Sintx Technologies, Inc.
Form 10-K
March 11, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

[X] Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2018

or

[ ] Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File No. 001-33624

SINTX Technologies, Inc.

(previously known as “Amedica Corporation”)

(Exact name of registrant as specified in its charter)

Delaware	**84-1375299**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

1885 West 2100 South, Salt Lake City, UT 84119

(Address of principal executive offices and Zip Code)

(801) 839-3500

(Registrant’s telephone number, including area code)

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value	**The NASDAQ Capital Market**

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [X]

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large Accelerated Filer	[ ]	Accelerated Filer	[ ]
Non-Accelerated Filer	[ ]	Smaller reporting company	[X]
		Emerging growth company	[X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common

equity, as of the last business day of the registrant's most recently completed second fiscal quarter was $20,592,811.

The number of shares outstanding of the registrant's common stock, $0.01 par value per share, as of February 25, 2019 was 21,793,641.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's definitive Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact are forward-looking statements. SINTX Technologies, Inc. ("we", "us", "ourselves") has tried to identify forward-looking statements by using words such as "believe," "may," "might," "could," "will," "aim," "estimate," "co "anticipate," "intend," "expect," "plan" and similar words. These forward-looking statements are based on our current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect our businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, factors affecting our quarterly and annual results, our ability to manage our growth, our ability to sustain our profitability, demand for our products, our ability to compete successfully, our ability to rapidly develop and introduce new products, our ability to develop and execute on successful business strategies, our ability to comply with changes and applicable laws and regulations that are applicable to our businesses, our ability to safeguard our intellectual property, our success in defending legal proceedings brought against us, trends in the medical device industry, and general economic conditions, and other risks set forth throughout this Annual Report, including under **"Item 1, Business," "Item 1A, Risk Factors,"** and **"Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations,"** and those discussed in other documents we file with the Securities and Exchange Commission (the "SEC"). Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this Annual Report speak only as of the date of this Annual Report. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act. Accordingly, we file periodic reports and other information with the SEC. We will make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports available through our Internet site, https://ir.sintx.com/ as soon as reasonably practicable after electronically filing such materials with the SEC. They may also be obtained free of charge by writing to SINTX Technologies, Inc., Attn: Investor Relations, 1885 West 2100 South, Salt Lake City, UT 84119. In addition, copies of these reports may be obtained through the SEC's website at www.sec.gov or by visiting the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 800-SEC-0330. Our common stock trades on The NASDAQ Capital Market under the symbol "SINT."

Unless otherwise indicated, all information contained in this Annual Report reflects a 1-for-15 reverse split of our common stock which was effected on January 25, 2016 and a 1-for-12 reverse split which was effected on November 10, 2017.

PART I

ITEM 1. BUSINESS

Overview – SINTX Technologies

We are a biomaterials company focused on providing ceramic based biomaterial solutions in a variety of medical and industrial applications. To date, our primary focus has been the research, development and commercialization of medical implant products manufactured with silicon nitride. We believe that silicon nitride has a superb combination of properties that make it ideally suited for long-term human implantation. Other biomaterials are based on bone grafts, metal alloys, and polymers- all of which have well-known practical limitations and disadvantages. In contrast, silicon nitride has a legacy of success in the most demanding and extreme industrial environments. As a human implant material, silicon nitride offers bone ingrowth, resistance to bacterial and viral infection, ease of diagnostic imaging, resistance to corrosion, and superior strength and fracture resistance, among other advantages, all of which claims are validated in our large and growing inventory of peer-reviewed, published literature reports. We believe that our versatile silicon nitride manufacturing expertise positions us favorably to introduce new and innovative devices in the medical and non-medical fields.

We also believe that we are the first and only company to commercialize silicon nitride medical implants. Prior to October 1, 2018, we designed, manufactured and commercialized silicon nitride products for our own behalf in the spine implant market. Over 33,000 of our spinal implants manufactured with silicon nitride have been implanted into patients, with an excellent safety record. On October 1, 2018, we sold our spine implant business to CTL Medical and now manufacture spine implants made with silicon nitride for CTL Medical. Prior to selling our spine implant business to CTL Medical, we had received 510(k) regulatory clearance in the United States, a CE mark in Europe, ANVISA approval in Brazil, and ARTG and Prostheses approvals in Australia for a number of silicon nitride spine implant products designed for spinal fusion surgery. Spine implant products manufactured by us from silicon nitride are currently marketed and sold by CTL Medical under the Valeo® brand to surgeons and hospitals in the United States and to selected markets in Europe and South America. These implants are designed for use in cervical (neck) and thoracolumbar (lower back) spine surgery. We are collaborating with CTL Medical to establish a commercial partner in Australia and also working with other partners to obtain regulatory approval for silicon nitride implants in Japan.

The sale of our spine implant business to CTL Medical enables us to now focus on our core competencies. These are research and development of silicon nitride and the design and manufacture of medical and nonmedical products manufactured from silicon nitride and other ceramic materials for our own account and in collaboration with other medical device manufacturers. We are targeting original equipment manufacturer (“OEM”) – including CTL Medical - and private label partnerships in order to accelerate adoption of silicon nitride in future markets such as coating

products with silicon nitride, hip and knee replacements, dental and maxillofacial implants, extremities, trauma, and sports medicine. Existing biomaterials, based on plastics, metals, and bone grafts have well-recognized limitations that we believe are addressed by silicon nitride, and we are uniquely positioned to convert existing, successful implant designs made by other companies into products manufactured with silicon nitride. OEM and private label partnerships allow us to work with a variety of partners, accelerate the adoption of silicon nitride, and realize incremental revenue at improved operating margins, when compared to the cost-intensive direct sales model.

We believe that silicon nitride addresses many of the biomaterial-related limitations in fields such as hip and knee replacements, dental and maxillofacial implants, sports medicine, extremities, and trauma surgery. We further believe that the inherent material properties of silicon nitride, and the ability to formulate the material in a variety of compositions, combined with precise control of the surface properties of the material, opens up a number of commercial opportunities across orthopedic surgery, neurological surgery, maxillofacial surgery, and other medical disciplines.

We operate a 30,000 square foot manufacturing facility at our corporate headquarters in Salt Lake City, Utah, and we believe we are the only vertically integrated silicon nitride medical device manufacturer in the world.

Overview - Biomaterials

Biomaterials are natural or synthetic biocompatible materials that are used in virtually every medical specialty to improve or preserve body functionality. Various types of biomaterials are used as essential components in medical devices, drug delivery systems, replacement and tissue repair technologies, prostheses, and diagnostic technologies.

There are four general categories of biomaterials:

Ceramics. Ceramics are hard, non-metallic, non-corrosive, heat-resistant materials made by shaping and then applying high temperatures. Traditional ceramics commonly used as biomaterials include carbon, oxides of aluminum, zirconium and titanium, calcium phosphate and zirconia-toughened alumina. Examples of medical uses of ceramics include repair, augmentation or stabilization of fractured bones, bone and joint replacements, spinal fusion devices, dental implants and restorations, heart valves and surgical instruments.

Metals. Metals commonly used as biomaterials include titanium, stainless steel, cobalt, chrome, gold, silver and platinum, and alloys of these metals. Examples of medical uses of metals include the repair or stabilization of fractured bones, stents, surgical instruments, bone and joint replacements, spinal fusion devices, dental implants and restorations and heart valves.

Natural biomaterials. Natural biomaterials are derived from human donors, animal or plant sources and include human bone, collagen, gelatin, cellulose, chitin, alginate and hyaluronic acid. Examples of medical uses of natural biomaterials include the addition or substitution of hard and soft tissue, cornea protectors, vascular grafts, repair and replacement of tendons and ligaments, bone and joint replacements, spinal fusion devices, dental restorations and heart valves.

Polymers. Polymers are synthetic compounds consisting of similar molecules linked together that can be created to have specific properties. Polymers commonly used as biomaterials include nylon, silicon rubber, polyester, polyethylene, cross-linked polyethylene (a stronger version), polymethylmethacrylate, polyvinyl chloride and polyetheretherketone – which is commonly referred to as PEEK. Examples of medical uses of polymers include soft-tissue replacement, sutures, drug delivery systems, joint replacements, spinal fusion devices and dental restorations.

Our Silicon Nitride Technology Platform

We believe we are the only FDA-cleared and ISO 13485 certified silicon nitride medical device manufacturing facility in the world, and the only provider of structural ceramics-based medical devices used for spinal fusion applications. Silicon nitride is a chemical compound comprised of the elements silicon and nitrogen, with the chemical formula Si_3N_4. Silicon nitride, an advanced ceramic, is lightweight, resistant to fracture and strong, and is used in many

demanding mechanical, thermal and wear applications, such as in space shuttle bearings, jet engine components and body armor.

We believe our silicon nitride is ideal as an implant material and is superior to other biomaterials currently used in the market such as PEEK, allograft and autograft bone, metal and traditional oxide ceramics, none of which possess all of the favorable characteristics of silicon nitride:

Promotes Bone Growth. Our silicon nitride is osteointegrative through its inherent surface topography and surface chemistry. The surface topography provides scaffolding for new bone growth. As a hydrophilic material, silicon nitride attracts protein cells and nutrients that stimulate osteoprogenitor cells to differentiate into osteoblasts, which are needed for optimal bone growth environments. Our silicon nitride has an inherent surface chemistry that favors bone formation and healing, much more so than PEEK and metals. These properties were highlighted in an *in vivo* study, where we measured the force required to separate devices from the spine after being implanted for three months, which indicates the quality of osteointegration. In the absence of bacteria, the force required to separate our silicon nitride from its surrounding bone was approximately three times that of PEEK, and nearly two times that of titanium. In the presence of bacteria, the force required to separate our silicon nitride from its surrounding bone was over five times that of titanium, while there was effectively no separation force required for PEEK, indicating essentially no osteointegration in a septic environment.

Antibacterial. We have demonstrated in *in vitro* and *in vivo* studies that silicon nitride has inherent surface antibacterial properties, which reduce the risk of bacterial infection and biofilm in and around a silicon nitride device. PEEK, traditional ceramics, metals and bone do not have this bacterial resistance. These properties were highlighted in an *in vitro* study (Acta Biomater. 2012 Dec;8(12):4447-54. doi: 10.1016/j.actbio.2012.07.038. Epub 2012 Jul 31.), where live bacteria counts were between 8 and 30 times lower on our silicon nitride than PEEK and up to 8 times lower on our silicon nitride than titanium. In addition to improving patient outcomes, we believe the antibacterial properties of our silicon nitride should make it an attractive biomaterial to hospitals and surgeons who are not reimbursed by third-party payers for the treatment of acute, implant-related infections. Additionally, silicon nitride is synthetic and, therefore, there is a lower risk of disease transmission through cross-contamination or of an adverse auto-immune response, sometimes associated with the use of allograft bone.

Antiviral: Solid-surface inactivation of microbial pathogens has ancient roots; the Smith Papyrus (2600~2200 B.C.) described the use of copper surfaces to sterilize chest wounds and drinking water. Today, brass and bronze on door-knobs help prevent microbial spread in hospitals, and metal particles and surface coatings of selected metals are used in hygiene-sensitive environments, both as inactivators and adjuvants in inducing cellular immunity. Cellular toxicity limits these approaches because while the reactive oxygen radicals generated at metal surfaces efficiently kill bacteria and viruses, they also damage cells by oxidizing their proteins and lipids. Recent data have shown that silicon nitride surfaces are effective against several types of viruses. With surface-contact transmission of viral pathogens, particularly influenza, and the increasing use of consumer touchscreens in various retail industries, we believe that our material has value to OEM partners focused on consumer glass-based surface coatings and treatments. We have filed a U.S. patent application on this effect.

Antifungal: We have conducted preliminary studies which suggest that our silicon nitride may be effective against fungal microbes. Plant-based viruses, bacteria, and fungi affect some 15% of the world's edible crops, or about 1 billion metric tons of edible produce annually, with an economic impact in the US and Canada alone estimated to be between $1.5 to $5 Billion per year. The mycotoxins produced by these plant fungi have an overall negative impact on human health and longevity. The inorganic nature of silicon nitride may prove to be more beneficial than the use of petrochemical or organometallic fungicides which are known to have residual effects in soil, on plants, and in fruit. Our goal is to identify industry partners who have interest in this technology, and potentially spin-off this agribusiness segment of our business, with SINTX Technologies as an OEM supplier.

Imaging Compatible. Our silicon nitride interbody spinal fusion devices are semi-radiolucent, clearly visible in X-rays, and produce no distortion under MRI and no scattering under CT. These characteristics enable an exact view of the device for precise intra-operative placement and post-operative bone fusion assessment in spinal fusion procedures. These qualities provide surgeons with greater certainty of outcomes with our silicon nitride devices than with other biomaterials, such as PEEK and metals.

Hard, Strong and Resistant to Fracture. Our silicon nitride is hard, strong and possesses superior resistance to fracture over traditional ceramics and greater strength than polymers currently on the market. For example, our silicon nitride's flexural strength is more than five times that of PEEK and our silicon nitride's compressive strength is over twenty times that of PEEK. Unlike PEEK interbody spinal fusion devices, we believe our silicon nitride interbody spinal fusion devices can withstand the forces exerted during implantation and daily activities over the long term.

Resistant to Wear. We believe our silicon nitride joint implant product candidates could have higher resistance to wear than metal-on-cross-linked polyethylene and traditional oxide ceramic-on-cross-linked polyethylene joint implants, the two most commonly used total hip replacement implants. Wear debris associated with metal implants

increases the risk of metal sensitivity and metallosis. It is a primary reason for early failures of metal and polymer articulating joint components.

Non-Corrosive. Our silicon nitride does not have the drawbacks associated with the corrosive nature of metal within the body, including metal sensitivity and metallosis, nor does it result in the release of metal ions into the body. As a result, we believe our silicon nitride products will have lower revision rates and fewer complications than comparable metal and traditional oxide ceramic products.

Supporting Data

We and a number of independent third parties have conducted extensive biocompatibility, biomechanical, *in vivo* and *in vitro* testing on our silicon nitride composition to establish its safety and efficacy in support of regulatory clearance of our biomaterial, products and product candidates. We have also completed additional testing of our silicon nitride products and product candidates. The results of this testing have been published in over 75 peer reviewed publications that include basic science studies, small- and large-animal data, and human clinical studies. We believe that our product development strategy is consistent with the manner in which other biomaterials have been successfully introduced into the market and adopted as the standard of care. Listed below is an overview of some of the key testing completed on our silicon nitride biomaterial, products and product candidates to date, as well as other information about our silicon nitride and other biomaterials.

Biocompatibility

Before our silicon nitride was cleared by the FDA in 2008, we conducted a series of biocompatibility tests following the guidelines of the FDA and ISO and submitted the results to the FDA as part of the regulatory clearance process. These tests confirmed that our silicon nitride products meet required biocompatibility standards for human use.

Promotion of Bone Growth

In 2012, we conducted two separate studies at Brown University, the results of which suggest that the chemistry and inherent surface topography of our solid silicon nitride provides an optimal environment for bone growth onto and around the device.

The first study was a series of *in vitro* analyses of protein adsorption, or presence on the surface of the biomaterial, onto silicon nitride, PEEK and titanium. The results of this study indicated that adsorption of two key proteins necessary for bone growth (fibronectin and vitronectin) were up to eight times greater on our silicon nitride than on PEEK, and up to four times greater than on titanium. A third important protein (laminin) had up to two times greater adsorption on our silicon nitride than on PEEK, and up to two-and-one-half times greater adsorption than on titanium.

The second study was an *in vivo* investigation of the osteointegration characteristics of these same three biomaterials after they had been surgically implanted into the skulls of laboratory rats. This study included an examination of the effect of Staphylococcus epidermidis bacteria on osteointegration. At time intervals of up to three months after

implantation of the biomaterial, the amount of new bone growth within the surgical site and in direct contact with the implanted biomaterial was evaluated. In the absence of bacteria, new bone formation within the surgical site surrounding our silicon nitride was approximately 69%, compared with 36% and 24% for titanium and PEEK, respectively. Similarly, bone in direct contact, or apposition, with our silicon nitride, titanium and PEEK was 59%, 19% and 8%, respectively. As is common, in the presence of bacteria, new bone formation within the surgical site was suppressed, but still significantly greater for our silicon nitride than for the other two biomaterials. Observed new bone growth within the surgical site surrounding our silicon nitride was 41%, compared with 26% and 21% for titanium and PEEK, respectively. At the implant interface, the bone apposition for our silicon nitride, titanium and PEEK was 23%, 9% and 5%, respectively. To further characterize the extent of osteointegration, the force needed to separate each implant from its surrounding bone was measured. A larger force needed to separate the implant is an indication of improved osteointegration. At three months after implantation, in the absence of bacteria, the force required to separate our silicon nitride from its surrounding bone was approximately three times that of PEEK, and nearly two times that of titanium. In the presence of bacteria, there was effectively no separation force required for PEEK, indicating essentially no osteointegration. Our silicon nitride required over five times the force to separate it from its surrounding bone in the presence of bacteria in comparison to titanium.

In 2008, we conducted an animal study in which we evaluated the level of osteointegration of our porous silicon nitride with a knee-defect model in adult sheep. At three months after implantation, three out of five of the silicon nitride implants had extensive new bone formation at and into the implant surface, showing that the bone had grown into our porous silicon nitride to a depth of 3 millimeters, or mm. This animal study demonstrated the rapid osteointegration potential of our porous silicon nitride composition.

Hardness, Strength and Resistance to Fracture

Comparative Information

As shown in the table of comparative information publicly available about various biomaterials below:

- the hardness, or a material's resistance to deformity, of silicon nitride is comparable to traditional ceramics, but is substantially higher than either polymers or metals;
- the strength of silicon nitride is comparable or higher than metals and traditional ceramics, and is about sixteen to fifty-five times stronger than highly-cross-linked polyethylene, and four to eight times stronger than PEEK; and
- silicon nitride has the highest fracture resistance of any medical ceramic material and is three to eleven times more resistant to fracture than PEEK or highly-cross-linked polyethylene. This is due to the interwoven microstructure of silicon nitride. Metals have the highest fracture resistance.

Comparison of Mechanical Properties Among Orthopedic Biomaterials

Material	**Hardness (GPa)(1)**	**Strength (MPa)(1)**	**Fracture Resistance (MPam1/2)(1)**
Silicon Nitride	**13 – 16**	**800 – 1200**	**8 – 11**
Aluminum Oxide Ceramic	14 – 19	300 – 500	3 – 5
Zirconia-Toughened Alumina Ceramic	12 – 19	700 – 1150	5 – 10
PEEK	0.09 – 0.28	160 – 180	2 – 3
Highly-Cross-Linked Polyethylene Polymer	0.03 – 0.07	22 – 48	1 – 2
Cobalt-Chromium Metal	3 – 4	700 – 1000	50 – 100
Titanium Alloy Metal	3 – 4	920 – 980	75

(1) GPa is a giga-pascal. Pascals are a measure of pressure. $MPam^{1/2}$ is mega-pascal times a square root meter and is a measure related to the energy required to initiate fracture of a material.

We believe that the combination of high hardness, strength and fracture resistance positions our silicon nitride as an ideal biomaterial for many medical applications.

Burst Strength

In 2006, we conducted in-house comparative "burst strength" tests on femoral heads made from our silicon nitride produced by a contract manufacturer to our specifications and femoral heads made from one of the strongest commercially available ceramics, BIOLOX® delta (zirconia-toughened alumina). These tests were performed on three designs of 28 mm femoral heads using accepted testing protocols. The tests involved applying a load to each femoral head while mounted on a cobalt-chromium simulated hip implant stem, until the head burst. This enabled us to directly compare the strength of the femoral heads made of the two biomaterials. The results also provided an indication of each biomaterial's resistance to fracture. The results of these tests are shown in the chart below.

The average burst test strength for the silicon nitride femoral heads in these tests was 75 kilonewtons, or kNs, compared with 65 kN for BIOLOX® delta, or about a 15% improvement. The burst strengths observed in our tests for BIOLOX® delta femoral heads are comparable to those observed by an independent party testing the same design BIOLOX® delta femoral heads as we did. We also conducted burst strength tests of 36 mm femoral heads made from our silicon nitride which showed those femoral heads had burst strengths that averaged 164 kN.

Resistance to Wear

In 2011, we commissioned an independent laboratory to conduct a wear study using our silicon nitride femoral heads. We tested our 28 mm silicon nitride femoral heads articulated against cross-linked polyethylene acetabular liners and our 40 mm silicon nitride femoral heads articulated against cross-linked polyethylene acetabular liners using well-established protocols in a hip simulator for their wear performance over 5 million cycles. We then compared the results for our silicon nitride product candidates to the results for the cobalt chrome femoral head and publicly available data from other commonly paired products. The results and comparison showed that:

- our silicon nitride-on-cross-linked polyethylene had approximately half the wear rate of that publicly reported for cobalt chrome-on-cross-linked polyethylene articulating hip components; and
- our silicon nitride-on-cross-linked polyethylene had comparable wear to that publicly reported for traditional oxide ceramic-on-cross-linked polyethylene articulating hip components.

Antibacterial Properties

The results of the two studies at Brown University in 2012, demonstrate that our solid silicon nitride has antibacterial properties. The objective of the *in vitro* study was to determine how our silicon nitride, PEEK and titanium interact with bacteria, protein and bone cells without the use of antibiotics and compared the growth of five different types of bacteria on silicon nitride, PEEK and titanium over time. Live bacteria counts were between 8 to 30 times lower on silicon nitride than PEEK and up to 8 times lower on silicon nitride than titanium.

In the *in vivo* study, bacteria were applied to the biomaterials before implantation. Three months after implantation, no infection was observed with silicon nitride, whereas both PEEK and titanium showed infection. The data demonstrate that our silicon nitride inhibits biofilm formation and bacterial colonization around the biomaterial.

Antiviral and Antifungal Properties

Antiviral: Our data have shown that off-stoichiometric reactions at the surface of our silicon nitride can inactivate different types of single-strand RNA viruses. This antiviral property derives from reactive nitrogen species without harm to mammalian cells. Testing based on polymerase chain reaction tests of viral RNA and *in situ* Raman spectroscopy suggest that our material is effective in counteracting several viruses relevant to public health concerns, such as Influenza A, Feline calcivirus, and Enterovirus.

Antfungal: We have conducted preliminary studies which suggest that our silicon nitride may be effective against fungal microbes. After sintering and processing, powdered silicon nitride was dissolved in a 1.5 vol.% aqueous solution that underwent field testing on two species of grape vine leaves that were infected with a fungal pathogen *Plasmopara viticola.* After 1 minute of exposure to our silicon nitride, the infected area of the leaves was reduced by ~95%. The likely mechanism likely involves electrical attraction to, and attachment of silicon nitride particles to oppositely-charged pathogen spores.

Imaging Compatibility

In 2007, we conducted a study to compare the imaging characteristics of test blanks made of PEEK, the metals titanium and tantalum, and silicon nitride using a cadaver human vertebral body. Images of the vertebral body and the blanks were obtained using X-ray, CT and MRI under identical conditions. We assessed the radiolucent characteristics of the blanks in X-ray images quantitatively, assessed the presence of scatter in CT qualitatively and assessed distortion in MRI quantitatively. In X-ray, the metal blanks did not permit visualization of the underlying bone of the vertebral body, while PEEK was transparent, rendering its location difficult to determine. The silicon nitride blank had an intermediate radiolucency that rendered it visible and allowed a visual assessment of the underlying bone of the vertebral body. CT and MRI of the metal blanks indicated the presence of distortion while silicon nitride and PEEK exhibited no scattering.

Our Forms of Silicon Nitride

To control the quality, cost and availability of our silicon nitride products and product candidates, we operate our own manufacturing facility. Our 54,000 square foot corporate building includes a 30,000 square foot FDA Registered and ISO 13485 certified medical device manufacturing space. It is equipped with state-of-the-art powder processing, spray drying, pressing and computerized machining equipment, sintering furnaces, and other testing equipment that enables us to control the entire manufacturing process for our silicon nitride products and product candidates. To our knowledge, we are the only vertically integrated silicon nitride orthopedic medical device manufacturer in the world. All operations with the exceptions of raw material production, cleaning, packaging and sterilization are performed in-house. We purchase raw materials, consisting of silicon nitride ceramic powder and dopant chemical compounds, from several vendors which are ISO registered and approved by us. These raw materials are characterized and tested in accordance with our specifications and then blended to formulate our silicon nitride. We believe that there are multiple vendors that can supply us these raw materials and we continually monitor the quality and pricing offered by our vendors to ensure high quality and cost-effective supply of these materials.

The chemical composition of our in-house formulation of silicon nitride and our processing and manufacturing experience allow us to produce silicon nitride in four distinct forms. This capability provides us with the ability to utilize our silicon nitride biomaterial in a variety of ways depending on the intended application, which, together with

our silicon nitride's key characteristics, distinguishes us from manufacturers of products using other biomaterials.

We currently produce silicon nitride for use in our commercial products and product candidates in the following forms:

Solid Silicon Nitride. This form of silicon nitride is a fully dense, load-bearing solid used for devices that require high strength, toughness, fracture resistance and low wear, including interbody spinal fusion devices, hip and knee replacement implants, and dental implants.

Porous Silicon Nitride. While this form of silicon nitride has a chemical composition that is identical to that of our monolithic solid silicon nitride, this formulation has a porous structure, which is engineered to mimic cancellous bone, the spongy bone tissue that typically makes up the interior of human bones. Our porous silicon nitride has interconnected pores ranging in size between about 90 and 600 microns, which is similar to that of cancellous bone. This form of silicon nitride can be used for the promotion of bone in-growth and attachment. We believe our porous silicon nitride can act as a substitute for the orthobiologics currently used to fill interbody devices in an effort to stimulate fusion, as a bone void filler, and as a porous scaffold for medical devices.

