

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2020

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.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

84-1375299
(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	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.01 par value	SINT	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

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

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

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

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

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 \$46,889,587.

The number of shares outstanding of the registrant's common stock, \$0.01 par value per share, as of March 17, 2021 was 24,684,574.

DOCUMENTS INCORPORATED BY REFERENCE:

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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”, “the Company”) has tried to identify forward-looking statements by using words such as “believe,” “may,” “might,” “could,” “will,” “aim,” “estimate,” “continue,” “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-30 reverse split which was effected on July 26, 2019.

Our business operations are subject to numerous risks, factors and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following:

Risks Related to Our Business and Strategy

- A pandemic, epidemic or outbreak of an infectious disease may adversely affect our business.
- We have incurred net losses since our inception and may never achieve or sustain profitability.
- Our success depends on our ability to successfully commercialize silicon nitride-based products for medical and industrial applications, which to date have experienced only limited market acceptance.
- Our current products and our future products may not be accepted by hospitals and surgeons and may not become commercially successful.
- We may not be able to compete effectively against the larger, well-established companies that dominate this market or emerging and small innovative companies seeking to increase their share of the market.
- We depend on CTL Medical's ability to sell the spinal fusion products we manufacture. If CTL Medical is not able to sell such products, our business and operating results will be adversely affected.
- 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.
- We depend on a limited number of third-party suppliers for key raw materials, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.
- We may not be able to successfully commercialize new silicon nitride-based medical device product candidates or identify other non-medical uses of silicon-nitride.
- 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.
- Part of our strategy is to establish and develop OEM partnerships and arrangements, which subjects us to various risks.
- 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.
- Prolonged negative economic conditions in domestic and international markets may adversely affect us and the global orthopedic market which could harm our financial position.
- We are dependent on our senior management team, engineering team, and external 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.
- If we experience significant disruptions in our information technology systems, our business, results of operations and financial condition could be adversely affected.
- Cyber security risks and the failure to maintain the integrity of company, employee or guest data could expose us to data loss, litigation and liability, and our reputation could be significantly harmed.

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.
- Raising additional capital by issuing securities or through debt financings or licensing arrangements may dilute existing stockholders, restrict our operations or require us to relinquish proprietary rights.
- In previous years we have indicated that there was substantial doubt as to our ability to continue as a going concern. Depending on the results of our future operations, we may again have substantial doubt as to our ability to continue as a going concern.

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

- We cannot be certain that we will be able to obtain regulatory clearance or approval and thereafter commercialize our product candidates in a timely manner or at all.
- 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 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.
- 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 various laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm administrative burdens and diminished profits and future earnings.
- U.S. federal income tax reform could adversely affect us.
- 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.

Risks Related to Our Intellectual Property and Litigation

- If our patents, trade secrets and contractual provisions are inadequate to protect our intellectual property, we may not be able to successfully our products or operate our business profitably.
- We have no patent protection covering the composition of matter for our solid silicon nitride or the related manufacturing process, and competitors may create formulations substantially similar to ours.
- We could become subject to intellectual property litigation that could be consume significant amounts of our resources and adversely affect our business and results of operations.
- We may be subject to damages resulting from claims that we 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.
- 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.

Risks Related to Potential Litigation from Operating Our Business

- We may become subject to potential product liability claims or claims relating to our improper handling, storage or disposal of biological or hazardous materials, which could be time consuming and costly.

Risks Related to Our Common Stock

- The price of our common stock is volatile and is likely to continue to fluctuate.
- 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.
- Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.
- We do not intend to pay cash dividends.

- Our outstanding shares of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock and our outstanding common stock warrants are convertible and exercisable into shares of our common stock and when converted or exercised, the issuance of additional shares of common stock may result in downward pressure on the trading price of our common shares.

Risks Related to Public Companies

- We are a “smaller reporting company” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.
- We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.
- 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.

PART I

ITEM 1. BUSINESS

Overview – SINTX Technologies

We are an advanced materials company focused on providing ceramic based solutions in a variety of medical, industrial, and antipathogenic applications. Prior to 2020, our primary focus has been the research, development and commercialization of medical implant products manufactured with silicon nitride. The discovery in 2020 that SINTX silicon nitride kills SARS-CoV-2, the virus which causes the disease COVID-19, has opened up new markets and applications for our material and we have refocused many of our resources on these opportunities.

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 35,000 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, Taiwan, 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 commercial partners in other parts of the world 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 enabled us to focus on our core competencies. These core competencies are research and development of silicon nitride and the design and manufacture of medical and nonmedical products manufactured from silicon nitride for our own account and in collaboration with other 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 personal protective equipment, 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.

Our grade of silicon nitride is of a very high quality and is well suited for a wide variety of applications that would benefit from its mechanical, thermal, and chemical properties. We have several commercial partnerships and have opportunities ranging from low-volume, highly engineered components to high-volume simple shapes. In 2020, we fulfilled the first non-medical orders for prototypes in the Company’s history.

Since at least 2012, we have been aware of the antibacterial properties of SINTX silicon nitride. This knowledge played an important role in our desire to expand the use of our silicon nitride into non-spine medical device implants. The 2020 discovery that our silicon nitride is also antiviral and kills SARS-CoV-2 dramatically expanded the range of potential applications for this material into non-medical applications. As a result, we have now pivoted from primarily manufacturing discrete components for third parties and are now adding powder manufacturing capabilities and resources. We are currently working with partners in the mask and consumer products industries to incorporate our silicon nitride into their products to enhance the antipathogenic properties of those products. To that effect, in February 2021 we entered into a Patent License Agreement (the “Agreement”) with O2 Design, Inc. (“O2 Design”), to commercialize face masks and mask filters that incorporate the Company’s sintered silicon nitride intended to inactivate the SARS-CoV-2 virus. Under the terms of the Agreement, the Company granted O2 Design an exclusive world-wide license under certain of the Company’s patents to make, use, and sell face masks and mask filters incorporating the Company’s proprietary silicon nitride materials for the purpose of enhancing the anti-viral properties of the face masks and mask filters, in partial consideration of an upfront fee by O2 Design, royalties on the sale of face masks and mask filters incorporating silicon nitride materials and potential performance-based milestone payments.

We operate a 30,000 square foot manufacturing, laboratory and administrative 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-registered and ISO 13485:2016 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 spine implant 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.

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- *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 doorknobs 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
- *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.

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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 130 peer reviewed publications and presentations 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.

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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

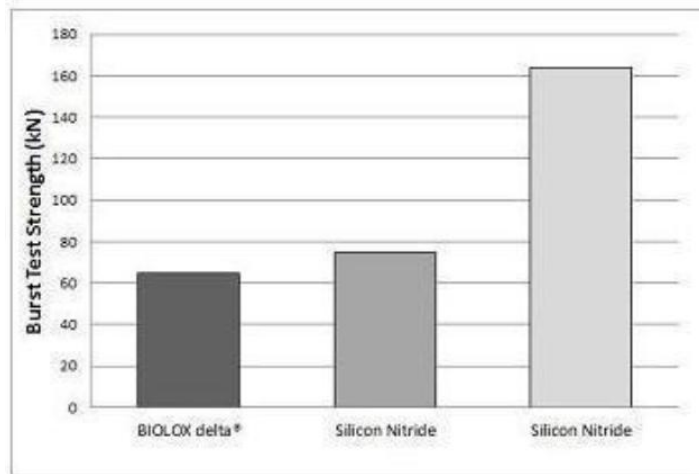
Material	Hardness (GPa)(1)	Strength (MPa)(1)	Fracture Resistance (MPam ^{1/2})(1)
Silicon Nitride	13 – 16	800 – 1200	8 – 11
Aluminum Oxide Ceramic	14 – 19	300 – 500	3 – 5
Zirconia-Toughened Alumina Ceramic	12 – 19	700 – 1150	5 – 10
PEEK	0.09 – 0.28	160 – 180	2 – 3
Highly-Cross-Linked Polyethylene Polymer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



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. The antibacterial attributes of silicon nitride have been confirmed by independent authors from China and Europe as well.

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 calicivirus, Enterovirus, and SARS-CoV-2 (the virus responsible for COVID-19). The Company has received positive testing results from independent studies that demonstrate the potential anti-viral properties of our silicon nitride. The results suggest that silicon nitride may be useful in the reduction of the spread of COVID-19. The study results demonstrated that our unique grade of silicon nitride inactivates the SARS-CoV-2 virus within a minute after exposure and has the potential to decrease the risk of viral disease spread on surfaces. Studies have shown that coronavirus spreads between humans when an infected person coughs or sneezes. Also, the virus can remain active on a variety of commonly touched surfaces for hours to days. We believe that by incorporating our unique composition of silicon nitride into products such as face masks, and personal protective equipment, it is possible to manufacture surfaces that inactivate viral particles, thereby limiting the spread of the disease. We envision incorporating our silicon nitride into high-contact surfaces such as medical equipment, screens, countertops, and doorknobs in locations where viral persistence is a concern, such as homes, casinos, and cruise ships. We believe this antiviral discovery will open many new opportunities for us. In composites, coatings, and mixtures, silicon nitride has maintained its antibacterial and osteogenic properties, even at small fractions. We believe that incorporating our material into a variety of commonly touched surfaces may discourage viral spread and contribute to global health by reducing the risk of disease.

Antifungal: 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 30,000 square foot corporate facility includes an 18,000 square foot FDA registered and ISO 13485:2016 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 exception of raw material production 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.



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- *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.



- *Silicon Nitride Powder.* We can produce silicon nitride powder that is osteogenic and antipathogenic. This powder can then be utilized to produce composites or coatings.



- *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.



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We believe we can use our silicon nitride technology platform to become a leading advanced ceramic 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.* We operate an 18,000 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 13485:2016 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 components.
- *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 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 silicon nitride products into multiple industries. We also collaborate with a network of leading technical 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:

- *Develop new products with anti-viral properties, including inactivation of the SARS-CoV-2 virus, utilizing our silicon nitride technology.* We have entered into a commercialization agreement with O2 DESIGN for the purpose of developing and commercializing a face mask with anti-viral properties. Should we be successful in developing such a face mask, we expect to supply O2 DESIGN'S requirements for silicon nitride powder in the manufacture of the face masks as well as earn royalties and milestone payments on sales of masks that incorporate our technology. We are also pursuing other opportunities for the potential application of our technology in other personal protective equipment and products.
- *Develop additional commercial opportunities outside of the spine implant market.* The Company made the first shipments of non-medical products in its history in 2020. These were primarily prototype orders and we expect some of these to transition into regular production orders. Furthermore, the potential use of the Company's silicon nitride in antipathogenic applications has opened up the potential to enter many new markets.
- *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.

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- *Apply our silicon nitride technology platform to 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 OEM and private label partnerships. We see specific opportunities in markets such as dental, maxillofacial, total hip and knee joint replacements, bearings, automotive and aerospace components, cutting tools, and antipathogenic devices such as masks and high-contact surfaces.

Market Opportunity

Overview

We believe our silicon nitride biomaterial technology platform provides us with numerous competitive advantages in the biomaterials market. We manufacture interbody spinal fusion devices for CTL Amedica, and have a 10-year exclusive right to continue to manufacture them for CTL Amedica. We are developing products on our own behalf and for third party manufacturers – including CTL - 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 medical 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 Amedica are:

Valeo Interbody Fusion Devices

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

Silicon Nitride – Polyetheretherketone (PEEK) composite material (SN-PEEK)

SN-PEEK is an innovative material platform that combines the best of two materials that are used to make spinal fusion implants, i.e., silicon nitride and PEEK. Clinical and basic science data demonstrate that our silicon nitride facilitates faster bone healing, improves radiographic imaging, avoids metal ion release in the body, and has broad-spectrum resistance to infection. PEEK is an accepted standard polymeric biomaterial that is used worldwide, especially by spine surgeons. This material is produced by compounding an extremely fine particulate form of our Si₃N₄ bioceramic into an implant grade PEEK matrix. Subsequent forming operations produce new surfaces with the same enhanced properties as the original PEEK stock composite, giving device manufacturers design and process flexibility when working with this material. PEEK’s advantages include its low cost, favorable material modulus, ease of manufacturing, established clinical record, and a familiar fit and feel. The most immediate biomedical applications of this product are expected to be in the spine and craniomaxillofacial medical device markets, with other applications to follow. We are exploring OEM opportunities for this product.

Personal Protective Equipment (PPE)

We believe that there is the opportunity for significant growth in the personal protective equipment or PPE market for products that are shown to have antiviral properties. The Company has demonstrated in controlled research studies the anti-viral properties of its silicon nitride which may be useful in the reduction of the spread of COVID-19 and other pathogens. The study results demonstrated that our unique grade of silicon nitride inactivates the SARS-CoV-2 virus within a minute after exposure and has the potential to decrease the risk of viral disease spread on surfaces. Studies have shown that coronavirus spreads between humans when an infected person coughs or sneezes. Also, the virus can remain active on a variety of commonly touched surfaces for hours to days. We believe that by incorporating our unique composition of silicon nitride into products such as face masks and personal protective equipment, it is possible to manufacture surfaces that inactivate viral particles, thereby limiting the spread of the disease. We envision incorporating our silicon nitride into high-contact surfaces such as medical equipment, screens, countertops, and doorknobs in locations where viral persistence is a concern, such as homes, casinos, and cruise ships. To that effect, we have successfully dispersed and embedded silicon nitride particles into nonwoven and woven fabric fibers.

The first area of focus for application of our unique silicon nitride powder is in face masks and face mask filters. Face masks used by healthcare workers today can capture virus particles, but the virus can remain viable in the mask, even as long 7 days after use. Inclusion of silicon nitride technology into the mask may enhance personal safety while reducing the risk of disease spread. To that effect, we announced in August 2020 that we entered into a joint development agreement with Salt Lake City, Utah based O2 DESIGN, an original equipment manufacturer company who develops and commercializes face masks for medical and non-medical applications, to develop a safe and effective consumer face mask with broad-spectrum antibacterial and antiviral activity, based on incorporating our unique silicon nitride powder into the mask filter and fabric. In February 2021 we entered into a worldwide exclusive worldwide licensing agreement with O2 DESIGN for the purpose of commercializing face masks and mask filters incorporating our silicon nitride technology. We expect the face mask and filters will inactivate pathogens in the fabric itself, therefore reducing the spread of viral diseases and effectively fighting against COVID-19. The February 2021 license agreement includes a license fee, a commercial agreement on silicon nitride sales, and royalties based upon product sales of the masks and filters.

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 a 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. We have engaged an investment banker to assist us in identifying partner companies for our technologies.

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. 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. 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.

We also see a wide variety of opportunities for our silicon nitride technology platform in non-medical applications. To that effect, we have begun applying our technology to the manufacture of products for several third-party ceramic companies which we are hopeful will result in commercial partnerships with opportunities ranging from low-volume, highly engineered components to high-volume simple shapes.

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.

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We have thirteen issued U.S. patents, one foreign patent, four pending U.S. non-provisional patent applications, ten pending U.S. provisional patent applications, twenty-five pending foreign applications and four pending PCT patent applications. 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 will expire in 2022 and 2035, respectively.

With respect to PCT patent application serial no. PCT/US2018/014781 directed to antibacterial biomedical implants, we entered the national stage in Europe, Australia, Brazil, Canada, China, Japan, Hong Kong, and South Korea as well as two divisional patent applications filed in Australia and Japan in order to seek potential patent protection for our proprietary technologies in those countries.

With respect to PCT patent application serial no. PCT/US2019/026789 directed to methods for improving the wear performance of ceramic-polyethylene or ceramic-ceramic articulation couples utilized in orthopaedic joint prostheses, we entered the national stage in Australia, Brazil, Canada, Europe, Japan, Korea, and Mexico in order to seek proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2019/048072 directed to antipathogenic devices and methods, we entered the national stage in Europe, Japan, Mexico, Australia, Brazil, Canada, South Korea, China and India in order to seek proprietary technologies in those countries. A patent license agreement was executed between SINTX Technologies and O2 Design on February 19, 2021 that provides a royalty-bearing exclusive license to make, have made, use, and sell the licensed invention claimed in PCT application serial no. PCT/US2019/048072 as well as the related U.S. patent application serial no. 16/550,605.

