar transactions, arrangements, or relationships) in which we are, were, or will be a participant and the amount involved exceeds \$120,000, and in which the related person has, had, or will have a direct or indirect material interest. We intend to adopt a written related party transaction policy to be effective upon the closing of this offering. Under our related party transaction policy, our management will be required to submit any related person transaction not previously approved or ratified by our audit committee to our audit committee. In approving or rejecting the proposed transactions, our audit committee will take into account all of the relevant facts and circumstances available. Our audit committee will approve only those transactions that, as determined by our audit committee, are in, or are not inconsistent with, our best interests and the best interests of our stockholders.

Although we have not had a written policy prior to this offering for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to a director’s or officer’s relationship or interest as to the agreement or transaction were disclosed to our board of directors. Our board of directors would take this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interests of all of our stockholders.

## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2018, and as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each stockholder known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 15,795,538 shares of common stock outstanding at June 30, 2018, after giving effect to the conversion of all outstanding shares of preferred stock as of that date into an aggregate of 12,066,654 shares of our common stock and the reclassification of all outstanding shares of series 1 common stock and series 2 common stock into an aggregate of 3,707,268 shares of our common stock, which will occur immediately prior to the closing of this offering. For purposes of computing percentage ownership after this offering, we have assumed that (i) 7,200,000 shares of common stock will be issued by us in this offering; (ii) 21,616 shares of common stock will be issued upon the automatic net exercise of outstanding warrants, with an exercise price of \$9.10 per share, immediately prior to the closing of this offering, at the initial public offering price of \$15.00 per share; and (iii) that the underwriters will not exercise their right to purchase 1,080,000 additional shares. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to stock options and warrants held by that person or entity that are currently exercisable or that will become exercisable within 60 days of June 30, 2018. We did not deem these shares outstanding; however, for the purpose of computing the percentage ownership of any other person or entity. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o SI-BONE, Inc., 471 El Camino Real, Suite 101, Santa Clara, California 95050.

## Table of Contents

Name of Beneficial Owner	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned Following this Offering	
	Shares	%	Shares	%
<b>Named Executive Officers and Directors:</b>				
David P. Bonita, M.D. <sup>(1)</sup>	785,368	5.0%	985,368	4.3%
Timothy E. Davis, Jr. <sup>(2)</sup>	39,601	*	39,601	*
Jeffrey W. Dunn <sup>(3)</sup>	1,164,561	7.1	1,164,561	4.9
Laura A. Francis <sup>(4)</sup>	251,039	1.6	251,039	1.1
John G. Freund, M.D. <sup>(5)</sup>	4,094,985	25.9	4,419,985	19.2
Gregory K. Hinckley <sup>(6)</sup>	116,394	*	116,394	*
Karen A. Licitra <sup>(7)</sup>	21,408	*	21,408	*
Timothy B. Petersen <sup>(8)</sup>	1,495,036	9.5	1,695,036	7.4
Anthony J. Recupero <sup>(9)</sup>	179,533	1.1	179,533	*
Mark A. Reiley, M.D. <sup>(10)</sup>	542,624	3.4	542,624	2.3
Keith C. Valentine <sup>(11)</sup>	31,374	*	31,374	*
All executive officers and directors as a group (14 persons) <sup>(12)</sup>	9,153,674	52.9	9,878,674	40.3
<b>5% Stockholders:</b>				
Skyline Venture Partners V, L.P. <sup>(13)</sup>	4,094,985	25.9	4,419,985	19.2
Entities affiliated with Montreux Equity Partners <sup>(14)</sup>	2,029,715	12.8	2,029,715	8.8
Arboretum Ventures IV, LP <sup>(15)</sup>	1,495,036	9.5	1,695,036	7.4
Redline Capital Management S.A. <sup>(16)</sup>	945,250	6.0	945,250	4.1
OrbiMed Private Investments V, LP <sup>(17)</sup>	785,368	5.0	985,368	4.3

\* Less than 1 percent.

- (1) Consists of shares of common stock held by OrbiMed Private Investments V, LP. (“OPI V”). OrbiMed Capital GP V LLC (“GP V”) is the general partner of OPI V and OrbiMed Advisors LLC (“OrbiMed Advisors”) is the managing member of GP V. OrbiMed Advisors exercises investment and voting power over the securities held by OPI V through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein. Dr. Bonita, a member of our board of directors, is an employee of OrbiMed Advisors. Each of GP V, OrbiMed Advisors, Mr. Gordon, Mr. Borho, Mr. Silverstein, and Dr. Bonita disclaims beneficial ownership of such shares, except to the extent of its or his pecuniary interest therein, if any.
- (2) Includes 33,175 shares of common stock issuable to Mr. Davis pursuant to options exercisable within 60 days of June 30, 2018, of which 5,529 of the shares would be unvested as of such date.
- (3) Consists of (i) 549,207 shares of common stock held by Jeffrey W. Dunn as Trustee of the Jeffrey W. Dunn Living Trust Dated May 17, 2012 and (ii) 615,354 shares of common stock issuable to Mr. Dunn pursuant to options exercisable within 60 days of June 30, 2018, of which 166,895 of the shares would be unvested as of such date.
- (4) Consists of 251,039 shares of common stock issuable to Ms. Francis pursuant to options exercisable within 60 days of June 30, 2018, of which 75,556 of the shares would be unvested as of such date.
- (5) Consists of (i) 4,079,468 shares of common stock held by Skyline Venture Partners V, L.P. (“SVP V”) and (ii) 15,517 shares of common stock issuable to SVP V upon the automatic net exercise of an outstanding warrant immediately prior to the closing of this offering, as reflected in footnote 13 below. Skyline Venture Management V, LLC (“LLC”) is the general partners of SVP V and as such may be deemed to have voting and investment power with respect to the securities of SVP V. Dr. Freund, a member of our board of directors, is the Managing Director of LLC and may be deemed to have voting and investment power with respect to the securities held by SVP V. Dr. Freund disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein.
- (6) Consists of (i) 40,791 shares of common stock held by Mr. Hinckley and (ii) 75,603 shares of common stock held by Gregory K. Hinckley and Mary C. Hinckley as Community Property with the Right of Survivorship.

## Table of Contents

- (7) Consists of 21,408 shares of common stock issuable to Ms. Licitra pursuant to options exercisable within 60 days of June 30, 2018, of which 7,496 of the shares would be unvested as of such date.
- (8) Consists of shares of common stock held by Arboretum Ventures IV, LP (“AV IV”). Arboretum Investment Manager IV, LLC (“AIM IV”) serves as the general partner of AV IV. Jan Garfinkle, Timothy B. Petersen, a member of our board of directors, and Paul McCreadie are managing members of AIM IV and share voting and dispositive power with regard to these shares and therefore each of the foregoing managing members may be deemed to have the same powers with respect to such shares. Mr. Petersen disclaims beneficial ownership of such shares except to the extent of his proportionate pecuniary interest, if any.
- (9) Consists of 179,533 shares of common stock issuable to Mr. Recuperero pursuant to options exercisable within 60 days of June 30, 2018, of which 101,759 of the shares would be unvested as of such date.
- (10) Consists of (i) 375,119 shares of common stock held by Dr. Reiley, (ii) 19,444 shares of common stock held by The Mark and Muriel Reiley Charitable Remainder Unitrust and (iii) 148,061 shares of common stock issuable to Dr. Reiley pursuant to options exercisable within 60 days of June 30, 2018, of which 23,361 of the shares would be unvested as of such date.
- (11) Includes of 21,408 shares of common stock issuable to Mr. Valentine pursuant to options exercisable within 60 days of June 30, 2018, of which 7,496 of the shares would be unvested as of such date.
- (12) Includes (i) 7,436,428 shares of common stock beneficially owned by the directors and named executive officers, (ii) 206,477 shares of common stock beneficially owned by other executive officers, (iii) 1,495,252 shares issuable pursuant to options exercisable within 60 days of June 30, 2018, of which 456,300 of the shares would be unvested as of such date and (iv) 15,517 shares of common stock issuable upon automatic net exercise of outstanding warrants immediately prior to the closing of this offering.
- (13) Consists of (i) 4,079,468 shares of common stock held by Skyline Venture Partners V, L.P. (“SVP V”) and (ii) 15,517 shares of common stock issuable to SVP V upon the automatic net exercise of an outstanding warrant immediately prior to the closing of this offering. Skyline Venture Management V, LLC (“LLC”) is the general partners of SVP V and as such may be deemed to have voting and investment power with respect to the securities of SVP V. Dr. Freund, a member of our board of directors, is the Managing Director of LLC and may be deemed to have voting and investment power with respect to the securities held by SVP V. Dr. Freund disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein. The address of each of the entities and individual listed above is 525 University Avenue, Suite 1350, Palo Alto, California 94301. SVP V has agreed to purchase 325,000 shares of our common stock in this offering at the initial public offering price.
- (14) Consists of (i) 1,721,296 shares of common stock held by Montreux Equity Partners IV, L.P. (“MEP IV”), (ii) 6,099 shares of common stock issuable to MEP IV upon the automatic net exercise of an outstanding warrant immediately prior to the closing of this offering, (iii) 171,929 shares of common stock held by Montreux IV Associates IV, L.L.C. (“Associates IV”), and (iv) 130,391 shares of common stock held by Montreux IV Associates, L.L.C. (“Associates”). Daniel K. Turner III is the Managing Director of Montreux Equity Management IV, L.L.C., the general partner of each of MEP IV, Associates IV and Associates, and may be deemed to have voting and investment power over the shares held by each of these entities. Mr. Turner disclaims beneficial ownership of such shares, except to the extent of his proportionate pecuniary interest, if any. The address of the principal place of business of each of the entities and individuals listed above is One Ferry Building, Suite 255, San Francisco, California 94111.
- (15) Arboretum Investment Manager IV, LLC (“AIM IV”) serves as the general partner of Arboretum Ventures IV, LP (“AV IV”). Jan Garfinkle, Timothy B. Petersen, a member of our board of directors, and Paul McCreadie are managing directors of AIM IV and share the power to vote or dispose of these shares and therefore each of the foregoing managing members may be deemed to have voting and investment power with respect to such shares. Each of these individuals disclaims beneficial ownership of such shares except to the extent of their respective proportionate pecuniary interest therein. The address of the principal place of business of each of the entities and individuals listed above is 303 Detroit Street, Suite 301, Ann Arbor, Michigan 48104. AV IV has agreed to purchase 200,000 shares of our common stock in this offering at the initial public offering price.
- (16) Shares held by Redline Capital Management S.A. (“Redline”), acting for the account of Redline Capital Fund – Universal Investments, a sub-fund of Redline Capital Fund FCP-FIS. Tatiana Evtushenkova and

## [Table of Contents](#)

Sabine Teske are managing directors of Redline. Ms. Evtushenkova, Robert Kocharyan, Robert Kenedi and Stefan Justinger are members of the Board of Directors of Redline and may be deemed to have voting and investment power over the shares held by Redline. Ms. Evtushenkova, Ms. Teske, Mr. Kocharyan, Mr. Kenedy and Mr. Justinger disclaim beneficial ownership of these shares except to the extent of their respective proportionate pecuniary interest therein, if any. The address of the principal place of business of each of Redline and individuals listed above is 26 Avenue Monterey, L-2163 Luxemborg, G.D. Luxemborg.

- (17) OrbiMed Capital GP V LLC (“GP V”) is the general partner of OPI V and OrbiMed Advisors LLC (“OrbiMed Advisors”) is the managing member of GP V. OrbiMed Advisors exercises investment and voting power over the securities held by OPI V through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein. Dr. Bonita, a member of our board of directors, is an employee of OrbiMed Advisors. Each of GP V, OrbiMed Advisors, Mr. Gordon, Mr. Borho, Mr. Silverstein, and Dr. Bonita disclaims beneficial ownership of such shares, except to the extent of its or his pecuniary interest therein, if any. The address of the principal place of business of each of the entities and individuals listed above is 601 Lexington Avenue, 54<sup>th</sup> Floor, New York, New York 10022. OPI V has agreed to purchase 200,000 shares of our common stock in this offering at the initial public offering price.

## DESCRIPTION OF CAPITAL STOCK

A description of our capital stock and the material terms and provisions of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering and affecting the rights of holders of our capital stock is set forth below. The forms of our amended and restated certificate of incorporation and our amended and restated bylaws to be adopted in connection with this offering will be filed as exhibits to the registration statement relating to this prospectus.

Upon the closing of this offering, our amended and restated certificate of incorporation will authorize shares of undesignated preferred stock, the rights, preferences, and privileges of which may be designated from time to time by our board of directors.

Upon the closing of this offering, our authorized capital stock will consist of 105,000,000 shares, all with a par value of \$0.0001 per share, of which:

- 100,000,000 shares are designated common stock; and
- 5,000,000 shares are designated preferred stock.

As of June 30, 2018, and after giving effect to the conversion of all of our outstanding preferred stock into 12,066,654 shares of common stock immediately prior to the closing of this offering, there were outstanding:

- 15,795,538 shares of common stock held of record by 422 stockholders;
- 2,900,842 shares of common stock issuable upon exercise of outstanding stock options; and
- 230,066 shares of common stock, as converted, issuable upon exercise of outstanding warrants.

