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, 2024

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

1885 West 2100 South, Salt Lake City, UT 84119
(Address of principal executive offices and Zip Code)

(801) 839-3500
(Registrant's telephone number, including area code)

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

Title of each class	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	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $3,592,025.

The number of shares outstanding of the registrant's common stock, $0.01 par value per share, as of March 11, 2025 was 2,515,179.

DOCUMENTS INCORPORATED BY REFERENCE:

None

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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 achieve and sustain 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://sintx.com/investorsv2/ 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."

SUMMARY OF PRINCIPAL RISK FACTORS

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 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.

Risks Related to Our Business and Strategy

- We have incurred net losses since our inception and may never achieve or sustain profitability.
- Our success depends on our ability to successfully commercialize advanced ceramic products for biomedical, technical, and antipathogenic applications, which to date have experienced only limited market acceptance and which we may not be able to successfully commercialize.

- We may not be able to compete effectively against the larger, well-established companies that dominate these markets or emerging and small innovative companies seeking to increase their share of the market.
- We depend on our aerospace and biomedical customers' ability to sell the products they manufacture. If our customers are not able to sell such products, our business and operating results will be adversely affected.
- If we are unable to manufacture our advanced ceramic 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.
- 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 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.
- Cyber security risks and the failure to maintain the integrity of company, employee or guest data could expose us to business disruptions, data loss, litigation and liability, and our reputation and operating results could be significantly harmed.

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

- Contracting with government entities exposes us to additional risks and regulatory requirements.
- We cannot be certain that we will be able to obtain regulatory clearance or approval and thereafter commercialize our biomedical or antipathogenic product candidates in a timely manner or at all.
- 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 commercialize our products or operate our business profitably.
- We have no patent protection covering the composition of matter for our solid silicon nitride or components of the related manufacturing process, and competitors may create formulations or processes substantially similar to ours.
- We could become subject to intellectual property litigation that could 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 advanced ceramic 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 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 may not be able to maintain our listing on the NASDAQ Capital Market, which would adversely affect the price and liquidity of our common stock.

PART I

ITEM 1. BUSINESS

Overview – SINTX Technologies

SINTX Technologies is an advanced ceramics company formed in December 1996, focused on providing biomedical solutions for medical devices. We have grown from focusing primarily on the research, development and commercialization of medical devices manufactured with silicon nitride to becoming an advanced ceramics company engaged in diverse fields, including biomedical and antipathogenic applications. This diversification enables us to focus on our core competencies which are the manufacturing, research, and development of products comprised from advanced ceramic materials. We seek to connect with new customers, partners and manufacturers to help them realize the goal of leveraging our expertise in advanced ceramics to create new, innovative products across these sectors.

SINTX Core Business

Biomedical Applications: Since its inception, SINTX has been focused on medical grade silicon nitride. SINTX biomedical products have been shown to be biocompatible, bioactive, antipathogenic, and to have superb bone affinity. Spinal implants made from SINTX silicon nitride have been successfully implanted in humans since 2008 in the U.S., Europe, South America and Asia. This established use, along with its inherent resistance to bacterial adhesion and bone affinity suggests that it may also be suitable in other fusion device applications such as arthroplasty implants, foot wedges, and dental implants. Bacterial infection of any biomaterial implants is always a concern. SINTX silicon nitride has been shown to be resistant to bacterial colonization and biofilm formation, making it antibacterial. SINTX silicon nitride products can be polished to a smooth and wear-resistant surface for articulating applications, such as bearings for hip and knee replacements.

We believe that silicon nitride has a superb combination of properties that make it 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, 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.

Antipathogenic Applications: Today, there is a global need to improve protection against pathogens in everyday life. SINTX believes that by incorporating its unique composition of silicon nitride antipathogenic powder into products such as face masks, filters, and wound care devices, it is possible to manufacture surfaces that inactivate pathogens, thereby limiting the spread of infection and disease. The discovery in 2020 that SINTX silicon nitride inactivates SARS-CoV-2, the virus which causes the disease COVID-19, has opened new markets and applications for our material.