In relation to the sale of our spine implant business to CTL Medical under the Asset Purchase Agreement dated September 5, 2018 we assigned our entire right to forty eight (48) U.S. patents, two (2) foreign patents and three (3) pending patent applications from our patent portfolio to CTL Medical under that transaction. In addition, three (3) U.S. patents (U.S. patent nos. 9,399,309; 9,517,136; and 9,649,197) directed to silicon nitride manufacturing processes were licensed to CTL Medical under an irrevocable, fully paid-up, worldwide license for a ten year term with CTL Medical also having a Right of First Negotiation to acquire these patents if SINTX decides to later sell these IP assets to a third party. The previously listed licensed patents under Schedule A that were licensed to SINTX (Amedica) by the Dr. Jackson and SMS Trust pursuant to a license agreement between the parties has been assigned to CTL Medical as part of the sale of the spine implant business.

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, antibacterial, antifungal, and antiviral compositions, devices, and methods.

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.

Licenses and Agreements

In February 2021 we entered into the Agreement with O2 Design, to commercialize face masks and mask filters that incorporate the Company's sintered silicon nitride intended to inactivate the SARS-CoV-2 virus. Under the terms of the Agreement, the Company granted O2 Design an exclusive world-wide license under certain of the Company's patents to make, use, and sell face masks and mask filters incorporating the Company's proprietary silicon nitride materials for the purpose of enhancing the anti-viral properties of the face masks and mask filters, in partial consideration of an upfront fee by O2 Design, royalties on the sale of face masks and mask filters incorporating silicon nitride materials and potential performance-based milestone payments. The Agreement also contains certain commercial diligence milestones with respect to timing for development of the face mask and minimum net sales to be met in order to retain the exclusive license to the Company patents.

The Company will be the exclusive supplier of silicon nitride to O2 Design. The Company has agreed to supply to O2 Design its commercially reasonable requirements of the Company's sintered silicon nitride powder (the "Material"). The Company has agreed to exercise commercially reasonable efforts to manufacture the Material more efficiently and to pass on any savings to O2 Design. The parties agreed to enter into a commercially standard supply agreement ("Supply Agreement") within 30 days of execution of the Agreement. The Supply Agreement will address, among other things, reasonable forecasting requirements and commitments, requirements, and specifications relating to the delivery of the Material, shipping requirements, product acceptance, rejection and returns, recalls, quality control and assurance, regulatory matters, returns, liability, indemnification, and other topics addressed in industry standard supply agreements for comparable types of products to be used in the medical industry.

O2 Design has agreed to indemnify the Company, and hold harmless and defend the Company and its officers, directors, trustees, employees and agents against any and all claims, suits, losses, damages, costs, liabilities, fees and expenses based on, resulting from or arising out of: (i) the exercise of any license granted under the Agreement; and, (ii) any act, error or omission of O2 Design, or its officers, directors, employees or agents, including any breach of the Agreement, any claim or negligent acts or omissions or misconduct, and product liability claim to the extent any such claims result from grossly negligent acts or omissions or willful misconduct.

Unless earlier terminated, the Agreement will expire on February 18, 2023. The Company may terminate the Agreement if O2 Design should: (a) fail to deliver to the Company any statement or report required when due; (b) fail to make any payment at the time that the same should be due; (c) violate or fail to perform any material covenant, condition, or undertaking of the Agreement to be performed by it; (d) cease use of commercially diligent efforts to commercialize a product; (e) file a bankruptcy action, or have a bankruptcy action against it, or become insolvent; or (f) enter into a composition with creditors, or have a receiver appointed for it. The Company may give written notice of such default to O2 Design. If O2 Design should fail to cure such default within ninety (90) days of such notice, the rights, privileges, and license granted under the Agreement will automatically terminate. Additionally, if O2 Design ceases to carry on its business with respect to the rights granted in the Agreement, the Agreement will terminate upon thirty (30) days written notice by the Company. No termination of this Agreement by the Company will relieve O2 Design of its obligation to pay any monetary obligation due or owing at the time of such termination and shall not impair any accrued right of the Company.

O2 Design may terminate this Agreement, in whole or as to any specified patent, at any time and from time to time without cause, by giving written notice thereof to the Company. Such termination shall be effective one hundred twenty (120) days after such notice and all O2 Design's rights associated therewith shall cease as of that date. Any termination by O2 Design will not relieve O2 Design of any obligation or liability accrued hereunder prior to such termination or rescind or give rise to any right to rescind any payments made or other consideration given to the Company prior to the time such termination becomes effective.

Upon expiration or termination of the Agreement by either party, O2 Design will provide Company with a written inventory of all product in process of manufacture, in use or in stock. O2 Design may dispose of any such product within the ninety (90) day period following such expiration or termination, provided, however, that O2 Design will pay royalties and render reports to Company in the manner specified in the Agreement.

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 of 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 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.

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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.

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.

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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. Further, beginning January 1, 2021 and over the

course of a three-year period, CMS will eliminate the inpatient only list for Medicare which will result in all spine procedures being payable in the outpatient setting. Reimbursement levels in the hospital outpatient and ASC settings are typically lower than for the hospital inpatient setting and may not be adequate to cover the cost of innovative and novel medical devices.

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 March 1, 2021, we had 32 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

A pandemic, epidemic or outbreak of an infectious disease in the United States or elsewhere may adversely affect our business.

We continue to monitor the rapidly evolving situation and guidance from domestic and international authorities, including federal, state and local public health authorities, regarding the COVID-19 pandemic, and we may need to make changes to our business based on their recommendations. In these circumstances, there may be developments outside our control requiring us to adjust our operating plan. Although the Company cannot reasonably estimate the length or severity of the impact that the pandemic will have on its financial results, the Company has experienced, and may continue to experience, a material adverse impact on its sales, results of operations, and cash flows in fiscal 2021.

A significant outbreak in the future of contagious diseases, such as COVID-19, could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn. As a result, our ability to raise additional funds, if necessary, may be adversely impacted by risks, or the public perception of the risks, related to the recent outbreak of COVID-19. Furthermore, the third parties we engage, or seek to engage, with respect to OEM manufacturing relationships, and, for supply and development activities, may be adversely impacted by risks, or the public perception of the risks, related to the recent outbreak of COVID-19, which may delay OEM relationships, and, product development opportunities, and increase our costs.

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, 2020 and 2019 we incurred a net loss of \$7.0 million and \$4.8 million, respectively, and used cash in operations of \$9.1 million and \$6.4 million, respectively. We have an accumulated deficit of \$241.1 million as of December 31, 2020. 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 products for medical and industrial applications, 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 prior to the disposition of our spine implant business to CTL, our product revenue was 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, successfully work together with O2 DESIGN on the development and commercialization of an anti-viral face mask and mask filter, 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 implant business to CTL we are now dependent on the efforts of CTL to sell the spinal fusion products that we manufacture and then sell to CTL. If CTL is not able to sell such products or is unable to 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 have not been able to obtain significant market share of the interbody spinal fusion market, and CTL may not obtain such market share in the future. Additionally, if successful in developing a face mask and mask filters with antiviral properties with O2 DESIGN, we will be dependent on O2 DESIGN's ability to successfully market and sell face masks and mask filters. As a result, our future revenues will also be dependent on O2 DESIGN. 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.

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; Zimmer-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;

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- 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 dependent on CTL's ability to sell the spinal fusion products we manufacture from silicon nitride. If CTL 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 account for all our revenues from the sale of products. We have entered into a 10-year manufacturing and supply agreement with CTL to supply CTL with its requirements of silicon nitride manufactured spinal fusion products. CTL is not under any obligation to purchase any minimum quantities of products from us. If CTL 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. A reduction or delay in orders from CTL, or a delay or default in payment by any significant customer, could materially harm our business and results of operations.

We are dependent on O2 DESIGN's ability to sell face mask products manufacture with silicon nitride. If O2 DESIGN 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.

We have entered into a two-year exclusive worldwide patent license agreement with O2 DESIGN giving the exclusive right to O2 DESIGN to commercialize face masks and mask filters that incorporate our silicon nitride technology. If O2 DESIGN is not successful in creating demand for such products and selling such products, our revenue could fluctuate significantly due to changes in economic conditions, the use of competitive products, future revenues will be adversely impacted. Failure of O2 DESIGN to successfully commercialize face masks and filters 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 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 exception of raw material production are performed at this facility.

We are the sole manufacturer of our silicon-nitride based products. 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 by commercializing new silicon nitride-based medical device product candidates and identify other non-medical uses of silicon-nitride, 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, and have entered into a commercialization agreement with O2 DESIGN to commercialize face masks and filters incorporating our silicon nitride technology, in order to be successful, we will need to expand our product lines to include other silicon nitride devices and products for both medical and non-medical applications. Therefore, we are developing silicon nitride product candidates for total hip and knee replacement procedures, dental implants, personal protective equipment, and are exploring the application of our silicon nitride technology for other potential applications. 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 and industrial applications, 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."

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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, former 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, former 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.

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We are dependent on our senior management team, engineering team, and external 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 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 external 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.

Cyber security risks and the failure to maintain the integrity of company, employee or guest data could expose us to data loss, litigation and liability, and our reputation could be significantly harmed.

We collect and third parties collaborating on our clinical trials collect and retain large volumes of data, including personally identifiable information regarding clinical trial participants and others, for business purposes, including for regulatory, research and development and commercialization purposes, and our collaborators' various information technology systems enter, process, summarize and report such data. We also maintain personally identifiable information about our employees. The integrity and protection of our company, employee and clinical data is critical to our business. We are subject to significant security and privacy regulations, as well as requirements imposed by government regulation. Maintaining compliance with these evolving regulations and requirements could be difficult and may increase our expenses. In addition, a penetrated or compromised data system or the intentional, inadvertent or negligent release or disclosure of data could result in theft, loss or fraudulent or unlawful use of company, employee or clinical data which could harm our reputation, disrupt our operations, or result in remedial and other costs, fines or lawsuits.

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, 2020 was \$25.4 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.

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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.

In previous years we have indicated that there was substantial doubt as to our ability to continue as a going concern. Depending on the results of our future operations, we may again have substantial doubt as to our ability to continue as a going concern.

If we seek additional financing to fund our business activities, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. If we seek additional funds and 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. Our future reports may disclose our doubt about our ability to continue as a going concern.

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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 spinal fusion products, spinal fusion product candidates, dental implant products, 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, 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. 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, former 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

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:

- 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, former 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, former 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 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 marketplace 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 or 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.

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We may be subject to damages resulting from claims that we 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.

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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.

General Risk Factors

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

The volatility of publicly traded 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:

- the sentiment of retail investors (including as may be expressed on financial trading and other social media sites and online forums);
- the direct access by retail investors to broadly available trading platforms;
- the amount and status of short interest in our securities;
- access to margin debt;
- trading in options and other derivatives on our common stock and any related hedging;
- CTL's ability to sell silicon nitride based spinal fusion products and our cost of manufacturing such products for CTL;
- 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;

- our ability to develop products that are effective in inactivating the SARS-CoV-2 virus;
- O2 DESIGN's ability to commercialize face masks and mask filters incorporating our silicon nitride technology;
- 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 our 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 been 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.

Our outstanding shares of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock and our outstanding common stock warrants are convertible and exercisable into shares of our common stock and when converted or exercised, the issuance of additional shares of common stock may result in downward pressure on the trading price of our common shares.

We have outstanding shares of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock that are each convertible into shares of common stock. We believe that as such holders convert their preferred shares into common shares, they will immediately sell their shares of common stock. The sale of such shares of common stock may result in downward pressure on the trading price of our common stock resulting in a lower stock price. Additionally, we have outstanding warrants to purchase shares of common stock. Many of these warrants have a cashless exercise provision that if exercised may also result in downward pressure on the trading price of our common stock and cause such price to decline.

Risks Related to Public Companies

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are currently a "smaller reporting company" as defined in the Securities Exchange Act of 1934. 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.

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.

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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 30,000 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 2024. 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.

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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:

	2020	
	High	Low
First Quarter	\$ 3.24	\$ 0.28
Second Quarter	\$ 3.13	\$ 0.34
Third Quarter	\$ 3.30	\$ 1.34
Fourth Quarter	\$ 2.25	\$ 1.55
	2019	
	High	Low
First Quarter	\$ 10.47	\$ 4.80
Second Quarter	\$ 7.20	\$ 2.25
Third Quarter	\$ 4.39	\$ 1.25
Fourth Quarter	\$ 2.78	\$ 1.38

Prices listed are adjusted to reflect the July 26, 2019 reverse stock split.

Holders of Record

As of March 1, 2021, we had approximately 157 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.

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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 an advanced materials company that develops and commercializes silicon nitride for medical and non-medical applications. The core strength of SINTX Technologies is the manufacturing, research, and development of silicon nitride ceramics for external partners. 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.

Additionally, we received positive results from an independent study that demonstrated the potential anti-viral properties of our silicon nitride. The results suggest that silicon nitride may be useful in the reduction of the spread of COVID-19. The study results demonstrated that our unique grade of silicon nitride inactivates the SARS-CoV-2 virus within a minute after exposure and has the potential to decrease the risk of viral disease spread on surfaces. Studies have shown that coronavirus spreads between humans when an infected person coughs or sneezes. Also, the virus can remain active on a variety of commonly touched surfaces for hours to days. We believe that by incorporating our unique composition of silicon nitride into products such as face masks, and personal protective equipment, it is possible to manufacture surfaces that inactivate viral particles, thereby limiting the spread of the disease. We envision incorporating our silicon nitride into high-contact surfaces such as medical equipment, screens, countertops, and doorknobs in locations where viral persistence is a concern, such as homes, casinos, and cruise ships. We believe this anti-viral discovery will open many new opportunities for us. In composites, coatings, and mixtures, silicon nitride has maintained its antibacterial and osteogenic properties, even at small fractions. We believe that incorporating our material into a variety of commonly touched surfaces may discourage viral spread, and contribute to global health by reducing the risk of disease. 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 35,000 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 Amedica and now manufacture spine implants made with silicon nitride for CTL. Prior to selling our spine implant business to CTL, 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 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 to establish commercial partners in other parts of the world 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 enables us to now focus on our core competencies. These include 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 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, bearings, automotive and aerospace components, cutting tools, and a wide range of antipathogenic applications. Existing biomaterials, based on plastics, metals, and bone grafts have well-recognized limitations that we believe are addressed by silicon nitride.

We believe that silicon nitride addresses many of the biomaterial-related limitations in medical related 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, other medical disciplines, as well as commodity items such as industrial fasteners, bushings, and valves to addressing more complex demands of hypersonic missile radomes, aerospace, air-conditioning systems, beverage dispensers, touch-screen glass, and agribusiness fungicides. During 2020, the Company shipped multiple small quantity orders of industrial products totaling \$33 thousand.

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, with whom we entered into a 10-year exclusive sales agreement in October 2018. We are currently pursuing other sales opportunities for silicon nitride products outside the spinal fusion application and have shipped new orders for these products. We generally recognize revenue from sales where control transfers at a point in time as the title and risk of loss passes to the customer, which is at the time the product is shipped. In general, our customer does not have rights of return or exchange.

We believe our product revenue will increase as CTL 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.

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Gross Profit

Our gross profit measures our product revenue relative to our cost of revenue. We expect our gross profit percentage 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 implant 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 our gross profit percentage.

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, product candidates for total joint replacements, dental applications, and other products 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, 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, 2020 Compared to the Year Ended December 31, 2019

The following table sets forth, for the periods indicated, our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		\$ Change	% Change
	2020	2019		
Product revenue	\$ 594	\$ 689	\$ (95)	-14%
Costs of revenue	475	551	(76)	-14%
Gross profit	119	138	(19)	-14%
Operating expenses:				
Research and development	4,808	3,394	1,414	42%
General and administrative	3,132	2,908	224	8%
Sales and marketing	683	430	253	59%
Total operating expenses	8,623	6,732	1,891	28%
Loss from operations	(8,504)	(6,594)	(1,910)	29%
Other income, net	1,475	1,797	(322)	-18%
Net loss before income taxes	(7,029)	(4,797)	(2,232)	47%
Provision for income taxes	-	-	-	N/A
Net loss	(7,029)	(4,797)	(2,232)	47%
Deemed dividend related to beneficial conversion feature and accretion of discount on convertible preferred stock	(9,565)	(2,703)	(6,862)	254%
Net loss attributable to common stockholders	\$ (16,594)	\$ (7,500)	\$ (9,094)	121%

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Product Revenue

Total silicon nitride revenue was \$0.6 million in 2020 as compared to \$0.7 million in 2019, a decrease of \$0.1 million or 14%. This decrease was primarily due to a decrease in orders from CTL.

Costs of Revenue and Gross Profit

The Company's cost of revenue decreased \$0.1 million, or 14%, as compared to the same period in 2019. Gross profit was approximately the same as compared to the same period in 2019. Cost of revenue decreased as a result of decreased revenue due to a decrease in orders from CTL.