### 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. See “Dividend Policy” for more information.

#### *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 that will be in effect upon the closing of this offering will 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.

### ***Reclassification of Common Stock***

Prior to this offering, we had two classes of common stock outstanding: Series 1 common stock and Series 2 common stock. The holders of our Series 2 common stock are entitled to one vote per share and the holders of our Series 1 common stock do not have voting rights, except as required by applicable law. Immediately prior to the closing of this offering, we will reclassify all outstanding shares of our Series 1 common stock and Series 2 common stock into a single class of common stock named “common stock,” which shall have the same voting powers, preferences, rights and qualifications, limitations, and restrictions as the current Series 2 common stock.

### **Preferred Stock**

Upon the closing of this offering, no shares of preferred stock will be outstanding, but we will be authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences, and rights of the shares of each series and any of its qualifications, limitations, or restrictions. Our board of directors also can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in control of our company and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plan to issue any shares of preferred stock.

### **Options**

As of June 30, 2018, we had options to purchase 2,900,842 shares of common stock outstanding, with a weighted-average exercise price of \$4.09 per share, under the 2008 Stock Plan.

For additional information regarding the terms of the 2008 Stock Plan, see “Executive Compensation—Equity Plans.”

### **Warrants**

As of June 30, 2018, we had outstanding warrants to purchase up to an aggregate of 280,876 shares of common stock and preferred stock with a weighted-average exercise price of \$8.66 per share. Immediately prior to the closing of this offering, outstanding warrants to purchase up to an aggregate of 54,917 shares will be deemed to be net exercised. Upon the closing of this offering, the balance of the warrants will become exercisable for up to an aggregate of 230,066 shares of our common stock with a weighted-average exercise price of \$8.69 per share.

#### ***Common Stock Warrants***

As of June 30, 2018, we had outstanding warrants to purchase up to an aggregate of 124,326 shares of our common stock with a weighted-average exercise price of \$3.89. Unless earlier exercised, these warrants will expire between July 2023 and March 2027.

#### ***Preferred Stock Warrants***

As of June 30, 2018, we had outstanding warrants to purchase up to an aggregate of 76,906 shares of our Series 5 preferred stock with an exercise price of \$9.10. Immediately prior to the closing of this offering, outstanding warrants to purchase 54,917 shares will be deemed to be net exercised. Upon the closing of this offering, the remaining warrant will become exercisable for 21,989 shares of our common stock with an exercise price of \$9.10 per share and, unless exercised earlier, will expire in July 2023.

## [Table of Contents](#)

As of June 30, 2018, we had outstanding warrants to purchase up to an aggregate of 69,932 shares of our Series 6 preferred stock with an exercise price of \$16.47 per share. Upon the closing of this offering, these warrants will become exercisable for up to an aggregate of 74,039 shares of our common stock with an exercise price of \$16.47 per share. Unless earlier exercised, these warrants will expire between November 2024 and November 2025.

As of June 30, 2018, we had outstanding warrants to purchase up to an aggregate of 9,712 shares of our Series 7 preferred stock with an exercise price of \$10.03 per share. Upon the closing of this offering, these warrants will become exercisable for up to an aggregate of 9,712 shares of our common stock with an exercise price of \$10.03 per share. Unless earlier exercised, these warrants will expire in November 2026.

The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the applicable warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications, and consolidations.

### **Registration Rights**

After this offering, the holders of 12,088,270 shares of common stock issued upon the conversion of our preferred stock will be entitled to contractual rights to require us to register those shares under the Securities Act. These rights are provided under the terms of our amended and restated investors' rights agreement. If we propose to register any of our securities under the Securities Act for our own account, holders of shares having registration rights are entitled to include their shares in our registration statement, provided, among other conditions, that the underwriters of any such offering have the right to limit the number of shares included in the registration.

We will pay all expenses relating to any demand, piggyback or Form S-3 registration described below, other than underwriting discounts and commissions. The registration rights terminate upon the earliest to occur of: (i) the fourth anniversary of the closing of this offering; (ii) a liquidation event; or (iii) with respect to the registration rights of an individual holder, the earlier of the date that all shares held by the holder can be sold in compliance with Rule 144 or if the holder holds one percent or less of our outstanding common stock and all such shares can be sold in any three-month period in compliance with Rule 144.

#### ***Demand Registration Rights***

The holders of the registrable securities will be entitled to certain demand registration rights. At any time beginning on the earlier of June 2021 or 180 days following the effectiveness of this offering, the holders of 40% or more of the registrable securities then outstanding, may make a written request that we register at least 20% of the registrable securities, subject to certain specified conditions and exceptions. Such request for registration must cover securities the aggregate offering price of at least \$10,000,000, net of underwriting discounts and commissions if the proposed number of securities to be registered is less than 20% of the total number of registrable securities. We not obligated to effect more than two of these registrations.

#### ***Piggyback Registration Rights***

If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of shares having registration rights will, subject to certain exceptions, be entitled to include their shares in our registration statement. These registration rights are subject to specified conditions and limitations, including but not limited to the right of the underwriters to limit the number of shares included in any such offering under certain circumstances, but not below 15% of the total amount of securities included in such offering.



### ***Form S-3 Registration Rights***

At any time after we are qualified to file a registration statement on Form S-3, and subject to limitations and conditions specified in the amended and restated investors' rights agreement, the holders of at least 277,778 of the registrable securities may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public, net of any underwriters' discounts and commissions, is at least \$3,000,000. We are not obligated to effect more than one of these Form S-3 registrations in any 12-month period.

### **Anti-Takeover Provisions**

#### ***Delaware Law***

Upon the closing of this offering, we will be 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; 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***

Upon the closing of this offering, our amended and restated certificate of incorporation and our amended and restated bylaws will 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 will authorize our board of directors to fill vacant directorships, including newly-created seats. In addition, the number of directors constituting our board of directors will be set only by resolution adopted by a majority vote of our entire board of directors. These provisions will 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 will provide that our board of directors will be 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 will provide that stockholders will not be able to take action by written consent, and will

## [Table of Contents](#)

only be able to take action at annual or special meetings of our stockholders. Stockholders will not be permitted to cumulate their votes for the election of directors. Our amended and restated bylaws will 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 will 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 will 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 will have the authority, without further action by the holders of common stock, to issue up to 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 will 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**

Upon the closing of this offering, our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be 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 would 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 will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

### **Transfer Agent and Registrar**

Upon the closing of this offering the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and the telephone number is (800) 937-5449.

### **Listing**

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "SIBN."

## SHARES ELIGIBLE FOR FUTURE SALE

Before this offering, there has not been a public market for shares of common stock. Future sales of substantial amounts of shares of our common stock, including shares issuable upon the exercise of outstanding options and warrants, in the public market following this offering or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Following this offering, we will have outstanding 22,995,538 shares of our common stock, based on the number of shares outstanding as of June 30, 2018. This includes 7,200,000 shares of common stock that we are selling in this offering, which shares may be resold in the public market immediately unless purchased by our affiliates, and assumes no additional exercise of outstanding options or warrants, other than as described elsewhere in this prospectus.

The remaining 15,795,538 shares of common stock that are not sold in this offering will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act of 1933. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below.

In addition, we, our executive officers and directors, and substantially all of our security holders have entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our capital stock until at least 181 days after the date of this prospectus, as described below. As a result of these agreements and the provisions of our investors’ rights agreement disclosed in “Description of Capital Stock—Registration Rights,” subject to the provisions of Rule 144 or Rule 701, the shares will generally become available for sale in the public market as follows:

- beginning on the date of this prospectus, the 7,200,000 shares sold in this offering will be immediately available for sale in the public market, unless purchased by our affiliates; and
- beginning 181 days after the date of this prospectus, 15,795,538 additional shares will become eligible for sale in the public market.

### Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned shares of our restricted common stock for at least six months would be entitled to sell their securities provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, and we are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least 90 days before the sale. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Persons who have beneficially owned shares of our restricted common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of common shares then outstanding, which will equal approximately 229,955 shares immediately after this offering assuming no exercise of the underwriters’ option to purchase additional shares, based on the number of common shares outstanding as of June 30, 2018; or
- the average weekly trading volume of our common shares during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

#### **Rule 701**

Any of our service providers who purchased shares under a written compensatory plan or contract prior to this offering may be entitled to rely on the resale provisions of Rule 701. Rule 701, as currently in effect, permits resales of shares, including by affiliates, in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirement, of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the public information, volume limitation or notice provisions of Rule 144. All holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares if such resale is pursuant to Rule 701. All Rule 701 shares are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of these lock-up agreements.

#### **Lock-Up Agreements**

In connection with this offering, we and all directors and officers and the holders of substantially all of our outstanding capital stock, warrants and stock options have agreed with the underwriters, subject to certain exceptions, not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, shares of our common stock or any securities convertible into or exchangeable for shares of our common stock or enter into any swap or other arrangement that transfers to another any of the economic consequences of ownership of our common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated. These agreements are subject to certain exceptions, as set forth in “Underwriting.”

Certain of our employees, including our executive officers, and directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Securities Exchange Act of 1934. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to our initial public offering described above.

#### **Registration Rights**

Upon the closing of this offering, the holders of 12,088,270 shares of common stock will be entitled to rights with respect to the registration of the sale of such shares of common stock under the Securities Act. See “Description of Capital Stock—Registration Rights.” All such shares are covered by lock-up agreements. Following the expiration of the lock-up period, registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration.

#### **Equity Plans**

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to options outstanding or reserved for issuance under our equity plans. We expect to file this registration statement as soon as practicable after the closing of this offering. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. For a more complete discussion of our stock plans, see “Executive Compensation—Equity Plans.”

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES  
TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership, and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local, or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service, or IRS, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- “controlled foreign corporations;”
- “passive foreign investment companies;”
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons subject to the alternative minimum tax;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- accrual-method taxpayers subject to special tax accounting rules under Section 451(b) of the Code;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE**

**PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL INCOME TAX LAWS WERE RECENTLY ENACTED. YOU SHOULD ALSO CONSULT WITH YOUR TAX ADVISOR WITH RESPECT TO SUCH CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.**

#### **Definition of Non-U.S. Holder**

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

#### **Distributions on Our Common Stock**

As described under the section titled “Dividend Policy,” we have not paid and do not anticipate paying dividends. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled “—Gain on Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and Sections 1471 through 1474 of the Code (commonly referred to as FATCA), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our paying agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) including a U.S. taxpayer identification number and certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder’s U.S. trade

or business (and are attributable to such holder's permanent establishment in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Gain on Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of dividends on our common stock paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because

## [Table of Contents](#)

the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

### **Withholding on Foreign Entities**

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock. FATCA will also apply to gross proceeds from sales or other dispositions of our common stock after December 31, 2018.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.



## UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	2,844,000
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,844,000
Canaccord Genuity LLC	864,000
JMP Securities LLC	648,000
<b>Total:</b>	<b><u>7,200,000</u></b>

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ over-allotment option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$0.63 a share under the public offering price. After the initial public offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,080,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

Certain of our existing stockholders or their affiliates, including entities affiliated with Arboretum Ventures, Novo Holdings A/S, OrbiMed, and Skyline Venture Partners, that had submitted indications of interest have agreed to purchase an aggregate of 1,225,000 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

## [Table of Contents](#)

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 1,080,000 shares of common stock.

	Per Share	Total	
		No Exercise	Full Exercise
Public offering price	\$ 15.00	\$108,000,000	\$124,200,000
Underwriting discounts and commissions to be paid by us.	\$ 1.05	\$ 7,560,000	\$ 8,694,000
Proceeds, before expenses	\$ 13.95	\$100,440,000	\$115,506,000

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$1.7 million. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$30,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "SIBN."