We presently manufacture advanced ceramic powders and components in our manufacturing facilities based in Salt Lake City, Utah.

Our Products

Silicon Nitride

To control the quality, cost and availability of our silicon nitride products and product candidates, we operate our own silicon nitride manufacturing facility. Our 31,000 square foot corporate facility includes a 19,000 square foot FDA registered ISO 13485:2016 certified, and AS9100D certified 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. 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 allows us to produce silicon nitride in multiple distinct forms. This capability provides us with the ability to utilize our silicon nitride in a variety of ways depending on the intended application, which, together with our silicon nitride's key characteristics, distinguishes us from other manufacturers of silicon nitride products.

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 which can be used for devices that require high strength, toughness, fracture resistance and low wear. Applications include medical devices – such as interbody spinal fusion implants – and non-medical such as electrical and aerospace components.
- *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.
- *Composites of Silicon Nitride and PEEK and PEKK.* We have demonstrated that it is possible to compound our silicon nitride powder and the polymers PEEK and PEKK and that the ensuing composite material maintains the bioactive properties of silicon nitride. We have engaged academic and commercial partners to assist us in developing this technology and have received NIH grants to assist in advancing this work. This composite material would allow the straightforward 3D printing of complex spine and CMF devices 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.

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 element's silicon and nitrogen, with the chemical formula Si_3N_4.

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.

- *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.

We are leveraging our proprietary Silicon Nitride (SiN) and Polyether Ether Ketone (PEEK) formulation to advance AI designed 3D printing capabilities for Custom and Patient-Specific medical implants. This innovative material combination integrates the superior biocompatibility, osteointegration, and antimicrobial properties of Silicon Nitride with the strength, durability, and radiolucency of PEEK, resulting in next-generation implants that enhance mechanical performance, reduce infection risks, and improve imaging compatibility.

The demand for personalized implants is growing as surgeons seek optimized solutions tailored to individual patient anatomy, improving surgical outcomes and reducing complications. Additionally, the regulatory pathway for custom and patient-specific medical devices is significantly more streamlined than traditional premarket approval (PMA) or even 510(k) clearance routes. Under the FDA's existing framework, many patient-matched implants can be commercialized through the Custom Device Exemption (CDE) pathway or through rapid 510(k) clearances, expediting market entry and adoption.

The benefits of AI designed 3D-printed SiN/PEEK implants extend across the entire healthcare ecosystem. For hospitals, these implants can reduce hospital stays and operative times related to traditional Custom implant manufacturing. It may also lower the costs associated with revision surgeries and improve patient satisfaction scores.

Physicians benefit from precision-engineered implants that enhance surgical predictability and performance, minimizing intraoperative adjustments. As well as accurate intraoperative placement of the implants because of radiolucency of SiN/PEEK. Additionally, the Patients may experience better functional outcomes, faster recovery times, and a reduced risk of complications due to the antimicrobial nature of Silicon Nitride and the superior biomechanical properties of the SiN/PEEK composite.

With its unique expertise and proprietary formulation and advanced manufacturing techniques of SiN/PEEK, we are well-positioned to capitalize on this rapidly expanding market, providing innovative solutions that meet the needs of healthcare providers and patients alike.

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.

Our Competitive Strengths

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 a 19,000 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.
- *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 advanced ceramics company. Key elements of our strategy to achieve this goal are the following:

- *Develop new silicon nitride manufacturing technologies.* Our current manufacturing process has allowed us to successfully produce spinal implants for over 10 years. We have made advancements in our processes – including the purchase of new manufacturing equipment – which we have leveraged to develop new porous and textured implants. In 2021, SINTX purchased new equipment for its research and development team to develop new composite products of silicon nitride with rigid polymers and fabrics. We have received three NIH grants to develop 3D printed silicon nitride / polymer implantable medical devices.