Research and Development Expenses

Research and development expenses increased \$1.4 million, or 42%, as compared to the same period in 2019. This increase was primarily attributable to an overall increase in R&D activity to support the Company's strategic objective of developing new technologies and related products.

General and Administrative Expenses

General and administrative expenses increased \$0.2 million, or 8%, as compared to the same period in 2019. This increase is largely due to an increase in franchise tax from the prior year.

Sales and Marketing Expenses

Sales and marketing expenses increased \$0.3 million, or 59%, as compared to the same period in 2019. This increase was primarily attributable to an overall increase in marketing activities to generate interest in and exposure to the Company's potential new product lines.

Deemed Dividends

Deemed dividends related to a beneficial conversion feature and accretion of discount on convertible preferred stock was recorded at \$9.6 million in 2020, compared to \$2.7 million for 2019. A beneficial conversion amount was calculated in association with the 2020 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. The accretion of a discount related to the actual conversion of the preferred stock into common stock. During 2020, 9,612 shares of the preferred stock were converted to common stock and 3,825 shares of the preferred stock were converted to common stock during 2019.

Other Income (Expense), Net

Other income decreased \$0.3 million, or 18%, as compared to the same period in 2019. This decrease was primarily due to offering costs in the amount of \$1.2 million, and a decrease in interest income of \$0.1 million offset by the increase in the change in the fair value of the derivative liabilities in the amount of \$0.8 million and the increase in the loss on the extinguishment of derivative liabilities of \$0.2 million.

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, 2020 and 2019, the Company incurred a net loss of \$7.0 million and \$4.8 million, respectively, and used cash in operations of \$9.1 million and \$6.4 million, respectively. The Company had an accumulated deficit of \$241.1 million and \$234.1 million as of December 31, 2020 and 2019, respectively. To date, the Company's operations have been principally financed from proceeds from the issuance of preferred and common stock 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, 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.

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. For instance, results from an independent study demonstrated the potential anti-viral properties of our silicon nitride. We believe that we may be able to apply our silicon nitride powder to personal protection products, such as face masks, gowns and gloves, resulting in inactivation of viruses that come into contact with the items.

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 February 2014. On February 6, 2020, the Company closed on a rights offering to its stockholders of units, consisting of convertible preferred stock and warrants, for gross proceeds of \$9.4 million, which excludes underwriting discounts and commissions and offering expenses payable by the Company. Additionally, during the period of June 2020 through August 2020, the Company closed four registered direct offerings of shares of its common stock, priced at-the-market under Nasdaq rules, resulting in the issuance of a total of 11,015,000 shares of its common stock for gross proceeds of approximately \$20.9 million, which excludes underwriting discounts and commissions and offering expenses payable by the Company.

During the year ended December 31, 2019, the Company entered into an ATM equity distribution agreement in which the Company may sell, from time to time, shares of common stock having an aggregate offering price of up to \$2.5 million. The Company sold 527,896 shares during the year ended December 31, 2019, raising approximately \$1.7 million before considering issuance costs. During the year ending December 31, 2020, the Company sold 354,381 shares of common stock, raising approximately \$0.8 million before considering issuance costs. As a result of the sales during the first half of 2020 there are no longer any funds available to the Company under the ATM.

On October 1, 2018, the Company sold the retail spine implant business to CTL Medical. The sale included a \$6 million noninterest bearing note receivable payable over a 36-month term. 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 to occur October 1, 2021. The Company expects cash flows \$1.9 million for the remaining ten months.

Management has concluded that together with its existing capital resources and payments on the note receivable from the sale of the spine implant business will be sufficient to fund operations for at least the next 12 months, or through March 2022.

Risks Related to COVID-19 Pandemic

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which we rely.

Cash Flows

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

	Year Ended December 31,	
	2020	2019
Net cash used in operating activities	\$ (9,112)	\$ (6,435)
Net cash provided by investing activities	1,751	1,381
Net cash provided by financing activities	30,925	1,394

Net cash provided (used)

\$ 23,564 \$ (3,660)

Net Cash Used in Operating Activities

Net cash used in operating activities was \$9.1 million in 2020, compared to \$6.4 million used in 2019, an increase of \$2.7 million. The increase in the net loss for operations, and related non-cash add backs to the net loss, was \$2.5 million from 2020 when compared to 2019. The increase in cash used for operating activities operations during 2020 was primarily due to the \$2.5 million mentioned above plus changes in the movement of working capital items during 2020 as compared to the same period in 2019 as follows: a \$0.6 million increase in cash used in accounts payable and accrued liabilities and a \$0.1 increase in cash used in prepaids, offset by a \$0.4 million decrease in cash payments on operating lease liability, and a \$0.1 million decrease in cash used in account and other receivables.

Net Cash Provided By Investing Activities

Net cash provided by investing activities was \$1.8 million during 2020, compared to \$1.4 million provided by investing activities during the same period in 2019, an increase of \$0.4 million. The increase in cash provided in investing activities during 2020 was primarily due to an increase of \$0.6 million for the proceeds from notes receivable, offset by the increase of \$0.2 million for the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$30.9 million during 2020, compared to \$1.4 million provided by financing activities during the same period in 2019, an increase of \$29.5 million. This increase was primarily attributable an increase in proceeds from warrant derivative liabilities of \$6.3 million, an increase in proceeds from issuance of common stock in the amount of \$18.5 million, an increase in proceeds from issuance of preferred stock in the amount of \$3.1 million, an increase in proceeds of \$1.0 million from warrants exercised for cash, a \$0.4 million increase from the issuance of debt, and a \$0.2 decrease in capital raise costs.

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Indebtedness

PPP Loan

On April 28, 2020, the Company received funding under a Paycheck Protection Program (“PPP”) loan (the “PPP Loan”) from First State Community Bank (the “Lender”). The principal amount of the PPP Loan is \$0.391 million. The PPP Loan has a two-year term, maturing on April 28, 2022. The term may be extended to five-years if the Lender and we agree to do so. The interest rate on the PPP Loan is 1.0% per annum. Principal and interest are payable in 18 monthly installments, beginning on November 28, 2020, until maturity with respect to any portion of the PPP Loan which is not forgiven as described below. The PPP Loan may be partially or fully forgiven if the Company complies with the provisions of the CARES Act, including the use of PPP Loan proceeds for payroll costs, rent, utilities and other expenses, provided that such amounts are incurred during a 24-week period that commenced on April 28, 2020 and at least 60% of any forgiven amount has been used for covered payroll costs as defined by the CARES Act. Any forgiveness of the PPP Loan will be subject to approval by the SBA and the Lender and will require the Company to apply for such treatment in the future.

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 Item 13 “Certain Relationships and Related Party Transactions, Director Independence” contained in Part III of this 2020 Annual Report on Form 10-K.

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 an exclusive sales agreement in place with a remaining term of 8-years. 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, 2020. There have been no material changes to those policies for the year ended December 31, 2020, except as explained below in Accounting Pronouncements Adopted in 2019. 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.

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New Accounting Pronouncement, Not Yet Adopted

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 no other pronouncements will have a significant effect on its financial statements upon adoption.

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, 8 years of which remain. The Company is currently pursuing other sales opportunities for silicon nitride outside the spinal fusion application. The sale of the Company’s products has a single performance obligation and revenue is recognized at the time the product is shipped to the customer. In general, the Company’s customers do not have any rights of return or exchange.

As of January 1, 2019, the Company adopted Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASC 606), and elected to use the modified retrospective method. Under the modified retrospective method, the Company has presented prior periods under legacy GAAP, with the cumulative effect of initial application adjusted through beginning retained earnings. The new standard did not have a material impact on the revenue recognition process of the Company and no cumulative effect was recognized upon initial application.

With the adoption of ASC 606 at the beginning of 2019, revenue is recognized when control of the goods or services promised under the contract is transferred to the customer either at a point in time (e.g., upon delivery) or over time (e.g., as performed under the contract). The Company accounts for a contract when it has approval and commitment from both parties, the rights and payment terms of the parties are identified, the contract has commercial substance and collectability of consideration is probable. Contracts are reviewed to determine whether there is one or multiple performance obligations. A performance obligation is a promise to transfer a distinct good or service to a customer and represents the unit of accounting for revenue recognition. For contracts with multiple performance obligations, the expected consideration, or the transaction price, is allocated to each performance obligation identified in the contract based on the relative standalone selling price of each performance obligation. Revenue is then recognized for the transaction price allocated to the performance obligation when control of the promised goods or services underlying the performance obligation is transferred. Contract consideration is not adjusted for the effects of a significant financing component when, at contract inception, the period between when control transfers and when the customer will pay for that good or service is one year or less. Contract modifications that provide for additional distinct goods or services at the standalone selling price are treated as separate contracts. The transaction price for our contracts reflects our estimate of returns, rebates and discounts, which historically have not been significant. Amounts billed to customers for shipping and handling are included in the transaction price and generally are not treated as separate performance obligations as these costs fulfill a promise to transfer the product to the customer. The Company does not employ salespeople to actively seek additional customers; there are no incremental costs for obtaining customers that need to be capitalized.

Account and Other Receivables and Allowance for Doubtful Accounts

Account and other receivables are carried at invoiced amount less an allowance for doubtful accounts. On a regular basis, the Company evaluates account and other receivables 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.

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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.

Long Lived Intangible Assets

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, 2020. 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.

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.

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.

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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, 2020 and 2019, 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.

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. 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.

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, 2020. Based on this evaluation, the Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020, the end of the period covered by this Annual Report on Form 10-K.

(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 U.S. 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, 2020. 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, 2020, the Company's internal control over financial reporting was effective.

There were no changes in our internal control over financial reporting that occurred during 2020 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

Directors

The following table sets forth the names, ages, and positions with SINTX for each of our directors.

<u>Name</u>	<u>Age</u>	<u>Positions</u>
B. Sonny Bal, M.D.	58	Chairman of the Board of Directors, President and Chief Executive Officer
David W. Truetzel	64	Director
Jeffrey S. White	67	Director
Eric A. Stookey	20	Director
Mark Froimson, M.D.	60	Director

Our Board is divided into three classes (Class I, Class II and Class III) with staggered three-year terms. Directors in each class are elected to serve for three-year staggered terms that expire in successive years. Officers serve at the discretion of our Board. The following is information on the business experience of each director now serving and a discussion of the qualifications, attributes and skills that led to the Board of Directors' conclusion that each one is qualified to serve as a director.

The following is a brief summary of the background of each of our directors.

B. Sonny Bal, M.D. has served on our Board of Directors since February 2012, as Chairman of our Board of Directors since August 2014 and as our President and Chief Executive Officer since October 2014. Dr. Bal was a tenured Professor in Orthopaedic Surgery at the University of Missouri, Columbia, and has an extensive history of research into silicon nitride ceramics. He is Adjunct Professor of Material Sciences at Missouri Science and Technology University at Rolla. Dr. Bal is a member of the American Academy of Orthopaedic Surgeons, the American Association of Hip and Knee Surgeons, and the International Society of Technology in Arthroplasty. Dr. Bal received his M.D. degree from Cornell University and an M.B.A. from Northwestern University, a J.D. from the University of Missouri, and a Ph.D. in Engineering from the Kyoto Institute of Technology in Japan. We believe that Dr. Bal's breadth of experience and scientific expertise in silicon nitride qualifies him to serve as our Chairman, President and Chief Executive Officer.

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Jeffrey S. White has served on our Board of Directors since January 2014. From January 2013 to 2018, Mr. White served as Principal at Medtech Advisory Group LLC, a firm he founded that advises early and mid-stage medical technology firms. In that capacity Mr. White has consulted MiMedx Group Inc., the leading amniotic tissue and allograft regenerative biomaterials firm since mid-2015 and served as Vice President, Product Management Strategies at MiMedix. Mr. White previously served as a director of Residency Select LLC, a company which offers psychometric assessment, training and compliance products to medical and surgical residency programs. Mr. White also served in 2014 and 2015 as President and director of Liventa Bioscience LLC, a provider of specialty amniotic tissue allografts for use in surgical and wound care applications. From May 2006 to December 2012 he served as Global Director of Business Development for Synthes Inc., a global orthopedic firm that was acquired by Johnson and Johnson in 2012. Mr. White has served as Chief Executive Officer and/or co-founder of several start-up surgical device firms and has previously held executive level positions at United States Surgical Corporation, now part of Medtronic. Mr. White holds a B.S. in Biology from Union College in Schenectady NY. We believe that Mr. White's experience as an executive and founder of medical device companies qualifies him to serve on our Board of Directors.

Class II Directors - continuing directors with a term expiring at the 2022 annual meeting of stockholders.

David W. Truetzel has served on our Board of Directors since our acquisition of US Spine, Inc. in September 2010. Mr. Truetzel has been the general partner of Augury Capital Partners, a private equity fund that invests in life sciences and information technology companies, which he co-founded in 2006. Mr. Truetzel is a director of Enterprise Bank, Inc., Bonfyre, LLC, a provider of enterprise technology management solutions, and Paranet, LLC, an IT services provider. Mr. Truetzel holds a B.S. in Business Administration from Saint Louis University and an M.B.A. from The Wharton School. We believe that Mr. Truetzel's financial and managerial expertise qualify him to serve on our Board of Directors.

Eric A. Stookey has served on our Board of Directors since October 2014. Mr. Stookey has served as Chief Operating Officer of Osteoremedies, LLC since March of 2015. From October 2011 until August 2014, Mr. Stookey served as the President of the Extremities-Biologics division at Wright Medical Group Inc. Mr. Stookey also served in various other marketing and sales positions at Wright Medical Group Inc. since 1995, including as the Senior Vice President and Chief Commercial Officer from January 2010 to November 2011, as the Vice President North American Sales from 2007 to January 2010, as the Vice President US Sales from 2005 to 2007, as the Senior Director of Sales, Central Region, from 2003 to 2005 and as the Director of Marketing for Large Joint Reconstruction Products from 2001 to 2003. Mr. Stookey earned his M.B.A. from Christian Brothers University and his B.S. in Business from the Indiana University School of Business. We believe that Mr. Stookey's industry and executive leadership experience qualifies him to serve on our Board of Directors.

Class I Directors - up for election at the 2021 Annual Meeting of Stockholders with a term expiring at the 2024 annual meeting of stockholder if re-elected.

Mark Froimson, M.D. has served on our Board of Directors since February 2019. Dr. Froimson is currently a Principal at Riverside Health Advisors, a consulting company that provides strategic advice and services to health care executive leaders. Dr. Froimson served as the President of the American Association of Hip and Knee Surgeons from March 2017 to March 2018. Previously, he was the Executive Vice President and Chief Clinical Officer of Trinity Health, a major national non-profit Catholic healthcare system comprising 93 hospitals in 22 states. Prior to his executive leadership position at Trinity Health, Dr. Froimson was President and Chief Executive Officer of Euclid Hospital, a Cleveland Clinic Hospital. Dr. Froimson served as a staff surgeon in the Department of Orthopedic Surgery at the Cleveland Clinic for over 16 years, during which time he held a variety of leadership positions, including President of the professional staff, Vice Chair of the Orthopedic and Rheumatologic Institute, and member of the board of governors and board of trustees. Dr. Froimson also serves on the board of directors of Pacira Biosciences, Inc., a publicly traded company on the NASDAQ Stock Market. Dr. Froimson received a B.S. in philosophy from Princeton University, an M.D. from Tulane University School of Medicine and an MBA from the Weatherhead School of Business at Case Western Reserve University.

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We believe Dr. Froimson's qualifications to sit on our Board include his clinical expertise and executive experience in the medical field.

Executive Officers

Our current executive officers and their respective ages and positions are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
B. Sonny Bal, M.D.	58	Chairman of the Board of Directors, President and Chief Executive Officer, Principal Financial Officer
Bryan J. McEntire	68	Chief Scientific Officer
David O'Brien	56	Chief Operating Officer

The following is a brief summary of the background of each of our executive officers.

B. Sonny Bal, M.D. has served on our Board of Directors since February 2012, as Chairman of our Board of Directors since August 2014 and as our President and Chief

Executive Officer since October 2014. Dr. Bal was a tenured Professor in Orthopaedic Surgery at the University of Missouri, Columbia, and has an extensive history of research into silicon nitride ceramics. He is Adjunct Professor of Material Sciences at Missouri Science and Technology University at Rolla. Dr. Bal is a member of the American Academy of Orthopaedic Surgeons, the American Association of Hip and Knee Surgeons, and the International Society of Technology in Arthroplasty. Dr. Bal received his M.D. degree from Cornell University and an M.B.A. from Northwestern University, a J.D. from the University of Missouri, and a Ph.D. in Engineering from the Kyoto Institute of Technology in Japan. We believe that Dr. Bal's breadth of experience and scientific expertise in silicon nitride qualifies him to serve as our Chairman, President and Chief Executive Officer.