Composite of Solid and Porous Silicon Nitride. This form of silicon nitride is a combination, or composite, of our solid monolithic and porous formulations of silicon nitride. This composite may be used to manufacture devices and implants that mimic the structure of natural bone by incorporating both a fully dense, load-bearing solid component on the outside and a porous component intended to promote bone in-growth on the inside. This composite form of silicon nitride is used in interbody spinal fusion devices and can be used in components for total hip and knee replacement implants.

Composite of Silicon Nitride and PEEK. We have demonstrated in the laboratory that it is possible to compound our silicon nitride powder and the polymer PEEK and that the ensuing composite material maintains the bioactive properties of silicon nitride. We have engaged commercial partners to assist us in developing this technology. This composite material would allow the straightforward machinability of a complex device that would be more challenging to manufacture from silicon nitride alone.

Silicon Nitride Coating. With a similar chemical composition as our other forms of silicon nitride, this form of silicon nitride can be applied as an adherent coating to metallic substrates, including cobalt-chromium, titanium and steel alloys, polymers, and ceramics. We believe applying an extremely thin layer of silicon nitride as a coating may provide a highly wear-resistant articulation surface, such as on femoral heads, which may reduce problems associated with metal or polymer wear debris. We also believe that the silicon nitride coating can be applied to devices that require firm fixation and functional connections between the device or implant and the surrounding tissue, such as hip stems and screws. The use of silicon nitride coating may also create an antibacterial, antiviral, and antifungal barrier between the device and the adjacent bone or tissue. We are currently evaluating several different coating technologies.

Our Competitive Strengths

We believe we can use our silicon nitride technology platform to become a leading biomaterial company and have the following principal competitive strengths:

Sole Provider of Silicon Nitride Medical Devices. We believe we are the only company that designs, develops, manufactures and sells medical grade silicon nitride-based products. Due to its key characteristics, we believe our silicon nitride enables us to offer new and transformative products across multiple medical specialties. In addition, with the FDA clearance of our silicon nitride Valeo products, we are the only company to develop and manufacture a ceramic for use in FDA cleared spinal fusion medical devices in the United States.

In-House Manufacturing Capabilities for Implantable Medical Devices. We operate a 30,000 square foot manufacturing facility located at our corporate headquarters in Salt Lake City, Utah. This operation complies with the FDA's quality system regulation, or QSR, and is certified under the International Organization for Standardization's, or ISO, standard 13485 for medical devices. This facility allows us to rapidly design and produce silicon nitride products while controlling the entire manufacturing process from raw material to finished goods.

Extensive Network of Scientific Collaborators. We have developed strong, multi-year, collaborative relationships with surgeons who have used our products. These surgeons have supported us in collecting clinical data on silicon nitride and on reporting the successful patient outcomes they have observed. We also have long standing relations with university laboratories in Japan and the US and have recently been invited to participate in a European consortium on silicon nitride. Our partner in Japan has been at the forefront of silicon nitride biomaterial research for several years and has published extensively on the subject.

Highly Experienced Management and Technical Advisory Team. Members of our management team have extensive experience in silicon nitride, ceramics, research and development, manufacturing and operations, product development, launching of new products into the orthopedics market and selling to hospitals through direct sales organizations, distributors, manufacturers and other orthopedic companies. We also collaborate with a network of leading technical (academic and surgeon) advisors in the design, development and use of our silicon nitride products and product candidates.

Our Strategy

Our goal is to become a leading biomaterial company focused on using our silicon nitride technology platform to develop, manufacture and commercialize a broad range of medical devices. Key elements of our strategy to achieve this goal are the following:

Support CTL and drive further adoption of silicon nitride interbody spinal fusion devices. We have entered into a 10-year agreement to manufacture all of CTL Medical's requirements of silicon nitride based spinal implant products. This includes the current product line as well as new applications for silicon nitride in the spine.

Develop a commercial opportunity outside of spine. We have had active programs outside of spine for several years. We expect to commercialize on one or more of these in the near future.

Develop new silicon nitride manufacturing technologies. Our current manufacturing process has allowed us to successfully produce spinal implants for over 10 years. However, this process has limitations and we are actively pursuing other manufacturing technologies such as additive manufacturing, and surface coating technologies.

Make improvements to our current formulation of silicon nitride to increase the bioactive properties of the material. We have demonstrated in the laboratory that we can make our material more bioactive. This work has been independently corroborated by researchers in other parts of the world. We expect that the availability of silicon nitride with enhanced bioactivity would open up new markets to us.

Apply our silicon nitride technology platform to other OEM opportunities – medical and non-medical We believe our biomaterial expertise, flexible manufacturing process, and strong intellectual property will allow us to transition currently available medical device products made of inferior biomaterials and manufacture them using silicon nitride and our technology platform to improve their characteristics. We are seeking partnerships to utilize our capabilities and manufacture products for medical and non-medical original equipment manufacturer ("OEM") and private label partnerships. We see specific opportunities in markets such as dental, maxillofacial, total hip and knee joint replacements, and sports medicine.

Market Opportunity

Overview

We believe our silicon nitride biomaterial technology platform provides us with numerous competitive advantages in the biomaterials market. We manufactured interbody spinal fusion devices for our own retail spine business from 2008 to 2018, presently manufacture these for CTL Medical, and have a 10-year exclusive right to continue to manufacture them for CTL Medical. We are developing products on our own behalf and for third party manufacturers – including CTL Medical - for use as components in spine, total hip and knee joint replacements, as well as dental and maxillofacial applications. We believe we can also utilize our silicon nitride technology platform to develop future products in additional markets, such as the sports medicine, extremities, trauma, and non-medical markets.

We believe that the main drivers for growth within the orthopedic biomaterials market are the following:

Introduction of New Technologies. Better performing and longer-lasting biomaterials, improved diagnostics, and advances in surgical procedures allow for surgical intervention earlier in the continuum of care and better outcomes for patients. We believe surgical options using better performing and longer-lasting biomaterials will gain acceptance among surgeons and younger patients and drive accelerated growth and increase the size of the spinal fusion and joint replacement markets.

Favorable and Changing Demographics. With the growing number of elderly people, age-related ailments are expected to rise sharply, which we believe will increase the demand and need for biomaterials and devices with improved performance capabilities. Also, middle-aged and older patients increasingly expect to enjoy active lifestyles, and consequently demand effective treatments for painful spine and joint conditions, including better performing and longer-lasting interbody spinal fusion devices and joint replacements.

Market Expansion into New Geographic Areas. We anticipate that demand for biomaterials and the associated medical devices will increase as the applications in which biomaterials are used are introduced to and become more widely accepted in underserved countries, such as Brazil and China. We also expect to introduce our products into established markets such as Australia and Japan.

The Interbody Spinal Fusion Market

We believe there is opportunity for significant growth in the spinal fusion market for interbody spinal fusion devices manufactured with silicon nitride. Currently, in spinal fusion procedures conducted in the United States today, a significant majority utilize interbody devices comprised of PEEK and bone, with occasional use of metals and other materials including ceramics. The market for interbody spinal fusion devices has shifted over time as new biomaterials with superior characteristics have been incorporated into these devices and have launched into the market. We believe the market has reached another inflection point as surgeons and hospitals recognized the limitations of devices currently available. Similarly, we believe silicon nitride interbody spinal fusion products address the key limitations of other biomaterials currently used in interbody spinal fusion devices and demonstrate superior characteristics needed to improve clinical outcomes.

We selected this market as the first application for our silicon nitride technology because of the limitations of currently available products, its size, and the key characteristics silicon nitride possesses, which are critical for superior interbody spinal fusion outcomes.

Promotion of Bone Growth. The biomaterial should be both osteoconductive and create an osteoinductive environment to promote bone growth in and around the interbody device to further support fusion and stability. Osteoconduction occurs when material serves as a scaffold to support the growth of new bone in and around the material. Osteoinduction involves the stimulation of osteoprogenitor cells to develop, or differentiate, into osteoblasts, which are cells that are needed for bone growth. A material which stimulates bone growth and accelerates fusion rates is ideal in spinal fusion procedures.

Antibacterial. Spinal fusion devices can become colonized with bacteria, which may limit fusion to adjacent vertebrae or cause serious infection. Treating device-related infection is costly and generally requires repeat surgery, including surgery to replace the device, referred to as revision surgery, which may extend hospital stays, suffering and disability for patients. A biomaterial that has antibacterial properties can reduce the incidence of bacteria colonization in and around the interbody device that can lead to infection, revision surgery and associated increased costs.

Imaging Compatibility. The biomaterial should be visible through, and not inhibit the effective use of, common surgical and diagnostic imaging techniques, such as X-ray, CT and MRI. These imaging techniques are used by surgeons during and after spinal fusion procedures to assist in the proper placement of interbody devices and to assess the quality of post-operative bone fusion.

Strength and Resistance to Fracture. The biomaterial should be strong and resistant to fracture during implantation of the device and to successfully restore intervertebral disc space and spinal alignment during the fusion process. The biomaterial should have high flexural strength, which is the ability to resist breakage during bending, and high compressive strength, which is the ability to resist compression under pressure, to withstand the static and dynamic forces exerted on the spine during daily activities over the long term.

Spinal Fusion Products

Current spinal fusion products that we manufacture for CTL Medical are:

Valeo Interbody Fusion Devices	Generation
AL: Anterior Lumbar	2nd
PL: Posterior Lumbar	1st and 2nd
OL: Oblique Lumbar	1st and 2nd
TL: Transforaminal Lumbar	1st and 2nd
LL: Lateral Lumbar	2nd
C: Cervical	1st and 2nd
CORP: Corpectomy	1st
C+CSC (cleared in Australia and the EU but not the USA)	1st
C+CSC with Lumen	1st

The Dental Market

We believe there is opportunity for significant growth in the dental implant market for dental implant devices manufactured with silicon nitride and are pursuing this opportunity aggressively. We have entered into a joint development agreement with a dental implant design company and distributor of dental technologies for the development of a silicon nitride based dental implant system and devices.

When a tooth is removed, one common approach to restoration is to use a multi-part construct consisting of an titanium implant (or screw), a zirconia abutment, and a crown. Potential applications for silicon nitride in this procedure include the implant and the abutment.

Silicon nitride is appealing because this application takes advantage of the same bioactive properties discussed in the spinal implant section:

Promotion of bone growth
Antibacterial
Imaging compatible
Hard, strong, resistant to fracture and wear

We also believe it may be possible to leverage our knowledge of medical device manufacturing of ceramics and commercialize products for the dental market made from ceramics other than silicon nitride.

The Hip and Knee Joint Replacement Market

We believe there is opportunity for significant growth in the hip and knee joint replacement market for interbody devices manufactured with silicon nitride.

Total joint replacement involves removing the diseased or damaged joint and replacing it with an artificial implant consisting of components made from several different types of biomaterials. The key components of a total hip implant include an artificial femoral head, consisting of a ball mounted on an artificial stem attached to the femur, and a liner, which is placed inside a cup affixed into the pelvic bone. The femoral head and liner move against each other to replicate natural motion in what is known as an articulating implant. Total knee replacement implants also use articulating components and are comprised of the following four main components: a femoral condyle, which is a specially shaped bearing that is affixed to the lower end of the femur; a tibial tray that is affixed to the upper-end of the tibia; a tibial insert that is rigidly fixed to the tibial tray and serves as the surface against which the femoral condyle articulates; and a patella, or knee cap, which also articulates against the femoral condyle.

Implants for total hip and knee replacements are primarily differentiated by the biomaterials used in the components that articulate against one another. The combinations of biomaterials most commonly used in hip and knee replacement implants in the United States are metal-on-cross-linked polyethylene and traditional oxide ceramic-on-cross-linked polyethylene. The use of hip replacement implants incorporating metal-on-metal and traditional oxide ceramic-on-traditional ceramic biomaterials experienced a steep decline in the United States over the last several years due to their significant limitations. We believe that the most commonly used biomaterials in joint replacement implants also have limitations, and do not possess all of the following key characteristics required for optimal total joint replacement implants:

Resistance to Wear. The biomaterials should have sufficient hardness and toughness, as well as extremely smooth surfaces, to effectively resist wear. Because the articulating implants move against each other, they are subject to friction, which frequently leads to abrasive wear and the release of small wear particles. This may cause an inflammatory response which results in osteolysis, or bone loss. Surgeons have identified osteolysis as a leading cause of joint implant failure, resulting in the need for costly revision surgery to replace the failed implant. One of the most commonly used combinations of biomaterials, metal-on-cross-linked polyethylene, as well as metal-on-metal implants, tends to generate a large number of metal wear particles, which can cause osteolysis and a moderate to severe allergic reaction to the metal, referred to as metal sensitivity. While less common, metal implants may also cause a serious medical condition called metallosis, which involves the deposition and build-up of metal debris in the soft tissues of the body. Both metal sensitivity and metallosis can result in revision surgery. In addition, we believe traditional oxide ceramics currently used in total joint replacements accelerate wear of the cross-linked polyethylene liner as compared to our non-oxide ceramic composition found in our silicon nitride biomaterial platform.

Non-Corrosive. The biomaterials should be non-corrosive and should not cause adverse patient reactions. Metal placed in the human body corrodes over time and also results in the formation of metal ions, which leads to metal sensitivity in approximately 10% to 15% of the population and, less commonly, metallosis. As a result, there are significant increased risks from using metal-on-cross-linked polyethylene and metal-on-metal implants.

Hardness, Strength and Resistance to Fracture. The biomaterials should be hard, strong and resistant to fracture to adequately bear the significant loads placed on the hip and knee joints during daily activities. We believe there are strength limitations associated with traditional oxide ceramic-on-cross-linked polyethylene and traditional oxide ceramic-on-traditional oxide ceramic implants.

Antibacterial. The biomaterials should have antibacterial properties to reduce the risk of bacteria colonization, infection, revision surgeries and associated increased costs. None of the most commonly used biomaterials in joint replacement implants have antibacterial properties.

Our Total Hip Implant Product Candidates

We have developed a femoral head that is made from our solid silicon nitride, which could be used for total hip replacement product candidates. This femoral head is expected to articulate against a cross-linked polyethylene liner fixed into a metal acetabular cup. Most recently we participated in a university study that demonstrated the comparatively better behavior of silicon nitride femoral heads in taper fretting corrosion behavior study. As we continue to gather evidence that silicon nitride femoral heads are superior in terms of wear performance, taper corrosion, strength and *in vitro* hydrothermal stability, we eventually intend to commercialize this product in cooperation with a strategic partner. However, clearance of these types of devices by the FDA will be required. Currently, the FDA has indicated that a limited one to two-year clinical trial may be necessary to obtain clearance.

Our Total Knee Implant Product Candidates

We have developed a femoral condyle design made from our solid silicon nitride. The femoral condyle component will attach to the lower end of the femur. The femoral condyle is expected to articulate against a cross-linked polyethylene tibial insert that will attach to the tibial tray at the upper end of the tibia, which we expect will be made from metal. We have successfully made prototypes of this design. Following the potential clearance of the femoral head components (discussed above), we intend to initiate biomechanical testing with a strategic partner for silicon nitride components for use in knee replacement procedures to support a 510(k) submission to the FDA. If this clearance is eventually obtained, we intend to commercialize our products for use in total knee replacement surgeries post-FDA clearance.

Other Product Opportunities

Our silicon nitride technology platform is adaptable, and we believe it may be used to develop products to address other significant opportunities, such as in the cranial-maxillofacial, extremities, sports medicine and trauma markets.

We also believe our coating technology may be used to enhance metal products as well as other commercially available metal or PEEK spinal fusion and joint replacement products. We have produced feasibility prototypes of dental implants, other components for use in total hip implants in addition to our total hip and knee implant product candidates discussed above, a suture anchor for sports medicine applications, an osteotomy wedge for extremities applications, and prototypes of silicon nitride-coated plates for potential trauma applications. We have also developed a process to apply our silicon nitride as a coating on other materials which may find applications in markets outside of the medical device industry.

Our recent discoveries of the antiviral and antifungal properties of silicon nitride have opened up completely new opportunities for us in the consumer and agriculture markets.

The FDA has not evaluated any of these potential products and we are not currently advancing the development of any of these product candidates. We plan to collaborate with medical device companies to complete the development of and commercialize any product candidates we advance in these areas or develop any one of them ourselves if sufficient resources should become available.

Intellectual Property

We rely on a combination of patents, trademarks, trade secrets, nondisclosure agreements, proprietary information ownership agreements and other intellectual property measures to protect our intellectual property rights. We believe that in order to have a competitive advantage, we must continue to develop and maintain the proprietary aspects of our technologies.

As of the end of January 2019, we had thirteen issued U.S. patents, three pending U.S. patent applications, and one pending PCT application. Our first issued patent expired in 2016, with the last of these patents expiring in 2036. The core patent (US 6,881,229) expires in 2022.

We have seven U.S. patents directed to articulating implants using our high-strength, high toughness doped silicon nitride solid ceramic. The issued patents, which include US 6,881,229; US 7,666,229; US 7,780,738; US 8,123,812; US 8,133,284; US 9,051,639; and US 9,517,136 begin to expire in 2022.

We also have two U.S. patents related to our CSC technology that are directed to implants that have both a dense load-bearing, or cortical, component and a porous, or cancellous, component, together with a surface coating. These issued patents, US 8,133,284 and US 9,649,197, expire in 2022 and 2035, respectively.

We also have three U.S. patents that we acquired in July 2012 from Dytech Corporation Ltd., or Dytech, directed to manufacturing processes for the production of porous ceramics for use in our orthopedic implants. These patents include US 5,563,106 and US 5,705,448, which have now expired; and US 6,617,270, which expires in 2019. Under our acquisition agreement with Dytech, Dytech granted to us a perpetual, irrevocable and exclusive license, including the right to grant sublicenses, to certain improvements and know-how related to the acquired patents. In return, we are required to pay Dytech a low single-digit royalty on net sales of products sold by us, our affiliates, or our licensees that are covered by one or more valid claims of these patents, and a percentage of any non-royalty licensing income we may receive in the event we grant a license to others.

Our remaining issued patents and pending applications are directed to additional aspects of our products and technologies including, among other things:

- designs for intervertebral fusion devices;
- designs for hip implants;
- designs for knee implants;
- implants with improved antibacterial characteristics;
- implants with improved wear performance; and
- Antipathogenic compositions.

We also expect to rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our intellectual property position. However, trade secrets are difficult to protect. We seek to protect the trade secrets in our proprietary technology and processes, in part, by entering into confidentiality agreements with commercial partners, collaborators, employees, consultants, scientific advisors and other contractors and into invention assignment agreements with our employees and some of our commercial partners and consultants.

These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of the technologies that are developed.

Competition

The main alternatives to our silicon nitride biomaterial include: PEEK, which is predominantly manufactured by Invibio; BIOLOX® *delta*, which is a traditional oxide ceramic manufactured by CeramTec; allograft bone; metals; and coated metals.

We believe our main competitors in the orthopedic implant market, which utilize a variety of competitive biomaterials, include: Medtronic, Inc.; DePuy Synthes Companies, a group of Johnson & Johnson companies; Stryker Corporation; Biomet, Inc.; Zimmer Holdings, Inc.; Smith & Nephew plc; and Aesculap Inc. Presently, these companies buy ceramic components on an OEM basis from manufacturers such as CeramTec, Kyocera and CoorsTek, Inc., among others. We anticipate that these and other orthopedic companies and OEMs will seek to introduce new biomaterials and products that compete with ours.

Competition within the industry is primarily based on technology, innovation, product quality, and product awareness and acceptance by surgeons. Our principal competitors have substantially greater financial, technical and marketing resources, as well as significantly greater manufacturing capabilities than we do, and they may succeed in developing products that render our implants and product candidates non-competitive. Our ability to compete successfully will depend upon our ability to develop innovative products with advanced performance features based on our silicon nitride technologies.

Government Regulation of Medical Devices

Governmental authorities in the United States, at the federal, state and local levels, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of products such as those we are commercializing and developing. Failure to obtain approval or clearance to market our products and products under development and to meet the ongoing requirements of these regulatory authorities could prevent us from continuing to market or develop our products and product candidates.

United States

Pre-Marketing Regulation

In the United States, medical devices are regulated by the FDA. Unless an exemption applies, a new medical device will require either prior 510(k) clearance or approval of a premarket approval application, or PMA, before it can be marketed in the United States. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which are those that have the lowest level or risk associated with them, are subject to general controls, including labeling, premarket notification and adherence to the QSR. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to most of the previously identified requirements as well as to premarket approval. Most Class I devices and some Class II devices are exempt from the 510(k) requirements, although manufacturers of these devices are still subject to registration, listing, labeling and QSR requirements.

A 510(k) premarket notification must demonstrate that the device in question is substantially equivalent to another legally marketed device, or predicate device, that did not require premarket approval. In evaluating the 510(k), the

FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (i) the data supporting the substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (ii) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. The FDA's goal is to review and act on each 510(k) within 90 days of submission, but it may take longer based on requests for additional information. In addition, requests for additional data, including clinical data, will increase the time necessary to review the notice. If the FDA does not agree that the new device is substantially equivalent to the predicate device, the new device will be classified in Class III, and the manufacturer must submit a PMA. Since July 2012, however, with the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, a de novo pathway is directly available for certain low to moderate risk devices that do not qualify for the 510(k) pathway due to lack of a predicate device. Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect the safety or effectiveness or constitute a major change in the intended use of the device.

Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary. For example, in its Device Advice on How to Prepare a Special 510(k), the FDA uses the example of a change in a material in a finger joint prosthesis from a known metal alloy to a ceramic that has not been used in a legally marketed predicate device as a type of change that should not be submitted as a Special 510(k). However, if the "new" material is a type that has been used in other legally marketed devices within the same classification for the same intended use, a Special 510(k) is appropriate. The FDA gives as an example a manufacturer of a hip implant who changes from one alloy to another that has been used in another legally marketed predicate. Special 510(k)s are typically processed within 30 days of receipt.

The PMA process is more complex, costly and time consuming than the 510(k) clearance procedure. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical, manufacturing, control and labeling information to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to performance goal review times for PMAs and may issue a decision letter as a first action on a PMA within 180 days of filing, but if it has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA to an FDA advisory panel for additional review and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR, either of which could extend the 180-day response target. While the FDA's ability to meet its performance goals has generally improved during the past few years, it may not meet these goals in the future. A PMA can take several years to complete and there is no assurance that any submitted PMA will ever be approved. Even when approved, the FDA may limit the indication for which the medical device may be marketed or to whom it may be sold. In addition, the FDA may request additional information or request the performance of additional clinical trials before it will reconsider the approval of the PMA or as a condition of approval, in which case the trials must be completed after the PMA is approved. Changes to the device, including changes to its manufacturing process, may require the approval of a supplemental PMA.

If a medical device is determined to present a "significant risk," the manufacturer may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval of the IDE from the FDA. The IDE must be supported by appropriate data, such as animal and laboratory testing results and include a proposed clinical protocol. These clinical trials are also subject to the review, approval and oversight of an institutional review board, or IRB, which is an independent and multi-disciplinary committee of volunteers who review and approve research proposals, and the reporting of adverse events and experiences, at each institution at which the clinical trial will be performed. The clinical trials must be conducted in accordance with applicable regulations, including but not limited to the FDA's IDE regulations and current good clinical practices. A clinical trial may be suspended by the FDA, the IRB or the sponsor at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Even if a clinical trial is completed, the results may not demonstrate the safety and efficacy of a device or may be equivocal or otherwise not be sufficient to obtain approval.

Post-Marketing Regulation

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

compliance with the QSR, which require manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;

labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling; and

medical device reporting obligations, which require that manufacturers investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters;
- fines, injunctions, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to grant 510(k) clearance or PMA approvals of new products;
- withdrawal of 510(k) clearance or PMA approvals; and
- criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors.

International Regulation

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. For example, the primary regulatory authority with respect to medical devices in Europe is that of the European Union. The European Union consists of 28 countries and has a total population of over 500 million people. The unification of these countries into a common market has resulted in the unification of laws, standards and procedures across these countries, which may expedite the introduction of medical devices like those we are offering and developing. Norway, Iceland, Lichtenstein and Switzerland are not members of the European Union but have transposed applicable European medical device laws into their national legislation. Thus, a device that is marketed in the European Union may also be recognized and accepted in those four non-member European countries as well.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of relevant directives will be entitled to bear CE Conformity Marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European

Union. Actual implementation of these directives, however, may vary on a country-by-country basis. The CE Mark is a mandatory conformity mark on medical devices distributed and sold in the European Union and certifies that a medical device has met applicable requirements.

The method of assessing conformity varies, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a “Notified Body.” Notified Bodies are independent testing houses, laboratories, or product certifiers authorized by the European Union member states to perform the required conformity assessment tasks, such as quality system audits and device compliance testing. An assessment by a Notified Body based within the European Union is required in order for a manufacturer to distribute the product commercially throughout the European Union. Medium and higher risk devices require the intervention of a Notified Body which will be responsible for auditing the manufacturer’s quality system. The Notified Body will also determine whether or not the product conforms to the requirements of the applicable directives. Devices that meet the applicable requirements of E.U. law and have undergone the appropriate conformity assessment routes will be granted CE “certification.” The CE Mark is mandatory for medical devices sold not only within the countries of the European Union but more generally within most of Europe. As many of the European standards are converging with international standards, the CE Mark is often used on medical devices manufactured and sold outside of Europe (notably in Asia that exports many manufactured products to Europe). CE Marking gives companies easier access into not only the European market but also to Asian and Latin American markets, most of whom recognize the CE Mark on medical device as a mark of quality and adhering to international standards of consumer safety, health or environmental requirements.