- *Apply our silicon nitride technology platform to new medical opportunities.* 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 OEM and private label partnerships. We see specific opportunities in markets such as foot and ankle, dental, maxillofacial, and arthroplasty.
- *Develop new products with anti-pathogenic properties, including inactivation of the SARS-CoV-2 virus, utilizing our silicon nitride technology.* We have conducted multiple tests over the last nine years which have identified and verified the antipathogenic properties of our silicon nitride powders, fully dense components, and silicon nitride-containing composites. Our research has explored the fundamental mechanisms responsible for these antipathogenic properties with the objective of developing commercial products and revenue from them. We have several partnerships exploring opportunities in face masks, filters, wound care, and coatings.

Market Opportunity

Biomedical

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 approximately 3 years remaining of 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, foot & ankle, and maxillofacial applications. We believe we can also utilize our silicon nitride technology platform to develop future products in additional medical markets.

We believe that the main drivers for growth within the medical device markets 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. We are leveraging proprietary Silicon Nitride (SiN) and Polyether Ether Ketone (PEEK) formulation to advance AI designed 3D printing capabilities for Custom and Patient-Specific medical implants. This innovative material combination integrates the superior biocompatibility, osteointegration, and antimicrobial properties of Silicon Nitride with the strength, durability, and radiolucency of PEEK, resulting in next-generation implants that enhance mechanical performance, reduce infection risks, and improve imaging compatibility.
- *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 South America and Asia.

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 to have a competitive advantage, we must continue to develop and maintain the proprietary aspects of our technologies.

We have fifteen issued U.S. patents, twelve issued foreign patents, fifteen pending U.S. non-provisional patent applications, eighty-one pending foreign applications and one pending PCT patent application. Our first issued patent expired in 2016, with the last of these patents expiring in 2039.

We have three U.S. patents directed to articulating implants using our high-strength, high toughness doped silicon nitride solid ceramic. These issued patents, which include US 7,666,229; US 9,051,639; and US 9,517,136 will expire in November 2023, September 2032, and March 2034, respectively.

We also have one U.S. patent 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. The issued patent US 9,649,197 will expire in July 2035.

In addition, U.S. Patent No. 10,806,831 directed to antibacterial implants and U.S. Patent No. 11,191,787 directed to antipathogenic devices were recently issued which will expire in 2037 and 2039, 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 one divisional patent application filed in Europe and two divisional applications filed in Japan 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 to seek patent protection for our 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 to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2020/037170 directed to methods of surface functionalization of zirconia-toughened alumina with silicon nitride, we entered the national stage in Europe, Australia, Brazil, Canada, China, India, Japan, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/014725 directed to antifungal composites and methods thereof, we entered the national stage in Europe, Brazil, Japan, Australia, Canada, China, India, Mexico, and South Korea to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/027258 directed to antipathogenic face mask, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/027263 directed to systems and methods for rapid inactivation of SARS-CoV2 by silicon nitride, copper, and aluminum nitride, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/038364 directed to antipathogenic devices and methods thereof for antifungal applications, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/028975 directed to methods for laser coating of silicon nitride on a metal substrate, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no PCT/US2021/028641 directed to methods of silicon nitride laser cladding, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/027270 directed to antiviral compositions and devices and methods of use thereof, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/056461 directed to systems and methods for selective laser sintering of silicon nitride and metal composites, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/056452 directed to systems and methods for hot-isostatic pressing to increase nitrogen content in silicon nitride, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2021/062650 directed to nitride based antipathogenic compositions and devices and method of use thereof, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

With respect to PCT application serial no. PCT/US2022/023868 directed to systems and methods for physical vapor deposition silicon nitride coatings having antimicrobial and osteogenic enhancements, we entered the national stage in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, and Mexico to seek patent protection for our proprietary technologies in those countries.

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.

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 coated, variable-density, and thin walled implants;
- designs for knee implants;
- implants with improved antibacterial characteristics;
- implants with improved wear performance and surface functionalization
- antipathogenic, antibacterial, antimicrobial, antifungal, and antiviral compositions, devices, and methods; and
- methods and systems for hot-isostatic pressing laser cladding, laser coating, and laser sintering of silicon nitride.