We and all directors and officers and the holders of all of our outstanding capital stock, warrants and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus (the "restricted period"):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply to:

- transactions by a securityholder relating to shares of common stock or other securities acquired (i) in open market transactions after the closing of this offering or (ii) except in the case where the securityholder is an officer or director of ours, in this offering; provided that, in each case (i) and (ii), no filing under Section 16(a) of the Exchange Act is required or voluntarily made during the restricted period in connection with subsequent sales of common stock or other securities acquired in such open market transactions or in this offering;
- transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift, (ii) to an immediate family member or a trust for the direct or

indirect benefit of the transferor or such immediate family member of the transferor, (iii) to any corporation, partnership, limited liability company, investment fund, or other entity controlled or managed, or under common control or management by the transferor or the immediate family of the transferor, or (iv) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary, or a member of the immediate family of the transferor, provided in each case that (a) each distributee or transferee signs and delivers a lock-up letter and (b) no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares shall be required or voluntarily made during the restricted period (other than a filing on a Form 5);

- distributions or transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock to general or limited partners, members, or stockholders of the transferor, provided that (i) each distributee or transferee shall sign and deliver a lock-up letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period (other than a filing on a Form 5);
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the person or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period;
- the exercise of options to purchase shares of common stock granted under any stock incentive plan or stock purchase plan described in this prospectus, provided that (i) the underlying shares shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement and (ii) any filing under Section 16 of the Exchange Act made during the restricted period shall clearly indicate that (A) the filing relates to the circumstances described above and (B) no securities were sold by the person, and (iii) the person does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;
- the receipt from us of shares of common stock upon (A) the exercise or settlement of options or restricted stock units granted under a stock incentive plan or other equity award plan, which plan is described in this prospectus or (B) the exercise of warrants outstanding and which are described in the this prospectus, or (ii) the transfer of shares of common stock or any securities convertible into common stock to us upon a vesting or settlement event of our securities or upon the exercise of options or warrants to purchase our securities on a “cashless” or “net exercise” basis to the extent permitted by the instruments representing such options or warrants (and any transfer to us necessary to generate such amount of cash needed for the payment of taxes, including estimated taxes, due as a result of such vesting or exercise whether by means of a “net settlement” or otherwise) so long as such “cashless exercise” or “net exercise” is effected solely by the surrender of outstanding options or warrants (or the common stock issuable upon the exercise thereof) to us and our cancellation of all or a portion thereof to pay the exercise price and/or withholding tax and remittance obligations, provided that (1) in the case of (i), the shares received upon exercise or settlement of the option, restricted stock unit, or warrant are subject to the terms of the lock-up agreement and (2) to the extent a filing under Section 16 of the Exchange Act is required to made during the restricted period as a result of transfers, it shall clearly indicate that (A) the filing relates to the circumstances described above and (B) no securities were sold by the transferor in the open market, and (3) the transferor does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;
- the transfer of shares of common stock or any security convertible into or exercisable or exchangeable for common stock to us pursuant to agreements under which we have the option to repurchase such shares or a right of first refusal with respect to transfers of such shares, provided that (1) to the extent a filing under Section 16 of the Exchange Act is required to made during the restricted period as a result

## Table of Contents

of such transfers, it shall clearly indicate that (A) the filing relates to the circumstances described above and (B) no securities were sold by the transferor in the open market, and (2) the transferor does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;

- the transfer of shares of common stock or any security convertible into or exercisable or exchangeable for common stock that occurs pursuant to a qualified domestic order or in connection with a divorce settlement, provided that (i) each transferee shall sign and deliver a lock-up agreement, (ii) any filing under Section 16 of the Exchange Act made during the restricted period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described above and (B) no securities were sold by the transferor, and (iii) the transferor does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;
- the conversion of the outstanding preferred stock into shares of our common stock, provided that such shares of common stock remain subject to the terms of the lock-up agreement; or
- the sale of shares of common stock to the underwriters pursuant to the underwriting agreement.

Morgan Stanley & Co. LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing, and brokerage activities. Certain of the underwriters and their respective affiliates have performed and may in the future perform various financial advisory and investment banking services for us, for which they will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Pricing of the Offering**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our results from operations and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

### **Selling Restrictions**

#### ***European Economic Area***

In relation to each Member State of the European Economic Area, an offer to the public of any shares of our common stock may not be made in that Member State, except that an offer to the public in that Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Member State:

- (i) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (ii) 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- (iii) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of our common stock in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive) and includes any relevant implementing measure in each Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

#### ***United Kingdom***

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, or FSMA) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

#### **Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### **Notice to Prospective Investors in Switzerland**

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or "SIX," or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

#### **Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

### **Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

### **Notice to Prospective Investors in Hong Kong**

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

### **Notice to Prospective Investors in Japan**

The shares of common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

## Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of common stock may not be circulated or distributed, nor may the shares of common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) the sole purpose of which is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law;
- (d) as specified in Section 276(7) of the SFA; or
- (e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.



## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Cooley LLP, Palo Alto, California. Latham & Watkins LLP, New York, New York is representing the underwriters in this offering.

## EXPERTS

The consolidated financial statements as of December 31, 2016 and December 31, 2017 and for each of the years then ended included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to our ability to continue as a going concern as described in Note 2 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules to the registration statement. Please refer to the registration statement, exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract or other document are only summaries. With respect to any contract or document that is filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract or document, and each statement in this prospectus regarding that contract or document is qualified by reference to the exhibit. You may read and copy the registration statement and its exhibits and schedules at the SEC's public reference room, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers, like us, that file documents electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov). The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

Upon closing of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at [www.si-bone.com](http://www.si-bone.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

**SI-BONE, INC.**  
**Index to Consolidated Financial Statements**

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<b>Consolidated Financial Statements</b>	
<a href="#">Consolidated Balance Sheets</a>	F-3
<a href="#">Consolidated Statements of Operations and Comprehensive Loss</a>	F-4
<a href="#">Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit</a>	F-5
<a href="#">Consolidated Statements of Cash Flows</a>	F-6
<a href="#">Notes to Consolidated Financial Statements</a>	F-7

**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 as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, of changes in redeemable convertible preferred stock and stockholders' deficit and of cash flows for 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, 2017 and 2016, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

*Substantial Doubt About the Company's Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has determined there is risk of future non-compliance with its debt covenants that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

July 31, 2018, except for the effects of the reverse stock split discussed in Note 2 to the consolidated financial statements, as to which the date is October 5, 2018

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

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

	<u>December 31,</u>		<u>June 30,</u>	<u>Pro Forma</u>
	<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>June 30,</u>
			<u>(unaudited)</u>	<u>2018</u>
				<u>(unaudited)</u>
<b>ASSETS</b>				
<b>CURRENT ASSETS</b>				
Cash and cash equivalents	\$ 27,900	\$ 22,408	\$ 16,233	\$ 16,233
Accounts receivable, net of allowance for doubtful accounts of \$316, \$268 and \$263 (unaudited) at December 31, 2016 and 2017 and June 30, 2018, respectively	5,951	7,416	7,254	7,254
Inventory	1,514	2,553	2,888	2,888
Prepaid expenses and other current assets	959	1,252	947	947
<b>Total current assets</b>	<b>36,324</b>	<b>33,629</b>	<b>27,322</b>	<b>27,322</b>
Property and equipment, net	2,608	1,896	2,211	2,211
Intangible assets, net	47	40	36	36
Other non-current assets	457	269	344	344
<b>TOTAL ASSETS</b>	<b>\$ 39,436</b>	<b>\$ 35,834</b>	<b>\$ 29,913</b>	<b>\$ 29,913</b>
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (EQUITY)</b>				
<b>CURRENT LIABILITIES</b>				
Accounts payable	\$ 1,025	\$ 1,814	\$ 1,358	\$ 1,358
Accrued liabilities and other	4,125	5,724	5,924	5,924
Short term borrowings	8,236	—	—	—
<b>Total current liabilities</b>	<b>13,386</b>	<b>7,538</b>	<b>7,282</b>	<b>7,282</b>
Redeemable convertible preferred stock warrants	588	422	646	—
Long term borrowings	21,074	38,704	38,834	38,834
Other long-term liabilities	—	—	306	306
<b>TOTAL LIABILITIES</b>	<b>35,048</b>	<b>46,664</b>	<b>47,068</b>	<b>46,422</b>
Commitments and contingencies (Note 5)				
Redeemable convertible preferred stock, \$0.0001 par value;				
Authorized: 11,552,989, 12,104,749 and 12,104,749 (unaudited) shares at December 31, 2016 and 2017 and June 30, 2018, respectively; issued and outstanding: 11,330,704, 11,871,578 and 11,871,578 (unaudited) shares at December 31, 2016 and 2017 and June 30, 2018, respectively; (Liquidation preference of \$113,767, \$119,194 and \$119,194 (unaudited) at December 31, 2016 and 2017 and June 30, 2018, respectively; no shares authorized, issued, or outstanding at June 30, 2018, pro forma (unaudited)	113,121	118,548	118,548	—
<b>STOCKHOLDERS' DEFICIT (EQUITY)</b>				
Common stock, \$0.0001 par value; Authorized: 18,777,777, 19,333,333 and 19,333,333 (unaudited) shares at December 31, 2016 and 2017 and June 30, 2018, respectively; issued and outstanding: 3,446,137, 3,603,140 and 3,707,268 (unaudited) shares, at December 31, 2016 and 2017 and June 30, 2018, respectively; 100,000,000 shares authorized and 15,795,538 shares issued and outstanding at June 30, 2018, pro forma (unaudited)	1	1	1	2
Additional paid-in capital	8,000	9,943	10,933	130,126
Stockholders' notes receivable	(521)	—	—	—
Accumulated other comprehensive income	472	402	435	435
Accumulated deficit	(116,685)	(139,724)	(147,072)	(147,072)
<b>TOTAL STOCKHOLDERS' DEFICIT (EQUITY)</b>	<b>(108,733)</b>	<b>(129,378)</b>	<b>(135,703)</b>	<b>(16,509)</b>
<b>TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (EQUITY)</b>	<b>\$ 39,436</b>	<b>\$ 35,834</b>	<b>\$ 29,913</b>	<b>\$ 29,913</b>

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,		Six Months Ended June 30,	
	2016	2017	2017 (unaudited)	2018
Revenue	\$ 42,101	\$ 47,983	\$ 22,531	\$ 26,375
Cost of goods sold	5,165	5,112	2,566	2,230
Gross profit	<u>36,936</u>	<u>42,871</u>	<u>19,965</u>	<u>24,145</u>
Operating expenses:				
Sales and marketing	35,215	41,646	21,130	21,285
Research and development	6,380	5,513	2,768	2,502
General and administrative	12,906	13,062	6,737	4,972
Total operating expenses	<u>54,501</u>	<u>60,221</u>	<u>30,635</u>	<u>28,759</u>
Loss from operations	(17,565)	(17,350)	(10,670)	(4,614)
Interest and other income (expense), net:				
Interest income	71	175	73	130
Interest expense	(3,308)	(6,204)	(1,920)	(2,544)
Other income (expense), net	213	340	66	(320)
Net loss	<u>(20,589)</u>	<u>(23,039)</u>	<u>(12,451)</u>	<u>(7,348)</u>
Other comprehensive income:				
Changes in foreign currency translation	67	(70)	(35)	33
Comprehensive loss	<u>\$ (20,522)</u>	<u>\$ (23,109)</u>	<u>\$ (12,486)</u>	<u>\$ (7,315)</u>
Net loss per share, basic and diluted (Note 14)	<u>\$ (6.21)</u>	<u>\$ (6.65)</u>	<u>\$ (3.63)</u>	<u>\$ (2.04)</u>
Weighted-average number of common shares used to compute basic and diluted net loss per share (Note 14)	<u>3,314,198</u>	<u>3,467,096</u>	<u>3,426,963</u>	<u>3,603,308</u>
Pro forma net loss per common share, basic and diluted (unaudited) (Note 14)		<u>\$ (1.50)</u>		<u>\$ (0.45)</u>
Pro forma weighted-average number of common shares used to compute basic and diluted net loss per share (unaudited) (Note 14)		<u>15,480,394</u>		<u>15,691,578</u>

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'**  
**DEFICIT**

(In thousands, except share and per share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Stockholders' Notes Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount					
<b>Balances at December 31, 2015</b>	9,291,176	\$ 92,796	3,333,160	\$ 1	\$ 6,127	\$ (634)	\$ 405	\$ (96,096)	\$ (90,197)
Issuance of common stock upon exercise of stock options	—	—	110,970	—	320	—	—	—	320
Issuance of common stock upon exercise of unvested stock options	—	—	10,837	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,398	—	—	—	1,398
Issuance of redeemable convertible preferred stock, net of issuance costs	2,039,528	20,325	—	—	—	—	—	—	—
Repurchase of unvested early exercised stock options	—	—	(8,553)	—	—	—	—	—	—
Repurchase of common stock	—	—	(277)	—	(3)	—	—	—	(3)
Repayment of stockholders' note receivable	—	—	—	—	—	113	—	—	113
Vesting of early exercised stock options	—	—	—	—	158	—	—	—	158
Foreign currency translation	—	—	—	—	—	—	67	—	67
Net loss	—	—	—	—	—	—	—	(20,589)	(20,589)
<b>Balances at December 31, 2016</b>	11,330,704	113,121	3,446,137	1	8,000	(521)	472	(116,685)	(108,733)
Issuance of common stock upon exercise of stock options	—	—	152,691	—	383	—	—	—	383
Issuance of common stock upon exercise of unvested stock options	—	—	4,312	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,438	—	—	—	1,438
Issuance of redeemable convertible preferred stock, net of issuance costs	540,874	5,427	—	—	—	—	—	—	—
Repayment of stockholders' notes receivable	—	—	—	—	—	84	—	—	84
Forgiveness of stockholders' note receivable	—	—	—	—	—	437	—	—	437
Vesting of early exercised stock options	—	—	—	—	122	—	—	—	122
Foreign currency translation	—	—	—	—	—	—	(70)	—	(70)
Net loss	—	—	—	—	—	—	—	(23,039)	(23,039)
<b>Balances at December 31, 2017</b>	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 (unaudited)	—	—	48,402	—	208	—	—	—	208
Issuance of common stock upon exercise of unvested stock options (unaudited)	—	—	55,726	—	—	—	—	—	—
Stock-based compensation (unaudited)	—	—	—	—	754	—	—	—	754
Vesting of early exercised stock options (unaudited)	—	—	—	—	28	—	—	—	28
Foreign currency translation (unaudited)	—	—	—	—	—	—	33	—	33
Net loss (unaudited)	—	—	—	—	—	—	—	(7,348)	(7,348)
<b>Balances at June 30, 2018 (unaudited)</b>	<u>11,871,578</u>	<u>\$ 118,548</u>	<u>3,707,268</u>	<u>\$ 1</u>	<u>\$ 10,933</u>	<u>\$ —</u>	<u>\$ 435</u>	<u>\$ (147,072)</u>	<u>\$ (135,703)</u>