Bryan J. McEntire has served as our Chief Scientific Officer since May 2012. From June 2004 to May 2012 he served as our Vice President of Manufacturing and as our Vice President of Research from December 2006 to May 2012. Dr. McEntire has worked in various advanced ceramic product development, quality engineering and manufacturing roles at Applied Materials, Inc., (Santa Clara, CA), Norton Advanced Ceramics, a division of Saint-Gobain Industrial Ceramics Corporation (E. Granby, CT), Norton/TRW Ceramics (Northboro, MA) and Ceramtec, Inc., (Salt Lake City, UT). Dr. McEntire has a BS degree in Materials Science and Engineering and an MBA both from the University of Utah (Salt Lake City, UT), and a Ph.D. from the Kyoto Institute of Technology (Kyoto, Japan).

David O'Brien has served as our Chief Operating Officer since July 2019. Mr. O'Brien previously served as the Company's Vice President and General Manager from October 2016 to July 2019 and from March 2014 through September 2016, he held prior roles as our Vice President of Operations and Vice President of Manufacturing. Mr. O'Brien has over 30 years of experience in engineering, manufacturing, and operations leadership in advanced materials and medical device organizations. From 2005 to 2014, he fulfilled several engineering leadership roles for Covidien. From 1991 to 2005, he worked for Arnold Magnetic Technologies in the production of ceramic, powder metal and molded magnets in multiple facilities across the U.S. and in England. He has extensive experience with Lean and other Continuous Improvement initiatives. Mr. O'Brien holds an M.S. in Ceramic Engineering from the Georgia Institute of Technology, and a B.S. in Physics from the University of Texas at San Antonio.

Arrangements between Officers and Directors

To our knowledge, there is no arrangement or understanding between any of our officers and any other person, including directors, pursuant to which the officer was selected to serve as an officer.

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Family Relationships

None of our directors are related by blood, marriage, or adoption to any other director, executive officer, or other key employees.

Other Directorships

With the exception of Dr. Froimson, who is also on the board of directors of Pacira Biosciences, Inc., a SEC public reporting company, none of the directors of the Company are also directors of issuers with a class of securities registered under Section 12 of the Exchange Act (or which otherwise are required to file periodic reports under the Exchange Act).

Other Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any bankruptcy or criminal proceedings (other than traffic and other minor offenses) or been subject to any of the items set forth under Item 401(f) of Regulation S-K, nor have there been any judgments or injunctions brought against any of our directors or executive officers during the last ten years that we consider material to the evaluation of the ability and integrity of any director or executive officer.

The Board and Committees

Our Board of Directors has five members. The Chairman of the Board and our Chief Executive Officer, B. Sonny Bal, MD, PhD, is a member of the Board and is a full-time employee of SINTX. David W. Truetzel, Eric A. Stookey, Jeffrey S. White, and Mark Froimson are non-employee directors, and the Board has determined that these persons (who constitute a majority of the Board) are "independent directors" under the criteria set forth in Rule 5605(a)(2) of the Nasdaq Listing Rules. The Board met eight (8) times during the year ended December 31, 2020. All directors attended more than seventy-five percent (75%) of the meetings of the Board and committee meetings of which such director was a member held during 2020.

In accordance with our restated Certificate of Incorporation, our Board of Directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following such election. Our directors are divided among the three classes as follows:

- The Class I director is Mark Froimson and his term will expire at the annual meeting of stockholders to be held in 2021.
- The Class II directors are David W. Truetzel and Eric A. Stookey, and their terms are expiring at the 2022 annual meeting of stockholders.
- The Class III directors are B. Sonny Bal, M.D. and Jeffrey S. White, and their terms will expire at the annual meeting of stockholders to be held in 2023

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

Our Board of Directors has three permanent committees: the Audit Committee, the Compensation Committee, and the Corporate Governance and Nominating Committee. The written charters for these committees are on our website at <https://ir.sintx.com/corporate-governance>. Our Board of Directors may from time to time establish other standing committees. In addition, from time to time, special committees may be established under the direction of our Board of Directors when necessary to address specific issues.

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The following table sets forth a description of the three permanent Board committees and the chairpersons and members of those committees, all of whom are independent directors:

Committee	Independent Chairman	Independent Members	
Audit Committee	David W. Truetzel	Eric A. Stookey	Jeffrey S. White
Compensation Committee	Jeffrey S. White	David W. Truetzel	Eric A. Stookey
Governance and Nominating Committee	Eric A. Stookey	Jeffrey S. White	David W. Truetzel

Corporate Governance and Nominating Committee

The Corporate Governance and Nominating Committee is currently comprised of the following members: Eric A. Stookey (Chairman), David W. Truetzel and Jeffrey S White. Among other items, the Corporate Governance and Nominating Committee is tasked by the Board to: (1) identify individuals qualified to serve as members of the Board and recommend individuals to be nominated by the Board for election by the stockholders or to be appointed by the Board to fill vacancies consistent with the criteria approved by the Board; (2) develop and periodically evaluate and recommend changes to SINTX's Corporate Governance Guidelines and Code of Ethics, and to review the Company's policies and programs that relate to matters of corporate responsibility, including public issues of significance to the Company and its stakeholders; and (3) oversee an annual evaluation of the performance of the Board. The Board has determined that each of the members of the Corporate Governance and Nominating Committee is "independent" under the standard set forth in Rule 5605(a)(2) of the Nasdaq Listing Rules. The Corporate Governance and Nominating Committee did not meet as a separate committee in 2019, but rather, because the committee is comprised of all three independent directors, governance matters were addressed as necessary in meetings of the Board. The Corporate Governance and Nominating Committee operates under a written charter adopted by the Board of Directors, which sets forth the responsibilities and powers delegated by the Board to the Corporate Governance and Nominating Committee.

Board Nominations

In considering Board candidates, the Board seeks individuals of proven judgment and competence who have strong reputations in their respective fields. Although we do not have a formal diversity policy, the Board considers such factors as experience, education, employment history, special talents or personal attributes, anticipated participation in Board activities, and geographic and diversity factors. The process for identifying and evaluating nominees would include detailed consideration of the recommendations and opinions of members of our Board, our executive officers, and our stockholders. There would be no difference in the process of evaluation of candidates recommended by a stockholder and those recommended by other sources.

The Nominating and Governance Committee has adopted a policy and procedures for shareholders to recommend nominees to the Company's Board. The Committee will only consider qualified proposed nominees that meet the qualification standards set forth on Appendix A to the Committee's charter available on the Company's website at www.SINTX.com. Pursuant to the policy, only shareholders who meet minimum percentage ownership requirements as established by the Board may make recommendations for consideration by the Committee. At this time, the Board has set a minimum percentage ownership of 5% of the Company's issued and outstanding shares of common stock for a period of at least one year. To make recommendations, a shareholder must submit the recommendation in writing by mail, courier or personal delivery to: Corporate Secretary, SINTX Technologies, Inc., 1885 West 2100 South, Salt Lake City, UT 84119. For each annual meeting the Committee will consider only one proposed nominee from each shareholder or shareholder group (within the meaning of Regulation 13D under the Exchange Act).

The recommendation must set forth (1) the name, address, including telephone number, of the recommending shareholder or shareholder group; (2) the number of the Company's shares of common stock held by such shareholder and proof of ownership if the shareholder is not a holder of record; and (3) a statement that the shareholder has a good faith intention of holding the shares through the record date of the Company's next annual meeting. For shareholder groups this information must be submitted for each shareholder in the group.

The recommendation must set forth in relation to the proposed nominee being recommended by the shareholder: (1) the information required by Items 401, 403 and 404 of Regulation S-K under the Exchange Act, (2) any material relationships or agreements between the proposed nominee and the recommending shareholder or the Company's competitors, customers, labor unions or other persons with special interests in the Company; (3) a statement regarding the qualifications of the proposed nominee to serve on the Board; (4) a statement that the proposed nominee can fairly represent the interests of all shareholders of the Company; and (5) a signed consent by the proposed nominee to being interviewed by the Nominating and Governance Committee.

Recommendations must be made not later than 120 calendar days prior to the first anniversary of the date of the proxy statement for the prior annual meeting of shareholders. In the event that the date of the annual meeting of shareholders for the current year is more than 30 days following the first anniversary date of the annual meeting of shareholders for the prior year, the submission of a recommendation will be considered timely if it is submitted not earlier than the close of business on the 120 days prior to such annual meeting and not later than the close of business on the later of 90 days prior to such annual meeting or the close of business 10 days following the day on which public announcement of the date of such meeting is first made by the Company.

Audit Committee

We have a standing Audit Committee and audit committee charter, which complies with Rule 10A-3 of the Exchange Act, and the requirements of the Nasdaq Listing Rules. Our Audit Committee was established in accordance with Section 3(a)(58)(A) of the Exchange Act. The Audit Committee is currently comprised of the following members: David W. Truetzel (Chairman), Eric A. Stookey and Jeffrey S White. The Audit Committee provides oversight for financial reporting matters, internal controls, and compliance with the Company's financial policies, and meets with its auditors when appropriate. The Audit Committee did not meet as a separate committee in 2020, but rather, because the committee is comprised of all three independent directors, committee matters were addressed as necessary in meetings of the Board. The Board has determined that David W. Truetzel is an "audit committee financial expert" within the meaning of Item 407(d)(5) of Regulation S-K. Further, the Board has determined that each of David W. Truetzel, Jeffrey S. White and Eric A. Stookey are "independent" under the standard set forth in Rule 5605(a)(2) of the Nasdaq Listing Rules. The Audit Committee operates under a written charter adopted by the Board of Directors, which sets forth the responsibilities and powers delegated by the Board to the Audit Committee.

Compensation Committee

The Compensation Committee of the Board is comprised of the following members: Jeffrey S. White, (Chairman), David W. Truetzel and Eric A. Stookey. The Board has determined that each of David W. Truetzel, Jeffrey S. White and Eric A. Stookey are "independent" under the standard set forth in Rule 5605(a)(2) of the Nasdaq Listing Rules. The Compensation Committee recommends to the Board for determination compensation of our executive officers, including the chief executive officer, and addresses salary and benefit matters for other key personnel and employees of the Company. The Compensation Committee did not meet as a separate committee in 2020, but rather, because the committee is comprised of all three independent directors, committee matters were addressed as necessary in meetings of the Board. The Compensation Committee operates under a written charter adopted by the Board of Directors, which sets forth the responsibilities and powers delegated by the Board to the Compensation Committee.

Code of Business Conduct

The Board has adopted a Code of Business Conduct that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct is available on our website at <https://ir.sintx.com/corporate-governance>. We intend to disclose any amendments to the code or any waivers of its requirements on our website.

The Bylaws of the Company provide that no contract or transaction between SINTX and one or more of its directors or officers, or between SINTX and any other corporation, firm, association, or other organization in which one or more of its directors or officers are financially interested, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board of Directors or committee that authorizes or approves the contract or transaction, or because their votes are counted for such purpose, provided that:

- the material facts as to his, her, or their relationship or interest as to the contract or transaction are disclosed or are known to the Board of Directors or the committee and noted in the minutes, and the Board of Directors or committee authorizes the contract or transaction in good faith by the affirmative vote of a majority of disinterested directors, even though the disinterested directors are less than a quorum;

- the material facts as to his, her, or their relationship or interest as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon and the contract or transaction is specifically approved in good faith by vote of the stockholders; or
- the contract or transaction is fair as to SINTX as of the time it is authorized, approved or ratified by the Board of Directors, a committee thereof, or the stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The following discussion relates to the compensation of our “named executive officers.”

Summary Compensation Table

The following table sets forth information about certain compensation awarded or paid to our named executive officers for the 2020 and 2019 fiscal years.

Name and Principal Position	Year	Salary	Bonus	Non-Equity Incentive Plan Compensation	Stock Awards	Option Awards	All Other Comp (1)	Total Compensation
B. Sonny Bal Chief Executive Officer	2020	\$ 415,385	\$ 59,750	\$ -	\$ -	\$ 4,398	\$ 7,909	\$ 487,442
	2019	400,000	-	-	-	-	1,231	401,231
Bryan McEntire Chief Scientific Officer	2020	253,942	29,553	-	-	4,398	9,780	297,673
	2019	238,702	4,001	-	-	-	6,610	249,313
David O’Brien Chief Operating Officer	2020	298,413	28,560	-	4,579	4,398	10,257	346,207
	2019	231,750	3,984	-	-	-	6,418	242,152

(1) Amount reflects matching of 401(k) contributions paid by us, unless otherwise noted.

Narrative Disclosure to Summary Compensation Table. We do not have written employment agreements with any of our executive officers. All of our executive officers serve on an at-will basis. The base salaries for our named executive officers were determined by our compensation committee after reviewing a number of factors, including: the responsibilities associated with the position, the seniority of the executive’s position, the base salary level in prior years, and our financial position; and for executive officers other than our Chief Executive Officer, recommendations made by our Chief Executive Officer.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding equity awards held by our named executive officers as of December 31, 2020:

Name	Number of Securities Underlying Unexercised Options (#)		Option Exercise Price	Option Expiration Date	Number of Restricted Stock Units that have not vested	Market value of shares or units of stock that have not vested (\$)
	Exercisable	Unexercisable				
Sonny Bal	1	-	\$ 139,158	3/15/2022	-	\$ -
	16	-	5,221	1/7/2025	-	-
	9	-	2,321	9/16/2025	-	-
	28	-	367	9/14/2026	-	-
	-	50,000	0.47	4/21/2030	-	-
Bryan McEntire	19	-	5,130	8/13/2024	-	-
	13	-	5,221	1/7/2025	-	-
	9	-	608	1/4/2026	-	-
	-	50,000	0.47	4/21/2030	-	-
David O’Brien	9	-	5,129	7/17/2024	-	-
	6	-	5,222	1/7/2025	-	-
	9	-	608	1/4/2026	-	-
	-	50,000	0.47	4/21/2030	50,000	78,500

401(k) Plan

We offer our executive officers, including our named executive officers, retirement benefits, including participation in our tax-qualified profit sharing plan that includes a “cash-or-deferred” (or 401(k)) feature in the same manner as other employees. The plan is intended to satisfy the requirements of Section 401 of the Internal Revenue Code. Our employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and have a like amount contributed to the plan. In addition, we may make discretionary and/or matching contributions to the plan in amounts determined annually by our Board. We currently elect to match the contributions of our employees who participate in our 401(k) plan as follows: a match of 100% on the first 3% of compensation contributed by a plan participant and a match of 50% on amounts above 3%, up to 5%, of compensation contributed by a plan participant.

Potential Payments upon Termination or Change in Control

We had entered into certain agreements and maintained certain plans that may have required us to make certain payments and/or provide certain benefits to the executive officers named in the Summary Compensation Table in the event of a termination of employment or change in control.

restricted stock and other such rights held by the executives will fully vest. Additionally, if a change in control occurs and at any time during the one-year period following the change in control (i) we or our successor terminate the executive's employment other than for cause (but not including termination due to the executive's death or disability) or (ii) the executive terminates his employment for good reason, then such executive has the right to receive payment consisting of a lump sum payment equal to two times his highest annual salary with us during the preceding three-year period, including the year of such termination and including bonus payments (measured on a fiscal year basis), but not including any reimbursements and amounts attributable to stock options and other non-cash compensation. "Change in control" is defined in the severance agreements as occurring upon: (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becoming the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities representing 50% or more of the total voting power represented by our then outstanding voting securities (excluding securities held by us or our affiliates or any of our employee benefit plans) pursuant to a transaction or a series of related transactions which our Board did not approve; (ii) a merger or consolidation of our company, other than a merger or consolidation which would result in our voting securities outstanding immediately prior thereto continuing to represent at least 50% of the total voting securities or such surviving entity or parent of such corporation outstanding immediately after such merger or consolidation; or (iii) the approval by our stockholders of an agreement for the sale or disposition of all or substantially all of our assets. As defined in the severance agreements, "cause" means: (i) the executive's commission of a felony (other than through vicarious liability or through a motor vehicle offense); (ii) the executive's material disloyalty or dishonesty to us; (iii) the commission by the executive of an act of fraud, embezzlement or misappropriation of funds; (iv) a material breach by the executive of any material provision of any agreement to which the executive and we are party, which breach is not cured within 30 days after our delivery to the executive of written notice of such breach; or (v) the executive's refusal to carry out a lawful written directive from our Board. "Good reason" as defined in the severance agreements means, without the executive's consent: (i) a change in the principal location at which the executive performs his duties to a new work location that is at least 50 miles from the prior location; or (ii) a material change in the executive's compensation, authority, functions, duties or responsibilities, which would cause his position with us to become of less responsibility, importance or scope than his prior position, provided, however, that such material change is not in connection with the termination of the executive's employment with us for any reason.