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 medical device market, which utilize a variety of competitive biomaterials, include: Medtronic, Inc.; DePuy Synthes Companies, a group of Johnson & Johnson companies; Stryker Corporation; and Zimmer Biomet, 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.

Our main competitors in the antipathogenic market segment include BactiGuard and MicroBan.

Competition within our industries is primarily based on technology, innovation, product quality, and product awareness and acceptance by customers. 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 products and product candidates non-competitive. Our ability to compete successfully will depend upon our ability to develop innovative products with advanced performance features.

Government Regulation of Medical Devices

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

United States

Pre-Marketing Regulation

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

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

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

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

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

Post-Marketing Regulation

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

- compliance with the QSR, which require manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling; and
- medical device reporting obligations, which require that manufacturers investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

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

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

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

International Regulation

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

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of relevant directives will be entitled to bear CE Conformity Marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European Union. Actual implementation of these directives, however, may vary on a country-by-country basis. The CE Mark is a mandatory conformity mark on medical devices distributed and sold in the European Union and certifies that a medical device has met applicable requirements.

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

Compliance with Healthcare Laws

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

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

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

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

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

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

There are also an increasing number of state "sunshine" laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices. In addition, a federal law known as the Physician Payments Sunshine Act, now requires medical device manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The first reporting period covered only payments or transfers of value made and ownership or investment interests held by physicians and their immediate family members from August 1, 2013 to December 31, 2013. The federal government disclosed the reported information on a publicly available website beginning in September 2014. For calendar year 2014, the Physician Payments Sunshine Act will require medical device manufacturers to report payments and transfers of values made and ownership or investment interests held by physicians and their immediate family members for the full calendar year. These laws may adversely affect our sales, marketing, and other activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or to otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

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

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

Third-Party Reimbursement

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

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

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

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

While it is expected that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Commercial insurers and managed care plans frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. These third-party payors may deny payment if they determine that a procedure was not medically necessary, a device used in a procedure was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved use. 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, 2025, we had 20 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. We strive toward having a diverse team of employees and are committed to equality, inclusion and workplace diversity.

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 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, 2024 was $3.6 million. In February 2025 we closed the public offering of $5.0 million of units consisting of shares of common stock, Pre-funded Warrants, and common stock purchase warrants, resulting in net proceeds to us of approximately $3.4 million. We expect our current cash and cash equivalents will be sufficient to fund our operations through the second quarter of 2026. We will require substantial future capital in order to continue to continue operating our business, conduct the research and development and regulatory clearance and approval activities necessary to bring our products to market, and 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 choose to conduct;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

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

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

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

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

Raising additional capital by issuing securities or through debt financings or licensing arrangements will likely 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 will likely 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.

Risks Related to Our Business and Strategy

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

We have incurred substantial net losses since our inception. For the years ended December 31, 2024 and 2023 we incurred a net loss of $11.0 million and $8.3 million, respectively, and used cash in operations of $8.6 million and $14.1 million, respectively. We have an accumulated deficit of $281.7 and $270.7 million as of December 31, 2024 and 2023 respectively. 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 advanced ceramic products for biomedical, and antipathogenic 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 advanced ceramics company, we must increase market awareness of our silicon nitride interbody spinal fusion products in conjunction with CTL, and develop and launch new biomedical, industrial, and antipathogenic 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 biomedical 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 largely 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 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. Even if we receive regulatory clearances or approvals for our other product candidates in development, these product candidates may not gain market acceptance among customers.

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 orthopedic 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 number of orthopedic sales worldwide.