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

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

	<u>Year Ended</u> <u>December 31,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
			(unaudited)	
<b>Cash flows from operating activities</b>				
Net loss	\$(20,589)	\$(23,039)	\$(12,451)	\$(7,348)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	1,038	1,013	566	356
Change in allowance for doubtful accounts	(84)	(36)	24	(7)
Stock-based compensation	1,398	1,438	694	754
Change in fair value of redeemable convertible preferred stock warrants	(414)	(166)	31	224
Loss on write-off of property and equipment	337	214	88	48
Write-off of debt discount	—	650	—	—
Amortization of debt discount	299	285	157	130
Write-off of public offering costs	1,460	1,292	—	—
Forgiveness of notes receivable	—	437	437	—
Changes in operating assets and liabilities				
Accounts receivable	(98)	(1,313)	(18)	201
Inventory	1,186	(980)	(608)	(320)
Prepaid expenses and other assets	215	72	(123)	237
Accounts payable	(1,469)	811	804	(462)
Accrued liabilities and other	(32)	1,792	879	514
Net cash used in operating activities	<u>(16,753)</u>	<u>(17,530)</u>	<u>(9,520)</u>	<u>(5,673)</u>
<b>Cash flows from investing activities</b>				
Purchase of property and equipment	(441)	(478)	(274)	(715)
Net cash used in investing activities	<u>(441)</u>	<u>(478)</u>	<u>(274)</u>	<u>(715)</u>
<b>Cash flows from financing activities</b>				
Proceeds from the exercise of common stock options, net	320	383	82	208
Repurchase of common stock	(3)	—	—	—
Repayment of stockholders' notes receivable	113	84	—	—
Repayment of debt financing	—	(1,119)	—	—
Extinguishment of debt financing	—	(29,081)	—	—
Proceeds from debt financing	4,000	40,000	—	—
Payment of debt issuance costs	—	(1,540)	—	—
Proceeds from the issuance of redeemable convertible preferred stock, net	20,325	5,427	5,427	—
Payments of public offering costs	—	(1,292)	(291)	—
Net cash provided by financing activities	<u>24,755</u>	<u>12,862</u>	<u>5,218</u>	<u>208</u>
Effect of exchange rate changes on cash and cash equivalents	67	(346)	27	5
Net increase (decrease) in cash and cash equivalents	<u>7,628</u>	<u>(5,492)</u>	<u>(4,549)</u>	<u>(6,175)</u>
<b>Cash and cash equivalents at</b>				
Beginning of year	20,272	27,900	27,900	22,408
End of year	<u>\$ 27,900</u>	<u>\$ 22,408</u>	<u>\$ 23,351</u>	<u>\$ 16,233</u>
<b>Supplemental disclosure of cash flow information</b>				
Cash paid for interest	<u>\$ 2,994</u>	<u>\$ 4,514</u>	<u>\$ 1,750</u>	<u>\$ 1,981</u>
<b>Supplemental disclosure of noncash information</b>				
Vesting of early exercised stock options	\$ 158	\$ 122	\$ 60	\$ 28
Issuance of redeemable convertible preferred stock warrants	45	—	—	—
Purchases of property and equipment included in accounts payable and accrued liabilities	—	97	67	97
Public offering costs included in accounts payable and accrued liabilities	—	—	959	—

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

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. The Company and Basis of Presentation**

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 iFuse Implant System, or iFuse, in 2009 in the United States, in 2010 in certain countries in the European Union, and in 2015 in certain countries in the rest of the world.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Principles of Consolidation***

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). The consolidated financial statements include the Company’s accounts, as well as those of the Company’s three wholly-owned international subsidiaries. All inter-company accounts and transactions have been eliminated.

***Unaudited Interim Financial Information***

The accompanying interim consolidated financial statements as of June 30, 2018 and for the six months ended June 30, 2017 and 2018, and the related interim information contained within the notes to the consolidated financial statements, are unaudited. The unaudited interim consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments consisting of only normal recurring adjustments necessary for a fair statement of the Company’s financial position as of June 30, 2018, and the results of its operations and cash flows for the six months ended June 30, 2017 and 2018. Such adjustments are of a normal and recurring nature. The results for the six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, or for any future period.

***Unaudited Pro Forma Balance Sheet and Pro Forma Net Loss Per Share***

The June 30, 2018 unaudited pro forma balance sheet has been prepared assuming immediately prior to the completion of the Company’s initial public offering, (“IPO”): (i) the automatic conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock; (ii) the automatic net exercise of certain redeemable convertible preferred stock warrants, at the IPO price of \$15.00 per share and the related reclassification of the warrant liability to common stock and additional paid-in-capital; and (iii) the automatic conversion of certain other redeemable convertible preferred stock warrants into common stock warrants.

The unaudited pro forma basic and diluted net loss per share has been computed to give effect to the automatic conversion of the shares of redeemable convertible preferred stock into common stock immediately prior to the closing of an IPO, as if such conversion had occurred at the earlier of the beginning of the period or the date of issuance, if later. In addition, the numerator in the pro forma basic and diluted net loss per share calculation has been adjusted to remove the change in the fair value resulting from the remeasurement of the redeemable convertible preferred stock warrant liability as the redeemable convertible preferred stock warrants will be converted into warrants to purchase common stock or net exercised into common stock, and the related redeemable convertible preferred stock warrant liability will be reclassified to stockholders’ deficit immediately prior to the



**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

closing of an IPO. The denominator in the pro forma basic and diluted net loss per share calculation has been adjusted to include the number of shares into which certain redeemable convertible preferred stock warrants would be converted upon their net exercise immediately prior to the closing of an IPO at the IPO price of \$15.00 per share.

The unaudited pro forma net loss per share does not include the shares to be sold and related proceeds to be received from an IPO.

#### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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.

#### ***Segments***

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

The Company derives substantially all of its revenue from sales to customers in the United States. Revenue by geography is based on billing address of the customer. No single country outside the United States accounts for more than 10% of the total revenue during the periods presented. Long-lived assets held outside the United States are immaterial.

	<b>Year Ended December 31,</b>		<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2017</b>	<b>2017</b>	<b>2018</b>
Domestic	\$38,791	\$43,351	\$20,385	\$23,456
International	3,310	4,632	2,146	2,919
	<u>\$42,101</u>	<u>\$47,983</u>	<u>\$22,531</u>	<u>\$26,375</u>

#### ***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 resulting from the translation of the Company's consolidated balance sheets are recorded as a component of accumulated other comprehensive income. Gains and losses from foreign currency transactions are recognized as a component of other income (expense), net.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***Concentration of Credit Risk***

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

The Company's revenue and accounts receivable are spread across a large number of customers, primarily in the United States, and no one 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 early-stage 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, uncertainty of market acceptance of products, and the need to obtain additional financing.

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 and for the year ended December 31, 2017, the Company had an accumulated deficit of \$139.7 million and used \$17.5 million of cash in operations. As of and for the six months ended June 30, 2018, the Company had an accumulated deficit of \$147.1 million (unaudited) and used \$5.7 million (unaudited) of cash in operations. The Company has not achieved positive cash flow from operations to date. The Company held cash and cash equivalents of \$22.4 million and \$16.2 million (unaudited) as of December 31, 2017 and June 30, 2018, respectively.

The Company's primary cash needs are for the ongoing commercialization of its iFuse products. 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 revenue target is assessed quarterly based on the rolling twelve months of revenue, and increases by approximately 2%-4% each quarter. Beginning with the three months ended March 31, 2019, the Company is required to meet either revenue or earnings targets. The Company has met the minimum liquidity and revenue targets as of June 30, 2018, however there can be no assurances that the Company will continue to meet these targets in the future.

Management has the responsibility to evaluate whether conditions and/or events raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. In performing this assessment, management considered the risk associated with its ongoing ability to meet the financial covenants. 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 products and the uncertainty of future revenues from new products; (b) changes made to the business

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

that affect ongoing operating expenses; (c) changes made in its business strategy; (d) regulatory developments affecting existing products; (e) changes made in research and development spending plans; and (f) other items affecting forecasted levels of expenditures and use of cash resources. Considering all of these factors, primarily the risk of non-compliance with debt covenants, Management has determined there is substantial doubt about the Company's ability to continue as a going concern within one year from the financial statement issuance date.

The Company is seeking to complete an IPO of its common stock. In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings, or other capital sources. The Company may not be able to obtain funding on acceptable terms, or at all. If the Company does raise additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. If the Company is unable to obtain adequate financing when needed, it may have to delay, reduce the scope of or suspend one or more of its sales and marketing efforts, research and development activities, or other operations. If the Company raises additional capital through debt financing, it may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If the Company is unable to raise capital, it will need to delay, reduce, or terminate planned activities to reduce costs. Doing so will likely harm the Company's ability to execute its business plans. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund operations.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classifications of liabilities that may result from the outcome of this uncertainty.

***Reverse Stock Split***

In October 2018, our board of directors and stockholders approved a 1-for-18 reverse stock split of our 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, options, and warrants included in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all periods presented.

***Fair Value of Financial Instruments***

Carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate fair value due to their relatively short maturities and market interest rates, if applicable. The 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 carrying amount of the redeemable convertible preferred stock warrants has been marked to fair value such that the carrying amount represents its estimated fair value.

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:

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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.

The Company did not have any cash equivalents as of December 31, 2016. The Company's cash equivalents consist of money market funds as of December 31, 2017 and June 30, 2018 (unaudited). The money market funds are classified as Level 1 of the fair value hierarchy. The Company's redeemable convertible preferred stock warrants are classified within Level 3 of the fair value hierarchy. The redeemable convertible preferred stock warrants have been valued using a Black-Scholes valuation model and are subsequently marked to fair value each reporting period. The related input assumptions are discussed in Note 9.

***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.

***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. As of December 31, 2016 and 2017 and June 30, 2018 (unaudited), inventory consisted entirely of finished goods.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***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.

***Intangible assets***

Intangible assets consist of intellectual property related to the sacroiliac-joint developed technologies acquired by the Company in March 2008. Intangible assets are amortized over the period of estimated benefit using the straight-line method and estimated useful lives of approximately 15 years. No residual value is estimated for intangible assets.

***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 an asset might not be recoverable. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. Through December 31, 2017 and June 30, 2018 (unaudited), the Company has not experienced impairment losses on its long-lived assets.

***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 IPO does not occur or is significantly delayed, all of the costs will be expensed. There were \$1.5 million, \$0, and \$0 (unaudited) of offering costs capitalized as of December 31, 2016 and 2017 and June 30, 2018, respectively, in other non-current assets on the consolidated balance sheets. The \$1.5 million of offering costs incurred in 2015 were expensed to General and Administrative expenses in 2016 when IPO plans were delayed. Offering costs of \$1.3 million were also incurred and expensed in 2017 as a result of further delays in the IPO process.

***Common Stock 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

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

consolidated balance sheet. The Company determined that the warrants for shares of common stock issued in connection with the debt arrangement 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.

***Redeemable Convertible Preferred Stock Warrants***

Warrants and other similar instruments related to shares that are contingently redeemable are classified as liabilities on the consolidated balance sheet at their estimated fair value because the shares underlying the warrants may obligate the Company to transfer assets to the holders at a future date under certain circumstances such as a deemed liquidation event. The warrants are exercisable into the Company's redeemable convertible preferred stock and are classified as liabilities on the consolidated balance sheet. The warrants, measured at fair value, are subject to re-measurement at each balance sheet date and the change in fair value, if any, is recognized as other income (expense), net. The Company will continue to adjust the liability for changes in fair value until the earlier of (i) exercise of the warrants, (ii) conversion into equity classified warrants to purchase common stock, or (iii) expiration of the warrants. The remaining value of the redeemable convertible preferred stock warrants will be reclassified to common stock with no further remeasurement required upon exercise of the warrants or conversion into equity classified warrants to purchase common stock.

The Company estimates the fair value of these liabilities using option pricing models and assumptions that are 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.

***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 United States and Europe.

In accordance with ASC Topic 605, Revenue Recognition ("ASC 605"), the Company recognizes 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. For the majority of product sales where the Company's sales representative delivers the product at the point of implantation at hospitals or other medical facilities, the Company recognizes revenue related to product sales upon completion of the procedure and authorization by the customer. Revenue is recognized upon receipt of a purchase agreement or agreement on pricing terms with the customer and when all other revenue recognition criteria are met. For the remaining sales, which include distributor and hospital sales where the product is ordered in advance of a procedure and a valid purchase order has been received, the Company recognizes revenue based upon shipping or delivery terms, which represents the point in time when the customer has taken ownership and assumed risk of loss and the required revenue recognition criteria are met. Such customers are obligated to pay within specified terms regardless of when or if they ever sell or use the products, and the Company has no post-delivery obligations.

***Warranty Program***

In January 2017, the Company implemented a warranty program which 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. These one-time credits are accounted for as sales reserves. Sales and warranty reserves from the warranty program were

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

\$0, \$0.1 million and \$0.2 million (unaudited) as of December 31, 2016, December 31, 2017, and June 30, 2018, respectively.