Compliance with Healthcare Laws

We must comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws, rules, and regulations, as well as other healthcare laws in connection with the commercialization of our products. Fraud and abuse laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the U.S. Department of Justice, the U.S. Office of Inspector General for the Department of Health and Human Services and various state agencies.

We have entered into agreements with certain surgeons for assistance with the design of our products, some of whom we anticipate may make referrals to us or order our products. A majority of these agreements contain provisions for the payments of royalties. In addition, some surgeons currently own shares of our stock. We have structured these transactions with the intention of complying with all applicable laws, including fraud and abuse, data privacy and security, and transparency laws. Despite this intention, there can be no assurance that a particular government agency or court would determine our practices to be in full compliance with such laws. We could be materially impacted if regulatory or enforcement agencies or courts interpret our financial arrangements with surgeons to be in violation of healthcare laws, including, without limitation, fraud and abuse, data privacy and security, or transparency laws.

The U.S. federal Anti-Kickback Statute prohibits persons, including a medical device manufacturer (or a party acting on its behalf), from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for a service or product or the purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by Medicare, Medicaid or any other federal healthcare program. This statute has been interpreted to apply to arrangements between medical device manufacturers on one hand and healthcare providers on the other. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, such as cash payments, gifts or gift certificates, discounts, waiver of payments, credit arrangements, ownership interests, the furnishing of services, supplies or equipment, and the provision of anything at less than its fair market value. Courts have broadly interpreted the scope of the law, holding that it may be violated if merely “one purpose” of an arrangement is to induce referrals, irrespective of the existence of other legitimate purposes. The Anti-Kickback Statute prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the recently enacted Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the Affordable Care Act or ACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that 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 federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to

have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition to the federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payments made by government healthcare programs but also to payments made by other third-party payors, including commercial insurance companies.

Sales, marketing, consulting, and advisory arrangements between medical device manufacturers and sales agents and physicians are subject to the Anti-Kickback Statute and other fraud and abuse laws. Government officials have focused recent enforcement efforts on, among other things, the sales and marketing activities of healthcare companies, including medical device manufacturers, and have brought cases against individuals or entities whose personnel allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. We expect these activities to continue to be a focus of government enforcement efforts. Settlements of these cases by healthcare companies have involved significant fines and penalties and, in some instances, criminal plea agreements. We are also aware of governmental investigations of some of the largest orthopedic device companies reportedly focusing on consulting and service agreements between these companies and orthopedic surgeons. These developments are ongoing, and we cannot predict the effects they will have on our business.

The federal False Claims Act imposes liability on any person that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim, or has caused such a claim to be submitted, to the federal government, and to share in any monetary recovery. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when a person knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks, and other improper referrals, and allegations as to misrepresentations with respect to the services rendered. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies, including medical device manufacturers, to defend false claim actions, pay damages and penalties, or be excluded from participation in Medicare, Medicaid or other federal or state healthcare programs as a result of investigations arising out of such actions. In addition, various states have enacted similar laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits 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.

In addition, we may be subject to, or our marketing or research activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. For example, HIPAA and its implementing regulations established uniform federal standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA’s privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to “business associates”—independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. These laws also require the reporting of breaches of protected health information to affected individuals, regulators and in some cases, local or national media. HIPAA and HITECH impose strict limits on our physician collaborators’ ability to use and disclose patient information on our behalf.

There are also an increasing number of state “sunshine” laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing

practices. In addition, a federal law known as the Physician Payments Sunshine Act, now requires medical device manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The first reporting period covered only payments or transfers of value made and ownership or investment interests held by physicians and their immediate family members from August 1, 2013 to December 31, 2013. The federal government disclosed the reported information on a publicly available website beginning in September 2014. For calendar year 2014, the Physician Payments Sunshine Act will require medical device manufacturers to report payments and transfers of values made and ownership or investment interests held by physicians and their immediate family members for the full calendar year. These laws may adversely affect our sales, marketing, and other activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or to otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Clinical research is heavily regulated by FDA regulations for the protection of human subjects (21 C.F.R. 50 and 56) and also the regulations of the U.S Department of Health and Human Services, or the Common Rule (45 C.F.R 46). Both FDA human subject regulations and the Common Rule impose restrictions on the involvement of human subjects in clinical research and require, among other things, the balancing of the risks and benefits of research, the documented informed consent of research participants, initial and ongoing review of research by an IRB. Similar regulations govern research conducted in foreign countries. Compliance with human subject protection regulations is costly and time consuming. Failure to comply could substantially and adversely impact our research program and the development of our products.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product clearances and approvals, private “qui tam” actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations. Public disclosure of privacy and data security violations could cause significant reputational harm. Any of these events could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, as well as laws and regulations requiring transparency of pricing and marketing information and governing the privacy and security of health information, such as the E.U.’s Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data, or the Data Directive, and the wide variety of national laws implementing the Data Directive.

Healthcare Reform

The regulations we are subject to may change as result of legislative and regulatory healthcare reform.

Significant healthcare reform was enacted in 2010 when the Patient Protection and Affordable Care Act or the PPACA, was signed into law. State laws also were enacted to implement the PPACA. While a primary goal of these healthcare reform efforts was to expand coverage to more individuals, it also involved increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA significantly impacts the medical device industry. Among other things, the PPACA:

imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, which began on January 1, 2013, but was suspended during 2016 and 2017 and has been suspended for 2018 and 2019;

establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and

implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, on January 2, 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, certain legislative changes to and regulatory changes under the PPACA have occurred in the 115th United States Congress and under the Trump Administration. For example, on December 22, 2017, President Trump signed a budget reconciliation act into law, which among other things, repealed the penalty for individuals who do not maintain minimum essential coverage, which was a central component of PPACA's approach to expanding coverage. On January 9, 2018, President Trump signed the Bipartisan Budget Act of 2018, which, among other things, repealed the PPACA provision establishing an independent payment advisory board that would have submitted recommendations to reduce Medicare spending if projected Medicare spending exceeded a specified growth rate.

Additional legislative changes to and regulatory changes under the PPACA remain possible. We expect that other state and federal healthcare reform measures will be adopted in the future, any of which could reduce the number of patients with coverage or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Third-Party Reimbursement

Because we and our customers typically receive payment directly from hospitals and surgical centers, we do not anticipate relying directly on payment for any of our products from third-party payors, such as Medicare, Medicaid, private insurers, and managed care companies. However, our business will be affected by policies administered by federal and state healthcare programs, such as Medicare and Medicaid, as well as private third-party payors, which often follow the policies of the state and federal healthcare programs. For example, our business will be indirectly impacted by the ability of a hospital or medical facility to obtain coverage and third-party reimbursement for procedures performed using our products. Many hospitals and clinics in the United States belong to group purchasing organizations (that typically incentivize their hospital members to make a relatively large proportion of purchases from a limited number of vendors of similar products that have contracted to offer discounted prices). Such contracts often include exceptions for purchasing certain innovative new technologies, however. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations or persuade hospitals and clinics to purchase our product "off contract." These third-party payors may deny reimbursement if they determine that a device used in a procedure was not medically necessary; was not used in accordance with cost-effective treatment methods, as determined by the third-party payor; or was used for an unapproved use. A national or local coverage decision denying Medicare coverage for one or more of our products could result in private insurers and other third party payors also denying coverage. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future. The cost containment measures that third-party payors and providers are instituting, both within the United States and abroad, could significantly reduce our potential revenues from the sale of our products and any product candidates. We cannot provide any assurances that we will be able to obtain and maintain third party coverage or adequate reimbursement for our products and product candidates in whole or in part.

For inpatient and outpatient procedures, including those that will involve use of our products, Medicare and many other third-party payors in the United States reimburse hospitals at a prospectively determined amount. This amount is generally based on one or more diagnosis related groups, or DRGs, associated with the patient's condition for inpatient treatment and generally based on ambulatory payment classifications, or APCs, associated with the procedures performed as an outpatient at an ambulation surgicenter. Each DRG or APC is associated with a level of payment and may be adjusted from time to time, usually annually. Prospective payments are intended to cover most of the non-physician hospital costs incurred in connection with the applicable diagnosis and related procedures. Implant products, such as those we plan to sell, represent part of the total procedure costs while labor, hospital room and board, and other supplies and services represent the balance of those costs. However, the prospective payment amounts are typically set independently of a particular hospital's actual costs associated with treating a particular patient and implanting a device. Therefore, the payment that a hospital would receive for a particular hospital visit would not typically take into account the cost of our products.

Medicare has established a number of DRGs for inpatient procedures that involve the use of products similar to ours. Although Medicare has authority to create special DRGs for hospital services that more properly reflect the actual costs of expensive or new-technology devices implanted as part of a procedure, it has declined to do so in the past, and we do not expect that it will do so with respect to our current products and product candidates. Medicare's DRG and APC classifications may have implications outside of Medicare, as many other U.S. third-party payors often use Medicare DRGs and APCs for purposes of determining reimbursement.

We believe that orthopedic implants generally have been well received by third-party payors because of the ability of these implants to greatly reduce long-term healthcare costs for patients with degenerative joint disease. However, coverage and reimbursement policies vary from payor to payor and are subject to change. As discussed above, hospitals that purchase medical devices for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Both government and private third-party coverage and reimbursement levels are critical to new product acceptance. Neither hospitals nor surgeons are likely to use our products if they do not receive reimbursement for the procedures adequate to cover the cost of our products.

While it is expected that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Commercial insurers and managed care plans frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. These third-party payors may deny payment if they determine that a procedure was not medically necessary, a device used in a procedure was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved use.

In addition, some payors are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies, or patient outcomes. These programs are intended to provide incentives to providers to find ways to deliver the same or better results while consuming fewer resources. As a result of these programs, and related payor efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device suppliers. Adverse changes in payment rates by payors to hospitals could adversely impact our ability to market and sell our products and negatively affect our financial performance.

In international markets, healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. There can be no assurance that our products will be considered cost-effective by third-party payors, that reimbursement will be available or, if available, that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Member countries of the European Union offer various combinations of centrally financed healthcare systems and private health insurance systems. The relative importance of government and private systems varies from country to country. Governments may influence the price of medical devices through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may be marketed only once a reimbursement price has been agreed upon. Some of these countries may require, as condition of obtaining reimbursement or pricing approval, the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Some E.U. member states allow companies to fix their own prices for devices but monitor and control company profits. The choice of devices is subject to constraints imposed by the availability of funds within the purchasing institution. Medical devices are most commonly sold to hospitals or healthcare facilities at a price set by negotiation between the buyer and the seller. A contract to purchase products may result from an individual initiative or as a result of a competitive bidding process. In either case, the purchaser pays the supplier, and payment terms vary widely throughout the European Union. Failure to obtain favorable negotiated prices with hospitals or healthcare facilities could adversely affect sales of our products.

Employees

As of February 28, 2019, we had 19 employees. We believe that our success will depend, in part, on our ability to attract and retain qualified personnel. We have never experienced a work stoppage due to labor difficulties and believe that our relations with our employees are good. None of our employees are represented by labor unions.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this Annual Report, the following risk factors should be considered carefully in evaluating our company. Our business, financial condition, liquidity or results of operations could be materially adversely affected by any of these risks.

Risks Related to Our Business and Strategy

We have incurred net losses since our inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We may never achieve or sustain profitability.

We have incurred substantial net losses since our inception. For the years ended December 31, 2018 and 2017 we incurred a net loss of $8.8 million and $9.3 million, respectively, and used cash in operations of $9.3 million and $4.7 million, respectively. We have an accumulated deficit of $229.4 million at December 31, 2018. Our losses have resulted principally from costs incurred in connection with our sales and marketing activities, research and development activities, manufacturing activities, general and administrative expenses associated with our operations, impairments on intangible assets and property and equipment, interest expense, loss on extinguishment of debt and offering costs. Even if we are successful in launching new products into the market, we expect to continue to incur substantial losses for the foreseeable future as we continue to manufacture products for CTL Medical and other OEM customers and research and develop and seek regulatory approvals for our product candidates.

If sales revenue from any of our products or product candidates that receive marketing clearance from the FDA or other regulatory body is insufficient, if we are unable to develop and commercialize any of our product candidates, or if our product development is delayed, we may never become profitable. Even if we do become profitable, we may be unable to sustain or increase our profitability on a quarterly or annual basis.

Our success depends on our ability to successfully commercialize silicon nitride-based medical devices, which to date have experienced only limited market acceptance.

We believe we are the first and only company to use silicon nitride in medical applications. To date, however, we have had limited acceptance of our silicon nitride-based products and our product revenue has been derived substantially from our non-silicon nitride products. In order to succeed in our goal of becoming a leading biomaterial technology company utilizing silicon nitride, we must increase market awareness of our silicon nitride interbody spinal fusion products in conjunction with CTL Medical, continue to develop our other product candidates outside of spinal fusion applications, enhance our commercial infrastructure and commercialize our silicon nitride joint replacement components and other products. If we fail in any of these endeavors or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

Our current products and our future products may not be accepted by hospitals and surgeons and may not become commercially successful.

With the sale of our spine business to CTL Medical we are now dependent on the efforts of CTL Medical to sell the spinal fusion products that we manufacture and then sell to CTL Medical. If CTL Medical is not able to sell such products or is unable increase demand for such products, then our revenues will substantially decline. Since obtaining regulatory clearance from the FDA for our first silicon nitride spinal fusion products in 2008, we were not been able to obtain significant market share of the interbody spinal fusion market, and CTL Medical may not obtain such market share in the future. Even if we receive regulatory clearances or approvals for our other product candidates in development, these product candidates may not gain market acceptance among orthopedic surgeons and the medical community. Orthopedic surgeons may elect not to use our products for a variety of reasons, including:

- lack or perceived lack of evidence supporting the beneficial characteristics of our silicon nitride technology;
- limited long-term data on the use of silicon nitride in medical devices;
- lower than expected clinical benefits in comparison with other products;

the perception by surgeons that there are insufficient advantages of our products relative to currently available products;

hospitals may choose not to purchase our products;

group purchasing organizations may choose not to contract for our products, thus limiting availability of our products to hospital purchasers;

the price of our products, which may be higher than products made of the other commonly used biomaterials in the interbody spinal fusion market and total joint market;

lack of coverage or adequate payment from managed care plans and other third-party payers for the procedures that use our products;

Medicare, Medicaid or other third-party payers may limit or not permit reimbursement for procedures using our products;

ineffective marketing and distribution support;

the time and resources that may be required for training, or the inadequate training, of surgeons in the proper use of our products;

the development of alternative biomaterials and products that render our products less competitive or obsolete; and

the development of or improvement of competitive products.

If surgeons do not perceive silicon nitride products and product candidates as superior alternatives to competing products, we will not be able to generate significant revenues, if any.

Even if surgeons are convinced of the superior characteristics of our silicon nitride products and our product candidates that we successfully introduce compared to the limitations of the current commonly used biomaterials, surgeons may find other methods or turn to other biomaterials besides silicon nitride to overcome such limitations. For instance, with respect to interbody spinal fusion products, surgeons or device manufacturers may use more effective markers for enhancing the imaging compatibility of PEEK devices, more effective antibiotics to prevent or treat implant-related infections, and more effective osteoconductive and osteoinductive materials when implanting an interbody spinal fusion device. Device manufacturers may also coat metal with existing traditional ceramics to reduce the risk of metal wear particles and corrosion in total joint replacement implants. Additionally, surgeons may increase their use of metal interbody spinal fusion devices if there is an increasing perception that PEEK devices are limited by their strength and resistance to fracture.

The orthopedic market is highly competitive, and we may not be able to compete effectively against the larger, well-established companies that dominate this market or emerging and small innovative companies that may seek to obtain or increase their share of the market.

The markets for spinal fusions and total hip and knee implant products are intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets. Medtronic, Inc.; DePuy Synthes Companies, a group of Johnson & Johnson companies; Stryker Corporation; Biomet, Inc.; Zimmer Holdings, Inc.; and Smith & Nephew plc, account for a significant amount of orthopedic sales worldwide.

These companies enjoy significant competitive advantages over us, including:

broad product offerings, which address the needs of orthopedic surgeons and hospitals in a wide range of procedures;

products that are supported by long-term clinical data;

greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;

existing relationships with orthopedic surgeons;

extensive intellectual property portfolios and greater resources for patent protection;

greater financial and other resources for product research and development;

greater experience in obtaining and maintaining FDA and other regulatory clearances and approvals for products and product enhancements;

established manufacturing operations and contract manufacturing relationships;

significantly greater name recognition and widely recognized trademarks; and

established relationships with healthcare providers and payers.

Our products and any product candidates that we may introduce into the market may not enable us to overcome the competitive advantages of these large and dominant orthopedic companies. In addition, even if we successfully introduce additional product candidates incorporating our silicon nitride biomaterial into the market, emerging and small innovative companies may seek to increase their market share and they may eventually possess competitive advantages, which could adversely impact our business. Our competitors may also employ pricing strategies that could adversely affect the pricing of our products and pricing in the spinal fusion and total joint replacement market generally.

Moreover, many other companies are seeking to develop new biomaterials and products which may compete effectively against our products in terms of performance and price. For example, Smith & Nephew has developed a ceramic-coated metal, known as Oxinium, which may overcome certain of the limitations of metal joint replacement products and could directly compete with our silicon nitride and silicon nitride-coated product candidates.

We are entirely dependent on CTL Medical's ability to sell the spinal fusion products we manufacture from silicon nitride. If CTL Medical is not able to sell such products or increase demand for the products our revenues will be substantially impacted which would have a significant impact on our business and operating results.

Sales of spinal fusion products manufactured from silicon nitride to CTL Medical accounts for all of our revenues from the sale of products. We have entered into a 10-year manufacturing and supply agreement with CTL Medical to supply CTL Medical with its requirements of silicon nitride manufactured spinal fusion products. CTL Medical is not under any obligation to purchase any minimum quantities of products from us. If CTL Medical is not successful in creating demand for such products and selling such products, then they are not required to purchase any products from us. Because of our significant customer concentration, our revenue could fluctuate significantly due to changes in economic conditions, the use of competitive products, or the loss of, reduction of business with, CTL Medical. A reduction or delay in orders from CTL Medical, or a delay or default in payment by any significant customer, could materially harm our business and results of operations.

The manufacturing process for our silicon nitride products is complex and requires sophisticated state-of-the-art equipment, experienced manufacturing personnel and highly specialized knowledge. If we are unable to manufacture our silicon nitride products on a timely basis consistent with our quality standards, our results of operation will be adversely impacted.

In order to control the quality, cost and availability of our silicon nitride products, we developed our own manufacturing capabilities. We operate a 30,000 square foot manufacturing facility which is certified under the ISO 13485 medical device manufacturing standard for medical devices and operates under the FDA's quality systems regulations, or QSRs. All operations with the exceptions of raw material production, cleaning, packaging and sterilization are performed at this facility.

In order to mitigate the risk associated with us being the sole manufacturer of our silicon nitride medical device products, in June 2014, we entered into a manufacturing development and supply agreement with Kyocera Industrial Ceramics Corporation, or Kyocera. We updated our material master file and submitted a 510(k) with the FDA in the third quarter of 2014 to qualify Kyocera as a second source supplier of our silicon nitride products. Kyocera has been qualified as a second source supplier of our silicon nitride products. Although we expect this arrangement with Kyocera to continue, if Kyocera ceases to continue as a qualified manufacturer of these products and product candidates, we will be the sole manufacturer of these products and will need to seek other potential secondary manufacturers. Our reliance solely on our internal resources to manufacture our silicon nitride products entails risks to which we would not be subject if we had secondary suppliers for their manufacture, including:

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity to meet additional demand for our products;
- manufacturing and product quality issues related to the scale-up of manufacturing;
- the inability to produce a sufficient supply of our products to meet product demands;
- the disruption of our manufacturing facility due to equipment failure, natural disaster or failure to retain key personnel; and
- our inability to ensure our compliance with regulations and standards of the FDA, including QSRs, and corresponding state and international regulatory authorities, including the CFDA.

Any of these events could lead to a reduction in our product sales, product launch delays, failure to obtain regulatory clearance or approval or impact our ability to successfully sell our products and commercialize our products candidates.

We depend on a limited number of third-party suppliers for key raw materials used in the manufacturing of our silicon nitride products, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on a limited number of third-party suppliers for the raw materials required for the production of our silicon nitride products and product candidates. Our dependence on a limited number of third-party suppliers involves several risks, including limited control over pricing, availability, quality, and delivery schedules for raw materials. We have no supply agreements in place with any of our suppliers and cannot be certain that our current suppliers will continue to provide us with the quantities of raw materials that we require or that satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or single sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. We may be

unable to find a sufficient alternative supply channel within a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the production of our silicon nitride products and product candidates and delay the development and commercialization of our product candidates, including limiting supplies necessary for commercial sale, clinical trials and regulatory approvals, which could have a material adverse effect on our business.

In order to be successful, we must expand our available product lines of silicon nitride-based medical devices by commercializing new product candidates, but we may not be able to do so in a timely fashion and at expected costs, or at all.

Although we are currently manufacturing silicon nitride interbody spinal fusion implants for CTL Medical, in order to be successful, we will need to expand our product lines to include other silicon nitride devices. Therefore, we are developing silicon nitride product candidates for total hip and knee replacement procedures, dental implants and are exploring the application of our silicon nitride technology for other potential applications. However, we have yet to commercialize any silicon nitride products beyond our spinal fusion products. To succeed in our commercialization efforts, we must effectively continue product development and testing, find new strategic partners, obtain regulatory clearances and approvals, and enhance our sales and marketing capabilities. Because of these uncertainties, there is no assurance that we will succeed in bringing any of our current or future product candidates to market. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

We will depend on one or more strategic partners to develop and commercialize our total joint replacement and dental implant product candidates, and if our strategic partners are unable to execute effectively on our agreements with them, we may never become profitable.

We are seeking a strategic partner to develop and commercialize our total joint replacement and dental implant product candidates. We will be reliant on our strategic partners to develop and commercialize a total hip or knee joint replacement product candidate that utilizes silicon nitride-coated components, although we have not yet entered into an agreement with any strategic partner to develop products with these silicon nitride-coated components and may be unable to do so on agreeable terms. In order to succeed in our joint commercialization efforts, we and any future partners must execute effectively on all elements of a combined business plan, including continuing to establish sales and marketing capabilities, manage certified, validated and effective commercial-scale manufacturing operations, conduct product development and testing, and obtain regulatory clearances and approvals for our product candidate. If we or any of our strategic partners fail in any of these endeavors, or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

Part of our strategy is to establish and develop OEM partnerships and arrangements, which subjects us to various risks.

Because we believe silicon nitride is a superior platform and technology for application in the spine, total joint and other markets, we are establishing OEM partnerships with other companies to replace their materials and products with silicon nitride. Sales of products to OEM customers will expose our business to a number of risks. Sales through OEM partners could be less profitable than direct sales. Sales of our products through multiple channels could also confuse customers and cause the sale of our products to decline. In addition, OEM customers will require that products meet strict standards. Our compliance with these requirements could result in increased development, manufacturing, warranty and administrative costs. A significant increase in these costs could adversely affect our operating results. If we fail to meet OEM specifications on a timely basis, our relationships with our OEM partners may be harmed. Furthermore, we would not control our OEM partners, and they could sell competing products, may not incorporate our technology into their products in a timely manner and may devote insufficient sales efforts to the OEM products.

If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, it is unlikely our products will be widely used.

In the United States, the commercial success of our products will depend, in part, on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for procedures utilizing our products.

Because we typically receive payment directly from the companies for whom we manufacture, such as CTL Medical, we do not anticipate relying directly on payment from third-party payers for our products. However, hospitals and other healthcare providers that purchase orthopedic products manufactured by us from our customers for treatment of their patients generally rely on third-party payers to pay for all or part of the costs and fees associated with our products as part of a "bundled" rate for the associated procedures. The existence of coverage and adequate reimbursement for our products and the procedures performed with them by government and private payers is critical to market acceptance of our existing and future products. Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products.

Many private payers currently base their reimbursement policies on the coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the procedures performed with our products in an adequate amount, if at all. A Medicare national or local coverage decision denying coverage for one or more of our products could result in private and other third-party payers also denying coverage for our products. Third-party payers also may deny reimbursement for our products if they determine that a product used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payer, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payers underscore the uncertainty that our products face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the United States belong to group purchasing organizations, which typically incentivize their hospital members to make a relatively large proportion of purchases from a limited number of vendors of similar products that have contracted to offer discounted prices. Such contracts often include exceptions for purchasing certain innovative new technologies, however. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations and/or persuade hospitals and clinics to purchase our product "off contract."

The healthcare industry in the United States has experienced a trend toward cost containment as government and private payers seek to control healthcare costs by paying service providers lower rates. While it is expected that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payers frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payers are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies, or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. As a result of these programs, and related payer efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our implants profitably if third-party payers deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payers to hospitals could adversely impact our ability to market and sell our products and negatively affect our financial performance.

In international markets, medical device regulatory requirements and healthcare payment systems vary significantly from country to country, and many countries have instituted price ceilings on specific product lines. We cannot assure you that our products will be considered cost-effective by international third-party payers, that reimbursement will be available or, if available, that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. Any failure to receive regulatory or reimbursement approvals would negatively impact market acceptance of our products in any international markets in which those approvals are sought.