In the event that an officer entitled to receive or receives payment or benefit under the severance agreements described above, or under any other plan, agreement or arrangement with us, or any person whose action results in a change in control or any other person affiliated with us and it is determined that the total amount of payments will be subject to excise tax under Section 4999 of the Internal Revenue Code, or any similar successor provisions, we will be obligated to pay such officer a "gross up" payment to cover all taxes, including any excise tax and any interest or penalties imposed with respect to such taxes due to such payment.

Code of Business Conduct Violations

It is our policy under our Code of Business Conduct to take appropriate action against any executive officer whose actions are found to violate the Code or any other policy of SINTX. Disciplinary actions may include immediate termination of employment and, where SINTX has suffered a loss, pursuing its remedies against the executive officer responsible. SINTX will cooperate fully with the appropriate authorities where laws have been violated.

Role of the Board in Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of the risks that we face, while our Board of Directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our Board of Directors is responsible for satisfying itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Our Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through our Board of Directors as a whole, as well as through various standing committees of the Board of Directors that address risks inherent in their respective areas of oversight. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for us. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors oversight of the performance of our internal audit function. Our Corporate Governance and Nominating Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs have the potential to encourage excessive risk-taking or promote behaviors contra to our Code of Business Conduct.

Board Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2020 to each of our non-employee directors.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Total (\$)
David W. Truetzel	\$ 125,507	\$ -	\$ 5,277	\$ 130,784
Jeffrey S. White	41,000	-	5,277	46,277
Eric A. Stookey	44,000	-	5,277	49,277
Mark Froimson	40,708	-	4,838	45,546

The following compensation schedule sets forth compensation for non-employee directors (paid on a quarterly basis) as approved by the Board:

- Annual Retainer of \$40,000 paid in four equal installments of \$10,000 each at the beginning of each calendar quarter;
- \$1,000 for each board and committee meeting attended in person;
- \$500 for each board and committee meeting attended via telephone or other remote medium; and
- Reimbursement of reasonable expenses as supported by documentation and receipts.

A new Board appointee receives an award of 40,000 stock options upon appointment. Further, each member of the Board is awarded an option grant for 15,000 stock options on an annual basis.

The chair of the Audit Committee is paid an annual retainer of \$120,000 payable in monthly increments of \$10,000 each.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2020 relating to all of our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued upon Exercise of Outstanding Options	(b) Weighted-average Exercise Price of Outstanding Options	(c) Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Referenced in Column (a))
Equity compensation plans approved by stockholders	515,393 ⁽¹⁾	\$ 5.53 ⁽²⁾	1,387,503
Equity compensation plans not approved by Stockholders	-	-	-
Total	515,393⁽¹⁾	\$ 5.53⁽²⁾	1,387,503

(1) Includes options outstanding under our 2012 Equity Incentive Plan.

(2) Represents weighted-average exercise price per share of common stock acquirable upon exercise of outstanding stock options.

2020 Equity Incentive Plan

The 2020 Plan provides for the grant of nonqualified stock options, incentive stock options, restricted stock, restricted stock units, stock appreciation rights (SARs), and performance share awards to employees, officers, consultants, advisors, non-employee directors and independent contractors designated by either the board of directors of the Company or if so authorized by the board of directors, the Compensation Committee (the “Committee”) of the Board of Directors. Under the 2020 Plan, the maximum number of shares of common stock which may be issued, subject to adjustment as described below, is 1,902,520 shares of common stock, which includes 2,520 shares that have been rolled over from our 2012 Plan. In addition, there are 377 shares subject to outstanding awards under our 2012 Plan that, if, after April 21, 2020, are forfeited or reacquired by the Company due to termination or cancellation of such awards shall also be permitted to be granted under the 2020 Plan. For stock options and SARs, the aggregate number of shares with respect to which such awards are exercisable, rather than the number of shares actually issued upon exercise, will be counted against the number of shares available for awards under the 2020 Plan. If awards under the 2020 Plan expire or otherwise terminate without being exercised, the shares not acquired pursuant to such awards again become available for issuance under the 2020 Plan in accordance with its terms. However, under the following circumstances, shares will not again be available for issuance under the 2020 Plan: (i) shares unissued due to a “net exercise” of a stock option, (ii) any shares withheld, or shares tendered to satisfy tax withholding obligations with respect to a stock option or SAR, (iii) shares covered by a SAR that is not settled in shares upon exercise and (iv) shares repurchased using stock option exercise proceeds.

Administration

The 2020 Plan will be administered by the Committee, or in the board of director’s sole discretion, by the board of directors. The Board of Directors will fill vacancies on and from time to time may remove or add members to the Committee, and the Committee will be so constituted to permit awards granted under the 2020 Plan to be exempt from Section 16(b) of the Securities Exchange Act of 1934 (the “Exchange Act”) and to permit grants of awards under the plan to comply with or any other statutory rule or regulatory requirements, unless otherwise determined by the Board of Directors.

Subject to the express provisions of the 2020 Plan, the Committee has authority to administer and interpret the 2020 Plan, including the authority to determine who is eligible to participate in the 2020 Plan and to whom and when awards are granted under the 2020 Plan, to grant awards, to determine the number of shares of common stock subject to awards and the exercise or purchase price of such shares under an award, to establish and verify the extent of satisfaction of any performance criteria applicable to awards, to prescribe and amend the terms of the agreements evidencing awards made under the 2020 Plan, and to make other determinations deemed necessary or advisable for the administration of the 2020 Plan. Also, subject to the requirements of Delaware General Corporation Law and any limitations under applicable stock exchange rules, the Committee also has the power to delegate to officers the authority to grant and determine the terms and conditions of awards granted under the 2020 Plan. These delegated officers shall not be permitted to grant awards to any person subject to Rule 16b-3 under the Exchange Act or Code.

Eligibility

Participants under the 2020 Plan are limited to employees, officers, non-employee directors, and consultants providing services to the Company, or any person to whom an offer of employment or engagement with the Company is extended. In determining to whom awards will be granted and the nature of such each award, the Committee may take into account the nature of the services rendered by the respective participant, their present and potential contributions to the success of the Company or such other factors as the Committee, in its discretion, deems relevant.

General Terms and Conditions of Awards

Nonqualified Stock Options

The Committee may grant nonqualified stock options under the 2020 Plan which do not meet the requirements of Section 422 of the Code and which will be subject to the following terms and conditions. The option exercise price per share will be determined by the Committee but will not be less than 100% of the “fair market value” of the common stock on the date of grant of such option. The term “fair market value” means either (a) if the common stock is listed on any established stock exchange, the closing price for the common stock on the date of grant or (b) in the absence of an established market for the common stock, the fair market value shall be determined in good faith by the Committee and such determination shall be conclusive and binding on all persons. The exercise price of an option may be paid through various means specified by the Committee, including in cash or check, by delivering to the Company shares of common stock or by a reduction in the number of shares issuable pursuant to such option. Except in limited circumstances, every option which has not been exercised within ten years of its date of grant will lapse upon the expiration of the ten-year period, unless it has lapsed at an earlier date as determined by the Committee.

During the lifetime of a participant, except as otherwise may be provided by the Committee in its discretion, options granted to that participant under the 2020 Plan generally will be nontransferable and exercisable only by the participant. A participant will have the right to transfer any options granted to such participant upon such participant’s death either by the terms of such participant’s will or under the laws of descent and distribution.

Incentive Stock Options

The Committee may grant incentive stock options under the 2020 Plan which meet the requirements of section 422 of the Code. Under the 2020 Plan, the aggregate fair market value, determined at the time the option is granted, of the common stock with respect to which incentive stock options are exercisable for the first time by any participant during any calendar year (under the 2020 Plan and any other incentive stock option plans of the Company) may not exceed \$100,000, or any other limit as may be prescribed by the Code from time to time. The option exercise price per share will be determined by the Committee but will not be less than 100% of the “fair market value” of the common stock

on the date of grant of such option. In the case of a grant of an incentive stock option to a participant who, at the time such option is granted, owns stock possessing more than 10% of the combined voting power of all classes of stock of the Company, the option exercise price per share under such option will not be less than 110% of the “fair market value” of the common stock on the date of grant of such option and such option will expire and no longer be exercisable no later than five years from the date of grant of such option.

SARs

The committee may grant SARs under the 2020 Plan. Subject to the express provisions of the 2020 Plan and as discussed in this paragraph, the Committee has discretion to determine the grant value, term, methods of exercise, dates of exercise, methods of settlement and any other terms and conditions of any SAR. The grant value of each SAR granted under the 2020 Plan will be determined by the Committee. Every SAR which has not been exercised within ten years of its date of grant will lapse upon the expiration of such ten-year period, unless it has lapsed at an earlier date as determined by the Committee.

Restricted Stock and Restricted Stock Units

The Committee may grant restricted stock or restricted stock units under the 2020 Plan. Restricted stock and restricted stock units will be subject to such restrictions as the Committee may impose (including, without limitation, any limitation on the right to vote a share of restricted stock or the right to receive any dividend or other right or property with respect thereto), which restrictions may lapse separately or in combination at such time or times, in such installments or otherwise as the Committee may deem appropriate. For example, awards may, at the Committee’s discretion, be conditioned upon a participant’s completion of a specified period of service, or upon the achievement of one or more performance goals established by the Committee, or upon any combination of service-based and performance-based conditions. A restricted stock or restricted stock unit award that is conditioned in whole or in part upon the achievement of one or more financial or other company-related performance goals (including goals specific to the participant’s individual performance, other than performance of service alone) is generally referred to as a performance share or performance share unit award.

Any restricted stock granted under the 2020 Plan shall be issued at the time such awards are granted and may be evidenced in such manner as the Committee may deem appropriate. In the case of restricted stock units, no common stock shall be issued at the time such awards are granted. Upon the lapse or waiver of restrictions and the restricted period relating to restricted stock units evidencing the right to receive common stock, such common stock shall be issued and delivered to the holder of the restricted stock units.

Except as otherwise determined by the Committee, if a director resigns or is removed or if the employment of an employee holding restricted stock or restricted stock units terminates during the applicable restricted period, the restricted stock and/or restricted stock units held by such director or employee will be forfeited and reacquired by the Company.

Transferability

Generally, no award (other than fully vested and unrestricted shares) and no right under any such award shall be transferable by a participant other than by will or by the laws of descent and distribution, and no award (other than fully vested and unrestricted shares) or right under any such award may be pledged, alienated, attached or otherwise encumbered. If a transfer is allowed by the Compensation Committee (other than for fully vested and unrestricted shares), the transfer will be for no value and shall comply with the Form S-8 rules. The Committee may establish procedures to allow a participant to designate a beneficiary or beneficiaries, to exercise the rights of the participant and receive any property distributable with respect to an award in the event of the participant’s death.

Corporate Transactions

In the event of any Change-in-Control Event (as defined in the 2020 Plan), reorganization, merger, consolidation, split-up, spin-off, combination, plan of arrangement, take-over bid or tender offer, repurchase or exchange of common stock or other securities of the Company or any other similar corporate transaction or event involving the Company, all outstanding options and SARs shall become immediately exercisable with respect to 100% of the shares subject to such options or SARs, and/or the restricted period shall expire immediately with respect to 100% of the outstanding shares of restricted stock awards or restricted stock units. Further, with respect to performance share awards and cash awards, in the event of a Change-in-Control, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions will be deemed met.

In addition, in the event of a Change-in-Control, the Committee may in its discretion and upon at least 10 days’ advance notice to the affected persons, cancel any outstanding awards and pay to the holders thereof, in cash or stock, or any combination thereof, the value of such awards based upon the price per share of common stock received or to be received by other shareholders of the Company in the event. In the case of any option or SAR with an exercise price (or SAR Exercise Price in the case of a SAR) that equals or exceeds the price paid for a share of common stock in connection with the Change-in-Control, the Committee may cancel the option or SAR without the payment of consideration therefor.

Amendment and Termination

No awards may be granted pursuant to the 2020 Plan after the ten-year anniversary of the effective date of the 2020 Plan which, if the shareholders approve the amendment and restatement of the 2020 Plan, will be April 21, 2030. Except to the extent stockholder approval or participant consent is required as provided by the 2020 Plan, the Board may amend, modify or terminate the 2020 Plan.

The Committee may amend, modify or terminate an outstanding award, provided, however, that, except as expressly provided in the 2020 Plan, the Committee may not, without the participant’s consent, amend, modify or terminate an outstanding award unless it determines that the action would not adversely alter or impair the terms or conditions of such award. However, the Committee reserves the right to reprice any previously granted “underwater” option or SAR by (i) lowering the exercise price, (ii) canceling the underwater option or SAR and granting a substitute award, or (iii) repurchasing the underwater option or SAR.

2012 Equity Incentive Plan

The Company is no longer making equity awards under the 2012 Plan. As outstanding awards under the 2012 Plan expire or terminate the shares allocated to such awards will rollover to the 2020 Plan. All shares that were available for award under the 2012 Plan have been rolled into the 2020 Plan.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 1, 2021 by:

- each of our current directors;
- each of our executive officers; and
- all of our directors and executive officers as a group;
- each stockholder known by us to own beneficially more than 5% of our Common Stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of March 1, 2021, pursuant to the exercise or vesting of options or warrants or conversion of convertible promissory notes, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of shares beneficially owned is based on 24,684,574 shares issued and outstanding on March 1, 2021.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. The address for each director and executive officer listed is: c/o SINTX Technologies, Inc., 1885 West 2100 South, Salt Lake City, Utah 84119.

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Name and Address of Beneficial Owner	Shares Beneficially Owned	
	Number	Percentage
Five Percent Stockholders:		
none		
Directors and Named Executive Officers:		
B. Sonny Bal, M.D. (1)	15,899	*
David W. Truetzel (2)	16,919	*
Jeffrey S. White (3)	16,815	*
Eric A. Stookey (4)	16,813	*
Bryan McEntire (5)	14,054	*
David O'Brien (6)	33,503	*
Mark Froimson, M.D. (7)	15,400	*
All executive officers and directors as a group (7 persons)	129,403	*

* Indicates ownership of less than 1% of the outstanding shares of the Company's common stock.

- (1) Represents 12 shares of Common Stock and options and warrants to purchase 15,887 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021.
- (2) Represents 71 shares of Common Stock and options to purchase 16,848 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021.
- (3) Represents 2 shares of Common Stock and options to purchase 16,813 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021.
- (4) Represents options to purchase 16,813 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021.
- (5) Represents 13 shares of Common Stock and options to purchase 14,041 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021.
- (6) Represents 5,477 shares of Common Stock, restricted stock units exercisable into 14,000 shares of Common Stock within 60 days of March 1, 2021, and options to purchase 14,026 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021
- (7) Represents options to purchase 15,400 shares of Common Stock that are currently exercisable within 60 days of March 1, 2021.

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

Transactions with Related Persons

We have not entered into any transactions since January 1, 2020 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of \$120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our common stock, on an as converted basis, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described above under "Executive and Director Compensation."

Indemnification Agreements. We have entered into indemnification agreements with each of our executive officers and directors that require us to indemnify such persons against any and all expenses, including judgments, fines or penalties, attorney's fees, witness fees or other professional fees and related disbursements and other out-of-pocket costs incurred, in connection with any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry or administrative hearing, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, officer, employee or agent of our company, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, our best interests. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers.

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Policy for Review of Related Party Transactions

We have a policy for the review of transactions with related persons as set forth in our Audit Committee Charter and internal practices. The policy requires review, approval or ratification of all transactions in which we are a participant and in which any of our directors, executive officers, shareholders holding more than 5% of our outstanding common stock, an immediate family member of any of the foregoing persons or any other person who the Board determines may be considered to be a related person has a direct or indirect material interest and which meet the threshold requirements set forth in Item 404 of Regulation S-K under the Exchange Act (typically \$120,000 or more in value). All related party transactions must be reported for review by the Audit Committee pursuant to the Audit Committee's charter.

In reviewing and approving such transactions, the Audit Committee shall obtain, or shall direct management to obtain on its behalf, all information that the Audit Committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by the Audit Committee prior to approval. No related party transaction shall be entered into prior to the completion of these procedures.

Following its review, the Audit Committee determines whether these transactions are in, or not inconsistent with, the best interests of the Company and its stockholders, taking into consideration whether they are on terms no less favorable to the Company than those available with other parties and the related person's interest in the transaction.

Our policy for review of transactions with related persons was followed in all of the transactions set forth above and all such transactions were reviewed and approved in accordance with our policy for review of transactions with related persons.