***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 United States. The medical device excise tax is included in cost of goods sold in the consolidated statements of operations and comprehensive loss for all the periods presented. Effective December 2015, the Act was amended to include a provision to suspend the tax on medical devices through 2017. In January 2018, the suspension on the tax on medical devices was further extended through 2019.

***Shipping and Handling Costs***

Shipping and handling costs are expensed as incurred and are included in cost of goods sold.

***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 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. Advertising costs totaled \$1.0 million and \$0.8 million for the years ended December 31, 2016 and 2017, respectively, and \$0.4 million (unaudited) and \$0.3 million (unaudited) for the six months ended June 30, 2017 and 2018, respectively.

***Stock-Based Compensation***

The Company measures its stock-based awards made to employees based on the estimated fair values of the awards as of the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions including expected volatility, expected life, risk-free interest rate and expected dividends. 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.

Equity instruments issued to nonemployees 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 nonemployees 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.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***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 adopted the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording uncertain tax positions taken, or expected to be taken, in a tax return in the financial statements. The guidance also prescribes treatment for derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The Company accrues for the estimated amount of taxes for uncertain tax positions if it is more likely than not that the Company would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has a less than 50% likelihood of being sustained.

***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' deficit except those resulting from distributions to stockholders. The Company's unrealized foreign currency translation income (losses) represents the only component of other comprehensive income that is 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.

***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, which required 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. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The



**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which clarifies the implementation guidance on principal versus agent considerations in ASU 2014-09. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, 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. These standards have the same effective date and transition date as ASU 2014-09. Management is undergoing its assessment of the new standard, which includes the review of contracts and revenue channels, and will adopt the standard for the fiscal year ending December 31, 2019.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 simplifies the guidance on the subsequent measurement of inventory, excluding inventory measured using last-in, first out or the retail inventory method. Under the new standard, in scope inventory should be measured at the lower of cost and net realizable value. The new standard will become effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2016, for public companies. For all other entities, the new standard is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017, with early adoption permitted. The Company has adopted this standard for the fiscal year ended December 31, 2017, which did not have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes. ASU 2015-17 specifies that deferred tax assets and liabilities shall be classified as noncurrent, or long-term, in a classified statement of financial position. The new standard is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. For private entities, the new standard is effective for fiscal years beginning after December 15, 2017, and interim periods within fiscal years beginning after December 15, 2018. Earlier application is permitted for all entities as of the beginning of an interim or an annual reporting period. The Company has early adopted this standard for the fiscal year ended December 31, 2017, which did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued its new lease accounting guidance. Under the new guidance, ASU 2016-02, Leases (Topic 842), lessor accounting is largely unchanged. The new lease guidance simplifies the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Under the new guidance, lessees will be required to recognize a lease liability, which is a lessor's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which 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. The new guidance is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018 for public companies and beginning after December 15, 2019 for private companies. Early adoption is permitted for any interim or annual financial statements net yet issued. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing and operating leases) must apply a modified retrospective approach for all leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact of this standard on its consolidated financial statements, and anticipates adopting the standard for the fiscal year ending December 31, 2020.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In March 2016, the FASB issued ASU 2016-09, which simplified several aspects of accounting for stock-based compensation transactions. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new guidance is effective for public entities for fiscal years beginning after December 15, 2016 and interim periods within those years. Other entities must apply the new guidance in fiscal years beginning after December 15, 2017 and in interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. The Company early adopted this standard in the first quarter of 2017 by recording the cumulative impact of applying this guidance to retained earnings, which was not material. The Company elected to continue to estimate the number of awards that are expected to vest.

In August 2016, the FASB issued ASU 2016-15 “Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments”. ASU 2016-15 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. Current GAAP does not include specific guidance on these eight cash flow classification issues. The amendments of this ASU are 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 is currently evaluating the impact of adopting ASU 2016-15 on its consolidated financial statements, and anticipates adopting the standard for the fiscal year ending December 31, 2019.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for all entities for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company has adopted this standard for the fiscal year ending December 31, 2018, which did not have a material impact on the Company’s consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public business entities, the amendments in Part I of this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update 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 for all entities, including adoption in an interim period. The Company is currently evaluating the

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

impact that the adoption of this standard will have on its consolidated financial statements, and anticipates adopting the standard for the fiscal year ending December 31, 2020.

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 (the 2017 Tax 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 is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements, and anticipates adopting the standard for the fiscal year ending December 31, 2019.

In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 expands the scope of Topic 718, Compensation—Stock Compensation, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees 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 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. Fair Value Measurement**

The following table sets forth the fair value of the Company’s financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	December 31, 2016			Total
	Level 1	Level 2	Level 3	
<b>Liabilities</b>				
Redeemable convertible preferred stock warrants	\$ —	\$ —	\$ 588	\$ 588
<b>Assets</b>				
Money market funds <sup>[1]</sup>	\$22,115	\$ —	\$ —	\$22,115
<b>Liabilities</b>				
Redeemable convertible preferred stock warrants	\$ —	\$ —	\$ 422	\$ 422
<b>Assets</b>				
Money market funds <sup>[1]</sup>	\$15,773	\$ —	\$ —	\$15,773
<b>Liabilities</b>				
Redeemable convertible preferred stock warrants	\$ —	\$ —	\$ 646	\$ 646

[1] Included in cash and cash equivalents on the consolidated balance sheet

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table sets forth a summary of the changes in the fair value of the redeemable convertible preferred stock warrants, the Company's Level 3 financial liability, which is measured on a recurring basis (in thousands):

<b>Balances at January 1, 2016</b>	<b>\$ 957</b>
Fair value of redeemable convertible preferred stock warrants issued	45
Change in fair value recorded in other (income) expense, net	<u>(414)</u>
<b>Balances at December 31, 2016</b>	<b>588</b>
Change in fair value recorded in other (income) expense, net	<u>(166)</u>
<b>Balances at December 31, 2017</b>	<b>422</b>
Change in fair value recorded in other (income) expense, net (unaudited)	<u>224</u>
<b>Balances at June 30, 2018 (unaudited)</b>	<b><u>\$ 646</u></b>

**4. Balance Sheet Components**

Property and Equipment, net (in thousands):

	<u>December 31,</u>		<u>June 30,</u>
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Machinery and equipment	\$ 2,942	\$ 3,428	\$ 3,522
Construction in progress	1,131	879	806
Computer and office equipment	275	310	340
Leasehold improvements	272	272	443
Furniture and fixtures	25	29	145
	<u>4,645</u>	<u>4,918</u>	<u>5,256</u>
Less: Accumulated depreciation and amortization	<u>(2,037)</u>	<u>(3,022)</u>	<u>(3,045)</u>
	<u>\$ 2,608</u>	<u>\$ 1,896</u>	<u>\$ 2,211</u>

Depreciation expense for the years ended December 31, 2016 and 2017 and for the six months ended June 30, 2017 and 2018 was \$1.0 million, \$1.0 million, \$0.6 million (unaudited), and \$0.3 million (unaudited), respectively.

Accrued Liabilities and Other (in thousands):

	<u>December 31,</u>		<u>June 30,</u>
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Accrued compensation, travel and related expenses	\$2,842	\$3,732	\$ 3,392
Sales tax payable	448	466	484
Accrued professional services	360	341	262
Liability for early exercise of unvested stock options	168	65	293
Accrued interest	86	831	1,163
Sales and warranty reserves	10	149	148
Others	211	140	182
	<u>\$4,125</u>	<u>\$5,724</u>	<u>\$ 5,924</u>

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 5. Commitments and Contingencies

### *Operating Leases*

In August 2012, the Company entered into a new four-year non-cancelable operating lease for its existing office building space in San Jose, California which commenced in January 2013. In February 2014, the Company expanded the existing lease space and extended the lease terms through June 2017. In May 2016, the Company entered into another extension of the lease with its lessor for additional 12 months beginning in July 2017. Effective May 2018, the Company entered into an early termination agreement on an operating lease for its San Jose office. No early termination fees were incurred and all previously agreed-to rent payments were released, with no further obligations. In February 2018, the Company entered into a new seven-year non-cancelable operating lease for an office building space in Santa Clara, California which commenced in April 2018.

In March 2011, the Company entered into a six-year non-cancelable operating lease for its office building space in Milan, Italy. In February 2017, the terms of the lease were extended for another six years under the same agreement. In September 2015, the Company entered into a six-year non-cancelable operating lease for additional floor space in its office building in Milan, Italy.

In November 2014, the Company entered into a five-year non-cancelable operating lease for its office building space in Mannheim, Germany.

In December 2015, the Company entered into a three-year non-cancelable operating lease for its office building space in Knaresborough, United Kingdom.

The Company also leases vehicles under operating lease arrangement for the Company's sales personnel in Europe. Operating leases under such arrangements expire during various times in 2021.

Rent expense is recorded over the lease terms on a straight-line basis. Rent expense charged to operations under operating leases totaled approximately \$1.0 million for each of the years ended December 31, 2016 and 2017 and \$0.5 million (unaudited) and \$0.6 million (unaudited) for the six-month periods ended June 30, 2017 and 2018, respectively.

The aggregate future minimum lease payments under all leases as of December 31, 2017 are as follows (in thousands):

<b>Year Ending December 31,</b>	
2017	\$721
2018	113
2019	56
2020	46
Thereafter	31
	<u>\$967</u>

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The aggregate future minimum lease payments under all leases as of June 30, 2018 (unaudited) are as follows (in thousands):

<b>Year Ending December 31,</b>	
2018 (six months remaining)	\$ 472
2019	1,014
2020	952
2021	829
2022	781
Thereafter	1,921
	<u>\$5,969</u>

### ***Contingencies***

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

### ***Purchase Commitments and Obligations***

The Company has certain purchase commitments related to inventory used in normal course of business. These commitments totaled \$0.1 million at December 31, 2017 and \$0.3 million (unaudited) at June 30, 2018. The amounts paid under these arrangements may be less in the event that the arrangement is renegotiated or cancelled.

### ***Legal Proceedings***

The Company is subject to claims and assessments from time to time in the ordinary course of business but does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's financial position, results of operations or cash flows.

### ***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.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**6. Borrowings**

The Company has the following outstanding debt, net of debt discounts, as of December 31, 2016 and 2017 and June 30, 2018 (unaudited) (in thousands):

	<u>December 31,</u>		<u>June 30,</u>
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Term Loan	\$29,310	\$38,704	\$ 38,834
Total Borrowings	29,310	38,704	38,834
Less: Short-Term Borrowings	8,236	—	—
Long-Term Borrowings	<u>\$21,074</u>	<u>\$38,704</u>	<u>\$ 38,834</u>

**Term Loan**

In October 2015, the Company entered into a Term Loan facility and a revolving line of credit with Silicon Valley Bank, or SVB and Oxford Finance LLC, or Oxford for \$35.2 million. The first tranche of the Term Loan closed in October 2015 for \$16.2 million, of which \$15.5 million (including \$0.3 million of interest) of the proceeds were used to pay off the existing loans with SVB. The additional \$0.7 million related to the payment of final fees due on previous loans. Prepayment fees on the then existing debt facilities were waived. The loan includes an interest-only period through March 31, 2017 and then to be repaid over thirty-three (33) months of equal principal payments plus interest. In November 2015, the Company drew the second tranche of \$10.0 million, which was coterminous with the first tranche. Under the Term Loan, the Company also had available a third tranche of \$4.0 million through September 30, 2016 and a fourth tranche of \$5.0 million through December 31, 2016. Both tranches were contingent upon the achievement of certain goals.

The Company accounted for SVB's portion of the term loan facility as a modification of its existing debt facility as the change in cash flows was less than 10%. As such, a new effective interest rate was established based on the carrying value of the debt and the revised cash flows. Based on the guidance for loan modification, no gains or losses were recorded on the old debt and new fees paid to or received from existing lenders were capitalized and amortized as part of the effective yield. As a result, the Company accounted for the portion of the \$0.7 million of final fees related to the previous loans, not yet recognized in interest expense, as a debt discount. This amount will be amortized over the remaining period of the Term Loan as part of the new effective interest rate.

In August 2016, the Company amended the agreement to remove the revenue requirement for the third tranche and extended the draw period of the fourth tranche for additional three months. In December 2016, the Company withdrew the third tranche of the Term Loan of \$4.0 million. The agreement also provided for the fourth tranche of \$5.0 million to be available through March 2017 contingent upon the Company achieving at least \$24.0 million in trailing six-month revenues. In February 2017, the Company amended the Term Loan to extend the interest only period by six months to October 1, 2017 and was then to be repaid over 27 months of equal principal payments plus interest. In addition, the amendment extended the draw period through January 2018 for the fourth tranche of \$5.0 million under the Term Loan upon achieving certain revenue milestones. The maturity date of the term loan was December 1, 2019, and it carried an interest rate equal to the greater of 11% or the WSJ Prime rate plus 7.75%. As of December 31, 2016, the total loan balance was \$30.2 million with an effective interest rate of 12.45%. The Term Loan borrowings were senior unsecured obligations of the Company, ranking equally and ratably among themselves and with the Company's existing and future unsecured and unsubordinated debt.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In conjunction with the above Term Loan agreements, the Company issued redeemable convertible preferred stock warrants (refer to Note 9 for details).