Moreover, certain legislative changes to and regulatory changes under the PPACA have occurred in the 115th United States Congress and under the Trump Administration. For example, on December 22, 2017, President Trump signed a budget reconciliation act into law, which among other things, repealed the penalty for individuals who do not maintain minimum essential coverage, which was a central component of PPACA's approach to expanding coverage. On January 9, 2018, President Trump signed the Bipartisan Budget Act of 2018, which, among other things, repealed the PPACA provision establishing an independent payment advisory board that would have submitted recommendations to reduce Medicare spending if projected Medicare spending exceeded a specified growth rate we cannot predict the ultimate content, timing or effect of any changes to the Health Care Reform Act or other federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

Prolonged negative economic conditions in domestic and international markets may adversely affect us, our suppliers, partners and consumers, and the global orthopedic market which could harm our financial position.

There is a risk that one or more of our current suppliers may not continue to operate. Any lender that is obligated to provide funding to us under any future credit agreement with us may not be able to provide funding in a timely manner, or at all, when we require it. The cost of, or lack of, available credit or equity financing could impact our ability to develop sufficient liquidity to maintain or grow our company. These negative changes in domestic and international economic conditions or additional disruptions of either or both of the financial and credit markets may also affect third-party payers and may have a material adverse effect on our business, results of operations, financial condition and liquidity.

In addition, we believe that various demographics and industry-specific trends will help drive growth in the orthopedics markets, but these demographics and trends are uncertain. Actual demand for orthopedic products generally, and our products in particular, could be significantly less than expected if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments gain widespread acceptance.

We are dependent on our senior management team, engineering team, and surgeon advisors, and the loss of any of them could harm our business. We may not have sufficient personnel to effectuate our business strategy due to our recent reduction in force.

The members of our current senior management team have worked together in their new positions with us for a limited time and may not be able to successfully implement our strategy. In addition, we have not entered into employment agreements, other than change-in-control severance agreements, with any of the members of our senior management team. There are no assurances that the services of any of these individuals will be available to us for any specified period of time. The successful integration of our senior management team, the loss of members of our senior management team, engineering team and key surgeon advisors, or our inability to attract or retain other qualified personnel or advisors could have a material adverse effect on our business, financial condition and results of operations. We may not have sufficient number of qualified personnel to effectuate our business strategy which could have a material adverse effect on our business, financial condition and results of operations.

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 our sales and marketing, accounting and financial functions; manufacturing processes; inventory; engineering and product development functions; and our research and development functions. As such, our information technology systems are vulnerable to damage or interruption including 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. 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, all of which could have a material adverse effect on our reputation, business, results of operations and financial condition.

Risks Related to Our Capital Resources and Impairments

We will require additional financing and our failure to obtain additional funding would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We currently have limited committed sources of capital and we have limited liquidity. Our cash and cash equivalents as of December 31, 2018 was $5.4 million. We require substantial future capital in order to continue to conduct the research and development and regulatory clearance and approval activities necessary to bring our products to market,

to establish effective marketing and sales capabilities. Our existing capital resources are not sufficient to enable us to fund the completion of the development and commercialization of all of our product candidates. We cannot determine with certainty the duration and completion costs of the current or future development and commercialization of our product candidates for spinal fusion, joint replacement and coated metals or if, when, or to what extent we will generate revenues from the commercialization and sale of any of these product candidates for which we obtain regulatory approval. We may never succeed in achieving regulatory approval for certain or all of these product candidates. The duration, costs and timing of clinical trials and development of our spinal fusion, joint replacement and coated metal product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results we may must or choose to conduct;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of spinal fusion, joint replacement or coated metal product candidates could mean a significant change in the costs and timing associated with the development of these product candidates.

In addition, if adequate funds to develop our product candidates are not available on a timely basis, we may terminate or delay the development of one or more of our product candidates, or delay activities necessary to commercialize our product candidates. Additional funding may not be available to us on acceptable terms, or at all. Any additional equity financing, if available, may not be available on favorable terms and will most likely be dilutive to our current stockholders, and debt financing, if available, may involve more restrictive covenants. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition and results of operations or could cause us to cease operations.

The timing and amount of our future capital requirements will depend on many factors, including:

- the level of sales of our current products and the cost of revenue and sales and marketing;
- the extent of any clinical trials that we will be required to conduct in support of the regulatory clearance of our total hip and knee replacement product candidates;
- the scope, progress, results and cost of our product development efforts;
- the costs, timing and outcomes of regulatory reviews of our product candidates;
- the number and types of products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to

relinquish valuable rights to our technologies or products or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future

Our report from our independent registered public accounting firm for the year ended December 31, 2018 includes an explanatory paragraph stating that our recurring losses from operations raises substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient additional funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to Regulatory Approval of Our Products and Other Government Regulations

Our long-term success depends substantially on our ability to obtain regulatory clearance or approval and thereafter commercialize our product candidates; we cannot be certain that we will be able to do so in a timely manner or at all.

The process of obtaining regulatory clearances or approvals to market a medical device from the FDA or similar regulatory authorities outside of the United States can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, or at all. The FDA's 510(k) clearance process generally takes one to six months from the date of submission, depending on whether a special or traditional 510(k) premarket notification has been submitted, but can take significantly longer. An application for premarket approval, or PMA, must be submitted to the FDA if the device cannot be cleared through the 510(k) clearance process or is not exempt from premarket review by the FDA. The PMA process almost always requires one or more clinical trials and can take two to three years from the date of filing, or even longer. In some cases, including in the case of our interbody spinal fusion devices which incorporate our CSC technology and our solid silicon nitride femoral head component, the FDA requires clinical data as part of the 510(k) clearance process.

It is possible that the FDA could raise questions about our spinal fusion products, our spinal fusion product candidates and our total hip and knee joint replacement product candidates and could require us to perform additional studies on our products and product candidates. Even if the FDA permits us to use the 510(k) clearance process, we cannot assure you that the FDA will not require either supporting data from laboratory tests or studies that we have not conducted, or substantial supporting clinical data. If we are unable to use the 510(k) clearance process for any of our product candidates, are required to provide clinical data or laboratory data that we do not possess to support our 510(k) premarket notifications for any of these product candidates, or otherwise experience delays in obtaining or fail to obtain regulatory clearances, the commercialization of our product candidates in the United States will be delayed or prevented, which will adversely affect our ability to generate additional revenues. It also may result in the loss of potential competitive advantages that we might otherwise attain by bringing our products to market earlier than our competitors. Additionally, although the FDA allows modifications to be made to devices that have received 510(k) clearance with supporting documentation, the FDA may disagree with our decision to modify our cleared devices without submission of a new 510(k) premarket notification, subjecting us to potential product recall, field alerts and corrective actions. Any of these contingencies could adversely affect our business.

Similar to our compliance with U.S. regulatory requirements, we must obtain and comply with international requirements, including those of the CFDA, in order to market and sell our products outside of the United States and we may only promote and market our products, if approved, as permitted by applicable regulatory authorities. There is no guarantee that we will receive the necessary regulatory approvals for our product candidates either inside the United States or internationally, including approvals from the CFDA. If our product candidates do not receive necessary regulatory approvals, our business could be materially and adversely affected.

The safety of our products is not yet supported by long-term clinical data, and they may prove to be less safe and effective than our laboratory data indicate.

We obtained FDA clearance for each of our spinal fusion products that we currently manufacture for CTL Medical, and we have sought and intend to seek FDA clearance or approval through the FDA's 510(k) or PMA process and, where applicable, CE marking for our product candidates. The 510(k) clearance process is based on the FDA's agreement that a new product candidate is substantially equivalent to an already marketed product for which a PMA was not required. While most 510(k) premarket notifications do not require clinical data for clearance, the FDA may request that such data be provided. Long-term clinical data or marketing experience obtained after clearance may indicate that our products cause unexpected complications or other unforeseen negative effects. If this happens, we could be subject to the withdrawal of our marketing clearance and other enforcement sanctions by the FDA or other regulatory authority, product recalls, significant legal liability, significant negative publicity, damage to our reputation and a dramatic reduction in our ability to sell our products, any one of which would have a material adverse effect on our business, financial condition and results of operations.

We expect to be required to conduct clinical trials to support regulatory approval of some of our product candidates. We have little experience conducting clinical trials, they may proceed more slowly than anticipated, and we cannot be certain that our product candidates will be shown to be safe and effective for human use.

In order to commercialize our product candidates in the United States, we must submit a PMA for some of these product candidates, which will require us to conduct clinical trials. We also plan to provide the FDA with clinical trial data to support some of our 510(k) premarket notifications. We will receive approval or clearance from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, through well-designed and properly conducted clinical trials, that our product candidates are safe and effective and otherwise meet the appropriate standards required for approval or clearance for specified indications.

Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Before we may begin clinical trials, we must submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi-year study. Because we do not have the experience or the infrastructure necessary to conduct clinical trials, we will have to hire one or more contract research organizations, or CROs, to conduct trials on our behalf. CRO contract negotiations may be costly and time consuming and we will rely heavily on the CRO to ensure that our trials are conducted in accordance with regulatory and industry standards. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials or delay the analysis of the data derived from them.

A number of events or factors, including any of the following, could delay the completion of our clinical trials in the future and negatively impact our ability to obtain FDA approval for, and to introduce our product candidates:

- failure to obtain financing necessary to bear the cost of designing and conducting clinical trials;
- failure to obtain approval from the FDA or foreign regulatory authorities to commence investigational studies;
- conditions imposed on us by the FDA or foreign regulatory authorities regarding the scope or design of our clinical trials;
- failure to find a qualified CRO to conduct our clinical trials or to negotiate a CRO services agreement on favorable terms;
- delays in obtaining or in our maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our product candidates or other materials necessary to conduct our clinical trials;

difficulties in enrolling patients in our clinical trials;

negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;

failure on the part of the CRO to conduct the clinical trial in accordance with regulatory requirements;

our failure to maintain a successful relationship with the CRO or termination of our contractual relationship with the CRO before completion of the clinical trials;

serious or unexpected side effects experienced by patients in whom our product candidates are implanted; or

failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

Our clinical trials may need to be redesigned or may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our product candidates, which could cause our stock price to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

Our current and future relationships with third-party payers and current and potential customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm administrative burdens and diminished profits and future earnings.

Our current and future arrangements with third-party payers and current and potential customers, including providers and physicians, as well as physician owned distributorships or PODs, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In addition, we may be subject to transparency laws and patient privacy regulations by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;

federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or

transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the Physician Payments Sunshine Act, which requires (i) manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals, with data collection beginning on August 1, 2013, (ii) applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held in such entities by physicians and their immediate family members, with data collection beginning on August 1, 2013, (iii) manufacturers to submit reports to CMS by March 31, 2014 and the 90th day of each subsequent calendar year, and (iv) disclosure of such information by CMS on a publicly available website beginning in September 2014; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers; state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, President Donald Trump signed into law sweeping tax reform, which overhauls individual, business and international taxes including, but not limited to:

Cutting the corporate federal statutory tax rate to 21%;

Limiting net interest expense deductions to 30% of adjusted taxable income; and

Limiting the net operating loss deduction to 80% of taxable income.

The reduction in tax rate will result in a reduction in the deferred tax assets. We have previously used the 35% federal statutory tax rate to calculate the value of those assets. Also, if we fail to generate significant taxable income, we may not be able to fully deduct the interest expense on our debt, which could result in us having to pay increased federal income taxes. We have also generated substantial taxable losses in the past and may continue to do so in the future. Although the treatment of tax losses generated before December 31, 2018 has not changed, tax losses generated in fiscal 2019 and beyond will only be able to offset 80% of taxable income, although the losses may be carried forward indefinitely. This could cause us to have to pay federal income taxes despite generating a loss for federal income tax purposes in the future. We continue to work with our tax advisors to determine the full impact that the new tax bill will have on our Company.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain and monitor regulatory approval or clearance of our product candidates and affect the prices we may obtain for our products.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay clearance and/or approval of our product candidates, restrict or regulate post-clearance and post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain marketing approval or clearance.

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 our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would have a material adverse effect on our business, results of operations and financial condition. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the medical device industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, a sweeping law intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our products and product candidates are:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, which began on January 1, 2013, but was suspended during 2016 and 2017 and has been suspended for 2018 and 2019;

- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and

- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, on January 2, 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, certain legislative changes to and regulatory changes under the PPACA have occurred in the 115th United States Congress and under the Trump Administration. For example, on December 22, 2017, President Trump signed a budget reconciliation act into law, which among other things, repealed the penalty for individuals who do not maintain minimum essential coverage, which was a central component of PPACA’s approach to expanding coverage. On January 9, 2018, President Trump signed the Bipartisan

Budget Act of 2018, which, among other things, repealed the PPACA provision establishing an independent payment advisory board that would have submitted recommendations to reduce Medicare spending if projected Medicare spending exceeded a specified growth rate.

Additional legislative changes to and regulatory changes under the PPACA remain possible. We expect that other state and federal healthcare reform measures will be adopted in the future, any of which could reduce the number of patients with coverage or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

In the European Union and some other international markets, the government provides health care at a low cost to consumers and regulates prices of healthcare products, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries are reducing their public expenditures and we expect to see strong efforts to reduce healthcare costs in international markets, including patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates and recoveries of past price increases. These cost control measures could reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the marketing of our products within that country but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third-party cross border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

Risks Related to Our Intellectual Property and Litigation

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to commercialize our orthopedic products successfully will be harmed, and we may not be able to operate our business profitably.

Our success depends significantly on our ability to protect our proprietary rights to the technologies incorporated in our products. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office, or the USPTO, or foreign patent offices. In addition, our pending patent applications include claims to numerous important aspects of our products under development that are not currently protected by any of our issued patents. We cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The USPTO or foreign patent offices may deny or require significant narrowing of claims in our pending patent applications. Patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the USPTO or foreign patent offices could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all.

Our competitors may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may issue in the future, which could prevent or limit our ability to market our products and could limit our

ability to stop competitors from marketing products that are substantially equivalent to ours. In addition, competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products but that are not covered by our patents.

We have also entered into confidentiality and assignment of intellectual property agreements with all of our employees, consultants and advisors as one of the ways we seek to protect our intellectual property and other proprietary technology. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time consuming and expensive, and would divert management’s attention from managing our business. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights.

We have no patent protection covering the composition of matter for our solid silicon nitride or the process we use for manufacturing our solid silicon nitride, and competitors may create silicon nitride formulations substantially similar to ours.

Although we have a number of U.S. and foreign patents and pending applications relating to our solid silicon nitride products or product candidates, we have no patent protection either for the composition of matter for our silicon nitride or for the processes of manufacturing solid silicon nitride. As a result, competitors may create silicon nitride formulations substantially similar to ours and use their formulations in products that may compete with our silicon nitride products, provided they do not violate our issued product patents. Although we have, and will continue to develop, significant know-how related to these processes, there can be no assurance that we will be able to maintain this know-how as trade secrets, and competitors may develop or acquire equally valuable or more valuable know-how related to the manufacture of silicon nitride.

We could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from marketing our commercially available products or product candidates and/or reduce the margins we may realize from our products that we may commercialize.

The medical devices industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of participants in the orthopedic market increases and as we achieve more visibility in the market place and introduce products to market.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In some cases, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we were found to infringe any patents, we could be required to pay substantial damages, including triple damages if an infringement is found to be willful, and royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe those patents. If we fail to obtain any required licenses or make any necessary changes to our technologies or the products that incorporate them, we may be unable to commercialize one or more of our products or may have to withdraw products from the market, all of which would have a material adverse effect on our business, financial condition and results of operations.

In addition, in order to further our product development efforts, we have entered into agreements with orthopedic surgeons to help us design and develop new products, and we expect to enter into similar agreements in the future. In certain instances, we have agreed to pay such surgeons royalties on sales of products which incorporate their product development contributions. There can be no assurance that surgeons with whom we have entered into such arrangements will not claim to be entitled to a royalty even if we do not believe that such products were developed by cooperative involvement between us and such surgeons. In addition, some of our surgeon advisors are employed by academic or medical institutions or have agreements with other orthopedic companies pursuant to which they have agreed to assign or are under an obligation to assign to those other companies or institutions their rights in inventions which they conceive or develop or help conceive or develop.

There can be no assurance that one or more of these orthopedic companies or institutions will not claim ownership rights to an invention we develop in collaboration with our surgeon advisors or consultants on the basis that an agreement with such orthopedic company or institution gives it ownership rights in the invention or that our surgeon advisors on consultants otherwise have an obligation to assign such inventions to such company or institution. Any such claim against us, even without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

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

Many of our employees were previously employed at other orthopedic companies, including our competitors and potential competitors. Many of our former distributors and potential distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that either we, or these employees or distributors, have inadvertently or otherwise used or disclosed the trade secrets or other proprietary information of our competitors. In addition, we have been and may in the future be subject to claims that we caused an employee or sales agent to break the terms of his or her non-competition agreement or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize products, which could have an adverse effect on our business, financial condition and results of operations.

If our silicon nitride products or our product candidates conflict with the rights of others, we may not be able to manufacture or market our products or product candidates, which could have a material and adverse effect on us.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Issued patents held by others may limit our ability to develop commercial products. All issued patents are entitled to a presumption of validity under the laws of the United States. If we need suitable licenses to such patents to permit us to develop or market our product candidates, we may be required to pay significant fees or royalties and we cannot be certain that we would even be able to obtain such licenses. Competitors or third parties may obtain patents that may cover subject matter we use in developing the technology required to bring our products to market, that we use in producing our products, or that we use in treating patients with our products. We know that others have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. If we were found to infringe any of these issued patents or any of the pending patent applications, when and if issued, we may be required to alter our processes or product candidates, pay licensing fees or cease activities. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us, in Europe, the United States and elsewhere, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Additionally, it is not possible to predict with certainty what patent claims may issue from pending applications. In the United States, for example, patent prosecution can proceed in secret prior to issuance of a patent, provided such application is not filed in foreign jurisdiction. For U.S. patent applications that are also filed in foreign jurisdictions, such patent applications will not publish until 18 months from the filing date of the application. As a result, third parties may be able to obtain patents with claims relating to our product candidates which they could attempt to assert against us. Further, as we develop our products, third parties may assert that we infringe the patents currently held or licensed by them, and we cannot predict the outcome of any such action.

There has been extensive litigation in the medical devices industry over patents and other proprietary rights. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license, grant cross-licenses and pay substantial royalties in order to continue to manufacture or market the affected products.

We cannot assure you that we would prevail in any legal action or that any license required under a third-party patent would be made available on acceptable terms, or at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of claims of patent infringement or violation of other intellectual property rights, which could have a material and adverse effect on our business, financial condition and results of operations.

Risks Related to Potential Litigation from Operating Our Business

We may become subject to potential product liability claims, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the design, testing, manufacture, sale and distribution of our currently marketed products and each of our product candidates that we are seeking to introduce to the market. The use of orthopedic medical devices can involve significant risks of serious complications, including bleeding, nerve injury, paralysis, infection, and even death. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or in our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess of this award out of our cash reserves, which could significantly harm our financial condition. If longer-term patient results and experience indicate that our products or any component of a product causes tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. A product liability claim, even one without merit, could harm our reputation in the industry, lead to significant legal fees, and result in the diversion of management's attention from managing our business.

Any claims relating to our improper handling, storage or disposal of biological or hazardous materials could be time consuming and costly.

Although we do not believe that the manufacture of our silicon nitride or non-silicon nitride products will involve the use of hazardous materials, it is possible that regulatory authorities may disagree or that changes to our manufacturing processes may result in such use. Our business and facilities and those of our suppliers and future suppliers may therefore be subject to foreign, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We may incur significant expenses in the future relating to any failure to comply with environmental laws. Any such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations.

Risks Related to Our Common Stock

The price of our common stock is volatile and is likely to continue to fluctuate due to reasons beyond our control.

The volatility of orthopedic company stocks, including shares of our common stock, often do not correlate to the operating performance of the companies represented by such stocks or our operating performance. Some of the factors that may cause the market price of our common stock to fluctuate include:

CTL Medical's ability to sell silicon nitride based spinal fusion products and our cost of manufacturing such products for CTL Medical;

our ability to develop, obtain regulatory clearances or approvals for, and market new and enhanced product candidates on a timely basis;

our ability to enter into OEM and private label partnership agreements and the terms of those agreements;

changes in governmental regulations or in the status of our regulatory approvals, clearances or future applications;

our announcements or our competitors' announcements regarding new products, product enhancements, significant contracts, number and productivity of distributors, number of hospitals and surgeons using products, acquisitions or strategic investments;

announcements of technological or medical innovations for the treatment of orthopedic pathology;

delays or other problems with the manufacturing of our products, product candidates and related instrumentation;

volume and timing of orders for our products and our product candidates, if and when commercialized;

changes in the availability of third-party reimbursement in the United States and other countries;

quarterly variations in our or our competitors' results of operations;

changes in earnings estimates or recommendations by securities analysts, if any, who cover our common stock;

failure to meet estimates or recommendations by securities analysts, if any, who cover our stock;

changes in the fair value of our derivative liabilities resulting from changes in the market price of our common stock, which may result in significant fluctuations in our quarterly and annual operating results;

changes in healthcare policy in the United States and internationally;

product liability claims or other litigation involving us;

sales of a substantial aggregate number of shares of our common stock;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

disputes or other developments with respect to intellectual property rights;

changes in accounting principles;

changes to tax policy; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent our stockholders from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit regardless of the merits of the case or the eventual outcome. Such a lawsuit also would divert the time and attention of our management from running our company.

Securities analysts may not continue to provide coverage of our common stock or may issue negative reports, which may have a negative impact on the market price of our common stock.

Since completing our initial public offering of shares of our common stock in February 2014, a limited number of securities analysts have begun providing research coverage of our common stock. If securities analysts do not continue to cover our common stock, the lack of research coverage may cause the market price of our common stock to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about our business. If one or more of the analysts who elect to cover us downgrade our stock, our stock price would likely decline rapidly. If one or more of these analysts cease coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, under the

Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and a global settlement among the Securities and Exchange Commission, or the SEC, other regulatory agencies and a number of investment banks, which was reached in 2003, many investment banking firms are required to contract with independent financial analysts for their stock research. It may be difficult for a company such as ours, with a smaller market capitalization, to attract independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and restated bylaws contain provisions that could discourage, delay or prevent a merger, acquisition or other change in control of our company or changes in our board of directors that our stockholders might consider favorable, including transactions in which you might receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove management. These provisions:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- provide for a classified board of directors, such that not all members of our board will be elected at one time;
- prohibit our stockholders from filling board vacancies, limit who may call stockholder meetings, and prohibit the taking of stockholder action by written consent;
- prohibit our stockholders from making certain changes to our restated certificate of incorporation or restated bylaws except with the approval of holders of 75% of the outstanding shares of our capital stock entitled to vote;
- require advance written notice of stockholder proposals that can be acted upon at stockholders meetings and of director nominations to our board of directors; and
- authorize our board of directors to create and issue, without prior stockholder approval, preferred stock that may have rights senior to those of our common stock and that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. Any delay or prevention of a change in control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and any future earnings for debt service and use in the operation and expansion of our business. In addition, the terms of any future debt or credit

facility may preclude us from paying any dividends.

Risks Related to Public Companies

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Additionally, under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We are electing to delay such adoption of new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of this election, our financial statements may not be comparable to the financial statements of other public companies.

We may take advantage of these exemptions until we are no longer an emerging growth company. Under the JOBS Act, we may be able to maintain emerging growth company status for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before the end of such five-year period or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31. Additionally, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

We are also currently a "smaller reporting company" as defined in the Securities Exchange Act of 1934, and in the event that we are still considered a smaller reporting company at such time as we cease being an emerging growth company, we will be required to provide additional disclosure in our SEC filings. However, similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosures in their filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting, and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of 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 could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.

On August 13, 2018, we received a notice from the Nasdaq Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") stating that the bid price of the Company's common stock for the last 30 consecutive trading days had closed below the minimum $1.00 per share required for continued listing under Listing Rule 5550(a)(2). If the Company does not regain compliance with Rule 5550(a)(2) by February 11, 2019, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period, which may include, if necessary, implementing a reverse stock split. There can be no assurance that the Company will be able to regain compliance with Nasdaq requirements or will otherwise be in compliance with other Nasdaq listing criteria.

On February 13, 2019, we received a notice from the Staff that we were eligible for an additional 180 calendar day period, or until August 12, 2019, to regain compliance. This second 180-day period relates exclusively to the bid price deficiency. We may be delisted during the 180 days for failure to maintain compliance with any other listing requirements for which we are currently on notice or which occurs during this period. If we choose to implement a

reverse stock split, it must be completed no later than ten business days prior to the expiration date in order to timely regain compliance.