Director Independence

Information regarding the independence of directors is disclosed above under Item 10 under the heading “The Board and Committees” and incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The aggregate fees and expenses incurred from our principal accounting firm, Tanner LLC, for fiscal years ended December 31, 2020 and 2019, were as follows (in thousands):

	Year Ended December 31, 2020	Year Ended December 31, 2019
Audit fees	\$ 163,434	\$ 259,929
Audit related fees	148,718	64,971
Tax Fees	-	16,750
Total Fees	<u>\$ 312,152</u>	<u>\$ 341,650</u>

Each of the permitted non-audit services has been pre-approved by the Audit Committee or the Audit Committee’s Chairman pursuant to delegated authority by the Audit Committee, other than de minimus non-audit services for which the pre-approval requirements are waived in accordance with the rules and regulations of the Securities and Exchange Commission.

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Audit Fees

Consist of fees billed for professional services rendered for the audit of our financial statements and review of interim consolidated financial statements included in quarterly reports and services that are normally provided by the principal accountants in connection with statutory and regulatory filings or engagements.

Audit Related Fees

Consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under “Audit Fees”.

Tax Fees

Consist of fees billed for professional services for tax compliance, tax advice and tax planning. These services include preparation of federal and state income tax returns for the year ended December 31, 2019.

All Other Fees

Consist of fees for product and services other than the services reported above.

Policy for Approval of Audit and Permitted Non-Audit Services

The Audit Committee charter provides that the Audit Committee will pre-approve audit services and non-audit services to be provided by our independent auditors before the accountant is engaged to render these services. The Audit Committee may consult with management in the decision-making process, but may not delegate this authority to management. The Audit Committee may delegate its authority to pre-approve services to one or more committee members, provided that the designees present the pre-approvals to the full committee at the next committee meeting.

PART IV

ITEM 15. EXHIBITS, 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 as of December 31, 2020 and 2019	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2020 and 2019	F-4
Consolidated Statements of Stockholders’ Equity for the years ended December 31, 2020 and 2019	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019	F-6
Notes to Consolidated Financial Statements	F-7

- (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.

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- (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
2.1	Asset Purchase Agreement by and among Amedica Corporation, CTL Corporation and US Spine Inc. dated as of September 5, 2018		Form 8-K (Exhibit 2.1)	10/5/18	001-33624
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
3.1.4	Certificate of Amendment to the Restated Certificate of Incorporation		Form 8-K (Exhibit 3.1)	11/02/18	001-33624
3.1.5	Certificate of Amendment to the Restated Certificate of Incorporation of SINTX Technologies, Inc.		Form 8-K (Exhibit 3.1)	7/26/19	001-33624
3.1.6	Certificate of Designation of Series C Preferred Stock		Form 8-K (Exhibit 3.1)	2/07/20	001-33624
3.2	Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.1)	2/20/14	001-33624
3.2.1	Amendment to the Bylaws of Amedica Corporation dated as of October 30, 2018.		Form 8-K (Exhibit 3.2)	11/02/18	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

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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
4.4	Form of Common Stock Purchase Warrant issued on April 4, 2016.		Form 8-K (Exhibit 4.1)	4/05/16	001-33624
4.5	Form of Series E Warrant		Amendment No. 3 to Form S-1 (Exhibit 4.25)	6/30/16	333-211520
4.6	Form of Warrant		Form 8-K (Exhibit 4.1)	1/20/17	001-33624
4.7	North Stadium Investments, LLC Warrant to Purchase Common Stock		Form 8-K (Exhibit 4.2)	8/3/17	001-33624
4.8	Common Stock Warrant		Form 8-K (Exhibit 3.2)	5/15/18	001-33624
4.9	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
4.10	Form of Indenture		Form S-3 (Exhibit 4.2)	3/25/19	333-230492

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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
4.11	Form of Common Stock Warrant		Form S-1/A	1/15/20	333-234438
4.12	Form of Warrant Agency Agreement between Amedica Corporation and American Stock Transfer and Trust Company, LLC, dated February 6, 2020		Form 8-K (Exhibit 10.1)	2/07/20	001-33624
4.13	Warrant Issued to Maxim Group LLC on February 6, 2020		Form 8-K (Exhibit 4.1)	2/07/20	001-33624
4.14	Warrant Issued to Ascendant Capital Markets, LLC on February 6, 2020		Form 8-K (Exhibit 4.2)	2/07/20	001-33624
4.15	Description of Registrant's Securities	X			
10.1	Centreponte Business Park Lease Agreement Net by and between the Registrant and Centreponte Properties, LLC, dated as of April 21, 2009		Form S-1 (Exhibit 10.10)	11/8/13	333-192232

10.2	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
10.3	Form of Change of Control Agreement*	Form 8-K (Exhibit 10.1)	7/22/15	001-33624
10.4	Form of Indemnification Agreement by and between the Registrant and its officers and directors	Amendment No. 2 Form S-1 (Exhibit 10.14)	12/20/13	333-192232
10.5	SINTX Technologies Amended and Restated 2012 Equity Incentive Plan*	Amendment No. 4 to Form S-1 (Exhibit 10.15)	2/12/14	333-192232
10.6	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
10.7	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

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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
10.8	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
10.9	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
10.10	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
10.11	Security Agreement, dated July 28, 2017		Form 8-K (Exhibit 10.1)	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
10.12	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
10.13	Amended and Restated Promissory Note payable to L2 Capital		Form S-1 (Exhibit 10.25)	4/26/18	333-223032
10.14	Form of Warrant Amendment Agreement		Form S-1 (Exhibit 10.26)	4/26/18	333-223032
10.15	Amendment to Centrepointe Business Park Lease Agreement, dated June 7, 2019, between SINTX Technologies, Inc. and Centrepointe Properties, LLC.		Form 8-K (Exhibit 10.1)	6/10/19	001-33624
10.16	Promissory Note issued by CTL Corporation in favor of Amedica Corporation dated as of October 1, 2018.		Form 8-K (Exhibit 10.1)	10/5/18	001-33624
10.17	Security Agreement between Amedica Corporation and CTL Corporation dated as of October 1, 2018.		Form 8-K (Exhibit 10.2)	10/5/18	001-33624
10.18	Guaranty between Amedica Corporation and Daniel Chon dated as of October 1, 2018.		Form 8-K (Exhibit 10.3)	10/5/18	001-33624
10.19	ROFN Security Agreement between Amedica Corporation and CTL Corporation dated as of October 1, 2018.		Form 8-K (Exhibit 10.4)	10/5/18	001-33624
10.20	Promissory Note, dated April 28, 2020 between SINTX Technologies, Inc. and First State Community Bank.		Form 8-K (Exhibit 10.1)	4/30/20	001-33624
10.21	Form of Share Purchase Agreement		Form 8-K (Exhibit 99.1)	6/29/20	001-33624
10.22	Placement Agency Agreement		Form 8-K (Exhibit 99.2)	6/29/20	001-33624
10.23	Form of Share Purchase Agreement		Form 8-K (Exhibit 99.1)	7/20/20	001-33624
10.24	Placement Agency Agreement		Form 8-K (Exhibit 99.2)	7/20/20	001-33624
10.25	Form of Share Purchase Agreement		Form 8-K (Exhibit 99.1)	8/6/20	001-33624
10.26	Placement Agency Agreement		Form 8-K (Exhibit 99.2)	8/6/20	001-33624

10.27	Form of Indenture	Form S-3 (Exhibit 4.18)	10/2/20	333-249267
10.28	Equity Distribution Agreement, dated as of February 25, 2021, by and between SINTX Technologies, Inc. and Maxim Group LLC	Form 8-K (Exhibit 10.1)	2/26/20	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
21.1	Lit of Subsidiaries (None)				
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. FORM 10-K SUMMARY

None.

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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 22, 2021

/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 22, 2021

/s/ B. Sonny Bal

B. Sonny Bal, M.D., Director

Date: March 22, 2021

/s/ David W. Truetzel

David W. Truetzel, Director

Date: March 22, 2021

/s/ Jeffrey S. White

Jeffrey S. White, Director

Date: March 22, 2021

/s/ Eric A. Stookey

Eric A. Stookey, Director

Date: March 22, 2021

/s/ Mark Froimson

Mark Froimson, M.D., Director

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of
SINTX Technologies, Inc.
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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Warrants classified as Derivative Liabilities Valuation

As described in Note 1 to the financial statements, the Company initially records warrants classified as derivative liabilities at fair value and is required to re-measure the fair value each reporting period. The Company estimates the fair value of these instruments using Monte-Carlo valuation models. 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.

We obtained an understanding, evaluated the design and implementation of controls over the Company's process for calculating the fair values of the warrants classified as derivative liabilities, including controls over management's review of the significant assumptions described above.

To test the estimated fair value of the warrants classified as derivative liabilities, we performed audit procedures that included, among others, assessing methodologies and testing the significant assumptions discussed above as well as underlying data used by the Company in its analysis, and evaluated management's specialist.

/s/ TANNER LLC

March 22, 2021
Lehi, Utah

We have served as the Company's auditors since 2017

**SINTX Technologies, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)**

	As of December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,351	\$ 1,787
Account and other receivables, net of allowance	41	136
Prepaid expenses and other current assets	243	310
Inventories	99	106
Note receivable, current portion	1,856	1,724

Total current assets	27,590	4,063
Inventories	388	533
Property and equipment, net	471	190
Intangible assets, net	36	41
Long-term note receivable, net of current portion	-	1,944
Operating lease right of use asset	1,926	2,341
Other long-term assets	36	35
Total assets	<u>\$ 30,447</u>	<u>\$ 9,147</u>

Liabilities and Stockholders' Equity

Current liabilities:

Accounts payable	\$ 194	\$ 191
Accrued liabilities	909	1,266
Current portion of long-term debt	109	6
Derivative liabilities	1,238	220
Current portion of operating lease liability	403	360
Other current liabilities	26	23
Total current liabilities	<u>2,879</u>	<u>2,066</u>

Operating lease liability, net of current portion	1,477	1,867
Long term debt, net of current portion	287	12
Total liabilities	<u>4,643</u>	<u>3,945</u>

Commitments and contingencies

Stockholders' equity:

Convertible preferred stock Series B, \$0.01 par value, 130,000,000 total shares authorized inclusive of all series of preferred; 26 shares and 249 shares issued and outstanding as of December 31, 2020 and 2019, respectively.	-	-
Convertible preferred stock Series C, \$0.01 par value, 130,000,000 total shares authorized inclusive of all series of preferred; 51 shares and 0 shares issued and outstanding as of December 31, 2020 and 2019, respectively.		
Common stock, \$0.01 par value, 250,000,000 shares authorized; 24,552,409 and 2,434,009 shares issued and outstanding as of December 31, 2020 and 2019, respectively.	245	24
Additional paid-in capital	266,666	239,256
Accumulated deficit	(241,107)	(234,078)
Total stockholders' equity	<u>25,804</u>	<u>5,202</u>
Total liabilities and stockholders' equity	<u>\$ 30,447</u>	<u>\$ 9,147</u>

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

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SINTX Technologies, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	<u>Years Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Product revenue	\$ 594	\$ 689
Costs of revenue	475	551
Gross profit	119	138
Operating expenses:		
Research and development	4,808	3,394
General and administrative	3,132	2,908
Sales and marketing	683	430
Total operating expenses	8,623	6,732
Loss from operations	(8,504)	(6,594)
Other income (expenses):		
Interest expense	(2)	(4)
Interest income	330	450
Offering costs	(1,246)	-
Change in fair value of derivative liabilities	2,111	1,303
Other income	282	48
Total other income, net	1,475	1,797
Net loss before income taxes	(7,029)	(4,797)
Provision for income taxes	-	-
Net loss	(7,029)	(4,797)
Deemed dividend related to beneficial conversion feature and accretion of discount on convertible preferred stock	(9,565)	(2,703)
Net loss attributable to common stockholders	<u>\$ (16,594)</u>	<u>\$ (7,500)</u>
Net loss per share – basic and diluted		
Basic – net loss	\$ (0.43)	\$ (3.08)
Basic – deemed dividend and accretion of a discount on conversion of preferred stock	(0.58)	(1.74)
Basic – attributable to common stockholders	<u>\$ (1.01)</u>	<u>\$ (4.82)</u>

Diluted – net loss	\$	(0.53)	\$	(3.95)
Diluted – deemed dividend and accretion of a discount on conversion of preferred stock		(0.55)		(1.74)
Diluted – attributable to common stockholders	\$	(1.08)	\$	(5.69)
Weighted average common shares outstanding:				
Basic		16,406,556		1,555,988
Diluted		17,446,148		1,555,988

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

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SINTX Technologies, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Preferred B Stock		Preferred C Stock		Common Stock		Paid-In	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2018	4,074	\$ -	-	\$ -	726,455	\$ 7	\$ 237,673	\$ (229,281)	\$ 8,399
Issuance of common stock upon exercise of warrants	-	-	-	-	35,874	-	103	-	103
Issuance of common stock for cash	-	-	-	-	527,896	5	1,446	-	1,451
Issuance of common stock due to conversion of preferred stock	(3,825)	-	-	-	1,143,784	12	(12)	-	-
Accretion of convertible preferred stock discount	-	-	-	-	-	-	2,703	-	2,703
Deemed dividend related to the issuance of preferred stock	-	-	-	-	-	-	(2,703)	-	(2,703)
Extinguishment of derivative liability upon exercise of warrant	-	-	-	-	-	-	44	-	44
Stock-based compensation	-	-	-	-	-	-	2	-	2
Net loss	-	-	-	-	-	-	-	(4,797)	(4,797)
Balance as of December 31, 2019	<u>249</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>2,434,009</u>	<u>24</u>	<u>239,256</u>	<u>(234,078)</u>	<u>5,202</u>
Extinguishment of derivative liability upon exercise of warrant	-	-	-	-	-	-	3,199	-	3,199
Common stock issued for cash, net of fees	-	-	-	-	11,369,381	114	19,882	-	19,996
Issuance of common stock from the cashless exercise of warrants	-	-	-	-	3,504,535	35	(35)	-	-
Issuance of common stock from the exercise of warrants for cash	-	-	-	-	740,968	7	1,104	-	1,111
Preferred stock issued for cash	-	-	9,440	-	-	-	3,112	-	3,112
Common stock issued on conversion of preferred stock	(223)	-	(9,389)	-	6,503,516	65	(65)	-	-
Issuance of agent warrants	-	-	-	-	-	-	168	-	168
Beneficial conversion feature on issuance of convertible preferred stock	-	-	-	-	-	-	3,111	-	3,111
Deemed dividend related to the issuance of preferred stock	-	-	-	-	-	-	(3,111)	-	(3,111)
Accretion of convertible preferred stock discount	-	-	-	-	-	-	6,454	-	6,454
Deemed dividend related to the conversion of preferred stock	-	-	-	-	-	-	(6,454)	-	(6,454)
Stock-based compensation	-	-	-	-	-	-	45	-	45
Net loss	-	-	-	-	-	-	-	(7,029)	(7,029)
Balance as of December 31, 2020	<u>26</u>	<u>\$ -</u>	<u>51</u>	<u>\$ -</u>	<u>24,552,409</u>	<u>\$ 245</u>	<u>\$ 266,666</u>	<u>\$ (241,107)</u>	<u>\$ 25,804</u>

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

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SINTX Technologies, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2020	2019
Cash flow from operating activities		
Net loss	\$ (7,029)	\$ (4,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	78	102
Amortization of right of use asset	415	363
Amortization of intangible assets	5	5
Non-cash interest income	(299)	(443)
Stock based compensation	45	2
Change in fair value of derivative liabilities	(2,111)	(1,303)
Offering costs	325	-
Bad debt expense	-	(3)
Changes in operating assets and liabilities:		
Account and other receivables	94	131
Prepaid expenses and other current assets	(91)	19

Inventories	153	37
Accounts payable and accrued liabilities	(350)	216
Payments on operating lease liability	(347)	(764)
Net cash used in operating activities	(9,112)	(6,435)
Cash flows from investing activities		
Purchase of property and equipment	(360)	(147)
Proceeds from note receivable, net of imputed interest	2,111	1,528
Net cash provided by investing activities	1,751	1,381
Cash flows from financing activities		
Proceeds from issuance of warrant derivative liabilities	6,328	-
Proceeds from issuance of common stock, net of fees	19,995	1,451
Proceeds from issuance of preferred stock, net of fees	3,112	-
Proceeds from issuance of common stock in connection with exercise of warrants	1,111	103
Capital raise costs	-	(157)
Principal payment on debt	(27)	(3)
Proceeds from issuance of debt	406	-
Net cash provided by financing activities	30,925	1,394
Net increase (decrease) in cash and cash equivalents	23,564	(3,660)
Cash and cash equivalents at beginning of year	1,787	5,447
Cash and cash equivalents at end of year	\$ 25,351	\$ 1,787

Years Ended December 31,

	2020	2019
Noncash investing and financing activities		
Extinguishment of derivative liabilities through exercise of warrants	\$ 3,199	\$ 44
Change in par value due to conversion of preferred stock to common stock	65	11
Issuance of Common Stock for the Cashless Exercise of Warrants	35	-
Right-of-Use Assets and assumption of operating lease liability	-	2,704
Issuance of debt for equipment	-	21
Supplemental cash flow information		
Cash paid for interest	\$ 2	\$ 4

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

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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. SINTX is an OEM ceramics company that develops and commercializes silicon nitride for medical and non-medical applications. The core strength of SINTX is the manufacturing, research, and development of silicon nitride ceramics for external partners. The Company presently manufactures silicon nitride spinal implant in its ISO 13485 certified manufacturing facility for CTL Amedica, the exclusive retail channel for silicon nitride spinal implants. The Company believes it is the first and only manufacturer to use silicon nitride in medical applications. The Company’s products are primarily sold in the United States.