These companies enjoy significant competitive advantages over us, including:

- broad product offerings, which address the needs of orthopedic surgeons and hospitals in a wide range of procedures;
- products that are supported by long-term clinical data;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;

- existing relationships with orthopedic surgeons;
- extensive intellectual property portfolios and greater resources for patent protection;
- greater financial and other resources for product research and development;
- greater experience in obtaining and maintaining FDA and other regulatory clearances and approvals for products and product enhancements;
- established manufacturing operations and contract manufacturing relationships;
- significantly greater name recognition and widely recognized trademarks; and
- established relationships with healthcare providers and payers.

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

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

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 31,000 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 product candidates, but we may not be able to do so in a timely fashion and at expected costs, or at all.

Although we are currently manufacturing silicon nitride interbody spinal fusion implants for CTL, in order to be successful, we will need to expand our product lines to include other advanced ceramic products for both medical and non-medical applications. Therefore, we are developing new manufacturing technologies and new product candidates including our new ceramic armor products. To succeed in our commercialization efforts, we must effectively continue product development and testing, find new strategic partners, obtain regulatory clearances and approvals, and enhance our sales and marketing capabilities. Because of these uncertainties, there is no assurance that we will succeed in bringing any of our current or future product candidates to market. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

We will depend on one or more strategic partners to develop and commercialize our biomedical and antipathogenic 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 strategic partners to develop and commercialize our biomedical and antipathogenic product candidates. We will be reliant on our strategic partners to develop and commercialize these product candidates, although we have not yet entered into an agreement with any strategic partner to develop products 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 candidates. 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 spinal 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, we do not anticipate relying directly on payment from third-party payers for our products. However, hospitals and other healthcare providers that purchase orthopedic products manufactured by us from our customers for treatment of their patients generally rely on third-party payers to pay for all or part of the costs and fees associated with our products as part of a "bundled" rate for the associated procedures. The existence of coverage and adequate reimbursement for our products and the procedures performed with them by government and private payers is critical to market acceptance of our existing and future products. Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products.

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

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

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

There is no assurance that federal or state healthcare reform will not also 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.

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

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.

Prolonged negative economic conditions in domestic and international markets may adversely affect us, our suppliers, partners and consumers, and 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 our target markets, but these demographics and trends are uncertain. Actual demand for our products could be significantly less than expected if our assumptions regarding these factors prove to be incorrect or do not materialize.

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 Regulatory Approval of Our Products and Other Government Regulations

Contracting with government entities exposes us to additional risks inherent in the government procurement process.

We provide products and services, directly and indirectly, to a variety of domestic government entities, which introduces certain risks, including extended sales and collection cycles, varying governmental budgeting processes and adherence to complex procurement regulations and other government-specific contractual requirements. We have been, are currently and may in the future be subject to audits and investigations relating to our government contracts and any violations could result in various civil and criminal penalties and administrative sanctions, including termination of contracts, payment of fines and suspension or debarment from future government business, as well as harm to our reputation and financial results.

We design, manufacture and service products that incorporate advanced technologies; the introduction of new products and technologies involves risks and we may not realize the degree or timing of benefits initially anticipated; competition may reduce our revenues and segment share and limit our future opportunities.