If we cease to be eligible to trade on the Nasdaq Capital Market:

- We may have to pursue trading on a less recognized or accepted market, such as the OTC Bulletin Board or the “pink sheets.”
- The trading price of our common stock could suffer, including an increased spread between the “bid” and “asked” prices quoted by market makers.
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a “penny stock,” transactions in our stock would be more difficult and cumbersome.
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

We incur substantial costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, insurance, accounting and other expenses, including costs associated with public company reporting. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development and commercialization activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. These laws and regulations could make it more difficult and costlier for us to obtain director and officer liability insurance for our directors and officers, 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 executive officers and qualified members of our board of directors, particularly to serve on our audit and compensation committees. In addition, if we are unable to continue to meet the legal, regulatory and other requirements related to being a public company, we may not be able to maintain the listing of our common stock on The NASDAQ Capital Market, which would likely have a material adverse effect on the trading price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our 54,000 square foot corporate office and manufacturing facilities are located in Salt Lake City, Utah. We occupy these facilities pursuant to a lease that expires in December 2019. Pursuant to the terms of the lease agreement, we may extend the lease for two additional periods of five years each. We believe that our existing facilities are adequate for our current and projected needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings. However, our industry is characterized by frequent claims and litigation, including claims regarding intellectual property and product liability. As a result, we may be subject to various legal proceedings in the future.

ITEM 4. MINE SAFETY DISCLOSURES

This item does not apply to our business.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our shares of common stock are currently quoted on The NASDAQ Capital Market under the symbol "SINT".

The following table sets forth the high and low sale prices of our common stock, as reported by NASDAQ Capital Markets for the periods indicated:

	2018	
	High	Low
First Quarter	$4.09	$1.37
Second Quarter	$4.12	$0.90
Third Quarter	$0.95	$0.18
Fourth Quarter	$0.41	$0.16

	2017	
	High	Low
First Quarter	$8.87	$4.24
Second Quarter	$5.39	$3.15
Third Quarter	$5.24	$3.24
Fourth Quarter	$6.94	$2.89

Prices listed are adjusted to reflect both the January 25, 2016 reverse stock split and the November 10, 2017 reverse stock split.

Holders of Record

As of February 25, 2019, we had approximately 365 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, this number is not

indicative of the total number of stockholders represented by these stockholders of record.

Dividends

We have not declared or paid dividends to stockholders since inception and do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our growth.

Issuer Purchases of Equity Securities

None

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. 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 our consolidated financial statements and related notes appearing elsewhere in this Annual Report. This discussion and analysis contain forward-looking statements based upon current beliefs, plans, expectations, intentions and projections that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report.

Overview

We are a biomaterials company focused on providing ceramic based biomaterial solutions in a variety of medical and industrial applications. To date, our primary focus has been the research, development and commercialization of medical implant products manufactured with silicon nitride. We believe that silicon nitride has a superb combination of properties that make it ideally suited for long-term human implantation. Other biomaterials are based on bone grafts, metal alloys, and polymers- all of which have well-known practical limitations and disadvantages. In contrast, silicon nitride has a legacy of success in the most demanding and extreme industrial environments. As a human implant material, silicon nitride offers bone ingrowth, resistance to bacterial and viral infection, ease of diagnostic imaging, resistance to corrosion, and superior strength and fracture resistance, among other advantages, all of which claims are validated in our large and growing inventory of peer-reviewed, published literature reports. We believe that our versatile silicon nitride manufacturing expertise positions us favorably to introduce new and innovative devices in the medical and non-medical fields.

We also believe that we are the first and only company to commercialize silicon nitride medical implants. Prior to October 1, 2018, we designed, manufactured and commercialized silicon nitride products for our own behalf in the spine implant market. Over 33,000 of our spinal implants manufactured with silicon nitride have been implanted into patients, with an excellent safety record. On October 1, 2018, we sold our spine implant business to CTL Medical and now manufacture spine implants made with silicon nitride for CTL Medical. Prior to selling our spine implant business to CTL Medical, we had received 510(k) regulatory clearance in the United States, a CE mark in Europe, ANVISA approval in Brazil, and ARTG and Prostheses approvals in Australia for a number of silicon nitride spine implant products designed for spinal fusion surgery. Spine implant products manufactured by us from silicon nitride are currently marketed and sold by CTL Medical under the Valeo® brand to surgeons and hospitals in the United States and to selected markets in Europe and South America. These implants are designed for use in cervical (neck) and thoracolumbar (lower back) spine surgery. We are collaborating with CTL Medical to establish a commercial partner in Australia and also working with other partners to obtain regulatory approval for silicon nitride implants in Japan.

The sale of our spine implant business to CTL Medical enables us to now focus on our core competencies. These are research and development of silicon nitride and the design and manufacture of medical and nonmedical products manufactured from silicon nitride and other ceramic materials for our own account and in collaboration with other medical device manufacturers. We are targeting original equipment manufacturer (“OEM”) – including CTL Medical - and private label partnerships in order to accelerate adoption of silicon nitride in future markets such as coating products with silicon nitride, hip and knee replacements, dental and maxillofacial implants, extremities, trauma, and sports medicine. Existing biomaterials, based on plastics, metals, and bone grafts have well-recognized limitations that we believe are addressed by silicon nitride, and we are uniquely positioned to convert existing, successful implant designs made by other companies into products manufactured with silicon nitride. OEM and private label partnerships allow us to work with a variety of partners, accelerate the adoption of silicon nitride, and realize incremental revenue at improved operating margins, when compared to the cost-intensive direct sales model.

We believe that silicon nitride addresses many of the biomaterial-related limitations in fields such as hip and knee replacements, dental and maxillofacial implants, sports medicine, extremities, and trauma surgery. We further believe that the inherent material properties of silicon nitride, and the ability to formulate the material in a variety of compositions, combined with precise control of the surface properties of the material, opens up a number of commercial opportunities across orthopedic surgery, neurological surgery, maxillofacial surgery, and other medical disciplines.

Components of our Results of Operations

We manage our business within one reportable segment, which is consistent with how our management reviews our business, makes investment and resource allocation decisions and assesses operating performance.

Product Revenue

We derive our product revenue primarily from the manufacture and sale of spinal fusion products, used in the treatment of spine disorders, to CTL Medical, with whom we have a 10-year exclusive sales agreement in place. We are currently pursuing other sales opportunities for silicon nitride products outside the spinal fusion application. We generally recognize revenue from sales at the time the product is shipped. In general, our customers do not have any rights of return or exchange.

We believe our product revenue will increase as CTL Medical increases sales of silicon nitride spinal fusion products, as we secure other opportunities to manufacture third party products with silicon nitride, and as we continue to introduce new products into the market.

Cost of Revenue

The expenses that are included in cost of revenue include all in-house manufacturing costs for the products we manufacture.

Gross Profit

Our gross profit measures our product revenue relative to our cost of revenue. We expect our gross profit to decrease as we expand the penetration of our silicon nitride technology platform through OEM and private label partnerships, which offer additional avenues for the adoption of silicon nitride. Prior to the sale of our retail spine business, our revenues and gross profits were based on our retail sales. With the focus on OEM and private label partnerships, the margins are lower, thus causing the decrease in gross profit.

Research and Development Expenses

Our research and development costs are expensed as incurred. Research and development costs consist of engineering, product development, clinical trials, test-part manufacturing, testing, developing and validating the manufacturing process, manufacturing, facility and regulatory-related costs. Research and development expenses also include employee compensation, employee and non-employee stock-based compensation, supplies and materials, consultant services, and travel and facilities expenses related to research and development activities.

We expect to incur additional research and development costs as we continue to develop new spinal fusion products, our product candidates for total joint replacements, such as our total hip replacement product candidate, and dental applications which, may increase our total research and development expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation for certain members of our executive team and other personnel employed in finance, legal, compliance, administrative, information technology, customer service, executive and human resource departments. General and administrative expenses also include other expenses not part of the other cost categories mentioned above, including facility expenses and professional fees for accounting and legal services.

Results of Operations

Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017

The following table sets forth, for the periods indicated, our results of operations for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,			
	2018	2017	$ Change	% Change
Product revenue	$95	$-	$95	100 %
Costs of revenue	56	-	56	100 %
Gross profit	39	-	39	100 %
Operating expenses:				
Research and development	2,991	3,506	(515)	-15 %
General and administrative	3,866	3,654	212	6 %
Sales and marketing	135	325	(190)	-58 %
Goodwill impairment	6,163	-	6,163	100 %
Total operating expenses	13,155	7,485	5,670	76 %
Loss from operations	(13,116)	(7,485)	(5,631)	75 %
Other income (expense)	3,427	1,724	1,703	99 %
Net loss before income taxes	(9,689)	(5,761)	(3,928)	-68 %
Provision for income taxes	-	-	-	N/A
Loss from continuing operations	(9,689)	(5,761)	(3,928)	-68 %
Loss from discontinued operations	(324)	(3,568)	3,244	-91 %
Gain on sale of discontinued operations	1,361	-	1,361	100 %
Net loss	(8,652)	(9,329)	677	7 %
Deemed dividend related to beneficial conversion feature and accretion of discount on convertible series A preferred stock	(13,900)	-	(13,900)	-100 %
Net loss attributable to common stockholders	$(22,552)	$(9,329)	$(13,223)	-142 %

Product Revenue

Total silicon nitride revenue was $0.1 million in 2018 as compared to $0.0 million in 2017, an increase of $0.1 million or 100%. This increase was due the sale of the retail spine business in October 2018, the restatement of 2017 revenues to $0.0 million as a result of the discontinued operations and the subsequent sale of only silicon nitride during the fourth quarter of 2018. Also, as a result of the discontinued operations treatment and the sale of the retail spine business, international revenue was eliminated completely.

Costs of Revenue and Gross Profit

Our cost of revenue increased $0.06 million, or 100%, as compared to the same period in 2017. Gross profit increased $0.04 million, or 100%, as compared to the same period in 2017. Both increases are due to the discontinued operations treatment and the sale of the retail spine business in October 2018.

Research and Development Expenses

Research and development expenses decreased $0.5 million, or 15%, as compared to the same period in 2017. This decrease was primarily due to a $0.2 million increase in consulting offset by a $0.4 million reduction in payroll and payroll related expenses and a $0.1 million reduction in clinical studies and testing. The remainder of the decrease is attributable to the calculation for discontinued operations.

General and Administrative Expenses

General and administrative expenses increased $0.2 million, or 6%, as compared to the same period in 2017. This increase was primarily due to a $0.1 million decrease in amortization expense, a $0.1 million decrease in business insurance expense and a $0.1 million decrease in travel and travel related expenses. All decreases were offset by an increase attributable to the calculation for discontinued operations.

Sales and Marketing Expenses

Sales and marketing expenses decreased $0.2 million, or 58%, as compared to the same period in 2017. This decrease was primarily due to a $0.3 million decrease in payroll and payroll related expenses, a $0.1 million decrease in depreciation expense, a $0.1 million decrease in advertising and marketing expense, a $0.1 million decrease in travel expenses, offset by a $0.1 million increase in clinical studies from prior period related studies. The remainder of the offsetting increase is attributable to the calculation for discontinued operations.

Deemed Dividend

Deemed dividend in 2018 related to a beneficial conversion feature and accretion of discount on convertible preferred stock valued at $13.9 million in 2018, compared to none for 2017. A beneficial conversion amount was calculated in association with the 2018 issuance of certain convertible preferred stock and warrants that could convert to common stock at a discount below the trading price on the date of issuance. 10,926 shares of the preferred stock were converted to common stock during 2018. No such stock was issued or converted during 2017.

Other Income (Expense), Net

Other income increased $1.7 million, or 99%, as compared to the same period in 2017. This increase was primarily due to a $3.9 million increase in the change in fair value of derivative liabilities and the $0.1 million increase in interest income and the disposal of surgical instruments. This increase was offset by increases in expenses as follows: an increase of $1.3 million in the loss on extinguishment of derivative liabilities, the increase of $0.6 million in offering costs, the increase of $0.3 million in the loss on the extinguishment of debt and the increase of $0.1 million in interest expense.

Liquidity and Capital Resources

The consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern within one year from the date of issuance of these consolidated financial statements.

For the years ended December 31, 2018 and 2017, we incurred a net loss of $8.8 million and $9.3 million, respectively, and used cash in operations of $9.3 million and $4.7 million, respectively. We had an accumulated deficit of $229.4 million and $220.6 million as of December 31, 2018 and 2017, respectively. To date, our operations have been principally financed from proceeds from the issuance of preferred and common stock, convertible debt and bank debt and, to a lesser extent, cash generated from product sales. It is anticipated that we will continue to generate operating losses in the foreseeable future and use cash in operations. Our continuation as a going concern is dependent upon our ability to increase sales, implement cost saving measures and/or raise additional funds through the capital markets. Whether and when we can attain profitability and positive cash flows from operations or obtain additional financing is uncertain.

In 2016 we implemented certain cost saving measures, including workforce and office space reductions, and have continued to evaluate additional cost savings alternatives during 2017 and 2018. These additional cost savings measures may include additional workforce and research and development reductions, as well as cuts to certain other operating expenses. We are actively generating additional scientific and clinical data to have it published in leading industry publications. The unique features of our silicon nitride material are not well known, and the publication of such data could help sales efforts as we approach new prospects. We are also making additional changes to the sales strategy, including a focus on revenue growth by expanding the use of silicon nitride in other areas outside of spinal fusion applications.

We have common stock that is publicly traded and have been able to successfully raise capital when needed since the date of our initial public offering. In March 2018, we closed on gross proceeds of $1.4 million, before payment of placement agent fees and costs on a warrant reprice and exercise transaction. Additionally, on May 14, 2018, we closed on a public offering of units, consisting of convertible preferred stock and warrants, for gross proceeds of $15 million, which excludes underwriting discounts and commissions and offering expenses payable by us. We are engaged in discussions with investment and banking firms to examine financing alternatives, including options for another public offering of our preferred or common stock. On October 1, 2018, we sold the retail spine business. This sale will provide cash flows totaling $2.5 million over the next eighteen months and $3.5 million for the following eighteen months. The buyer also assumed the Company’s $2.5 million related party note payable.

Although we are seeking to obtain additional equity and/or debt financing, such funding is not assured and may not be available to us on favorable or acceptable terms and may involve significant restrictive covenants. Any additional equity financing is also not assured and, if available to us, will most likely be dilutive to our current stockholders. If we are not able to obtain additional debt or equity financing on a timely basis, the impact on us will be material and adverse.

These uncertainties create substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Cash Flows

The following table summarizes, for the periods indicated, cash flows from operating, investing and financing activities (in thousands):

	Year Ended December 31,	
	2018	2017
Net cash used in operating activities – continuing operations	$(9,328)	$(7,127)
Cash loss on sale – discontinued operations	(695)	-
Net cash provided by operating activities – discontinued operations	675	2,447
Net cash used in operating activities	(9,348)	(4,680)
Net cash used in investing activities – continuing operations	(61)	(6)
Net cash used in investing activities – discontinued operations	(84)	(1,131)
Net cashed used in investing activities	(145)	(1,137)
Net cash provided by (used in) financing activities – continuing operations	14,401	(3,009)
Net cash provided by financing activities – discontinued operations	-	2,450
Net cash provided by (used in) financing activities	14,401	(559)
Net cash provided (used)	$4,908	$(6,376)

Net Cash Used in Operating Activities

Net cash used in operating activities was $9.3 million in 2018, compared to $4.7 million used in 2017, an increase of $4.6 million. Offset by the decrease in the net loss, and related non-cash add backs to the net loss, the decrease in cash used for operating activities during 2018 was primarily due to changes in the movement of working capital items during 2018 as compared to the same period in 2017 as follows: a $0.1 million decrease in trade accounts receivable, a $0.03 million decrease in prepaid expenses and other current assets, a $0.01 million decrease in inventories, a $1.8

million decrease in accounts payable and accrued liabilities and included a decrease of $1.8 million in the net cash provided by discontinued operations and an increase of $0.7 million in the cash loss on the sale of discontinued operations. The $9.3 million amount for 2018 was comprised of net cash used in continuing operations of $9.4 million, a cash loss on sale of discontinued operations of $0.7 million and net cash provided by discontinued operations of $0.8 million. The $4.7 million amount for 2017 was comprised of net cash used in continuing operations of $7.2 million and net cash provided by discontinued operations of $2.5 million. The $2.5 million in net cash provided by discontinued operations during 2017 would have transitioned to $2.1 million in net cash used by discontinued operations were it not for a $4.6 million increase in the slow-moving reserve during 2017. No inventory reserve was recorded in 2018.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.2 million during 2018, compared to $1.1 million used in investing activities during the same period in 2017, a decrease of $1.1 million. The decrease in cash used in investing activities during 2018 was due to an increase of $0.1 million for the purchase of an intangible asset, the increase of $0.05 million for the purchase of property and equipment, offset by a decrease of $1.1 million in cash used by discontinued operations. The $0.2 million amount for 2018 was comprised of net cash used in continuing operations of $0.1 million and net cash used discontinued operations of $0.1 million. The $0.9 million for 2017 was comprised of net cash used in continuing operations of $0.01 million and net cash used in discontinued operations of $1.1 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $14.4 million during 2018, compared to $0.6 million used in financing activities during the same period in 2017, an increase of $15.0 million. The increase was primarily due to a $6.9 million increase in cash generated from the issuance of warrant derivative liabilities, a $6.7 million increase in cash generated from the issuance of preferred stock, a $1.7 million increase in cash generated from the exercise of warrants, a $0.7 million increase in proceeds from the issuance of debt and included a $4.5 million decrease in payment on debt, all of which was offset by a decrease of $3.1 million in cash generated from the issuance of common stock and a decrease of $2.4 million in cash provided by discontinued operations. The $14.4 million for 2018 is comprised of net cash provided by discontinued operations. The $1.2 million for 2017 was comprised of net cash used in continuing operations of $3.0 million and net cash provided by discontinued operations of $2.5 million.

L2 Capital Debt

On January 31, 2018, we signed a promissory note in the aggregate principal amount of up to $0.84 million (the "L2 Note") for an aggregate purchase price of up to $0.75 million and issued warrants to purchase up to an aggregate of 68,257 shares of common stock (the "Warrants") at an exercise price of $3.31 per share. The maturity date was six months from date of funding. The L2 Note's interest rate was 8% per year and a default interest rate of 18% per year. The L2 Note was able to be converted into common shares by the holder of the Note at any time following an event of default. The conversion price of the L2 Note in the event of a default was equal to the product of (i) 0.70 multiplied by (ii) the lowest volume weighted average price, or VWAP, of our common stock during the 20-day trading period ending in the Holder's sole discretion on the last complete trading day prior to conversion, or, the conversion date.

On May 14, 2018, we closed on an underwritten public offering of units, consisting of convertible preferred stock and warrants, for gross proceeds of $15.0 million. Part of the proceeds from this offering were used to pay off the outstanding debt with L2 Capital. The total payoff was $1.1 million, with $0.7 million in principal and $0.4 million in interest.

Hercules and MEF I, LP/Anson Investments Debt Exchange

On January 3, 2018, we entered into an Assignment Agreement (the "Assignment Agreement") with MEF I, LP and Anson Investments Master Fund (collectively the "Assignees" and each an "Assignee"), Hercules Technology III, L.P. ("HT III") and Hercules Capital, Inc. ("HC" and, together with HT III, "Hercules"), pursuant to which Hercules assigned to the Assignees all amounts remaining due under the Loan and Security Agreement, dated June 30, 2014, as amended, between us and Hercules (the "Loan and Security Agreement") and (2) the note (the "Hercules Note") between us and Hercules evidencing the amounts due under the Loan and Security Agreement. The total amount assigned by Hercules to the Assignees in the aggregate was $2.3 million and was secured by the same collateral underlying the Loan and Security Agreement. Subsequently, we entered into an exchange agreement pursuant to which the Assignees agreed to exchange the Hercules Term Loan obligation acquired by them for two senior secured convertible promissory notes issued by us, each in the principal amount of $1.1 million for an aggregate principal amount of $2.2 million, (the "Exchange Notes"). The Exchange Notes were scheduled to mature on February 3, 2019 (the "Maturity Date"). The Exchange Notes had interest at a rate of 15% per annum. Prior to the Maturity Date, principal and interest accrued under the Exchange Notes was payable in cash or, if certain conditions were met, payable in shares of our common stock. All principal accrued under the Exchange Notes was convertible into shares of our common stock ("Conversion Shares") at the election of the holders at any time at a fixed conversion price of $3.87 per share. Upon the occurrence of an event of default, the Assignees were entitled to convert all or any part of their Exchange Notes at a conversion price (the "Alternate Conversion Price") equal to 70% of the lowest traded price of our common stock during the ten trading days prior to the conversion date, provided that (i) in no event was the Alternate Conversion Price less than $1.75 per share and (ii) the Assignees were not entitled to receive more than 19.99% of the outstanding Common Stock. So long as these Exchange Notes remained outstanding or the Assignees held any Conversion Shares, we were prohibited from entering into any financing transaction pursuant to which we sell our securities at a price lower than $1.75 per share. The Exchange Notes were secured by a first priority security interest in substantially all of our assets, including

intellectual property, and contains covenants restricting payments to certain of our affiliates.

On May 14, 2018, we closed on an underwritten public offering of units, consisting of convertible preferred stock and warrants, for gross proceeds of $15.0 million. Part of the proceeds from this offering were used to pay off the outstanding debt with MEF I, L.P and Anson Investments. The total payoff was $1.6 million, with $1.4 million in principal and $0.2 million in interest.

North Stadium Term Loan – Related Party

On July 28, 2017, we entered into a $2.5 million term loan (the “North Stadium Loan”) with North Stadium Investments, LLC (“North Stadium”), a company owned and controlled by our Chief Executive Officer and Chairman of the Board. The North Stadium Loan bore interest at 10% per annum and required us to make monthly interest only payments from September 5, 2017 through July 5, 2018. All principal and unpaid interest (if any) under the North Stadium Loan was due and payable on July 28, 2018, which was later extended to October 1, 2018. The North Stadium Loan was secured by substantially all of the assets of the Company and was junior to security interest in assets encumbered by the Hercules Term Loan (see below). In connection with the North Stadium Loan we also issued North Stadium a warrant to purchase up to 55,000 shares of our common stock at a purchase price of $5.04 per share, subject to a 5-year term. The relative estimated value of the warrants on the date of grant approximated $0.2 million, which was being amortized as interest expense over the life of the term loan.

On October 1, 2018, CTL Medical assumed the North Stadium Term Loan debt as part of the sale of the retail spine business. As of December 31, 2018, the Company has been released by North Stadium from any and all obligations related to this debt.

Hercules Term Loan

On June 30, 2014, we entered into a Loan and Security Agreement with Hercules which provided us with a $20.0 million term loan. The Hercules Term Loan matured on January 1, 2018. The Hercules Term Loan included a $0.2 million closing fee, which was paid to Hercules on the closing date of the loan. The closing fee was recorded as a debt discount and was being amortized to interest expense over the life of the loan. The Hercules Term Loan also included a non-refundable final payment fee of $1.7 million. The final payment fee was being accrued and recorded to interest expense over the life of the loan.

On January 3, 2018, the Hercules Term Loan and all amounts owing thereunder was assigned to MEF I and Anson Investments. See discussion above for a more detailed description of that transaction

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4) of Regulation S-K.

Related-Party Transactions

For a description of our related-party transactions, see “Certain Relationships and Related Party Transactions” which will be contained in our definitive Proxy Statement with respect to our 2019 Annual Meeting of Stockholders under the captions “Certain Relationships and Related Transactions” and “Director Independence”.

Seasonality and Backlog

Our business is generally not seasonal in nature. We derive our product revenue primarily from the sale of spinal fusion products, used in the treatment of spine disorders, to CTL Medical, with whom we have a 10-year exclusive sales agreement in place. CTL Medical's sales generally consist of products that are in stock with them or maintained at hospitals or with their sales distributors. Accordingly, we do not have a backlog of sales orders.

Critical Accounting Policies and Estimates

A summary of our significant accounting policies and estimates is discussed in Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018. There have been no material changes to those policies for the year ended December 31, 2018. The preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles requires us to make judgments, estimates and assumptions regarding uncertainties that affect the reported amounts of assets and liabilities. Significant areas of uncertainty that require judgments, estimates and assumptions include the accounting for income taxes and other contingencies as well as valuation of derivative liabilities, asset impairment and collectability of accounts receivable. We use historical and other information that we consider to be relevant to make these judgments and estimates. However, actual results may differ from those estimates and assumptions that are used to prepare our consolidated financial statements.

Revenue Recognition

We derive our product revenue primarily from the sale of spinal fusion products, used in the treatment of spine disorders, to CTL Medical, with whom we have a 10-year exclusive sales agreement in place. We are currently pursuing other sales opportunities for silicon nitride outside the spinal fusion application. We generally recognize revenue from sales at the time the product is shipped. In general, our customers do not have any rights of return or exchange.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are carried at invoiced amount less an allowance for doubtful accounts. On a regular basis, we evaluate accounts receivable and estimate an allowance for doubtful accounts, as needed, based on various factors such as customers' current credit conditions, length of time past due, and the general economy as a whole. Receivables are written off against the allowance when they are deemed uncollectible.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost for manufactured inventory determined under the standard costs, which approximate actual costs, determined on the first-in first-out ("FIFO") method. Manufactured inventory consists of raw material, direct labor and manufacturing overhead cost components. We review the carrying value of inventory on a periodic basis for excess or obsolete items, and records any write-down as a cost of revenue, as necessary.

Long-Lived Assets and Goodwill

We periodically evaluate the carrying value of definite-lived intangibles when events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important which could trigger an impairment review include, but are not limited to, significant under-performance relative to historical or projected future operating results, significant changes in the manner of its use of acquired assets or its overall business strategy, and significant industry or economic trends. We amortize definite-lived intangible assets on a straight-line basis over their useful lives. We recorded no impairment loss for definite-lived intangible assets during the year ended December 31, 2017. On October 1, 2018, our retail spine business was sold to CTL Medical, which included the sale of most intangible assets that had a carrying value, retaining the carrying value of only one trademark asset.