On October 1, 2018, the Company completed the sale of its retail spine implant 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 implant 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 implants. 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 U.S. generally accepted accounting principles (“U.S. GAAP”) and include all assets, liabilities and operations of the Company. In May 2020, the Company dissolved its wholly owned subsidiary ST Sub, Inc. At the time of dissolution the subsidiary had no assets, liabilities, equity, or operations. The financial statements after May 8, 2020, are not consolidated.

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, 2020 and 2019, the Company incurred a net loss of \$7.0 million and \$4.8 million, respectively, and used cash in operations of \$9.1 million and \$6.4 million, respectively. The Company had an accumulated deficit of \$241.1 million and \$234.1 million as of December 31, 2020 and 2019, respectively. To date, the Company’s operations have been principally financed from proceeds from the issuance of preferred and common stock 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, 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.

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 February 2014. On February 6, 2020, the Company closed on a rights offering to its stockholders of units, consisting of convertible preferred stock and warrants, for gross proceeds of \$9.4 million, which excludes underwriting discounts and commissions and offering expenses payable by the Company of approximately \$1.2 million. Additionally, during the period of June 2020 through August 2020, the Company closed four registered direct offerings of shares of its common stock, priced at-the-market under Nasdaq rules, resulting in the issuance of a total of 11,015,000 shares of its common stock for gross proceeds of approximately \$20.9 million, before considering issuance costs of approximately \$1.6 million (see Note 8).

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During the year ended December 31, 2019, the Company entered into an at-the-market (ATM) equity distribution agreement in which the Company may sell, from time to time, shares of common stock having an aggregate offering price of up to \$2.5 million. The Company sold 527,896 shares during the year ended December 31, 2019, raising approximately \$1.7 million before deducting fees to the placement agent and other offering expenses of approximately \$0.2 million. During the year ended December 31, 2020, the Company sold 354,381 shares of common stock, raising approximately \$0.8 million deducting fees to the placement agent and other offering expenses of approximately \$0.034 million. As of December 31, 2020, no funding capacity is available under the ATM. (see Note 8).

On October 1, 2018, the Company sold the retail spine implant business to CTL Medical. The sale included a \$6 million noninterest bearing note receivable payable over a 36-month term. With the maturing of the note receivable to occur October 1, 2021, the Company expects cash flows of approximately \$1.9 million from the note during 2021.

Management has concluded existing capital resources will be sufficient to fund operations for at least the next 12 months, or through March 2022.

Reverse Stock Split

On July 26, 2019, the Company effected a 1 for 30 reverse stock split of the Company's common stock. The par value and the authorized shares of the common and preferred stock were not adjusted as a result of the reverse stock split. All common stock shares, equivalents, and per-share amounts for all periods presented in these consolidated financial statements 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, 2020, the most significant estimate relates to derivative liabilities and stock based compensation.

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, and note receivables. 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.

As of December 31, 2020, two customer's receivable balance was 91 % of the Company's total accounts receivable. One customer accounted for 95 % and 100% of the Company's total revenues for the years ended December 31, 2020 and 2019 respectively.

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 signed a 10-year exclusive sales agreement in October 2018. The Company is currently pursuing other sales opportunities for silicon nitride outside the spinal fusion application.

Revenue is recognized when control of the goods or services promised under the contract is transferred to the customer either at a point in time (e.g., upon delivery) or over time (e.g., as performed under the contract). The Company accounts for a contract when it has approval and commitment from both parties, the rights and payment terms of the parties are identified, the contract has commercial substance and collectability of consideration is probable. Contracts are reviewed to determine whether there is one or multiple performance obligations. A performance obligation is a promise to transfer a distinct good or service to a customer and represents the unit of accounting for revenue recognition. For contracts with multiple performance obligations, the expected consideration, or the transaction price, is allocated to each performance obligation identified in the contract based on the relative standalone selling price of each performance obligation. Revenue is then recognized for the transaction price allocated to the performance obligation when control of the promised goods or services underlying the performance obligation is transferred. Contract consideration is not adjusted for the effects of a significant financing component when, at contract inception, the period between when control transfers and when the customer will pay for that good or service is one year or less. Contract modifications that provide for additional distinct goods or services at the standalone selling price are treated as separate contracts. The transaction price for our contracts reflects our estimate of returns, rebates and discounts, which historically have not been significant. Amounts billed to customers for shipping and handling are included in the transaction price and generally are not treated as separate performance obligations as these costs fulfill a promise to transfer the product to the customer. The Company does not employ salespeople to actively seek additional customers; there are no incremental costs for obtaining customers that need to be capitalized.

The Company recognizes revenue from sales at the time the product is shipped.

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Costs of Revenue

The expenses that are included in costs of revenue include all raw material and 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.

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Leases

The Company determines if an arrangement is a lease at inception. Operating leases are in operating lease right of use asset and operating lease liability in our consolidated balance sheet. Finance leases, if any, are included in property and equipment in our consolidated balance sheet. Leases with an initial term of 12 months or less are not presented on the consolidated balance sheet. The Company accounts for lease payments separately than from non-lease components. The depreciable life of the asset and leasehold improvement are limited by the expected lease term.

Account and Other Receivables and Allowance for Doubtful Accounts

Account and other receivables are carried at invoiced amount less an allowance for doubtful accounts. On a regular basis, the Company evaluates account and other receivables 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

The Company evaluates the carrying value of 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, 2020.

Derivative Liabilities

Derivative liabilities include the fair value of certain common stock warrants, that are initially recorded at fair value and are required to be re-measured to fair value at each reporting period. 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 primarily using Monte-Carlo valuation models. 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.

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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 biomedical and antipathogenic products ..

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 not significant for each of the years ended December 31, 2020 and 2019.

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, 2020 and 2019, 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 subjective 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.

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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 expensed in the case of failed offerings.

New Accounting Pronouncement, Not Yet Adopted

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 no other pronouncements will have a significant effect on its financial statements upon adoption.

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Net Loss Per Share – Basic and Diluted

Basic net income (loss) per share is calculated by dividing the net income (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. Common stock equivalents are primarily comprised of preferred stock, options and warrants for the purchase of common stock. The Company had potentially dilutive securities, totaling approximately 1.5 million and 0.5 million shares of common stock as of December 31, 2020 and 2019, respectively.

Below are basic and diluted loss per share data for the year ended December 31, 2020, which are in thousands except for share and per share data:

	Basic Calculation	Effect of Dilutive Warrant Securities	Diluted Calculation
Numerator:			
Net loss	\$ (7,029)	\$ (2,293)	\$ (9,323)
Deemed dividend and accretion of a discount	(9,565)	-	(9,565)
Net loss attributable to common stockholders	<u>\$ (16,594)</u>	<u>\$ (2,293)</u>	<u>\$ (18,888)</u>
Denominator:			
Number of shares used in per common share calculations:	16,406,556	1,039,592	17,446,148
Net loss per common share:			
Net loss	\$ (0.43)	\$ (0.10)	\$ (0.53)
Deemed dividend and accretion of a discount	(0.58)	0.03	(0.55)
Net loss attributable to common stockholders	<u>\$ (1.01)</u>	<u>\$ (0.07)</u>	<u>\$ (1.08)</u>

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Below are basic and diluted loss per share data for the year ended December 31, 2019, which are in thousands except for share and per share data:

	Basic Calculation	Effect of Dilutive Warrant Securities	Diluted Calculation
Numerator:			
Net loss	\$ (4,797)	\$ (1,346)	\$ (6,143)
Deemed dividend and accretion of a discount	(2,703)	-	(2,703)
Net loss attributable to common stockholders	<u>\$ (7,500)</u>	<u>\$ (1,346)</u>	<u>\$ (8,846)</u>
Denominator:			
Number of shares used in per common share calculations:	1,555,988	-	1,555,988
Net loss per common share:			
Net loss	\$ (3.08)	\$ (0.87)	\$ (3.95)
Deemed dividend and accretion of a discount	(1.74)	-	(1.74)
Net loss attributable to common stockholders	<u>\$ (4.82)</u>	<u>\$ (0.87)</u>	<u>\$ (5.69)</u>

2. Inventories

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

As of December 31,	
2020	2019

Raw materials	\$	388	\$	533
WIP		97		106
Finished goods		2		-
	\$	487	\$	639

3. Property and Equipment

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

	As of December 31,	
	2020	2019
Manufacturing and lab equipment	\$ 558	\$ 247
Leasehold improvements	941	941
Software and computer equipment	684	636
Furniture and equipment	82	82
	2,265	1,906
Less: accumulated depreciation	(1,794)	(1,716)
	\$ 471	\$ 190

Depreciation expense for 2020 was approximately \$0.1 million. Depreciation expense for 2019 was approximately \$0.1 million.

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4. Intangible Assets

Intangible assets consisted of the following (in thousands):

	Years Ended December 31,	
	2020	2019
Trademarks	\$ 50	\$ 50
Less: accumulated amortization	(14)	(9)
	\$ 36	\$ 41

Amortization expense for 2020 was approximately \$5.0 thousand. Amortization expense for 2019 was approximately \$5.0 thousand.

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.
- 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, 2020 and 2019. 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, 2020 and 2019.

Description	Fair Value Measurements as of December 31, 2020 (in thousands)			
	Level 1	Level 2	Level 3	Total
Derivative liability				
Common stock warrants	\$ -	\$ -	\$ 1,238	\$ 1,238

Description	Fair Value Measurements as of December 31, 2019 (in thousands)			
	Level 1	Level 2	Level 3	Total
Derivative liability				
Common stock warrants	\$ -	\$ -	\$ 220	\$ 220

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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, 2020 and 2019. 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, 2020 and 2019 (in thousands):

	Common Stock Warrants
Balance as of December 31, 2018	\$ (1,566)
Issuance of derivatives	-
Change in fair value	1,303

Exercise of warrants	44
Other, net	(1)
Balance as of December 31, 2019	(220)
Issuance of derivatives	(6,328)
Change in fair value	2,111
Exercise of warrants	3,199
Balance as of December 31, 2020	<u>\$ (1,238)</u>

Common Stock Warrants

The Company has issued certain warrants to purchase shares of common stock, which are considered derivative liabilities because they have registration rights which could require a cash settlement and are re-measured to fair value at each reporting period in accordance with accounting guidance. As of December 31, 2020, and 2019, the derivative liability was calculated using the Monte Carlo Simulation valuation.

The assumptions used in estimating the common stock warrant liability using the Monte Carlo simulation valuation model as of December 31, 2020 and 2019 were as follows:

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Weighted-average risk-free interest rate	0.09%-0.27%	1.62%
Weighted-average expected life (in years)	0.63-4.10	3.4
Expected dividend yield	-%	-%
Weighted average expected volatility	138.3%-175.6%	64%

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Other Financial Instruments

The Company's recorded values of cash and cash equivalents, account and other receivables, 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):

	<u>Years Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Payroll and related expenses	\$ 600	\$ 589
Resteralization and repackaging costs	-	392
Other	309	285
	<u>\$ 909</u>	<u>\$ 1,266</u>

7. Debt

PPP Loan

On April 28, 2020, the Company received funding under a Paycheck Protection Program ("PPP") loan (the "PPP Loan") from First State Community Bank (the "Lender"). The principal amount of the PPP Loan is \$0.391 million. The PPP was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration (the "SBA"). The PPP Loan has a two-year term, maturing on April 28, 2022. The term may be extended to five-years if the Lender and we agree to do so. The interest rate on the PPP Loan is 1.0% per annum. Principal and interest are payable in 18 monthly installments, beginning on November 28, 2020, until maturity with respect to any portion of the PPP Loan which is not forgiven as described below. The Company did not provide any collateral or guarantees for the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The PPP Loan provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company is permitted to prepay or partially prepay the PPP Loan at any time with no prepayment penalties. The PPP Loan may be partially or fully forgiven if the Company complies with the provisions of the CARES Act, including the use of PPP Loan proceeds for payroll costs, rent, utilities and other expenses, provided that such amounts are incurred during a 24-week period that commenced on April 28, 2020 and at least 60% of any forgiven amount has been used for covered payroll costs as defined by the CARES Act. As explained in Note 15, the Company received notice the principal amount and accrued interest had been forgiven subsequent to December 31, 2020.

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8. Equity

2020 Rights Offering

During February 2020, the Company closed on a rights offering capital raise wherein the Company's holders of common stock, Series C Preferred Stock, and certain outstanding warrants on the date of record, obtained, at no charge, non-transferable subscription rights to purchase units ("Units"). Each Unit consisted of one share of Series C Convertible Preferred Stock ("Preferred Stock") and 675 warrants to purchase common stock ("Warrants"). Each Unit sold for \$1,000. Each share of the Preferred Stock is convertible, at the Company's option at any time on or after the first anniversary of the expiration of the rights offering or at the option of the holder at any time, into a number of shares of our common stock equal to the quotient of the stated value of the Preferred Stock (\$1,000) divided by the Conversion Price (\$1.4814 per share). Each Warrant is exercisable for one share of our common stock at an exercise price of \$1.50 per share from the date of issuance through its expiration five years from the date of issuance. The Warrants also contain a cashless exercise provision that allows the holder to receive 70% of the common stock otherwise available under the warrant to the holder electing the cashless exercise provision. The Company issued 9,440 Units, which includes 6,372,000 Warrants exercisable into shares of our common stock and preferred shares that are convertible into 6,372,350 shares of Common Stock, for gross proceeds of \$9.4 million.

The Company raised \$9.4 million, before consideration of issuance costs, associated with the issuance of the Units, with \$3.1 million allocated to the preferred stock (with no offering costs allocated to the preferred stock) and \$5.1 million, net of offering costs of approximately \$1.2 million, allocated to the warrants. In association with the warrants that were recorded as a derivative liability, the Company immediately expensed approximately \$1.2 million of the offering costs.

During the year ended December 31, 2020, Series B Convertible Preferred stockholders of the Company converted 223 shares of Series B Convertible Preferred Stock into 165,586 shares of common stock, and Series C Convertible Preferred stockholders of the Company converted 9,389 shares of Series C Convertible Preferred Stock into 6,337,930 shares of common stock.

Also, during the year ended December 31, 2020, holders of Warrants electing to use the cashless exercise option exercised 5,006,475 warrants, which resulted in the issuance of 3,504,535 shares of common stock. During the same period of time, holders of Warrants electing to exercise warrants for cash exercised 709,425 warrants, which resulted in the issuance of 709,425 shares of common stock, and the receipt of \$1.1 million of cash.

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2020 Registered Direct Offerings

During June 2020, the Company closed two registered direct offerings of shares of its common stock, priced at-the-market under Nasdaq rules, resulting in the issuance of a total of 6,100,000 shares of its common stock for gross proceeds of approximately \$9.6 million, before considering offering costs of approximately \$0.8 million. On June 23, 2020, the Company entered into the first Share Purchase Agreement with certain institutional purchasers, pursuant to which the Company agreed to issue and sell to the purchasers, in a registered direct offering, an aggregate of 3,700,000 shares of common stock, par value \$0.01 per share. The shares were sold at a negotiated purchase price of \$1.50 per share for aggregate gross proceeds to the Company of approximately \$5.5 million, before deducting offering costs. Following the initial registered direct offering, on June 26, 2020, the Company entered into the second Share Purchase Agreement with certain institutional purchasers pursuant to which the Company offered to the purchasers, in a registered direct offering, an aggregate of 2,400,000 shares of common stock, par value \$0.01 per share. The shares were sold at a negotiated purchase price of \$1.72 per share for aggregate gross proceeds to the Company of approximately \$4.1 million, before deducting offering costs.