In October 2017, the Company extinguished the Term Loan with SVB and Oxford. Concurrently, the Company entered into a New Term Loan with Pharmakon Advisors, or Pharmakon. As a result of the extinguished debt, the Company paid \$29.1 million in principal payments to SVB and Oxford. The Company also paid \$1.5 million in early termination fees and recorded \$0.7 million of unamortized debt discounts. This loss on extinguishment of \$2.2 million is reflected as interest expense in the consolidated statement of operations.

The Company entered into the New Term Loan with Pharmakon for \$40.0 million in October 2017. Debt issuance costs of \$1.3 million were recorded as a direct deduction from the carrying amount of the New Term Loan on the consolidated balance sheet, and are being amortized over the period of the New Term Loan using the effective interest method to interest expense in the consolidated statement of operations. The New 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, and is classified as long-term borrowings on the consolidated balance sheet. The New 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 New 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 New Term Loan requires the Company to maintain a minimum cash balance of \$5.0 million and revenue targets. Beginning with the three months ended March 31, 2019, the Company is required to meet either revenue or earnings targets. Under the New Term Loan, the Company also has a second tranche of \$10.0 million available through January 2019, contingent upon the achievement of certain revenue milestones. The New Term Loan is a senior obligation secured with a blanket first lien on the assets of the Company. As of December 31, 2017 and June 30, 2018, the total loan balance, net of debt discount, was \$38.7 million and \$38.8 million (unaudited), respectively, with an effective interest rate of 12.0% and 12.2% (unaudited) and the Company was in compliance with all debt covenants.

Approximate annual future minimum principal payments under the loan agreements as of December 31, 2017 are as follows (in thousands):

<b>Year Ending at December 31,</b>	
2018	\$ —
2019	—
2020	4,444
2021	17,778
2022	17,778
Total future minimum payments	40,000
Less:	
Amount representing debt discount	(1,296)
Total minimum payments	<u>\$38,704</u>

***Line of Credit***

In October 2015, the Company entered into an agreement with its existing lender SVB and Oxford. The amount of the revolving line of credit is \$4.0 million (or 80% of the amount of certain customer accounts receivable). It carried an interest rate equal to the WSJ Prime rate plus 3% with a maturity of December 1, 2019. In October 2017, this line of credit was cancelled in conjunction with the SVB and Oxford debt extinguishment discussed above. No draws were made on this facility through its termination. Cancellation fees of \$0.2 million were included in the loss on extinguishment of the Term Loan of \$1.5 million discussed above.



**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

### 7. Common Stock

In March 2017, the Board of Directors approved an increase of 555,555 Series 2 common stock. As a result, the Company's restated certificate of incorporation, as amended, authorizes the Company to issue 19,333,333 shares of \$0.0001 par value common stock, of which 6,000,000 has been designated as Series 1 common stock and 13,333,333 has been designated as Series 2 common stock. The holders of Series 1 common stock shall have no voting rights; the holders of Series 2 common stock shall have the right to one vote for each such share. The holders of common stock are also 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.

The Company has reserved shares of common stock, on an issued and as-converted basis, for future issuance as follows:

	<u>December 31, 2017</u>		<u>June 30, 2018</u>	
	<u>Issued and Outstanding Shares</u>	<u>Common Stock Equivalent Shares</u>	<u>Issued and Outstanding Shares</u>	<u>Common Stock Equivalent Shares</u>
			(unaudited)	
Series 1 common stock	3,112,955	3,112,955	3,217,083	3,217,083
Series 2 common stock	490,185	490,185	490,185	490,185
Redeemable convertible preferred stock	11,871,578	12,066,654	11,871,578	12,066,654
Stock options outstanding	3,001,929	3,001,929	2,900,842	2,900,842
Stock options available for grant	29,654	29,654	26,613	26,613
Common stock warrants	124,326	124,326	124,326	124,326
Redeemable convertible preferred stock warrants	156,550	160,657	156,550	160,657
Total	<u>18,787,177</u>	<u>18,986,360</u>	<u>18,787,177</u>	<u>18,986,360</u>

### 8. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock ("preferred stock") at December 31, 2016 consisted of the following:

<u>Series</u>	<u>Shares</u>		<u>Carrying Value</u>	<u>Liquidation Value</u>
	<u>Authorized</u>	<u>Issued and Outstanding</u>		
			(in thousands)	
Series 1	245,096	245,096	\$ 154	\$ 154
Series 2	709,617	709,608	1,489	1,520
Series 3	498,958	498,938	2,862	2,874
Series 4	2,509,047	2,509,032	15,656	15,807
Series 5	2,086,138	2,009,226	18,127	18,275
Series 6	3,389,227	3,319,274	54,508	54,674
Series 7	2,114,906	2,039,530	20,325	20,463
Total	<u>11,552,989</u>	<u>11,330,704</u>	<u>\$ 113,121</u>	<u>\$ 113,767</u>

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Preferred stock at December 31, 2017 and June 30, 2018 (unaudited) consisted of the following:

Series	Shares		Carrying Value	Liquidation Value
	Authorized	Issued and Outstanding		
			(in thousands)	
Series 1	245,096	245,096	\$ 154	\$ 154
Series 2	709,617	709,608	1,489	1,520
Series 3	498,958	498,938	2,862	2,874
Series 4	2,509,047	2,509,032	15,656	15,807
Series 5	2,086,138	2,009,226	18,127	18,275
Series 6	3,389,227	3,319,274	54,508	54,674
Series 7	2,666,666	2,580,404	25,752	25,890
Total	<u>12,104,749</u>	<u>11,871,578</u>	<u>\$ 118,548</u>	<u>\$ 119,194</u>

The holders of preferred stock have various rights and preferences as follows:

#### ***Voting Rights***

The holders of Series 1, Series 2, Series 3, Series 4, Series 5, Series 6, and Series 7 preferred stock shares are entitled to vote on all matters on which the common stockholders are entitled to vote. The holders of Series 1, Series 2, Series 3 shall have the right to 0.352941 votes for each share of Series 2 common stock into which such preferred stock would convert and the holders of Series 4, Series 5, Series 6 and Series 7 shall have the right to one vote for each share of Series 2 common stock into which such preferred stock would convert. As long as there are any shares of Series 4, Series 5, Series 6, and Series 7 shares are outstanding, the holders of such Series 4, Series 5, Series 6 and Series 7 shall, at each respective series, be entitled to elect one member of the Board of Directors each; the holders of Series 2 common stock shall be entitled to elect two members of the Board of Directors; and the holders of the preferred stock and Series 2 common stock, voting together as a single class shall be entitled to elect the remaining members of the Board of Directors, as determined at each annual meeting of the Board of Directors.

As long as at least 277,778 preferred stock shares remain outstanding, the Company must obtain approval from a majority of the holders of the then outstanding shares of preferred stockholders and a majority of the voting power of all outstanding shares of Series 5 preferred stock in order to (i) consummate or agree to consummate a Liquidation Event (as defined in the Company's certificate of incorporation); (ii) amend, alter, restate or repeal any provision of the Company's certificate of incorporation or bylaws so as to adversely alter, affect or change the powers, preferences, rights or privileges of the shares of preferred stock; (iii) increase or decrease (other than by redemption or conversion) the total number of authorized shares of common stock or preferred stock or designated shares of any series of preferred stock; (iv) authorize or issue, or obligate itself to issue, any equity security (including any other security convertible into or exercisable for any such equity security) having a preference over, or being on a parity with, any series of preferred stock with respect to dividends, liquidation or redemption, other than the issuance of any authorized but unissued shares of Series 6 preferred stock designated in the Company's certificate of incorporation (including any security convertible into or exercisable for such shares of preferred stock); (v) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any share or shares of preferred stock or common stock; provided, however, that this restriction shall not apply to the repurchase of shares of common stock from employees, officers, directors, consultants or other persons performing services for the Company or any subsidiary pursuant to agreements under which the Company has the option to repurchase such shares upon the occurrence of certain events, such as the termination of employment or service, or pursuant to an agreement providing for a right of

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

first refusal in favor of the Company, in each case, provided that such agreement has been approved by the Company's board of directors; or (vi) pay or declare any dividend on any shares of capital stock of the Company.

***Dividends***

The holders of preferred stock are entitled to receive noncumulative dividends, when and if declared by the Board of Directors, out of any assets legally available, prior to and in preference to any declaration or payment of dividends on the common stock of the Company. Dividend rates, on a per annum basis, for Series 1, Series 2, Series 3, Series 4, Series 5, Series 6, and Series 7 preferred stock are \$0.050112, \$0.171360, \$0.4608, \$0.504, \$0.72774, \$1.317744, and \$0.802656, respectively, (adjusted to reflect subsequent stock dividends, stock splits or recapitalization).

After payment of such dividends, any additional dividends shall be distributed to the holders of all preferred stock and common stock on a pro rata basis in proportion to the number of common stock held by each shareholder as if the preferred stock had been converted at the effective conversion rate. No dividends on preferred stock or common stock have been declared as of December 31, 2017 and June 30, 2018 (unaudited).

***Liquidation***

In the event of (A) the closing of the sale, lease, transfer, exclusive license or other disposition of all or substantially all of the Company's assets, in a single transaction or series of related transactions, by the Company or any subsidiary or subsidiaries of the Company, of all or substantially all the assets of the Company and its subsidiaries taken as a whole (or, if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by one or more subsidiaries, the sale or disposition (whether by consolidation, merger, conversion or otherwise) of such subsidiaries of the Company or all or substantially all of the assets of such subsidiaries), except where such sale, lease, transfer, exclusive license or other disposition is made the Company or one or more wholly owned subsidiaries of the Company, (B) the consummation of a merger, consolidation or acquisition in which (x) the Company is a constituent party or (y) a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger, consolidation or acquisition (except a merger, consolidation or acquisition involving the Company or a subsidiary in which the capital stock of the Company outstanding immediately prior to such merger, consolidation or acquisition continue to represent or are converted or exchanged for shares of capital stock which represent, immediately following such merger, consolidation or acquisition at least a majority of the voting power of the capital stock of (1) the surviving or resulting corporation or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger, consolidation or acquisition, the parent corporation of such surviving or resulting corporation); (C) any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; provided that it shall not include any transaction or series of related transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof occurs, or (D) a liquidation, dissolution or winding up of the Company, the holders of the preferred stock are entitled to receive prior to and in preference to any distribution to holders of the common stock, an amount equal to their respective original issuance price per share (original issuance price per share for Series 1, Series 2, Series 3, Series 4, Series 5, Series 6, and Series 7 preferred stock are \$0.6264, \$2.142, \$5.76, \$6.30, \$9.0954, \$16.4718, and \$10.0332, respectively), plus any declared but unpaid dividends on such shares. Should the Company's legally available assets be insufficient to satisfy the full liquidation preference, the funds will be distributed ratably among the holders of the preferred stock in proportion to the preferential amount each holder is otherwise entitled to receive.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Upon the closing of the distribution as above, the remaining proceeds shall be distributed among the holders of Series 4, Series 5, Series 6, Series 7 preferred stock and common stock pro rata based on the number of shares of common stock held by each until the holders of the preferred stock have received the "participation cap." Thereafter, if proceeds remain, the holders of Series 7 preferred stock and common stock of this corporation shall receive all of the remaining proceeds pro rata based on the number of shares of common stock held by each (assuming full conversion of all such Series 7 preferred stock). The Company has a per share "Participation Cap" of \$32.9436 for the Series 6 preferred stock, \$18.1908 for the Series 5 preferred stock, and \$12.60 for the Series 4 preferred stock (each as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations or the like with respect to such series of preferred stock).

***Conversion***

Each share of Series 1, Series 2, Series 3, Series 4, Series 5, Series 6, and Series 7 preferred stock is convertible at the option of the holder, into the number of shares of Series 2 common stock into which such shares are at the then effective conversion ratio or one to one ratio. The conversion price per share for Series 1, Series 2, Series 3 and Series 4, Series 5, Series 6, and Series 7 preferred stock shall be the respective issuance price per share, respectively. The initial conversion price is subject to adjustment from time to time. In March 2017, the conversion price per share for the Series 6 preferred stock was amended from \$15.714 per share to \$15.5574 per share which resulted in the conversion ratio increasing from 1.05 to 1.06 per share.

Each share of preferred stock shall be converted into common stock shares upon the earlier of (i) immediately before the closing of a firm commitment underwritten public offering in which the aggregate gross proceeds of not less than \$50.0 million and a per share public offering of not less than \$30.0996, or (ii) the Company's receipt of a written request for such conversion from the holders of at least the voting majority of all outstanding preferred stock (voting as a single class and on an as-converted basis).