We seek to achieve growth through the design, development, production, sale and support of innovative commercial products that incorporate advanced technologies. The product, program and service needs of our customers change and evolve regularly, and we invest substantial amounts in research and development efforts to pursue advancements in a wide range of technologies, products and services. Our ability to realize the anticipated benefits of our technological advancements depends on a variety of factors, including meeting development, production, certification and regulatory approval schedules; receiving regulatory approvals; execution of internal and external performance plans; availability of supplier and internally produced parts and materials; performance of suppliers and subcontractors; availability of supplier and internal facility capacity to perform maintenance, repair and overhaul services on our products; hiring and training of qualified personnel; achieving cost and production efficiencies; identification of emerging technological trends for our target end-customers (such as sustainable technologies, as described below); validation of innovative technologies; risks associated with the development of complex software; the level of customer interest in new technologies and products; and customer acceptance of products we manufacture or that incorporate technologies we develop. In addition, many of our products must adhere to strict regulatory and market-driven safety and performance standards in a variety of jurisdictions. The evolving nature of these standards, along with the long duration of development, production and aftermarket support programs, creates uncertainty regarding program profitability, particularly with our aircraft engine products. Development efforts divert resources from other potential investments in our businesses, and these efforts may not lead to the development of new technologies or products on a timely basis or meet the needs of our customers as fully as competitive offerings. In addition, the industries for our products or products that incorporate our technologies may not develop or grow as we anticipate. We or our customers, suppliers or subcontractors may encounter difficulties in developing and producing new products and services, and may not realize the degree or timing of benefits initially anticipated or may otherwise suffer significant adverse financial consequences. Due to the design complexity of our products or those of our customers or third party manufacturers that incorporate our products into theirs or our customers' products, we may experience delays in completing the development and introduction of new products or we may experience the suspension of production after these products enter into service due to safety concerns. Delays and/or suspension of production could result in increased development costs or deflect resources from other projects. We operate in highly competitive industries and our competitors may have more extensive or more specialized engineering, manufacturing, marketing and servicing capabilities than we do. Our contracts are typically awarded on a competitive basis. Our bids are based upon, among other items, the cost to provide the products and services. To generate an acceptable return on our investment in these contracts, we must be able to accurately estimate our costs to provide the services and deliver the products and to be able to complete the contracts in a timely manner. If we fail to accurately estimate our costs or the time required to complete a contract, the profitability of our contracts may be materially and adversely affected. Furthermore, our competitors, including our customers, may develop competing technologies which gain industry acceptance in advance of or instead of our products, or meet particular in-demand technological needs before us or with technology that is superior to our existing or new technologies. For example, the enhanced focus on climate change has increased demand for more environmentally sustainable products and services, as described below. Our competitors may develop sustainable products or services that are available to our customers before our products or services, or that are adopted more readily than our products or services. In addition, our competitors or customers might develop new technologies or offerings that might cause our existing technologies and offerings to become obsolete or otherwise decrease demand for our offerings. In addition, the possibility exists that competitors or customers will develop aftermarket services and aftermarket parts for our products that attract customers and adversely impact our return on investment on new products. If we are unable to continue to compete successfully against our current or future competitors in our core businesses, we may experience declines in revenues and industry segment share. Any of the foregoing could have a material adverse effect on our competitive position, results of operations, financial condition or liquidity.

Exports and imports of certain of our products are subject to various export control, sanctions and import regulations and may require authorization from regulatory agencies of the U.S. or other countries.

We must comply with various laws and regulations relating to the export and import of products, services and technology from and into the U.S. and other countries having jurisdiction over our operations. In the U.S., these laws and regulations include, among others, the EAR administered by the U.S. Department of Commerce, the ITAR administered by the U.S. Department of State, embargoes and sanctions regulations administered by the U.S. Department of the Treasury, and import regulations administered by the U.S. Department of Homeland Security and the U.S. Department of Justice. Certain of our products, services and technologies have military or strategic applications and we are required to obtain licenses and authorizations from the appropriate U.S. government agencies before selling these products outside of the U.S. or importing these products into the U.S. U.S. foreign policy or foreign policy of other licensing jurisdictions may affect the licensing process or otherwise prevent us from engaging in business dealings with certain individuals, entities or countries. Any failure by us, our customers or our suppliers to comply with these laws and regulations could result in civil or criminal penalties, fines, seizure of our products, adverse publicity, restrictions on our ability to export or import our products, or the suspension or debarment from doing business with the U.S. government. Moreover, any changes in export control, sanctions or import regulations may further restrict the export of our products or services, and the possibility of such changes requires constant monitoring to ensure we remain compliant. Our ability to obtain required licenses and authorizations on a timely basis or at all is subject to risks and uncertainties, including changing U.S. government foreign policies or laws, delays in Congressional action, or geopolitical and other factors. If we are not successful in obtaining or maintaining the necessary licenses or authorizations in a timely manner, our sales relating to those approvals may be prevented or delayed, and revenue and profit previously recognized may be reversed. Any restrictions on the export or import of our products or product lines could have a material adverse effect on our competitive position, results of operations, financial condition or liquidity.