When we determine that the carrying value of a long-lived asset may not be recoverable based upon the existence of one or more of the above indicators, we determine the recoverability by comparing the carrying amount of the asset to net future undiscounted cash flows that the asset is expected to generate and recognizes an impairment charge equal to the amount by which the carrying amount exceeds the fair market value of the asset.

If our revenues or other estimated operating results are not achieved at or above our forecasted level, and we are unable to recover such costs through price increases, the carrying value of certain of our assets may prove to be unrecoverable and we may incur impairment charges of definitive-live intangible assets.

In accordance with ASC 350, Goodwill and Other Intangible Assets, goodwill was not amortized but was required to be reviewed for impairment at least annually or when events or circumstances indicate that carrying value may exceed fair value. As part of the annual review, we determined that circumstance and events indicated that goodwill needed to be completely impaired and did so during the third quarter 2018.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term, generally five years.

Periodically we review the carrying value of our property and equipment that are held and used in our operations for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is determined based upon expected undiscounted future net cash flows from the operations to which the assets relate, utilizing management’s best estimate, assumptions, and projections at the time. If the carrying value is determined to be unrecoverable from future operating cash flows, the asset is deemed impaired and an impairment charge would be recognized to the extent the carrying value exceeded the estimated fair value of the asset. We estimate the fair value of assets based on the estimated future discounted cash flows arising from the use of the asset. No impairment was identified during the year ended December 31, 2018.

Income Taxes

We recognize deferred tax assets and liabilities for the future tax consequences attributable to the differences between the financial statement carrying value of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the fiscal year in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

We operate in various tax jurisdictions and is subject to audit by various tax authorities. We provide for tax contingencies whenever it is deemed probable that a tax asset has been impaired, or a tax liability has been incurred for events such as tax claims or changes in tax laws. Tax contingencies are based upon their technical merits relative tax law and the specific facts and circumstances as of each reporting period. Changes in facts and circumstances could result in material changes to the amounts recorded for such tax contingencies.

We recognize uncertain income tax positions taken on income tax returns at the largest amount that is more-likely than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Our policy for recording interest and penalties associated with uncertain tax positions is to record such items as a component of our income tax provision. For the years ended December 31, 2018 and 2017, we did not record any material interest income, interest expense or penalties related to uncertain tax positions or the settlement of audits for prior periods.

Stock-Based Compensation

We measure stock-based compensation expense related to employee stock-based awards based on the estimated fair value of the awards as determined on the date of grant and is recognized as expense over the remaining requisite service period. We utilize the Black-Scholes-Merton option pricing model to estimate the fair value of employee stock options. The Black-Scholes-Merton model requires the input of highly subjective and complex assumptions, including the estimated fair value of our common stock on the date of grant, the expected term of the stock option, and the expected volatility of our common stock over the period equal to the expected term of the grant. We estimate forfeitures at the date of grant and revises the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We account for stock options to purchase shares of stock that are issued to non-employees based on the estimated fair value of such instruments using the Black-Scholes-Merton option pricing model. The measurement of stock-based compensation expense for these instruments is variable and subject to periodic adjustments to the estimated fair value until the awards vest. Any resulting change in the estimated fair value is recognized in our consolidated statements of operations during the period in which the related services are rendered.

Because we were a privately-held company with no trading history prior to February 2014 and have limited stock history since February 2014, we utilize the historical stock price volatility from a representative group of public companies to estimate expected stock price volatility and our historical stock price. We selected companies from the medical device industry, specifically those who are focused on the design, development and commercialization of products for the treatment of spine disorders, and who have similar characteristics to us, such as stage of life cycle and size. We intend to continue to utilize the historical volatility of the same or similar public companies to estimate expected volatility until a sufficient amount of historical information regarding the price of our publicly traded stock

becomes available. We use the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, Share-based Payment, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero because we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free rate of return used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

We account for stock options to purchase shares of stock that are issued to non-employees based on the estimated fair value of such instruments using the Black-Scholes-Merton option pricing model. The measurement of stock-based compensation expense for these instruments is variable and subject to periodic adjustments to the estimated fair value until the awards vest. Any resulting change in the estimated fair value is recognized in our consolidated statements of operations during the period in which the related services are rendered.

Derivative Liabilities

Derivative liabilities include the fair value of instruments such as common stock warrants, preferred stock warrants and convertible features of notes, that are initially recorded at fair value and are required to be re-measured to fair value at each reporting period under provisions of ASC 480, *Distinguishing Liabilities from Equity,* or ASC 815, *Derivatives and Hedging*. The change in fair value of the instruments is recognized as a component of other income (expense) in our consolidated statements of operations until the instruments settle, expire or are no longer classified as derivative liabilities. We estimate the fair value of these instruments using the Black-Scholes-Merton or Monte-Carlo valuation models depending on the complexity of the underlying instrument. The significant assumptions used in estimating the fair value include the exercise price, volatility of the stock underlying the instrument, risk-free interest rate, estimated fair value of the stock underlying the instrument and the estimated life of the instrument.

Accounting Pronouncement Adopted In 2018

In March 2016, the FASB updated the accounting guidance related to stock compensation. This update simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as the well as classification in the statement of cash flows. The standard is effective for us with its annual period beginning January 1, 2018. The adoption of this standard did not have a material impact on the consolidated financial statements.

New Accounting Pronouncement, Not Yet Adopted

In August 2016, the Financial Accounting Standards Board (“FASB”) updated accounting 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. These updates are effective for us with its annual period beginning January 1, 2019, and interim periods therein, with early adoption permitted. The guidance in this standard is not expected to have a material impact on the consolidated financial statements.

In February 2016, the FASB updated the accounting guidance related to leases as part of a joint project with the International Accounting Standards Board (“IASB”) to increase transparency and comparability among organizations by

recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, a lessee will be required to recognize assets and liabilities for capital and operating leases with lease terms of more than 12 months. Additionally, this update will require disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases, including qualitative and quantitative requirements. The standard is effective for us with its annual period beginning January 1, 2020, and interim periods therein, with early adoption permitted. We are currently evaluating the potential impact this new standard may have on its consolidated financial statements.

In May 2014, in addition to several amendments issued during 2016, the FASB updated the accounting guidance related to revenue from contracts with customers, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle is that a company should recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The standard defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for us with the annual period beginning January 1, 2019, and interim periods therein. We believe the adoption of this standard will not have a significant impact on the consolidated financial statements.

We have reviewed all other recently issued, but not yet adopted, accounting standards, in order to determine their effects, if any, on its results of operations, financial position or cash flows. Based on that review, we believe that none of these pronouncements will have a significant effect on its consolidated financial statements.

Jumpstart Our Business Startups Act of 2012

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 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 of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of this election, our financial statements may not be comparable to the financial statements of other public companies. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (1) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the consolidated financial statements, known as the auditor discussion and analysis. We may be able to remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the date of our IPO, (c) the date on which we have issued more than $1 billion in non-convertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Additionally, we are also currently a "smaller reporting company" as defined in the Securities Exchange Act of 1934, and in the event that we are still considered a smaller reporting company at such time as we cease being an emerging growth company, we will be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

The consolidated financial statements of the Company appear at the end of this Annual Report beginning with the index to Financial Statements on page F-1 (see Part IV, Item 15 “Financial Statements”), and are incorporated herein.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified by the Commission's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act are properly recorded, processed, summarized and reported within the time periods required by the Commission's rules and forms.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (principal executive officer and principal financial officer), of the effectiveness of the design and operation of these disclosure controls and procedures, as such term is defined in Exchange Act Rule 13a-15(e), as of December 31, 2018. Based on this evaluation, the Chief Executive Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2018, the end of the period covered by this Annual Report on Form 10-K due to the material weaknesses described below.

(b) Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our internal control over financial reporting is designed to provide reasonable assurance of achieving its objectives as specified above. Management does not expect, however, that our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, 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, if any, within the Company have been detected.

Management, including our Chief Executive Officer, has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making our assessment of the effectiveness of internal control over financial reporting, management used the criteria set forth in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

As defined in SEC Regulation S-X, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on this assessment, management determined that, as of December 31, 2018, the Company's internal control over financial reporting was not effective due to the material weaknesses described below.

The design and operating effectiveness of our controls were inadequate to ensure that complex accounting matters are always properly accounted for and reviewed in a timely manner, as outlined below:

Control Activities – The Company did not always have adequate control activities that were designed and operating effectively, including timely management review controls and controls to verify the completeness and adequacy of information prior to presentation of the information to the independent auditors.

Monitoring Activities – The Company did not always maintain effective monitoring controls related to the financial reporting process.

Our Chief Executive Officer continues with a review of our controls relating to complex accounting matters. Although our analysis is not complete, we have added additional resources with expertise in accounting for complex accounting matters. We are also considering redesigning controls to add additional layers of review and approval whenever entering into or subsequently converting, exercising, amending, repricing, exiting or otherwise experiencing changes in or to complex financial instruments.

Notwithstanding the identified material weaknesses, the Company believes the consolidated financial statements included in this Annual Report on Form 10-K fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with accounting principles generally accepted in the United States of America.

(d) Changes in Internal Control Over Financial Reporting

Other than described above in the Item 9A. Controls and Procedures, there were no changes in our internal control over financial reporting that occurred during the fourth quarter of 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2019 Annual Meeting of Stockholders, under the captions “Election of Directors,” and “Compliance with Section 16(a) of the Exchange Act” and is incorporated into this item by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2019 Annual Meeting of Stockholders, under the captions “Executive Compensation”, and is incorporated into this item by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2019 Annual Meeting of Stockholders, under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Related Stockholder Matters” and is incorporated into this item by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2019 Annual Meeting of Stockholders under the captions “Certain Relationships and Related Transactions” and “Director Independence” and is incorporated into this item by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2019 Annual Meeting of Stockholders, under the caption “Principal Accountant Fees and Services” and is incorporated into this item by reference.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Reference is made to the Index to Consolidated Financial Statements beginning on Page F-1 hereof.

(1) *Financial Statements*. The following consolidated financial statements and the notes thereto, and the Report of Independent Registered Public Accounting Firm are incorporated by reference as provided in Item 8 of this report:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets at December 31, 2018 and 2017	F-3
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(2) Consolidated Financial Statement Schedules

Consolidated Financial Statement Schedules have been omitted because they are either not required or not applicable, or because the information required to be presented is included in the consolidated financial statements or the notes thereto included in this Annual Report.

(3) Exhibits

The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report and such Exhibit Index is incorporated by reference.

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number

3.1	Restated Certificate of Incorporation of the Registrant	Form 8-K (Exhibit 3.1)	2/20/14	001-33624
3.1.1	Certificate of Amendment to the Restated Certificate of Incorporation of SINTX Corporation	Form 8-K (Exhibit 3.1)	1/22/16	001-33624
3.1.2	Certificate of Amendment to the Restated Certificate of Incorporation of SINTX Corporation	Form 8-K (Exhibit 3.1)	11/16/17	001-33624
3.1.3	Certificate of Designation of Series B Preferred Stock	Form 8-K (Exhibit 3.1)	5/15/18	001-33624
3.2	Restated Bylaws of the Registrant	Form 8-K (Exhibit 3.1)	2/20/14	001-33624
4.1	Form of Common Stock Certificate of the Registrant	Amendment No. 3 to Form S-1 (Exhibit 4.1)	1/29/14	333-192232
4.2	Warrant to Purchase Shares of Series F Convertible Preferred Stock by and between the Registrant and GE Capital Equity Investments, Inc., dated as of December 17, 2012	Form S-1 (Exhibit 4.10)	11/8/13	333-192232
4.3	Warrant to Purchase Shares of Series F Convertible Preferred Stock by and between the Registrant and Zions First National Bank, dated as of December 17, 2012	Form S-1 (Exhibit 4.11)	11/8/13	333-192232

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
4.4	Hercules Warrant to Purchase Common Stock		Form 8-K (Exhibit 4.3)	7/1/2014	001-33624
4.5	Form of Warrant to be Issued to Investors in the Offering		Amendment No. 3 to Form S-1 (Exhibit 4.24)	11/20/14	333-199753
4.6	Form of Unit Purchase Option to be Issued to the Underwriters in the Offering		Amendment No. 3 to Form S-1 (Exhibit 4.25)	11/20/14	333-199753
4.7	Form of Warrant Agent Agreement by and between the Registrant and American Stock Transfer and Trust Company		Amendment No. 3 to Form S-1 (Exhibit 4.26)	11/19/14	333-199753
4.8	Form of Warrant to Purchase Shares of Common Stock of the Registrant issued on September 17, 2014.		Form 10-K (Exhibit 4.27)	3/24/15	001-33624
4.9	Form of Warrant to Purchase Shares of Common Stock of the Registrant issued on November 12, 2014.		Form 10-K (Exhibit 4.28)	3/24/15	001-33624
4.10	Form of Amended and Restated Series A warrant		Form 8-K (Exhibit 4.1)	12/14/15	001-33624
4.11	Form of Common Stock Purchase Warrant issued on April 4, 2016.		Form 8-K (Exhibit 4.1)	4/05/16	001-33624
4.12	Form of Series E Warrant		Amendment No. 3 to Form S-1 (Exhibit 4.25)	6/30/16	333-211520
4.13	Form of Underwriters Warrant Issued in 2016 Offering		Amendment No. 3 to Form S-1 (Exhibit 4.26)	6/30/16	333-211520
4.14	Form of Warrant		Form 8-K (Exhibit 4.1)	1/20/17	001-33624
4.15	Secured Promissory Note with North Stadium Investments, LLC		Form 8-K (Exhibit 4.1)	8/3/17	001-33624

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Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
4.16	North Stadium Investments, LLC Warrant to Purchase Common Stock		Form 8-K (Exhibit 4.2)	8/3/17	001-33624
4.17	Form of Warrant Issued to Karl Kipke		Form S-1 (Exhibit 4.25)	4/26/18	333-223032
4.18	Form of Series F Common Stock Purchase Warrant		Form S-1 (Exhibit 4.26)	4/26/18	333-223032
4.19	Common Stock Warrant		Form 8-K (Exhibit 3.2)	5/15/18	001-33624
4.20	Form of Warrant Agency Agreement between Amedica Corporation and American Stock Transfer and Trust Company, LLC		Form S-1 (Exhibit 4.28)	4/26/18	333-223032
4.21	Form of Warrant to be Issued to the Underwriters		Form S-1 (Exhibit 4.29)	5/1/18	333-223032
4.22	Westlake Securities LLC Common Stock Purchase Warrant		Form S-1 (Exhibit 4.30)	4/26/18	333-223032
4.23	Form of Common Stock Purchase Warrant Issued on September 11, 2015		Form 8-K (Exhibit 4.1)	9/18/15	001-33624
10.1	Loan and Security Agreement by and among the Registrant, its subsidiary, Hercules Technology Growth Capital, Inc., and Hercules Technology III, L.P., dated as of June 30, 2014		Form 8-K (Exhibit 10.3)	7/1/2014	001-33624

10.2	Centrepointe Business Park Lease Agreement Net by and between the Registrant and Centrepointe Properties, LLC, dated as of April 21, 2009	Form S-1 (Exhibit 10.10)	11/8/13	333-192232
10.3	First Addendum to Centrepointe Business Park Lease Agreement Net by and between the Registrant and Centrepointe Properties, LLC, dated as of January 31, 2012	Form S-1 (Exhibit 10.11)	11/8/13	333-192232
10.4	Form of Change of Control Agreement*	Form 8-K (Exhibit 10.1)	7/22/15	001-33624
10.5	Form of Indemnification Agreement by and between the Registrant and its officers and directors	Amendment No. 2 to Form S-1 (Exhibit 10.14)	12/20/13	333-192232
10.6	SINTX Technologies Amended and Restated 2012 Equity Incentive Plan*	Amendment No. 4 to Form S-1 (Exhibit 10.15)	2/12/14	333-192232
10.7	Form of 2012 Stock Option Grant Notice and Stock Option Agreement*	Amendment No. 4 to Form S-1 (Exhibit 10.16)	2/12/14	333-192232
10.8	Form of 2012 Restricted Stock Award and Restricted Stock Unit Agreement*	Amendment No. 4 to Form S-1 (Exhibit 10.17)	2/12/14	333-192232
10.9	SINTX Technologies 2003 Stock Option Plan*	Form S-1 (Exhibit 10.18)	11/8/13	333-192232
10.10	Form of 2003 Non-Qualified Stock Option Agreement and Notice of Exercise of Non-Qualified Stock Option thereunder*	Form S-1 (Exhibit 10.19)	11/8/13	333-192232

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.11	Form of 2003 Incentive Stock Option Agreement and Notice of Exercise of Incentive Stock Option thereunder*		Form S-1 (Exhibit 10.20)	11/8/13	333-192232
10.12	Consent and First Amendment to Loan and Security Agreement dated September 8, 2015 by and among Hercules Technology Growth Capital Inc., the financial institutions signatory thereto, SINTX Corporation, and the guarantors signatory thereto.		Form 8-K (Exhibit 10.1)	9/8/15	001-33624
10.13	First Amendment to Warrant to Purchase Shares of Common Stock of SINTX Corporation dated September 8, 2015, by and between SINTX Corporation and Hercules Technology III, L.P.		Form 8-K (Exhibit 10.2)	9/8/15	001-33624
10.14	Form of Securities Purchase Agreement between SINTX Technologies and the Purchasers Dated September 8, 2015		Form 8-K (Exhibit 10.5)	9/8/15	001-33624
10.15	Exchange Agreement dated April 4, 2016, by and among SINTX Corporation and Riverside Merchant Partners, LLC		Form 8-K (Exhibit 10.2)	5/05/16	001-33624
10.16	Warrant Agency Agreement, dated July 8, 2016, by and between SINTX Corporation and American Stock Transfer & Trust Company, LLC		Form 8-K (Exhibit 10.1)	7/8/16	001-33624
10.17	Warrant Agency Agreement dated January 24, 2017, by and between SINTX Corporation and American Stock Transfer & Trust Company, LLC		Form 8-K (Exhibit 8-K)	1/24/17	001-33624
10.18	Security Agreement, dated July 28, 2017		Form 8-K (Exhibit 10.1)	8/3/17	001-33624

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.19	Assignment Agreement, dated January 3, 2018, by and among the Company, US Spine, Inc., MEF I, L.P., Anson Investments Master Fund LP, Hercules Technology III, L.P. and Hercules Capital, Inc.		Form 8-K (Exhibit 10.1)	1/4/18	001-33624
10.20	Exchange Agreement, dated January 3, 2018, by and among SINTX Corporation and MEF I, L.P.		Form 8-K (Exhibit 10.2)	1/4/18	001-33624
10.21	Exchange Agreement, dated January 3, 2018, by and among Amedica Corporation and Anson Investments Master Fund LP		Form 8-K (Exhibit 10.3)	1/4/18	001-33624
10.22	Senior Secured Convertible Promissory Note, dated January 3, 2018, by and among Amedica Corporation and MEF I, L.P.		Form 8-K (Exhibit 10.4)	1/4/18	001-33624
10.23	Senior Secured Convertible Promissory Note, dated January 3, 2018, by and among Amedica Corporation and Anson Investments		Form 8-K (Exhibit 10.5)	1/4/18	001-33624
10.24	Securities Purchase Agreement, dated January 30, 2018, by and among the Company and L2 Capital, LLC.		Form 8-K (Exhibit 10.1)	2/1/18	001-33624
10.25	Amended and Restated Promissory Note payable to L2 Capital		Form S-1 (Exhibit 10.25)	4/26/18	333-223032
10.26	Form of Warrant Amendment Agreement		Form S-1 (Exhibit 10.26)	4/26/18	333-223032

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
16	Letter of BDO, dated September 22, 2017		Form 8-K (Exhibit 16.1)	9/22/17	001-33624
21.1	List of Subsidiaries of the Registrant		Form S-1 (Exhibit 21.1)	11/8/13	333-192232
23.1	Consent of Independent Registered Public Accounting Firm, Tanner LLC	X			
31.1	Certification of Chief Executive Officer	X			
31.2	Certification of Principal Financial Officer	X			
32	Certification pursuant to Section 906 of the Sarbanes Oxley Act of 2002	X			
101 SCH	XBRL Taxonomy Extension Schema Document (A)	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (A)	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (A)	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (A)	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (A)	X			

* Management contract of compensatory plan or arrangement

(A) XBRL (Extensible Business Reporting Language) information is furnished and not filed for purposes of Section 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

ITEM 16. 10-K Summary

None.

SIGNATURES

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

SINTX Technologies, Inc.

Date: March 8, 2019 */s/ B. Sonny Bal*
B. Sonny Bal
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

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

Date: March 8, 2019 */s/ B. Sonny Bal*
B. Sonny Bal, M.D., Director

Date: March 8, 2019 */s/ David W. Truetzel*
David W. Truetzel, Director

Date: March 8, 2019 */s/ Jeffrey S. White*
Jeffrey S. White, Director

Date: March 8, 2019 */s/ Eric A. Stookey*
Eric A. Stookey, Director

SINTX TECHNOLOGIES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

As of and For the Years ended December 31, 2018 and 2017

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of

SINTX Technologies, Inc. (previously known as Amedica Corporation)

Salt Lake City, Utah

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of SINTX Technologies, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017 and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, 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 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.

Other Matter

The financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and negative operating cash flows and needs to obtain additional financing to finance its operations. These issues raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ TANNER LLC

We have served as the Company's auditors since 2017

Date: March 8, 2019

Salt Lake City, Utah

SINTX Technologies, Inc.

(previously known as Amedica Corporation)

Consolidated Balance Sheets

(in thousands, except share and per share data)

	As of December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$5,447	$539
Trade accounts receivable, net of allowance of $56 and $63, respectively	263	1,240
Prepaid expenses and other current assets	171	190
Inventories	52	117
Notes receivable, current portion	1,084	-
Current assets held for sale	-	1,585
Total current assets	7,017	3,671
Inventories, net	624	675
Property and equipment, net	124	218
Intangible assets, net	46	-
Goodwill	-	6,163
Long-term note receivable, net of current portion	3,669	-
Other long-term assets	35	35
Long-term assets held for sale	-	1,228
Long-term intangible assets held for sale	-	2,651
Total assets	$11,515	$14,641
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$301	$1,732
Accrued liabilities	838	2,682
Debt	-	605
Derivative liabilities, current portion	1,062	896
Deferred rent, current portion	169	-
Other current liabilities	10	-
Current liabilities held for sale	-	2,356
Total current liabilities	2,380	8,271
Deferred rent	-	179
Derivative liabilities, net of current portion	504	461
Other long-term liabilities	232	288
Total liabilities	3,116	9,199

Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, $0.01 par value, 130,000,000 shares authorized; 4,074 and 0 shares issued and outstanding at December 31, 2018 and 2017, respectively.	-	-
Common stock, $0.01 par value, 250,000,000 shares authorized; 21,793,641 and 3,028,065 shares issued and outstanding at December 31, 2018 and 2017, respectively.	218	30
Additional paid-in capital	237,462	226,041
Accumulated deficit	(229,281)	(220,629)
Total stockholders' equity	8,399	5,442
Total liabilities and stockholders' equity	$11,515	$14,641

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

SINTX Technologies, Inc.

(previously known as Amedica Corporation)

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,	
	2018	**2017**
Product revenue	$95	$-
Costs of revenue	56	-
Gross profit	39	-
Operating expenses:		
Research and development	2,991	3,506
General and administrative	3,866	3,654
Sales and marketing	135	325
Goodwill impairment	6,163	-
Total operating expenses	13,155	7,485
Loss from operations	(13,116)	(7,485)
Other income (expenses):		
Interest expense	(1,388)	(1,263)
Offering costs	(682)	(131)
Change in fair value of derivative liabilities	7,005	3,118
Loss on extinguishment of debt	(339)	-
Loss on extinguishment of derivative liabilities	(1,252)	-
Other income	83	-
Total other income (expense), net	3,427	1,724
Net loss before income taxes	(9,689)	(5,761)
Provision for income taxes	-	-
Loss from continuing operations	(9,689)	(5,761)
Loss from discontinued operations	(324)	(3,568)
Gain from disposal of discontinued operations	1,361	-
Net loss	(8,652)	(9,329)
Deemed dividend related to beneficial conversion feature and accretion of discount on convertible Series A preferred stock	(13,900)	-
Net loss attributable to common stockholders	$(22,552)	$(9,329)
Net loss per share – basic and diluted		
Basic – continuing operations	$(0.88)	$(1.93)
Basic – discontinued operations	(0.03)	(1.20)
Basic – gain from sale of discontinued operations	0.12	-
Basic – deemed dividend and accretion of a discount on conversion of Series B preferred stock	(1.27)	-
Basic – attributable to common stockholders	$(2.06)	$(3.13)

Diluted – continuing operations	(1.44)	-
Diluted – discontinued operations	(0.03)	-
Diluted – gain from sale of discontinued operations	0.12	-
Diluted – deemed dividend and accretion of a discount on conversion of Series B preferred stock	(1.21)	-
Diluted – attributable to common stockholders	$(2.56)	$-
Weighted average common shares outstanding:		
Basic	10,938,047	2,978,904
Diluted	11,515,638	-

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

SINTX Technologies, Inc.