***Other Matters***

The Company has classified the preferred stock as temporary equity on the consolidated balance sheets as the shares can be redeemed upon the occurrence of certain change in control events that are outside the Company's control, including deemed liquidation, sale or transfer of the Company. The Company has not adjusted the carrying values of the preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. Warrants**

Warrants issued and outstanding at December 31, 2016 are as follows (in thousands, except share and per share data):

<b>Warrants to purchase</b>	<b>Series</b>	<b>Date</b>			<b>Number of Shares Underlying Warrants</b>	<b>Price per Share</b>	<b>Fair Value at the Date of Issuance</b>
		<b>Issuance</b>	<b>Expiration</b>				
Common stock		7/19/2013	7/22/2023	[a]	101,010	\$ 3.96	\$ 244
Common stock		11/26/2014	11/26/2024	[a]	21,928	\$ 3.42	\$ 47
Total common stock warrants					<u>122,938</u>		
Redeemable convertible preferred stock	Series 5	7/1/2012	7/25/2019	[b]	54,917	\$ 9.10	\$ 255
Redeemable convertible preferred stock	Series 5	7/19/2013	7/22/2023	[c]	21,989	\$ 9.10	\$ 122
Redeemable convertible preferred stock	Series 6	11/26/2014	11/26/2024	[c]	6,310	\$ 16.47	\$ 49
Redeemable convertible preferred stock	Series 6	10/20/2015	10/20/2025	[c]	39,339	\$ 16.47	\$ 396
Redeemable convertible preferred stock	Series 6	11/9/2015	11/9/2025	[c]	24,283	\$ 16.47	\$ 244
Redeemable convertible preferred stock	Series 7	12/22/2016	12/22/2026	[c]	9,712	\$ 10.03	\$ 45
Total redeemable convertible preferred stock warrants					<u>156,550</u>		
Total outstanding common and redeemable convertible preferred stock warrants					<u>279,488</u>		

[a] Common stock warrants will remain outstanding until exercised by the holder.

[b] These warrants will be net exercised immediately upon the closing of the Company's IPO, or upon a corporate transaction as defined in the Note and Warrant Purchase Agreement dated July 25, 2012.

[c] Convertible preferred stock warrants will remain outstanding until exercised by the holder and will convert to common stock warrants upon an IPO and the convertible preferred stock warrant liability will be re-measured through the date of the IPO and if these warrants on common stock subsequently qualify for equity classification, no further re-measurement will be required thereafter. The warrants will be exercisable for 10 years from the date of issuance.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Warrants issued and outstanding at December 31, 2017 are as follows (in thousands, except share and per share data):

Warrants to purchase	Series	Date			Number of Shares Underlying Warrants	Price per Share	Fair Value at the Date of Issuance
		Issuance	Expiration				
Common stock		7/19/2013	7/22/2023	[a]	101,010	\$ 3.96	\$ 244
Common stock		11/26/2014	11/26/2024	[a]	21,928	\$ 3.42	\$ 47
Common stock		3/1/2017	3/1/2027	[a]	1,388	\$ 5.94	\$ 5
Total common stock warrants					124,326		
Redeemable convertible preferred stock	Series 5	7/1/2012	7/25/2019	[b]	54,917	\$ 9.10	\$ 255
Redeemable convertible preferred stock	Series 5	7/19/2013	7/22/2023	[c]	21,989	\$ 9.10	\$ 122
Redeemable convertible preferred stock	Series 6	11/26/2014	11/26/2024	[c]	6,310	\$ 16.47	\$ 49
Redeemable convertible preferred stock	Series 6	10/20/2015	10/20/2025	[c]	39,339	\$ 16.47	\$ 396
Redeemable convertible preferred stock	Series 6	11/9/2015	11/9/2025	[c]	24,283	\$ 16.47	\$ 244
Redeemable convertible preferred stock	Series 7	12/22/2016	12/22/2026	[c]	9,712	\$ 10.03	\$ 45
Total redeemable convertible preferred stock warrants					156,550		
Total outstanding common and redeemable convertible preferred stock warrants					280,876		

[a] Common stock warrants will remain outstanding until exercised by the holder.

[b] These warrants will be net exercised immediately upon the closing of the Company's IPO, or upon a corporate transaction as defined in the Note and Warrant Purchase Agreement dated July 25, 2012.

[c] Convertible preferred stock warrants will remain outstanding until exercised by the holder and will convert to common stock warrants upon an IPO. The warrants will be exercisable for 10 years from the date of issuance.

In connection with previously issued debt, the Company issued 101,010 warrants to purchase common shares of the Company at an exercise price of \$3.96 per share in July 2013. Additionally, the Company issued warrants to purchase an additional 21,928 shares of common stock at an exercise price of \$3.42 per share in November 2014. The Company determined that its warrants to purchase shares of common stock meet the requirements for equity classification.

In conjunction with debt issued in July 2012, the Company issued warrants to purchase an aggregate of 54,917 shares of Series 5 preferred stock of the Company at an exercise price of \$9.10 per share.

In conjunction with debt issued in 2013 and 2014, the Company issued 21,989 warrants to purchase Series 5 redeemable convertible preferred stock of the Company at an exercise price of \$9.10 per share. Subsequently, the Company issued additional warrants to purchase 6,310 shares of Series 6 redeemable convertible preferred stock at an exercise price of \$16.47 per share.

In conjunction with the debt agreement with SVB and Oxford, or Term Loan agreement (refer to Note 6), the Company issued warrants to purchase 39,339 shares of Series 6 redeemable convertible preferred stock at an exercise price of \$16.47 per share in October 2015 and additional 24,283 shares of Series 6 redeemable convertible preferred stock at an exercise price of \$16.47 per share in November 2015.

In conjunction with the Term Loan agreement and its modification (refer to Note 6), the Company issued additional warrants for the purchase of 9,712 shares of Series 7 redeemable convertible preferred stock at an exercise price of \$10.03 per share in December 2016.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The fair value of warrants to purchase preferred stock were recorded at the date of issuance as a discount to debt and amortized to interest expense over the term of the note. The changes in the fair value of the redeemable convertible preferred stock warrants are recorded in other income and expense.

In March 2017, the Company issued a warrant to purchase 1,388 shares of common stock at an exercise price of \$5.94 to a non-employee. The Company determined that such warrant meets the requirements for equity classification.

In October 2017, the Company extinguished its debt with SVB and Oxford. All related debt discounts were written off upon repayment of the loan.

Weighted-average assumptions used in computation of the fair value of the redeemable convertible preferred stock warrants are summarized in the table below:

	<u>December 31,</u>		<u>June 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
Remaining contractual term (in years)	4.6	5.3	5.8	4.9
Expected volatility	44.77%	59.06%	49.70%	53.83%
Risk-free interest rate	1.71%	2.16%	2.06%	2.64%
Dividend yield	0%	0%	0%	0%

#### **10. Stock Option Plan**

In April 2008, the Company adopted the 2008 Stock Option Plan (the "Plan"), as amended, under which the Board of Directors may issue incentive and nonqualified stock options to employees, directors and consultants. 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 nonqualified stock option shall not be less than 100% and 85%, respectively, of the fair market value on the date of grant. As of December 31, 2017, a total of 5,350,080 shares of common stock have been reserved for issuance under the Plan. 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.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes activity under the Plan for the years ended December 31, 2016 and 2017 and June 30, 2018 (unaudited):

	<u>Options Outstanding</u>			<u>Weighted-Average Remaining Contractual Life (in years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
	<u>Shares Available for Grant</u>	<u>Number of Shares</u>	<u>Weighted- Average Exercise Price</u>		
<b>Balances at January 1, 2016</b>	295,371	2,034,892	\$ 4.32		\$ 10,840
Additions to the Plan	538,244	—			
Options granted	(664,735)	664,735	4.45		
Options exercised	—	(121,807)	3.00		
Options cancelled	115,871	(115,871)	4.32		\$ 452
Options repurchased	8,553	—	3.67		
<b>Balances at December 31, 2016</b>	293,304	2,461,949	3.63		\$ 5,592
Additions to the Plan	433,333	—			
Options granted	(875,873)	875,873	5.94		
Options exercised	—	(157,003)	2.52		
Options cancelled	178,890	(178,890)	4.68		\$ 411
<b>Balances at December 31, 2017</b>	29,654	3,001,929	4.15		\$ 3,585
Options granted (unaudited)	(53,785)	53,785	4.68		
Options exercised (unaudited)	—	(104,128)	4.50		\$ 151
Options cancelled (unaudited)	50,744	(50,744)	4.68		
<b>Balances at June 30, 2018 (unaudited)</b>	<u>26,613</u>	<u>2,900,842</u>	<u>\$ 4.09</u>	<u>7.0</u>	<u>\$ 10,597</u>
Options vested and exercisable - December 31, 2017		<u>1,535,335</u>	<u>\$ 3.60</u>	<u>6.6</u>	<u>\$ 2,655</u>
Options vested and expected to vest - December 31, 2017		<u>2,771,444</u>	<u>\$ 3.96</u>	<u>7.4</u>	<u>\$ 2,053</u>
Options vested and exercisable - June 30, 2018 (unaudited)		<u>1,770,228</u>	<u>\$ 3.60</u>	<u>6.4</u>	<u>\$ 7,422</u>
Options vested and expected to vest - June 30, 2018 (unaudited)		<u>2,674,388</u>	<u>\$ 3.96</u>	<u>6.9</u>	<u>\$ 10,059</u>

The aggregate intrinsic values of options outstanding, options exercisable, options vested and exercisable, and options vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the board of directors, as of December 31, 2016, December 31, 2017 and June 30, 2018 (unaudited). The total grant date fair value of options that vested during each of the years ended December 31, 2016 and 2017 was \$0.9 million, and \$0.3 million (unaudited) and \$0.6 million (unaudited) for the six months ended June 30, 2017 and 2018, respectively.



**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes information about stock options outstanding under the Plan at December 31, 2017:

Options Outstanding			Options Vested and Exercisable	
Exercise Price	Number Outstanding	Average Remaining Contractual Life (Years)	Number Vested	Weighted-Average Exercise Price
\$0.27 – \$3.25	307,143	4.1	296,696	\$ 1.94
\$3.26 – \$3.80	606,491	6.6	510,992	\$ 3.42
\$3.81– \$4.29	168,244	5.3	159,911	\$ 3.96
\$4.30 – \$4.49	1,067,667	8.0	525,515	\$ 4.32
\$4.50 – \$4.85	580,953	9.4	32,388	\$ 4.64
\$4.86 – \$9.75	271,431	9.2	9,833	\$ 6.29
	<u>3,001,929</u>		<u>1,535,335</u>	

The following table summarizes information about stock options outstanding under the Plan at June 30, 2018 (unaudited):

Options Outstanding			Options Vested and Exercisable	
Exercise Price	Number Outstanding	Average Remaining Contractual Life (Years)	Number Vested	Weighted-Average Exercise Price
\$0.27 – \$3.25	306,727	3.6	295,616	\$ 2.02
\$3.26 – \$3.80	595,757	6.1	595,672	\$ 3.42
\$3.81 – \$4.29	159,810	4.8	159,810	\$ 3.96
\$4.30 – \$4.49	1,013,897	7.5	1,001,220	\$ 4.32
\$4.50 – \$4.85	565,764	8.9	527,633	\$ 4.67
\$4.86 – \$9.75	258,887	8.7	94,437	\$ 6.19
	<u>2,900,842</u>		<u>2,674,388</u>	

**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' deficit as the options vest. At December 31, 2016 and 2017, and June 30, 2018, the Company had a total of 47,447, 16,117 and 64,107 (unaudited) shares of common stock, respectively, subject to repurchase under the Plan and \$0.2 million, \$0.1 million and \$0.3 million (unaudited), respectively, of associated liabilities for the repurchase.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***Stock-Based Compensation***

The following table sets forth stock-based compensation expense related to options granted for the periods presented (in thousands):

	<u>Year Ended December 31,</u>		<u>Six Months Ended</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>June 30, 2018</u>
			<u>(unaudited)</u>	
Cost of goods sold	\$ 20	\$ 23	\$ 13	\$ 12
Research and development	137	143	65	70
Sales and marketing	399	438	206	240
General and administrative	842	1,271	847	432
	<u>\$ 1,398</u>	<u>\$ 1,875</u>	<u>\$ 1,131</u>	<u>\$ 754</u>

Amounts above do not include \$0.4 million of stock-based compensation expense related to forgiveness of notes receivable for the year ended December 31, 2017 and the six months ended June 30, 2018. Refer to Note 13 for details.

*Employee Stock-Based Compensation*

During the years ended December 31, 2016 and 2017 and the six months ended June 30, 2017 and 2018, the Company granted stock options to employees to purchase 661,958, 875,207, 697,241 (unaudited) and 53,092 (unaudited) shares of common stock, respectively, with a weighted-average grant date fair value of \$3.60, \$1.80, \$3.06 (unaudited) and \$1.98 (unaudited), respectively. As of December 31, 2017, there was a total unrecognized compensation cost of \$2.9 million. These costs are expected to be recognized over a period of approximately 2.5 years. The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the assumptions below. Each of these inputs is subjective and its determination generally requires significant judgment.

*Performance Stock Options*

In March 2017, the Company granted 564,098 performance stock options at a grant price of \$5.94, of which 408,544 performance options will vest monthly over four years and 155,554 performance options will vest monthly over three years. The vesting period will begin on the date of the closing of an IPO, the performance condition, subject to the optionee's continuous service. Stock-based compensation expense for performance stock options is based on the probability of achieving certain performance criteria, as defined in the individual option grant agreement. Periodically, the Company estimates the number of performance options ultimately expected to vest and recognizes stock-based compensation expense for those options when it becomes probable that the performance criteria will be met. As of December 31, 2017 and June 30, 2018, an IPO was not deemed probable and thus no expense was recognized. In December 2017, a portion of these option grants were modified as described in the options modification/repricing section below.