During July and August 2020, the Company closed two registered direct offerings of shares of its common stock, priced at-the-market under Nasdaq rules, resulting in the issuance of a total of 4,915,000 shares of its common stock for gross proceeds of approximately \$11.2 million, before considering offering costs of approximately \$0.8 million. On July 16, 2020, the Company entered into a Share Purchase Agreement with certain institutional purchasers, pursuant to which the Company agreed to issue and sell to the purchasers, in a registered direct offering, an aggregate of 1,500,000 shares of common stock, par value \$0.01 per share. The shares were sold at a negotiated purchase price of \$2.00 per share for aggregate gross proceeds to the Company of \$3.0 million, before deducting offering costs. On August 4, 2020, the Company entered into a Share Purchase Agreement with certain institutional purchasers, pursuant to which the Company agreed to issue and sell to the purchasers, in a registered direct offering, an aggregate of 3,415,000 shares of common stock, par value \$0.01 per share. The shares were sold at a negotiated purchase price of \$2.40 per share for aggregate gross proceeds to the Company of \$8.2 million, before deducting offering costs.

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2019 ATM Stock Offerings

On June 4, 2019, the Company entered into an Equity Distribution Agreement, (the "Distribution Agreement"), with Maxim Group LLC ("Maxim"), pursuant to which the Company may sell from time to time, shares of its common stock, having an aggregate offering price of up to \$1.6 million through Maxim, as agent (the "ATM Offering"). On September 12, 2019, the Company entered into an amendment to the Distribution Agreement with Maxim, which increased the maximum aggregate offering price of the shares of the Company's common stock from \$1.6 million to \$2.5 million. Subject to the terms and conditions of the Distribution Agreement, Maxim will use its commercially reasonable efforts to sell the shares from time to time, based on the Company's instructions. The Company has no obligation to sell any of the shares and may at any time suspend offers under the Distribution Agreement. The Company agreed to pay Maxim a transaction fee at a fixed rate of 4.25% of the gross sales price of shares sold under the Distribution Agreement and agreed to provide indemnification and contribution to Maxim with respect to certain liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended. During the year ended December 31, 2019, the Company raised approximately \$1.7 million before deducting fees to the placement agent and other offering costs of approximately \$0.2 million, through the issuance of 527,896 shares of common stock under the Distribution Agreement with Maxim. During the year ending December 31, 2020, the Company sold 354,381 shares of common stock, raising approximately \$0.8 million before deducting offering costs of approximately \$0.034 million. As of December 31, 2020, no funding capacity is available under the ATM, and the Distribution Agreement was terminated.

9. Stock-Based Compensation

During the year ended December 31, 2020, the shareholders approved the 2020 Equity Incentive Plan. The 2020 Plan provides for the grant of nonqualified stock options, incentive stock options, restricted stock, restricted stock units, stock appreciation rights (SARs), and performance share awards to employees, officers, consultants, advisors, non-employee directors and independent contractors designated by either the board of directors of the Company or if so authorized by the board of directors, the Compensation Committee (the "Committee") of the board of directors. Under the 2020 Plan, the maximum number of shares of common stock which may be issued is 1,902,520 shares of common stock, which includes 2,520 shares that have been rolled over from our 2012 Plan, as amended.

A summary of the Company's outstanding stock option activity for the years ended December 31, 2020 and 2019 is as follows:

	December 31, 2020			
	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Intrinsic Value
As of December 31, 2019	377	\$ 7,446.69	5.3	-
Granted	465,017	0.47	10.0	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	(1)	-	-	-
As of December 31, 2020	465,393	\$ 5.53	9.3	\$ 511,518
Exercisable at December 31, 2020	376	\$ 6,977.42	4.3	\$ -
Vested and expected to vest at December 31, 2020	465,393	\$ 5.53	9.3	\$ 511,518

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	December 31, 2019			
	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Intrinsic Value
As of December 31, 2018	377	\$ 7,446.69	6.3	\$ -

Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	-	-
As of December 31, 2019	377	\$ 7,446.69	5.3	\$ -
Exercisable and vested at December 31, 2019	377	\$ 7,446.69	5.3	\$ -

The Company estimates the fair value of each stock option on the grant date using the Black-Scholes-Merton valuation model, which requires several estimates including an estimate of the fair value of the underlying common stock on grant date. The expected volatility was based on an average of the historical volatility of the Company. The expected term was contractual life of option. The risk-free interest rate was based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the option. The following weighted average assumptions were used in the calculation to estimate the fair value of options granted to employees and non-employees during the year ended December 31, 2020.

	Year Ended December 31, 2020
Weighted-average risk-free interest rate	0.34%
Weighted-average expected life (in years)	10
Expected dividend yield	-9%
Weighted-average expected volatility	130%

Of the 465,017 options granted during 2020, 235,000 were to non-employees. During the year ended December 31, 2020, the Company granted 50,000 common stock grants with a fair value of \$24 thousand. The stock grants vest over three years and were valued using the closing price of the Company's common stock on the date of grant.

Unrecognized stock-based compensation as of December 31, 2020, is as follows (in thousands):

	Unrecognized Stock- Based Compensation	Weighted Average Remaining of Recognition (in years)
Stock options	\$ 169	2.3
Stock grants	\$ 19	2.3

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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,	
	2020	2019
Federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(4.4)%	(7.0)%
Return to provision	0.0%	(11.2)%
Equity related expenses	(2.6)%	(5.7)%
Change in valuation allowance	28.0%	44.9%
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,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 50,005	\$ 48,104
Stock-based compensation	2,929	2,918
Federal R&D credit	2,222	2,222
Accrued expenses	135	112
Depreciation	-	27
Intangibles	103	1
Total deferred tax assets	55,394	53,384
Deferred tax liabilities:		
Depreciation	(29)	-
Right of Use Asset/Liabilities	(11)	-
Total deferred tax liabilities	(40)	-
Less valuation allowance	(55,354)	(53,384)
Net deferred tax liability	\$ -	\$ -

	December 31,	
	2020	2019
Pre-tax book income tax at statutory rate	\$ (1,476)	\$ (1,007)
State taxes, net of federal benefit	(312)	(336)
Return to provision	1	(538)
Equity related expenses	(182)	(274)
Change in valuation allowance	1,970	2,153

Other		(1)	2
Total income tax expense	\$	-	\$ -

As of December 31, 2020 and 2019, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately \$200.4 million and \$192.8 million, respectively. The federal and state net operating loss carryforwards will expire from 2024 to 2039 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, 2020 and 2019, 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 \$2.0 million and \$2.2 million for the years ended December 31, 2020 and 2019, respectively.

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11. Commitment and Contingencies

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, 2020 and 2019.

13. Note Receivable

On October 1, 2018, the Company completed the sale of its spine implant business to CTL Medical. The sale included a \$6 million noninterest bearing note receivable payable over a 36 month term, with maturing of the note receivable on October 1, 2021. The note receivable includes an imputed interest rate of 10%. As of December 31, 2020, the net carrying value of the note receivable was \$1.9 million, with expected cash proceeds of \$1.9 million.

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14. Leases

The Company leases office, warehouse and manufacturing space under a single operating lease, which lease originally expired during 2019. On June 7, 2019, the lease was amended to extend the rental period through 2024 and reduce the amount of space leased from 54,428 square feet to 29,534 square feet. The new rent is effective January 1, 2020. The amended lease has two five-year extension options. As of December 31, 2020, the operating lease right-of-use asset totaled approximately \$1.9 million and the operating lease liability totaled approximately \$1.9 million. Amortization of right of use asset expense during the year ended December 31, 2020, totaled approximately \$0.4 million. As of December 31, 2020, the weighted-average discount rate for the Company's operating lease totaled 6.5 %.

Leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease expense is recognized on a straight-line basis over the term of the lease. The Company accounts for lease components separately from the non-lease components. The depreciable life of the assets and leasehold improvements are limited by the expected lease term.

Operating lease future minimum payments together with the present values as of December 31, 2020, are summarized as follows:

	December 31, 2020
2021	\$ 513
2022	528
2023	544
2024	560
Total future minimum lease payments	2,145
Less amounts representing interests	(265)
Present value of lease liability	1,880
Current-portion of operating lease liability	403
Long-term portion operating lease liability	\$ 1,477

15. Subsequent Events

2020 PPP Loan

On January 5, 2021, the Lender of the PPP loan (see Note 7) provided notice to the Company the principal amount and accrued interest had been forgiven. During 2021, the Company will remove the PPP Loan obligation and record other income for forgiveness of debt totaling \$0.4 million. The SBA has until January of 2027 to audit the Company's compliance with the CARES Act relating to the PPP Loan.

2021 ATM Stock Offerings

On February 25, 2021, we entered into an Equity Distribution Agreement (the “2021 Distribution Agreement”) with Maxim Group LLC (“Maxim”), pursuant to which we may sell from time to time, shares of our common stock, \$0.01 par value per share, having an aggregate offering price of up to \$15,000,000 million through Maxim, as agent.

Subject to the terms and conditions of the 2021 Distribution Agreement, Maxim will use its commercially reasonable efforts to sell the Shares from time to time, based on our instructions. Under the 2021 Distribution Agreement, Maxim may sell the Shares by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), including, without limitation, sales made directly on the Nasdaq Capital Market. We have no obligation to sell any shares under the ATM and may at any time suspend offers under the 2021 Distribution Agreement. The Offering will terminate upon the earlier of (i) the sale of shares having an aggregate offering price of \$15,000,000 million, (ii) the termination by either Maxim or the Company upon the provision of fifteen (15) days written notice, or (iii) February 25, 2022. Under the terms of the 2021 Distribution Agreement, Maxim will be entitled to a transaction fee at a fixed rate of 2.0% of the gross sales price of Shares sold under the 2021 Distribution Agreement. The Company will also reimburse Maxim for certain expenses incurred in connection with the 2021 Distribution Agreement, and agreed to provide indemnification and contribution to Maxim with respect to certain liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended.

O2 Design Patent License Agreement

On February 25, 2021, the Company entered into an exclusive, two-year, worldwide license with O2 Design to commercialize face masks and mask filters that incorporate the Company’s sintered silicon nitride intended to inactivate the SARS-VoV-2 virus. When the face mask incorporating the silicon nitride becomes available for sale the Company will receive an upfront fee and royalties and potential performance-based milestone payments based on the sale of products incorporating the silicon nitride materials. The Company will also be the exclusive supplier of silicon nitride to O2 Design.

2021 PPP Loan

On March 15, 2021, the “Company received funding under the SBA Second Draw Program under the Paycheck Protection Program (“2021 PPP”) (the “2021 PPP Loan”) from First State Community Bank (the “Lender”). The principal amount of the 2021 PPP Loan is \$509,148.00. The 2021 PPP was established under the CARES Act and is administered by the SBA. The 2021 PPP Loan has a five-year term, maturing on March 15, 2026. The interest rate on the 2021 PPP Loan is 1.0% per annum.

The Company will not be obligated to make any payments of principal or interest if the Company submits a loan forgiveness application to the Bank within 10 months after the end of the Company's covered loan forgiveness period (as defined and interpreted by the 2021 PPP Rules) and such loan forgiveness is allowed. Generally, all or a portion of the 2021 PPP Loan may be forgiven if the Company maintains its employment and compensation within certain parameters during the twenty-four (24) week period following the loan origination date and the proceeds of the 2021 PPP Loan are spent on payroll costs, rent or lease agreements dated before February 15, 2020 and utility payments arising under service agreements dated before February 15, 2020.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934**

SINTX Technologies, Inc. ("SINTX," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

Authorized Shares of Capital Stock

Our Restated Certificate of Incorporation authorizes us to issue 250,000,000 shares of common stock, par value \$0.01 per share, and 130,000,000 shares of preferred stock, par value \$0.01 per share. The following is a summary of the rights of our common stock and some of the provisions of our Restated Certificate of Incorporation and Restated Bylaws, and the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you and is subject to and qualified in its entirety by our Restated Certificate of Incorporation and our Restated Bylaws.

Our Restated Certificate of Incorporation and our Restated Bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors, which may have the effect of delaying, deferring or preventing a future takeover or change in control of the Company unless such takeover or change in control is approved by our board of directors.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote can elect all of the directors standing for election. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments. All outstanding shares of our common stock are fully paid and nonassessable. The holders of common stock have no preferences or rights of conversion, exchange, pre-emption or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of our common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company. The transfer agent and the registrar's address is 59 Maiden Lane, New York, New York 10038.

Our common stock is listed on The NASDAQ Capital Market under the symbol "SINT".

Effects of Anti-Takeover Provisions of Our Restated Certificate of Incorporation, Our Restated Bylaws and Delaware Law

The provisions of (1) Delaware law, (2) our Restated Certificate of Incorporation and (3) our Restated Bylaws discussed below could discourage or make it more difficult to prevail in a proxy contest or effect other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change in control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. These provisions also are intended to discourage certain tactics that may be used in proxy fights. These provisions also may have the effect of preventing changes in our management.

Delaware Statutory Business Combinations Provision. We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a "business combination" is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an "interested stockholder" is a person who, together with his or her affiliates and associates, owns (or within three years prior, did own) 15% or more of the corporation's voting stock.

Classified Board of Directors; Appointment of Directors to Fill Vacancies; Removal of Directors for Cause. Our Restated Certificate of Incorporation provides that our board of directors will be divided into three classes as nearly equal in number as possible. Each year the stockholders will elect the members of one of the three classes to a three-year term of office. All directors elected to our classified board of directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. The board of directors is authorized to create new directorships and to fill any positions so created and is permitted to specify the class to which any new position is assigned. The person filling any of these positions would serve for the term applicable to that class. The board of directors (or its remaining members, even if less than a quorum) is also empowered to fill vacancies on the board of directors occurring for any reason for the remainder of the term of the class of directors in which the vacancy occurred. Members of the board of directors may only be removed for cause and only by the affirmative vote of holders of at least 80% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the board of directors. For example, in general, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the board of directors.

Authorization of Blank Check Preferred Stock. Our Restated Certificate of Incorporation provides that our board of directors is authorized to issue, without stockholder approval, blank check preferred stock. Blank check preferred stock can operate as a defensive measure known as a "poison pill" by diluting the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors. Our Restated Bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 90 days nor more than 120 days prior to the anniversary of the mailing date of the proxy statement for the previous year's annual meeting. For a special meeting, the notice must generally be delivered no less than 60 days nor more than 90 days prior to the special meeting or ten days following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in our Restated Bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaw provisions, this business will not be conducted at the meeting.

Special Meetings of Stockholders. Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

No Stockholder Action by Written Consent. Our Restated Certificate of Incorporation does not permit our stockholders to act by written consent. As a result, any action to be affected by our stockholders must be affected at a duly called annual or special meeting of the stockholders.

Super-Majority Stockholder Vote required for Certain Actions. The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless the corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our Restated Certificate of Incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section entitled "Effect of Anti-Takeover Provisions of Our Restated Certificate of Incorporation, Our Restated Bylaws and Delaware Law" or to reduce the number of authorized shares of common stock or preferred stock. This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. An 80% vote is also required for any amendment to, or repeal of, our Restated Bylaws by the stockholders. Our Restated Bylaws may be amended or repealed by a simple majority vote of the board of directors.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

SINTX Technologies, Inc.
Salt Lake City, Utah

We hereby consent to the incorporation by reference in Registration Statements on Form S-1 (Nos. 333-223032 and 333-234438), Form S-3 (Nos. 333-207289, 333-205545, 333-214804, 333-230492, and 333-249267) and Form S-8 (No. 333-194977 and 333-248846) of SINTX Technologies, Inc. (the Company) of our report dated March 22, 2021, relating to our audit of the financial statements, which appears in this Annual Report on Form 10-K of SINTX Technologies, Inc. for the year ended December 31, 2020.

/s/ Tanner LLC
March 22, 2021
Lehi, Utah

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, B. Sonny Bal, certify that:

1. I have reviewed this annual report on Form 10-K of SINTX Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 22, 2021

By: /s/ B. Sonny Bal

B. Sonny Bal
Chief Executive Officer

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, B. Sonny Bal, certify that:

1. I have reviewed this annual report on Form 10-K of SINTX Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 22, 2021

By: /s/ B. Sonny Bal

B. Sonny Bal
Principal Financial Officer

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of SINTX Technologies, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2020 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 22, 2021

By: /s/ B. Sonny Bal

B. Sonny Bal

Chief Executive Officer and Principal Financial Officer