(previously known as Amedica Corporation)

Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

	Preferred Stock		Common Stock		Paid-In	Accumulated	Total
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2016	-	$ -	2,280,407	$ 22	$222,513	$ (211,300)	$11,235
Issuance of common stock with offering, net of issuance costs	-	-	741,667	8	3,120	-	3,128
Round-up common shares issued in association with reverse stock split	-	-	5,991	-	-	-	-
Stock-based compensation	-	-	-	-	219	-	219
Warrants issued in association with debt	-	-	-	-	189	-	189
Net loss	-	-	-	-	-	(9,329)	(9,329)
Balance at December 31, 2017	-	-	3,028,065	30	226,041	(220,629)	5,442
Issuance of common stock upon exercise of warrants	-	-	1,086,159	11	1,641	-	1,652
Issuance of common stock from the reduction in debt	-	-	580,444	6	1,447	-	1,453
Issuance of preferred stock from offering, net of issuance costs	15,000	-	-	-	6,749	-	6,749
Issuance of common stock due to conversion of preferred stock	(10,926)	-	17,098,973	171	(171)	-	-
Loss on extinguishment of derivative liability	-	-	-	-	1,040	-	1,040
Warrants issued in association with debt	-	-	-	-	98	-	98
Deemed dividend related to adjustment of the exercise price of warrants issued with debt	-	-	-	-	(9)	-	(9)
Accretion of change in warrant exercise price	-	-	-	-	9	-	9
Accretion of convertible preferred stock discount	-	-	-	-	13,900	-	13,900
Deemed dividend related to the issuance of preferred stock	-	-	-	-	(13,900)	-	(13,900)
Extinguishment of derivative liability	-	-	-	-	575	-	575
Stock-based compensation	-	-	-	-	42	-	42
Net loss	-	-	-	-	-	(8,652)	(8,652)

Balance at December 31, 2018	4,074	$ -	21,793,641	$ 218	$237,462	$ (229,281)	$8,399

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

SINTX Technologies, Inc.

(previously known as Amedica Corporation)

Consolidated Statements of Cash Flow

(in thousands)

	Year Ended December 31,	
	2018	**2017**
Cash flow from operating activities		
Net loss from continuing operations	$(9,689)	$(5,761)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	105	105
Amortization of intangible assets	4	-
Amortization of lease incentive for tenant improvements	-	20
Non-cash interest income	(86)	-
Non-cash interest expense	956	726
Loss on extinguishment of debt	339	-
Stock based compensation	42	219
Change in fair value of derivative liabilities	(7,005)	(3,118)
Loss on extinguishment of derivative liabilities	1,252	-
Offering costs	-	131
Loss on impairment of goodwill	6,163	-
Changes in operating assets and liabilities:		
Trade accounts receivable	(139)	-
Prepaid expenses and other current assets	19	48
Inventories	(8)	-
Accounts payable and accrued liabilities	(1,281)	503
Net cash used in operating activities – continuing operations	(9,328)	(7,127)
Cash loss on sale – discontinued operations	(695)	-
Net cash provided by operating activities – discontinued operations	675	2,447
Net cash used in operating activities	(9,348)	(4,680)
Cash flows from investing activities		
Purchase of property and equipment	(11)	(6)
Purchase of intangible asset	(50)	-
Net cash used in investing activities – continuing operations	(61)	(6)
Net cash used in investing activities – discontinued operations	(84)	(1,131)
Net cash used in investing activities	(145)	(1,137)
Cash flows from financing activities		
Proceeds from issuance of warrant derivative liability, net of issuance costs ($682 and $131)	7,577	679
Proceeds from issuance of preferred stock, net of issuance costs ($668)	6,749	-
Proceeds from issuance of common stock, net of issuance costs ($601)	-	3,128
Proceeds from exercise of warrants, net of fees	1,652	-

Proceeds from issuance of debt	705	-
Payments on debt	(2,282)	(6,816)
Net cash provided by (used in) financing activities – continuing operations	14,401	(3,009)
Net cash provided by financing activities – discontinued operations	-	2,450
Net cash provided by (used in) financing activities	14,401	(559)
Net increase (decrease) in cash and cash equivalents	4,908	(6,376)
Cash and cash equivalents at beginning of year	539	6,915
Cash and cash equivalents at end of year	$5,447	$539

	Year Ended December 31,	
	2018	2017
Noncash investing and financing activities		
Debt exchange	$2,265	$-
Payment of debt with common stock	1,453	-
Extinguishment of derivative liabilities through exercise of warrants	565	-
Warrants issued in association with debt	98	-
Debt discount from warrants issued with debt	-	189
Supplemental cash flow information		
Cash paid for interest	$426	$442

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

1. Organization and Summary of Significant Accounting Policies

SINTX Technologies, Inc. ("SINTX" or "the Company") was incorporated in the state of Delaware on December 10, 1996 (and was previously known as Amedica Corporation). SINTX is a commercial-stage biomaterial company focused on using its silicon nitride technology platform to develop, manufacture, and commercialize a broad range of medical devices. The Company believes it is the first and only manufacturer to use silicon nitride in medical applications. The Company acquired US Spine, Inc. ("US Spine"), a Delaware spinal products corporation with operations in Florida, on September 20, 2010. The Company's products are primarily sold in the United States.

As further explained in Note 14, On October 1, 2018, the Company completed the sale of its retail spine business to CTL Medical, a Dallas, Texas-based privately held medical device manufacturer. As a result of the sale, CTL Medical is now the exclusive owner of Amedica's portfolio of metal and silicon nitride spine products, which are presently sold under the brand names of Taurus, Preference, and Valeo, with access to future silicon nitride spine technologies. Manufacturing, R&D, and all intellectual property related to the core, non-spine, biomaterial technology of silicon nitride remains with the Company. The Company will serve as CTL's exclusive OEM provider of silicon nitride products.

On October 30, 2018, the Company amended its Certificate of Incorporation with the State of Delaware to change its corporate name to SINTX Technologies, Inc. in order to better reflect its focus on silicon nitride science and technologies and pipeline of silicon nitride-based products in various biomedical applications. The Company also changed its trading symbol on the NASDAQ Capital Market to "SINT".

The previous name, Amedica, has transferred to CTL Medical, which is now CTL-Amedica. The Company's new corporate brand reflects both the Company's core competence in the science and production of silicon nitride ceramics, as well as encouraging prospects for the future, as an OEM supplier of spine implants to CTL-Amedica, and several opportunities outside of spine. As SINTX Technologies Inc., the Company will focus on developing silicon nitride in terms of product design, and future biomaterial formulations, for a variety of OEM customers.

Basis of Presentation and Principles of Consolidation

These consolidated financial statements have been prepared by management in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and include all assets, liabilities and operations of the Company and its wholly-owned subsidiary, US Spine. All material intercompany transactions and balances have been eliminated in consolidation.

Liquidity and Capital Resources

The consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern within one year from the date of issuance of these consolidated financial statements.

For the years ended December 31, 2018 and 2017, the Company incurred a net loss of $8.7 million and $9.3 million, respectively, and used cash in operations of $9.3 million and $4.7 million, respectively. The Company had an accumulated deficit of $229.3 million and $220.6 million as of December 31, 2018 and 2017, respectively. To date, the Company's operations have been principally financed from proceeds from the issuance of preferred and common stock, convertible debt and bank debt and, to a lesser extent, cash generated from product sales. It is anticipated that the Company will continue to generate operating losses and use cash in operations. The Company's continuation as a going concern is dependent upon its ability to increase sales, implement cost saving measures and/or raise additional funds through the capital markets. Whether and when the Company can attain profitability and positive cash flows from operations or obtain additional financing is uncertain.

In 2016, the Company implemented certain cost saving measures, including workforce and office space reductions, and continued to evaluate additional cost savings alternatives during 2017 and 2018. These additional cost savings measures may include additional workforce and research and development reductions, as well as cuts to certain other operating expenses. The Company is actively generating additional scientific and clinical data to have it published in leading industry publications. The unique features of our silicon nitride material are not well known, and we believe the publication of such data would help sales efforts as the Company approaches new prospects. The Company is also making additional changes to the sales strategy, including a focus on revenue growth by expanding the use of silicon nitride in other areas outside of spinal fusion applications.

The Company has common stock that is publicly traded and has been able to successfully raise capital when needed since the date of the Company's initial public offering. In March 2018, the Company closed on gross proceeds of $1.4 million, before payment of placement agent fees and costs on a warrant reprice and exercise transaction (see Note 8). Additionally, on May 14, 2018, the Company closed on a public offering of units, consisting of convertible preferred stock and warrants, for gross proceeds of $15 million, which excludes underwriting discounts and commissions and offering expenses payable by the Company. The Company is engaged in discussions with investment and banking firms to examine financing alternatives, including options for a public offering of the Company's preferred or common stock. On October 1, 2018, the Company sold the retail spine business. This sale will provide cash flows totaling $2.5 million over the next eighteen months (See Notes 13 and 14) and $3.5 million for the following eighteen months. The buyer also assumed the Company's $2.5 million related party note payable.

Although the Company is seeking to obtain additional equity and/or debt financing, such funding is not assured and may not be available to the Company on favorable or acceptable terms and may involve significant restrictive covenants. Any additional equity financing is also not assured and, if available to the Company, will most likely be dilutive to its current stockholders. If the Company is not able to obtain additional debt or equity financing on a timely basis, the impact on the Company will be material and adverse.

These uncertainties create substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Reverse Stock Split

On November 10, 2017, the Company effected a 1 for 12 reverse stock split of the Company's common stock. The par value and the authorized shares of the common and convertible preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these consolidated financial statements prior to November 10, 2017 have been adjusted retroactively to reflect the reverse stock split.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the period. Actual results could differ from those estimates. As of December 31, 2018, the most significant estimate relates to derivative liabilities.

Concentrations of Credit Risk and Significant Customers

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities and accounts receivable. Because the financial institution that the Company currently uses does not participate in the Certificate of Deposit Account Registry Service ("CDARS"), the Company does not presently have a program to limit its exposure to credit loss. The Company's deposits, at times, may exceed federally insured limits.

At December 31, 2018, one customer receivable balance was 51% of the Company's total trade accounts receivable from continuing operations. One customer accounted for 100% of the Company's total revenues from continuing operations for the year ended December 31, 2018.

Revenue Recognition

The Company derives its product revenue primarily from the sale of spinal fusion products, used in the treatment of spine disorders to CTL Medical, with whom the Company has a 10-year exclusive sales agreement in place. The Company is currently pursuing other sales opportunities for silicon nitride outside the spinal fusion application. The Company recognizes revenue from sales at the time the product is shipped. In general, the Company's customers do not have any rights of return or exchange.

Costs of Revenue

The expenses that are included in costs of revenue include all in-house manufacturing costs for the products we manufacture.

Cash and Cash Equivalents

The Company considers all cash on deposit, money market accounts and highly-liquid debt instruments purchased with original maturities of three months or less to be cash and cash equivalents.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost for manufactured inventory determined under the standard costs, which approximate actual costs, determined on the first-in first-out ("FIFO") method. Manufactured inventory consists of raw material, direct labor and manufacturing overhead cost components. The Company reviews the carrying value of inventory on a periodic basis for excess or obsolete items, and records any write-down as a cost of revenue, as necessary.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term, generally five years.

The Company reviews the carrying value of the Company's property and equipment that are held and used in the Company's operations for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is determined based upon expected undiscounted future net cash flows from the operations to which the assets relate, utilizing management's best estimate, assumptions, and projections at the time. If the carrying value is determined to be unrecoverable from future operating cash flows, the asset is deemed impaired and an impairment charge would be recognized to the extent the carrying value exceeded

the estimated fair value of the asset. The Company estimates the fair value of assets based on the estimated future discounted cash flows of the asset.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are carried at invoiced amount less an allowance for doubtful accounts. On a regular basis, the Company evaluates accounts receivable and estimates an allowance for doubtful accounts, as needed, based on various factors such as customers' current credit conditions, length of time past due, and the general economy as a whole. Receivables are written off against the allowance when they are deemed uncollectible.

Long Lived Intangible Assets and Goodwill

The Company evaluates the carrying value of definite-lived intangibles when events or changes in circumstances indicate that the carrying value may not be recoverable. Factors the Company considers important which could trigger an impairment review include, but are not limited to, significant under-performance relative to historical or projected future operating results, significant changes in the manner of its use of acquired assets or its overall business strategy, and significant industry or economic trends. The Company amortizes definite-lived intangible assets on a straight-line basis over their useful lives. The Company recorded no impairment loss for definite-lived intangible assets during the year ended December 31, 2017. As explained above, the Company sold most intangible assets that had a carrying value to CTL Medical, retaining the carrying value of only one trademark asset.

When the Company determines that the carrying value of a long-lived asset may not be recoverable based upon the existence of one or more of the above indicators, the Company determines the recoverability by comparing the carrying amount of the asset to net future undiscounted cash flows that the asset is expected to generate and recognizes an impairment charge equal to the amount by which the carrying amount exceeds the fair market value of the asset.

If the Company's revenues or other estimated operating results are not achieved at or above our forecasted level, and the Company is unable to recover such costs through price increases, the carrying value of certain of the Company's assets may prove to be unrecoverable and we may incur impairment charges of definitive-live intangible assets.

In accordance with ASC 350, Goodwill and Other Intangible Assets, goodwill is not amortized but is required to be reviewed for impairment at least annually or when events or circumstances indicate that carrying value may exceed fair value. As part of that annual review, the Company determined that circumstances and events indicted that goodwill needed to be completely impaired and did so during the third quarter 2018.

Derivative Liabilities

Derivative liabilities include the fair value of instruments such as common stock warrants, preferred stock warrants and convertible features of notes, that are initially recorded at fair value and are required to be re-measured to fair value at each reporting period under provisions of ASC 480, *Distinguishing Liabilities from Equity,* or ASC 815, *Derivatives and Hedging*. The change in fair value of the instruments is recognized as a component of other income (expense) in the Company's consolidated statements of operations until the instruments settle, expire or are no longer classified as derivative liabilities. The Company estimates the fair value of these instruments using the Black-Scholes-Merton or Monte-Carlo valuation models depending on the complexity of the underlying instrument. The significant assumptions used in estimating the fair value include the exercise price, volatility of the stock underlying the instrument, risk-free interest rate, estimated fair value of the stock underlying the instrument and the estimated life of the instrument.

Research and Development

All research and development costs, including those funded by third parties, are expensed as incurred. Research and development costs consist of engineering, product development, test-part manufacturing, testing, developing and validating the manufacturing process, and regulatory related costs. Research and development expenses also include employee compensation, employee and nonemployee stock-based compensation, supplies and materials, consultant services, and travel and facilities expenses related to research activities.

We expect to incur additional research and development costs as we continue to develop new spinal fusion products, our product candidates for total joint replacements, such as our total hip replacement product candidate, and dental applications, which may increase our total research and development expenses.

Advertising Costs

Advertising costs are expensed as incurred. The primary component of the Company's advertising expenses is advertising in trade periodicals. Advertising costs were less than $0.1 million for each of the years ended December 31, 2018 and 2017.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to the differences between the financial statement carrying value of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the fiscal year in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company operates in various tax jurisdictions and is subject to audit by various tax authorities. The Company provides for tax contingencies whenever it is deemed probable that a tax asset has been impaired, or a tax liability has been incurred for events such as tax claims or changes in tax laws. Tax contingencies are based upon their technical merits relative tax law and the specific facts and circumstances as of each reporting period. Changes in facts and circumstances could result in material changes to the amounts recorded for such tax contingencies.

The Company recognizes uncertain income tax positions taken on income tax returns at the largest amount that is more-likely than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company's policy for recording interest and penalties associated with uncertain tax positions is to record such items as a component of our income tax provision. For the years ended December 31, 2018 and 2017, the Company did not record any material interest income, interest expense or penalties related to uncertain tax positions or the settlement of audits for prior periods.

Stock-Based Compensation

The Company measures stock-based compensation expense related to employee stock-based awards based on the estimated fair value of the awards as determined on the date of grant and is recognized as expense over the remaining requisite service period. The Company utilizes the Black-Scholes-Merton option pricing model to estimate the fair value of employee stock options. The Black-Scholes-Merton model requires the input of highly subjective and complex assumptions, including the estimated fair value of the Company's common stock on the date of grant, the expected term of the stock option, and the expected volatility of the Company's common stock over the period equal to the expected term of the grant. The Company estimates forfeitures at the date of grant and revises the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company accounts for stock options to purchase shares of stock that are issued to non-employees based on the estimated fair value of such instruments using the Black-Scholes-Merton option pricing model.

Because the Company was a privately-held company with no trading history prior to February 2014 and has limited stock history since February 2014, the Company utilizes the historical stock price volatility from a representative group of public companies to estimate expected stock price volatility and our historical stock price. The Company selected companies from the medical device industry, specifically those who are focused on the design, development and commercialization of products for the treatment of spine disorders, and who have similar characteristics to us, such as stage of life cycle and size. The Company intends to continue to utilize the historical volatility of the same or similar public companies to estimate expected volatility until a sufficient amount of historical information regarding the price of our publicly traded stock becomes available. The Company uses the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, Share-based Payment, to calculate the expected term of stock option grants to employees as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. The Company utilizes a dividend yield of zero because the Company has never paid cash dividends and has no current intention to pay cash dividends. The risk-free rate of return used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

Offering Costs

Offering costs consist of legal, accounting, and other advisory costs related to the Company’s efforts to raise debt and equity capital.

Offering costs paid in cash or by issuing warrants associated with the Company’s equity fundraising activities are either recorded to additional paid in capital as a reduction of the proceeds or immediately expensed.

Offering costs paid in cash or by issuing warrants associated with the Company’s debt fundraising activities are recorded as a debt discount and amortized as interest expense over the life of the debt or immediately expensed with the offset to additional paid in capital.

Accounting Pronouncement Adopted In 2018

In March 2016, the FASB updated the accounting guidance related to stock compensation. This update simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as the well as classification in the statement of cash flows. The standard is effective for the Company for its annual period beginning January 1, 2018. The adoptions of this standard did not have a material impact on the consolidated financial statements.

Accounting Pronouncement Adopted in 2017

In July 2015, the FASB issued ASU 2015-11, “Inventory (Topic 330) Simplifying the Measurement of Inventory”. The amendments clarify that an entity should measure inventory within the scope of this update at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Substantial and unusual losses that result from subsequent measurement of inventory should be disclosed in the consolidated financial statements. This guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those annual periods. The amendments are to be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of this guidance did not have a material impact on the consolidated financial statements.

New Accounting Pronouncement, Not Yet Adopted

In August 2016, the Financial Accounting Standards Board (“FASB”) updated accounting 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. These updates are effective for the Company for its annual period beginning January 1, 2019, and interim periods therein, with early adoption permitted. The guidance in this standard is not expected to have a material impact on the consolidated financial statements.

In February 2016, the FASB updated the accounting guidance related to leases as part of a joint project with the International Accounting Standards Board ("IASB") to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, a lessee will be required to recognize assets and liabilities for capital and operating leases with lease terms of more than 12 months. Additionally, this update will require disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases, including qualitative and quantitative requirements. The standard is effective for the Company for its annual period beginning January 1, 2020, and interim periods therein, with early adoption permitted. The Company is currently evaluating the potential impact this new standard may have on its consolidated financial statements.

In May 2014, in addition to several amendments issued during 2016, the FASB updated the accounting guidance related to revenue from contracts with customers, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle is that a company should recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The standard defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for the Company for its annual period beginning January 1, 2019, and interim periods therein, and shall be applied either retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. The Company has performed an evaluation of the new accounting standard and has determined the impact that the new standard will have on its consolidated financial statements is not significant.

In January of 2017, the FASB issued ASU 2017-04—*Intangibles—Goodwill and Other (Topic 350)*: Simplifying the Test for Goodwill Impairment. The amendments in this guidance to eliminate the requirement to calculate the implied fair value of goodwill to measure goodwill impairment charge (Step 2). As a result, an impairment charge will equal the amount by which a reporting unit's carrying amount exceeds its fair value, not to exceed the amount of goodwill allocated to the reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The amendment should be applied on a prospective basis. The guidance is effective for goodwill impairment tests in fiscal years beginning after December 15, 2021. Early adoption is permitted for goodwill impairment tests performed after January 1, 2017. The impact of this guidance for the Company will depend on the outcomes of future goodwill impairment tests.

The Company has reviewed all other recently issued, but not yet adopted, accounting standards, in order to determine their effects, if any, on its results of operations, financial position or cash flows. Based on that review, the Company believes that none of these pronouncements will have a significant effect on its consolidated financial statements.

Net Loss Per Share – Basic and Diluted

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period that are determined to be dilutive. Dilutive common stock equivalents are comprised of convertible preferred stock, warrants for the purchase of common stock and stock options outstanding under the Company's equity incentive plans.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	As of December 31,	
	2018	2017
Convertible preferred stock	9,336,264	-
Common stock warrants	1,454,657	1,503,711
Common stock options	11,301	11,302
	10,802,222	1,515,013

Below are basic and diluted loss per share data for the year ended December 31, 2018, which are in thousands except for share and per share data:

	Basic Calculation	Effect of Dilutive Warrant Securities	Diluted Calculation
Numerator:			
Loss from continuing operations	$(9,689)	$(6,899)	$(16,588)
Loss from discontinued operations	(324)	-	(324)
Gain from disposal of discontinued operations	1,361	-	1,361
Deemed dividend and accretion of a discount	(13,900)	-	(13,900)
Net loss attributable to common stockholders	$(22,522)	$(6,899)	$(29,451)
Denominator:			
Number of shares used in per common share calculations:	10,938,047	577,591	11,515,638

Net loss per common share:

Loss from continuing operations	$(0.88)	$-	$(1.44)
Loss from discontinued operations	(0.03)	-	(0.03)
Gain from disposal of discontinued operations	0.12	-	0.12
Deemed dividend and accretion of a discount	(1.27)	-	(1.21)
Net loss attributable to common stockholders	$(2.06)	$-	$(2.56)

Below are basic and diluted loss per share data for the year ended December 31, 2017, which are in thousands except for share and per share data:

	Basic Calculation	Effect of Dilutive Warrant Securities	Diluted Calculation
Numerator:			
Loss from continuing operations	$(5,761)	$ -	$ -
Loss from discontinued operations	(3,568)	-	-
Gain from disposal of discontinued operations	-	-	-
Deemed dividend and accretion of a discount	-	-	-
Net loss attributable to common stockholders	$(9,329)	$ -	$ -
Denominator:			
Number of shares used in per common share calculations:	2,978,904	-	-
Net loss per common share:			
Loss from continuing operations	$(1.93)	$ -	$ -
Loss from discontinued operations	(1.20)	-	-
Gain from disposal of discontinued operations	-	-	-
Deemed dividend and accretion of a discount	-	-	-
Net loss attributable to common stockholders	$(3.13)	$ -	$ -

2. Inventories

The components of inventory were as follows (in thousands):

	As of December 31,	
	2018	2017
Raw materials	$624	$740
WIP	47	52
Finished goods	5	-
Inventories held for sale	-	1,585
	$676	$2,377

3. Property and Equipment

The following is a summary of the components of property and equipment (in thousands):

	As of December 31,	
	2018	2017
Manufacturing and lab equipment	$234	$223
Leasehold improvements	863	863
Software and computer equipment	745	745
Furniture and equipment	635	635
Long-term assets held for sale	-	1,228
	2,477	3,694
Less: accumulated depreciation	(2,353)	(2,248)
	$124	$1,446

Depreciation expense for 2018 was approximately $0.5 million, with $0.1 million from continuing operations and $0.4 million from discontinued operations. Depreciation expense for 2017 was approximately $0.6 million, with $0.1 million from continuing operations and $0.5 million from discontinued operations.

4. Intangible Assets

Intangible assets consisted of the following (in thousands):

	Year Ended December 31,	
	2018	2017
Trademarks	$50	$-
Intangible assets held for sale	-	9,587
	50	9,587
Less: accumulated amortization	(4)	(6,936)
	$46	$2,651

Amortization expense for 2018 was approximately $0.4 million, with $0.1 from continued operations and $0.3 million from discontinued operations. Amortization expense for 2017 was approximately $0.5 million, with the entire amount from discontinued operations.

5. Fair Value Measurements

Financial Instruments Measured and Recorded at Fair Value on a Recurring Basis

The Company has issued certain warrants to purchase shares of common stock, which are considered mark-to-market liabilities and are re-measured to fair value at each reporting period in accordance with accounting guidance. Fair value is based on the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, under a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

Level 1 - quoted market prices for identical assets or liabilities in active markets.

Level 2 - observable prices that are based on inputs not quoted on active markets but corroborated by market data.

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Level 3	unobservable inputs reflecting management's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The Company classifies assets and liabilities measured at fair value in their entirety based on the lowest level of input that is significant to their fair value measurement. No financial assets were measured on a recurring basis as of December 31, 2018 and 2017. The following tables set forth the financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2018 and 2017.

	Fair Value Measurements as of December 31, 2018 (in thousands)			
Description	Level 1	Level 2	Level 3	Total
Derivative liability				
Common stock warrants	$-	$ -	$1,566	$1,566

	Fair Value Measurements as of December 31, 2017 (in thousands)			
Description	Level 1	Level 2	Level 3	Total
Derivative liability				
Common stock warrants	$-	$ -	$1,357	$1,357

The Company did not have any transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy during the years ended December 31, 2018 and 2017. The following table presents a reconciliation of the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the years ended December 31, 2018 and 2017 (in thousands):

	Common Stock Warrants
Balance at December 31, 2016	$ (3,665)
Issuance of derivatives	(810)
Change in fair value	3,118
Balance at December 31, 2017	(1,357)
Issuance of derivatives	(7,577)
Change in fair value	7,005
Exercise of warrants	575
Other, net	(212)
Balance at December 31, 2018	$ (1,566)

Common Stock Warrants

The Company has issued certain warrants to purchase shares of common stock, which are considered mark-to-market liabilities and are re-measured to fair value at each reporting period in accordance with accounting guidance. As of December 31, 2018 and 2017, approximately $1.6 million and $0.5 million respectively, of the derivative liabilities were calculated using the Black-Scholes-Merton valuation model. As of December 31, 2018, and 2017, less than $0.1 million and approximately $0.9 million respectively, were calculated using the Monte Carlo Simulation valuation model. Issuances of common stock warrants deemed to be derivative liabilities during the year ended December 31, 2018 were valued at approximately $7.6 million on the date of issuance using the Black-Scholes-Merton valuation model. Issuance of common stock warrants deemed to be derivative liabilities during the year ended December 31, 2017, were valued at approximately $0.8 million on the date of issuance using the Monte Carlo Simulation valuation model.