*Fair Value of Common Stock*

The fair value of the shares of the Company's common stock underlying the stock options has historically been determined by the Company's Board of Directors. Because there has been no public market for the

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Company's common stock, its Board of Directors has determined the fair value of the Company's common stock at the time of grant of the option by considering a number of objective and subjective factors, including independent third-party valuations, the Company's stage of development, sales of the Company's redeemable convertible preferred stock, the Company's operating and financial performance, equity market conditions affecting comparable public companies, the lack of liquidity of the Company's capital stock, and the general and industry-specific economic outlooks.

*Expected Term*

The expected term represents the period that the share-based awards are expected to be outstanding. The Company used the simplified method to determine the expected term, which is calculated as the average of the time to vesting and the contractual life of the options.

*Expected Volatility*

As the Company's common stock has never been publicly traded, the expected volatility is derived from 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 issues in effect at the time of grant for periods corresponding with the expected term of the option.

*Dividend Yield*

The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

*Expected Forfeiture Rate*

The Company is required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option 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 grant date fair value of the stock option awards granted to employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		June 30,	
	2016	2017	2017	2018
Expected term	6.25	5.71	6.25	6.25
Expected volatility	44%-54%	42%-55%	43%-55%	42%-45%
Risk-free interest rate	1.14%-2.19%	1.73%-2.31%	1.76%-2.28%	2.35%-2.93%
Dividend yield	0%	0%	0%	0%

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

*Non-Employee Stock-Based Compensation*

During the years ended December 31, 2016 and 2017 and the six months ended June 30, 2017 and 2018, the Company granted 2,777, 666, 666 (unaudited) and 693 (unaudited) stock options, respectively, to nonemployees, at an average exercise price of \$9.72, \$5.94, \$5.94 (unaudited) and \$4.68 (unaudited) per share, respectively. The stock-based compensation expense was insignificant for the all periods presented.

*Option Modification/Repricing*

In July 2016, the Company modified the terms of 575,742 vested and unvested stock option awards by reducing their exercise price from \$7.92 – \$9.72 to \$4.32 per share. There was no change in any of the other terms of the option awards. The modification resulted in an incremental value of \$0.4 million being allocated to the options, of which \$0.1 million was recognized to expense immediately based on options that were vested at the time of the modification. The remaining incremental value of \$0.3 million attributable to unvested shares at December 31, 2016 will be recognized over a weighted-average remaining term of 2.55 years.

In December 2017, the Company modified the terms of 394,652 unvested stock option awards granted in March 2017, by reducing their exercise price from \$5.94 to \$4.68 per share. In addition, the vesting performance conditions for these options were removed and the vesting commencement date changed from the IPO date to September 2017. There were no other changes in any of the other terms of the option awards. Due to these options previously subject to performance conditions that were not deemed probable of occurring, the Company had not recognized any expense related to these grants. The modification resulted in total expense of \$0.8 million that is recognized over the amended vesting period of forty-eight months.

**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.

**12. Income Taxes**

The components of the Company's loss before income taxes are as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2017</b>
Domestic	\$ (20,429)	\$ (22,706)
Foreign	(160)	(322)
Loss before income taxes	<u>\$ (20,589)</u>	<u>\$ (23,028)</u>

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The components of income tax expense are as follows (in thousands):

	Year Ended December 31,	
	2016	2017
Current tax expense:		
Federal	\$ —	\$ —
State	—	—
Foreign	—	—
Total current tax expense	—	—
Deferred tax expense:		
Federal	6,810	(9,574)
State	941	2,061
Foreign	—	—
Total deferred tax expense	7,751	(7,513)
Change in deferred tax valuation allowance	(7,751)	7,513
Net deferred tax expense	—	—
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

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

	Year Ended December 31,	
	2016	2017
Tax at statutory federal rate	(34.0%)	(34.0%)
State tax, net of federal benefit	(4.3%)	(4.3%)
Measurement of deferred taxes as a result of tax reform	0.0%	68.7%
Tax credits	(1.3%)	(0.3%)
Change in deferred tax valuation allowance	37.6%	(32.6%)
Other	2.0%	2.5%
Total income tax expense	<u>0.0%</u>	<u>0.0%</u>

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

	December 31,	
	2016	2017
Net operating loss carryforwards	\$ 39,966	\$ 32,210
Research and development credits	1,868	2,070
Depreciation and amortization	192	179
Accruals and reserves	1,321	1,376
	<u>43,347</u>	<u>35,835</u>
Less: Valuation allowance	(43,347)	(35,835)
Total deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The valuation allowance decreased by \$7.5 million in the year ended

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2017, due to an increase in total deferred tax assets and a decrease in the deferred tax assets related to the reduction of the U.S. corporate income tax rate from the Tax Cuts and Jobs Act ("2017 Tax Act").

As of December 31, 2017, the Company had net operating loss ("NOL") carryforwards of approximately \$124.9 million and \$101.7 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. If not utilized, the Company's federal NOL carryforward begins to expire in 2029, and the state NOL carryforward begins to expire in 2019.

As of December 31, 2017, the Company had research credit carryforwards of approximately \$1.6 million and \$1.7 million available to reduce future taxable income, if any, for both federal and state income tax purposes, respectively. The federal research credits begin to expire in 2030, and the state research credits have no expiration date.

Utilization of the Company's NOL and tax credit carryforwards may be subject to a substantial annual limitation due to the ownership change limitations included in the Internal Revenue Code of 1986 ("Section 382") and similar state provisions. The annual limitation may result in the expiration of NOL and credits before utilization. The Company has determined that it experienced Section 382 ownership changes in 2010 and \$1.4 million of its NOLs are limited. The Company does not expect any additional NOL carryforwards or its credits as of December 31, 2017 to expire as a result of Section 382.

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, 2016 and 2017 consisted of the following (in thousands):

<b>Beginning balance as of January 1, 2016</b>	<b>\$831</b>
Increases in balances related to tax positions taken during 2016	<u>119</u>
<b>Ending balance as of December 31, 2016</b>	<b>950</b>
Increases in balances related to tax positions taken during 2017	<u>43</u>
<b>Ending balance as of December 31, 2017</b>	<b><u>\$993</u></b>

The Company has elected to recognize interest and penalties related to uncertain tax positions as a component of income tax expense. The Company has accrued zero at December 31, 2016 and 2017 for payment of interest related to unrecognized tax benefits. None of the Company's unrecognized tax benefits that, if recognized, would affect its effective tax rate at December 31, 2017.

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 NOL carryforwards, all of its tax years are subject to federal and state tax examinations.

The Company is subject to the provisions of the ASC 740-10, Income Taxes, which requires that the effect on deferred tax assets and liabilities of a change in tax rates be recognized in the period the tax rate change was enacted. The carrying value of U.S. deferred taxes is determined by the enacted U.S. corporate income tax rate. Consequently, the reduction in the U.S. corporate income tax rate as a result of the United States enacted law commonly known as the 2017 Tax Act, which makes widespread changes to the Internal Revenue Code, impacts the carrying value of deferred tax assets. Under the new corporate income tax rate of 21% of the U.S. net deferred tax asset position decreased by approximately \$15.8 million. Uncertainty regarding the impact of tax reform remains, as a result of factors including future regulatory and rulemaking processes, the prospects of additional corrective or supplemental legislation, potential trade or other litigation, and other factors.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”), which provides guidance for the tax effect of the 2017 Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the 2017 Tax Act’s enactment date for companies to complete the accounting under Accounting Standards Codification Topic 740, Income Taxes (“ASC 740”). In accordance with SAB 118, the Company must reflect the income tax effects of those aspects of the 2017 Tax Act for which the accounting under ASC 740 is complete. To the extent that its accounting for certain income tax effects of the 2017 Tax Act is incomplete, but the Company is able to determine a reasonable estimate, the Company must record a provisional estimate in its consolidated financial statements. If the Company cannot determine a provisional estimate to be included in its consolidated financial statements, the Company should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the 2017 Tax Act. It is expected that the U.S. Treasury will issue regulations and other guidance on the application of certain provisions of the 2017 Tax Act. The Company will analyze that guidance and other necessary information to refine its estimates and complete its accounting for the tax effects of the 2017 Tax Act, as necessary. The Company considers the accounting of the deferred tax re-measurements to be complete. However, ongoing guidance and accounting interpretation are expected in the near term and the Company expects to complete its analysis within the measurement period in accordance with SAB 118.

**13. Related Party Transactions**

In March 2013, the Company granted a loan to its then current Chief Financial Officer to assist with the exercise of his stock option grants in the form of a full recourse promissory note with an aggregate principal amount of \$0.2 million. The note is collateralized by the common stock issued upon the exercise of the stock options, as well as personal assets of the borrower. Interest under this note will accrue at the rate of 1.09% per annum. In November 2016, the loan amount was partially repaid in the amount of \$0.1 million (including principal and interest). The remainder of the principal balance of this note, together with all accrued and unpaid interest to date, was fully paid in December 2017.

In February 2014, the Company granted a loan to its Chief Executive Officer to assist with the exercise of his stock option grants in the form of a full recourse promissory note with an aggregate principal amount of \$0.4 million. The note is collateralized by the common stock issued upon the exercise of the stock options, as well as personal assets of the borrower. At the time of issuance, the Company accounted for the note as a full recourse promissory note based on historical pattern of collecting payment on notes in full and no other notes had been forgiven, nor had any recourse notes been substantively converted to nonrecourse. Interest under this note will accrue at the rate of 1.97% per annum. The principal balance of this note, together with all accrued and unpaid interest to date, is due in February 2019.

In March 2017, the Company forgave \$0.2 million of principal and interest due on a promissory note from its Chief Executive Officer. In addition, the Board of Directors approved the forgiveness of the remaining 50% of the principal balance of the note upon the earlier of an IPO, change of control, or January 1, 2018. At the time of the forgiveness, all of the related stock options were fully vested. As a result, the Company has expensed the principal note balance of \$0.4 million to stock-based compensation expense and accrued interest of \$0.1 million to general and administrative expenses in the consolidated statement of operations.

**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**14. Net Loss Per Share of Common Stock**

*Basic and Diluted Net Loss per Share*

The following table summarizes the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	<u>Year Ended December 31,</u>		<u>Six Months Ended</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
			(unaudited)	
Net loss	\$ (20,589)	\$ (23,039)	\$ (12,451)	\$ (7,348)
Weighted-average shares used to compute basic and diluted net loss per share	3,314,198	3,467,096	3,426,963	3,603,308
Net loss per share, basic and diluted	\$ (6.21)	\$ (6.65)	\$ (3.63)	\$ (2.04)

Unvested shares for the years ended December 31, 2016 and 2017 and the six months ended June 30, 2017 (unaudited) and 2018 (unaudited) were excluded from the weighted-average shares used to compute basic and diluted net loss per share.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	<u>December 31,</u>		<u>June 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
			(unaudited)	
Stock options	2,461,949	3,001,929	3,001,929	2,900,842
Shares subject to repurchase	47,447	16,117	34,177	64,107
Redeemable convertible preferred stock	11,490,776	12,066,654	12,066,654	12,066,654
Redeemable convertible preferred stock warrants	159,920	160,657	160,657	160,657
Common stock warrants	122,938	124,326	124,326	124,326



**SI-BONE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

*Unaudited Pro Forma Net Loss Per Share*

Unaudited pro forma basic and diluted loss per share is computed as follows (in thousands, except share and per share data):

	Year Ended December 31, 2017	Six Months Ended June 30, 2018
	(unaudited)	
<b>Numerator:</b>		
Net loss	\$ (23,039)	\$ (7,348)
Change in fair value of redeemable convertible preferred stock warrant liability	(166)	224
Pro forma net loss attributable to common shareholder—basic and diluted	\$ (23,205)	\$ (7,124)
<b>Denominator:</b>		
Weighted-average shares used to compute basic and diluted net loss per share	3,467,096	3,603,308
Adjustment to reflect the assumed conversion of redeemable convertible preferred stock	11,991,682	12,066,654
Adjustment to reflect automatic net exercise of redeemable convertible preferred stock warrants into common stock	21,616	21,616
Pro forma weighted average common shares used to compute net loss per share, basic and diluted preferred stock outstanding	15,480,394	15,691,578
Net loss per share, basic and diluted	<u>\$ (1.50)</u>	<u>\$ (0.45)</u>

### 15. Subsequent Events

The consolidated financial statements reflect management's evaluation of subsequent events through July 31, 2018, the date the consolidated financial statements were available to be issued.

*Events Subsequent to Original Issuance of Consolidated Financial Statements (unaudited)*

In August 2018, the Company granted stock options to purchase 19,998 (unaudited) shares of common stock with an exercise price of \$7.74 (unaudited) per share and a weighted-average grant date fair value of \$3.42 (unaudited). In addition, in August 2018, the Company granted 37,036 (unaudited) restricted stock units with a grant-date fair value of \$7.74 (unaudited) per share. Fifty percent of these awards will vest on the first day of the first open trading window that occurs after the one-year anniversary of the closing of an IPO, and fifty percent will vest on the first day of the first open trading window that occurs after the two-year anniversary of the closing of an IPO, subject to continued service through each relevant vesting date.

**7,200,000 Shares**



**Common Stock**

**Prospectus**

**Morgan Stanley**

**Canaccord Genuity**

**BofA Merrill Lynch**

**JMP Securities**

October 16, 2018