The assumptions used in estimating the common stock warrant liability using the Black-Scholes-Merton valuation model at December 31, 2018 and 2017 were as follows:

	December 31, 2018	December 31, 2017
Weighted-average risk-free interest rate	2.51 %	1.89 %
Weighted-average expected life (in years)	0.9	1.9

Expected dividend yield	-	%	-	%
Weighted average expected volatility	157	%	107	%

The assumptions used in estimating the common stock warrant liability using the Monte Carlo Simulation valuation model at December 31, 2018 and 2017 were as follows:

	December 31, 2018		December 31, 2017	
Weighted-average risk-free interest rate	2.46	%	2.20	%
Weighted-average expected life (in years)	3.1		3.6	
Expected dividend yield	-	%	-	%
Weighted average expected volatility	68	%	64	%

In addition, if any time after the second anniversary of the issuance of the warrant, both: (1) the 30-day volume weighted average price of the Company's stock exceeds $3.00; and (2) the average daily trading volume for such 30-day period exceeds $0.4 million, the Company may call this warrant for $0.01 per share. For those warrants that have a call provision, management believes the Monte Carlo Simulation valuation model provides a better estimate of fair value for the warrants issued during 2018 and 2017 than the Black-Scholes-Merton valuation model.

Other Financial Instruments

The Company's recorded values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The recorded value of notes payable approximates the fair value as the interest rate approximates market interest rates.

6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	Year Ended December 31,	
	2018	2017
Payroll and related expenses	$388	$477
Commissions	-	311
Royalties	-	96
Interest payable	-	6
Final loan payment fees	-	1,650
Resterilization and repackaging costs	344	-
Other	106	142
	$838	$2,682

7. Debt

L2 Capital Debt

On January 31, 2018, the Company signed a promissory note in the aggregate principal amount of up to $0.84 million (the “L2 Note”) for an aggregate purchase price of up to $0.75 million and warrants to purchase up to an aggregate of 68,257 shares of common stock (the “Warrants”) at an exercise price of $3.31 per share. The maturity date was six months from date of funding. The L2 Note’s interest rate was 8% per year and a default interest rate of 18% per year. The L2 Note was able to be converted by the holder of the Note at any time following an event of default. The conversion price of the L2 Note in the event of a default was equal to the product of (i) 0.70 multiplied by (ii) the lowest volume weighted average price, or VWAP, of the Company’s common stock during the 20-day trading period ending in the Holder’s sole discretion on the last complete trading day prior to conversion, or, the conversion date.

On May 14, 2018, the Company closed on an underwritten public offering of units, consisting of convertible preferred stock and warrants, for gross proceeds of $15.0 million. Part of the proceeds from this offering were used to pay off the outstanding debt with L2 Capital. The total payoff was $1.1 million, with $0.7 million in principal and $0.4 million in interest.

Hercules and MEF I, LP/Anson Investments Debt Exchange

On January 3, 2018, the Company entered into an Assignment Agreement (the "Assignment Agreement") with MEF I, LP and Anson Investments Master Fund (collectively the "Assignees" and each an "Assignee"), Hercules Technology III, L.P. ("HT III") and Hercules Capital, Inc. ("HC" and, together with HT III, "Hercules"), pursuant to which Hercules assigned to the Assignees all amounts remaining due under the Loan and Security Agreement, dated June 30, 2014, as amended, between the Company and Hercules (the "Loan and Security Agreement") and (2) the note (the "Hercules Note") between the Company and Hercules evidencing the amounts due under the Loan and Security Agreement. The total amount assigned by Hercules to the Assignees in the aggregate was $2.3 million and was secured by the same collateral underlying the Loan and Security Agreement. Subsequently, the Company entered into an exchange agreement pursuant to which the Assignees agreed to exchange the Hercules Term Loan obligation acquired by them for two senior secured convertible promissory notes issued by the Company, each in the principal amount of $1.1 million for an aggregate principal amount of $2.2 million, (the "Exchange Notes"). The Exchange Notes were scheduled to mature on February 3, 2019 (the "Maturity Date"). The Exchange Notes had interest at a rate of 15% per annum. Prior to the Maturity Date, principal and interest accrued under the Exchange Notes was payable in cash or, if certain conditions were met, payable in shares of our common stock. All principal accrued under the Exchange Notes was convertible into shares of our common stock ("Conversion Shares") at the election of the holders at any time at a fixed conversion price of $3.87 per share. Upon the occurrence of an event of default, the Assignees were entitled to convert all or any part of their Exchange Notes at a conversion price (the "Alternate Conversion Price") equal to 70% of the lowest traded price of our common stock during the ten trading days prior to the conversion date, provided that (i) in no event was the Alternate Conversion Price less than $1.75 per share and (ii) the Assignees were not entitled to receive more than 19.99% of the outstanding Common Stock. So long as these Exchange Notes remained outstanding or the Assignees held any Conversion Shares, the Company was prohibited from entering into any financing transaction pursuant to which the Company sell its securities at a price lower than $1.75 per share. The Exchange Notes were secured by a first priority security interest in substantially all of the Company assets, including intellectual property, and contains covenants restricting payments to certain of our affiliates.

On May 14, 2018, the Company closed on an underwritten public offering of units, consisting of convertible preferred stock and warrants, for gross proceeds of $15.0 million. Part of the proceeds from this offering were used to pay off the outstanding debt with MEF I, L.P and Anson Investments. The total payoff was $1.6 million, with $1.4 million in principal and $0.2 million in interest.

North Stadium Term Loan – Related Party

On July 28, 2017, the Company entered into a $2.5 million term loan (the "North Stadium Loan") with North Stadium Investments, LLC ("North Stadium"), a company owned and controlled by the Company's Chief Executive Officer and Chairman of the Board. The North Stadium Loan bore interest at 10% per annum and required the Company to make monthly interest only payments from September 5, 2017 through July 5, 2018. All principal and unpaid interest (if any) under the North Stadium Loan was due and payable on July 28, 2018. The North Stadium Loan was secured by

substantially all of the Company's assets but was junior to security interest in assets encumbered by the Hercules Term Loan (see below). In connection with the North Stadium Loan the Company also issued North Stadium a warrant to purchase up to 55,000 shares of the Company's common stock at a purchase price of $5.04 per share, subject to a 5-year term. The relative estimated value of the warrants on the date of grant approximated $0.2 million, which was being amortized as interest expense over the life of the term loan.

On October 1, 2018, CTL Medical assumed the North Stadium Term Loan debt as part of the sale of the retail spine business. As of December 31, 2018, the Company has been released by North Stadium from any and all obligations related to this debt.

Hercules Term Loan

On June 30, 2014, the Company entered into a Loan and Security Agreement with Hercules which provided the Company with a $20.0 million term loan. The Hercules Term Loan matured on January 1, 2018. The Hercules Term Loan included a $0.2 million closing fee, which was paid to Hercules on the closing date of the loan. The closing fee was recorded as a debt discount and was being amortized to interest expense over the life of the loan. The Hercules Term Loan also included a non-refundable final payment fee of $1.7 million. The final payment fee was being accrued and recorded to interest expense over the life of the loan.

On January 3, 2018, the Hercules Term Loan and all amounts owing thereunder was assigned to MEF I and Anson Investments. See discussion above for a more detailed description of that transaction.

Long-term debt consisted of the following (in thousands):

	December 31, 2018			December 31, 2017		
	Outstanding Principle	Unamortized Discount and Debt Issuance Costs	Net Carrying Amount	Outstanding Principle	Unamortized Discount and Debt Issuance Costs	Net Carrying Amount
Hercules Term Loan	$-	$ -	$ -	$605	$ -	$ 605
North Stadium	-	-	-	2,500	(144)	2,356
Total debt	-	-	-	3,105	(144)	2,961
Less: Current portion	-	-	-	(3,105)	144	(2,961)
Long-term debt	$-	$ -	$ -	$-	$ -	$ -

8. Equity

July-December 2018 Preferred Stock Conversion

From July through December of 2018, Series B Convertible Preferred shareholders of the Company converted 10,926 shares of Series B Convertible Preferred Stock into 17,098,973 shares of common stock.

August 2018 Warrant Exercise

During August 2018, pursuant to the cashless exercise provision contained in their warrant, L2 Capital exercised its warrants and was issued 242,063 shares of common stock. The L2 Capital warrant is no longer outstanding.

July 2018 Warrant Exercise

During May 2018, the Company closed on a public offering, consisting of both convertible preferred stock and warrants. During July 2018, 29,927 of the warrants were exercised and converted into 29,927 shares of common stock.

May-June 2018 Preferred Stock Conversion

During both May 2018 and June 2018, Series B Convertible Preferred shareholders of the Company converted 4,072 shares of Series B Convertible Preferred Stock into 3,086,570 shares of common stock.

May 2018 Warrant Exercise (July 2016 Warrants)

During March 2018, the Company repriced 832,000 warrants dated July 8, 2016, from $12 to $2.125 (for further description see *Warrant Reprice March 2018 below*). During May 2018, an additional 145,834 of the repriced warrants were exercised resulting in gross proceeds to the Company of $0.3 million.

May 2018 Unit Offering

On May 14, 2018, the Company closed on an underwritten public offering of units ("the Units"), consisting of convertible preferred stock and warrants, for gross proceeds of $15.0 million, which excludes underwriting discounts and commissions and offering expenses payable by SINTX. The offering was priced at a public offering price of $1,000 per unit. Each unit consisted of one share of Series B Convertible Preferred Stock, with a stated value of $1,100, and warrants to purchase up to 758 shares of common stock (the "May 2018 Warrants"). The May 2018 Warrants are initially exercisable at an exercise price of $1.60 per share and expire 5 years from the date of issuance. The Series B Preferred Stock is convertible into shares of common stock by dividing the stated value of $1,100 by: (i) for the first 40 trading days following the closing of this offering, $1.4512 (the "Conversion Price"), (ii) after 40 trading days but prior to the 81st trading day, the lesser of (a) the Conversion Price and (b) 87.5% of the lowest volume weighted average price for our Common Stock as reported at the close of trading on the market reporting trade prices for the Common Stock during the five trading days prior to the 41st trading day, and (iii) after 80 trading days, the lesser of (a) the Conversion Price and (b) 87.5% of the lowest volume weighted average price for our Common Stock as reported at the close of trading on the market reporting trade prices for the Common Stock during the five trading days prior to the date of the notice of conversion. In the case of (ii)(b) and (iii)(b) above, the share price shall not be less than $0.48 (the "Floor Price"). Each of the Conversion Price and Floor Price is subject to adjustment in certain circumstances.

The Company raised $15.0 million associated with the issuance of the Units, with $6.8 million, net of issuance costs of $0.6 million, allocated to the preferred stock and $6.9 million, net of issuance costs of $0.7 million, allocated to the warrants. In association with the warrants that were recorded as a derivative liability, the Company immediately expensed approximately $0.7 million of issuance costs. The 15,000 preferred shares were initially convertible into 11,369,900 shares of common stock and had an effective conversion rate of $1.45 per share based on the proceeds that were allocated to them. The conversion price was adjusted to $0.6543, effective July 12, 2018, and was adjusted again on September 7, 2018 to $0.48.

Warrant Reprice March 2018

During the three months ended March 31, 2018, the Company entered into a warrant amendment agreement (the "Amendment Agreement") with certain holders of previously issued Series E Common Stock Purchase Warrants (collectively, "Investors"). In connection with that certain Series E Common Stock Purchase Warrant between the Company and Investors dated July 8, 2016, the Company issued to Investors warrants to purchase up to 832,000 shares of common stock (the "Warrant Shares") at an exercise price of $12.00 per share, (the "Investors Warrants"). Under the terms of the Amendment Agreement, in consideration of Investors exercising 668,335 of the Investors Warrants (the "Warrant Exercise"), the exercise price per share of the Investors Warrants was reduced to $2.125 per share. 668,335 of the Investors Warrants were exercised resulting in gross proceeds to the Company of $1.4 million before payment of placement agent fees and costs. In addition, and as further consideration, the Company issued to Investors new warrants to purchase up to the number of shares of common stock equal to 100% of the number of Warrant Shares issued pursuant to the Warrant Exercise at an exercise price per share equal to $2.00 per share.

January 2017 Offering

During 2017, the Company completed a secondary offering in which the Company sold 741,667 shares of common stock and warrants to purchase 333,750 shares of common stock. The Company received approximately $3.9 million in proceeds from the offering, with $3.1 million, net of issuance costs of $0.6 million, allocated to common stock and $0.8 million allocated to the warrants. In association with the warrants that were recorded as a derivative liability, the Company immediately expensed $0.1 million of issuance costs. The warrants became exercisable on the closing date, expire on the five-year anniversary of the closing date, and have an initial exercise price per share equal to $6.60 subject to adjustments for events of recapitalization, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock.

On February 24, 2017, the underwriter in the 2017 secondary offering exercised its option to purchase additional warrants for 30,000 shares of the Company's common stock.

July 2016 Offering

In July 2016, the Company completed a secondary offering in which the Company sold 5,258,000 Class A Units, including 1,650,000 units sold pursuant to the exercise by the underwriters of their over-allotment option, priced at $1.00 per unit, and 7,392 Class B Units, priced at $1,000 per unit. Each Class A Unit consisted of 1/12th share of common stock and one warrant to purchase 1/12th share of common stock. Each Class B Unit consisted of one share of preferred stock convertible into 83 shares of common stock and warrants to purchase 83 shares of common stock. The securities comprising the units were immediately separable and were issued separately. In total, the Company issued 438,167 shares of common stock, 7,392 shares of preferred stock convertible into 616,000 shares of common stock and warrants to purchase 1,054,167 shares of common stock at a fixed exercise price of $12.00 per share. The Company received proceeds of approximately $11.4 million, net of underwriting and other offering costs.

The Company raised $4.9 million associated with the Class A Units, with $2.5 million, net of issuance costs of $0.3 million, allocated to the common stock and $2.4 million allocated to the warrants. The Company also raised $7.0 million associated with the Class B Units with $3.6 million, net of issuance costs of $0.4 million, allocated to preferred stock and $3.4 million allocated to the warrants. The $5.8 million allocated to warrants were recorded as a derivative liability. In association with the warrants that were recorded as a derivative liability, the Company immediately expensed approximately $0.5 million of issuance costs. The 7,392 preferred shares were convertible into 616,000 shares of common stock and had an effective conversion rate of $6.48 per share based on the proceeds that were allocated to them. The stock price on July 8, 2016, was $10.56 per share which resulted in a fair value in excess of carrying value of $4.08 per share or $2.5 million in total. The fair value in excess of carrying value, or beneficial conversion feature, was recorded as an adjustment within equity (e.g., deemed dividend). The Company recorded a non-cash, deemed dividend of $6.3 million ($2.5 and $3.8 million—calculated as $0.4 million in offering costs plus $3.4 million measured as the difference between the stated value and the allocated proceeds) related to a beneficial conversion feature and accretion of a discount on convertible preferred stock.

Subsequent to the secondary offering, all 7,392 shares of convertible preferred stock have been converted into 616,000 shares of common stock. Furthermore, the Company received $0.4 million and issued 37,208 shares of common stock upon the exercise of certain warrants issued in the secondary offering.

9. Stock-Based Compensation

A summary of the Company's outstanding stock option activity for the years ended December 31, 2018 and 2017 is as follows:

	December 31, 2018			
	Options	**Weighted-Average** Exercise Price	**Weighted-Average Remaining Contractual Life** (Years)	Intrinsic Value
Outstanding at December 31, 2017	11,302	$264.26	7.3	$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	(1)	$7,423.20	-	-
Outstanding at December 31, 2018	11,301	$263.85	6.3	$ -
Exercisable at December 31, 2018	10,636	$261.61	7.1	$ -
Vested and expected to vest at December 31, 2018	11,301	$263.85	6.3	$ -

	December 31, 2017			
	Options	**Weighted-Average** Exercise Price	**Weighted-Average Remaining Contractual Life** (Years)	Intrinsic Value
Outstanding at December 31, 2016	11,446	$367.08	8.2	$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	(144)	$8,719.64	-	-
Outstanding at December 31, 2017	11,302	$264.26	7.3	$ -

Exercisable at December 31, 2017	9,835	$287.31	8.3	$ -
Vested and expected to vest at December 31, 2017	11,302	$264.26	7.3	$ -

Total stock-based compensation expense included in the consolidated statements of operations is allocated as follows (in thousands):

	As of December 31,	
	2018	2017
Cost of revenue	$-	$10
Research and development	1	64
General and administrative	22	92
Selling and marketing	19	53
	$42	$219

There was no significant unrecognized stock-based compensation at December 31, 2018 and 2017.

10. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The following is a reconciliation of the expected statutory federal income tax provision to the actual income tax expense:

	December 31,	
	2018	2017
Federal statutory rate	(21.0)%	(35.0)%
State taxes, net of federal benefit	(2.9)%	(5.1)%
Return to provision	0.0 %	(0.2)%
Equity related expenses	(10.7)%	(10.4)%
Change in statutory rate	0.0 %	272.7 %
Change in valuation allowance	17.7 %	(222.1)%
Goodwill impairment	14.7 %	0.0 %
Other permanent differences	2.2 %	0.1 %
Total income tax expense	0.0 %	0.0 %

Significant components of the Company’s deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$46,096	$41,840
Stock-based compensation	2,918	2,907
Inventory reserve	-	2,340
Federal R&D credit	2,222	2,222
Accrued expenses	49	492
Depreciation	-	-
Other	98	108
Total deferred tax assets	51,383	49,909
Deferred tax liabilities:		
Depreciation	(31)	(37)
Intangibles	(134)	(210)

Total deferred tax liabilities	(165)	(247)
Less valuation allowance	(51,352)	(49,796)
Net deferred tax liability	$(134)	$(134)

	December 31,	
	2018	2017
Pre-tax book income at statutory rate	$(1,845)	$(3,265)
State taxes, net of federal benefit	(252)	(479)
Return to provision	4	(21)
Equity related expenses	501	(970)
Changer in statutory rate	-	25,447
Change in valuation allowance	1,556	(20,723)
Other	36	11
Total income tax expense	$-	$-

As of December 31, 2018 and 2017, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $184.8 million and $167.7 million, respectively. The federal and state net operating loss carryforwards will expire from 2023 to 2037, unless previously utilized. Additionally, the Company believes an ownership change has occurred that would trigger the limitation on usage of net operating losses imposed by Internal Revenue Code section 382. Because of this limitation, a significant portion of the net operating losses would more likely than not expire unused.

During the years ended December 31, 2018 and 2017, the Company recognized no amounts related to interest or penalties related to uncertain tax positions. The Company is subject to taxation in the United States and various state jurisdictions. The Company currently has no years under examination by any jurisdiction.

A valuation allowance has been established as realization of such deferred tax assets has not met the more likely-than-not threshold requirement. If the Company’s judgment changes and it is determined that the Company will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be accounted for as a reduction to income tax expense. The tax valuation allowance increased by approximately $1.6 million and decreased by $20.7 million for the years ended December 31, 2018 and 2017, respectively.

Recent Tax Legislation

On December 22, 2017, the Tax Cuts and Jobs Act ("Tax Reform Act") was signed into law by the President of the United States. The Tax Reform Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. federal corporate tax rate from 35% to 21% effective for our calendar year ending December 31, 2018. U.S. GAAP requires that the impact of tax legislation be recognized in the period in which the law was enacted.

The Tax Reform Act reduces the federal corporate tax rate to 21% effective for our calendar year ending December 31, 2018. We recognized the effects of the Tax Reform Act for the re-measurement of the net deferred tax liabilities during the year ended December 31, 2017.

We recognized the income tax effects of the Tax Reform Act in our 2017 financial statements in accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), which provides SEC staff guidance for the application of ASC Topic 740, Income Taxes, in the reporting period in which the 2017 Tax Reform Act was signed into law. The guidance addresses how a company recognizes provision amounts when a company does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the effect of the changes in the Tax Reform Act. As such, the financial results reflect the income tax effects of the Tax Reform Act for which the accounting under ASC Topic 740 is complete and provisional amounts for those specific income tax effects of the Tax Reform Act for which the accounting under ASC 740 is incomplete, but a reasonable estimate could be determined. Pursuant to the SAB 118, we are allowed a measurement period of up to one year after the enactment date of the Tax Reform Act to finalize the recording of the related tax impacts.

11. Commitment and Contingencies

The Company currently leases laboratory, manufacturing and office space and equipment under noncancelable operating leases which provide for rent holidays and escalating payments; this lease ends 2019. Lease incentives, including rent holidays, allowances for tenant improvements and rent escalation provisions, are recorded as deferred rent. Rent under operating leases is recognized on a straight-line basis beginning with lease commencement through the end of the lease term. Sublease income is recorded as a reduction of rent expense. For each of the years ended December 31, 2018 and 2017, rental expense was $1.0 million and $1.0 million, respectively. Sublease income was $0.1 million and $0.1 million during both of the years ended December 31, 2018 and 2017.

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2018 are $980,000, which is due during 2019.

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The Company has executed agreements with certain executive officers of the Company which, upon the occurrence of certain events related to a change in control, call for payments to the executives up to three times their annual salary and accelerated vesting of previously granted stock options.

From time to time, the Company is subject to various claims and legal proceedings covering matters that arise in the ordinary course of its business activities. Management believes any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on the Company's consolidated financial position, operating results or cash flows.

12. 401(k) Plan

Effective June 1, 2004, the Company adopted a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. Eligible employees may contribute amounts to the plan, via payroll withholdings, subject to certain limitations. The plan permits, but does not require, additional matching contributions to the plan by the Company on behalf of the participants in the plan. The Company incurred approximately $0.1 million relating to retirement contributions for each of the years ended December 31, 2018 and 2017.

13. Note Receivable

On October 1, 2018, the Company completed the sale of its spine business to CTL Medical. The sale included a $6 million noninterest bearing note receivable. The 36-month term of the note receivable requires 18 payments of $138,889 followed by 18 payments of $194,444, with maturing of the note receivable on October 1, 2021. The note receivable includes an imputed interest rate of 10%, which totaled $915,725 as of October 31, 2018, and has a 36-month amortization. As of December 31, 2018, the net carrying value of the note receivable was $4.8 million.

14. Discontinued Operations

As explained in Note 1, on October 1, 2018, the Company completed the sale of its retail spine business to CTL Medical The gain on the sale of the retail spine business is estimated to approximate $1.4 million, which was recognized during the quarter ended December 31, 2018.

The Company and CTL Medical entered in an asset purchase agreement whereby CTL Medical agreed to acquire all of the Company's commercial spine business for total consideration of $8.5 million, which includes a $6.0 million (including interest) note receivable (See Note 13) and CTL Medical's assumption of the Company's $2.5 million related party note payable (see Note 8). As a result of the closing, CTL Medical is now the exclusive owner of Amedica's portfolio of metal and silicon nitride spine products, which are presently sold under the brand names of Taurus, Preference, and Valeo, with access to future silicon nitride spine technologies. The Company has agreed to pay the cost, if any, to re-sterilize and re-package select silicon nitride spinal inventories sold to CTL Medical if the sterilization date expires prior to CTL Medical selling the inventories to a third-party customer. The Company estimates the sterilization and repackaging cost to approximate $0.5 million. Manufacturing, R&D, and all intellectual property related to the core, non-spine, biomaterial technology of silicon nitride remains with the Company in Salt Lake City. The Company will serve as CTL's exclusive OEM provider of silicon nitride products.

Assets and liabilities held for sale consisted of the following:

	September 30, 2018	December 31, 2017
Assets		
Current assets held for sale:		
Retail spine inventory, net	$ 1,708	$ 1,602
Long-term assets held for sale:		
Property and equipment, net	959	1,162
Intangible assets, net	2,249	2,651
Total assets	$ 4,916	$ 5,415
Liabilities		
Current liabilities held for sale:		
Debt – related party	$ 2,500	$ 2,356

Operating results related to discontinued operations consisted of the following:

	Year Ended December 31,	
	2018	2017
Product revenue	$6,222	$11,227
Costs of revenue	1,474	6,351
Gross profit	4,748	4,876
Operating expenses:		
Research and development	1,524	1,571
General and administrative	190	726
Sales and marketing	3,358	6,147
Total operating expenses	5,072	8,444
Loss from discontinued operations	$(324)	$(3,568)

During the nine-months ended September 30, 2018 and year ended December 31, 2017, the Company only recorded product revenues and cost of revenues related to the spine business. Because of the sale of the retail spine business to CTL Medical, all product revenues and costs of product revenues for these periods have been removed from the consolidated statements of operations. The only product revenues and cost of product revenues recorded in the statement of operations for the years ended December 31, 2018 and 2017, related to the three months ended December 31, 2018, which was subsequent to the sale of the spine business to CTL Medical.