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 or other medical device 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 may 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.

Changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results of operations and financial condition.

We are subject to taxes by the U.S. federal, state, local and foreign tax authorities, and our tax liabilities will be affected by the allocation of expenses to differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors, including:

- changes in the valuation of our deferred tax assets and liabilities;
- expected timing and amount of the release of any tax valuation allowance;
- tax effects of equity-based compensation;
- changes in tax laws, regulations or interpretations thereof; or
- future earnings being lower than anticipated in jurisdictions where we have lower statutory tax rates and higher than anticipated earnings in jurisdictions where we have higher statutory tax rates.

We may also be subject to audits of our income, sales and other transaction taxes by U.S. federal, state, local and foreign taxing authorities. Outcomes from these audits could have an adverse effect on our operating results and financial condition.

Proposed legislation in the U.S. Congress, including changes in U.S. tax law, and the recently enacted Inflation Reduction Act of 2022 may adversely impact us and the value of common shares, pre-funded warrants, and Warrants.

Changes to U.S. tax laws (which changes may have retroactive application) could adversely affect us or holders of common shares, pre-funded warrants and Warrants. In recent years, many changes to U.S. federal income tax laws have been proposed and made, and additional changes to U.S. federal income tax laws are likely to continue to occur in the future.

The U.S. Congress is currently considering numerous items of legislation which may be enacted prospectively or with retroactive effect, which legislation could adversely impact our financial performance and the value of common shares, pre-funded warrants, and Warrants. Additionally, states in which we operate or own assets may impose new or increased taxes. If enacted, most of the proposals would be effective for the current or later years. The proposed legislation remains subject to change, and its impact on us and holders of common shares, pre-funded warrants, or Warrants is uncertain.

In addition, the Inflation Reduction Act of 2022 was recently signed into law and includes provisions that will impact the U.S. federal income taxation of corporations. Among other items, this legislation includes provisions that will impose a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. It is unclear how this legislation will be implemented by the U.S. Department of the Treasury and we cannot predict how this legislation or any future changes in tax laws might affect us or holders of common shares, pre-funded warrants or Warrants.

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

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

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would have a material adverse effect on our business, results of operations and financial condition. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the medical device industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

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 for all of the components of the process we use for manufacturing our 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 on consultants otherwise have an obligation to assign such inventions to such company or institution. Any such claim against us, even without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

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

Some of our employees were previously employed at other medical device or ceramic 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 advanced ceramic products or our product candidates conflict with the rights of others, we may not be able to manufacture or market our products or product candidates, which could have a material and adverse effect on us.

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

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

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

Risks Related to Potential Litigation from Operating Our Business

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

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

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

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

Risks Related to 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 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.

We may not be able to maintain our listing on the NASDAQ Capital Market, which would adversely affect the price and liquidity of our common stock.

As a small capitalization company, the price of our common shares has been, and is likely to continue to be, highly volatile. Any announcements concerning us or our competitors, quarterly variations in operating results, introduction of new products, delays in the introduction of new products or changes in product pricing policies by us or our competitors, acquisition or loss of significant customers, partners and suppliers, changes in earnings estimates or our ratings by analysts, regulatory developments, or fluctuations in the economy or general market conditions, among other factors, could cause the market price of our common shares to fluctuate substantially. There can be no assurance that the market price of our common shares will not decline below its current price or that it will not experience significant fluctuations in the future, including fluctuations that are unrelated to our performance.

Currently our common stock is quoted on the NASDAQ Capital Market under the symbol "SINT". We must satisfy certain minimum listing maintenance requirements to maintain the NASDAQ Capital Market quotation, including certain governance requirements and a series of financial tests relating to stockholders' equity or net income or market value, public float, number of market makers and stockholder, market capitalization, and maintaining a minimum bid price of $1.00 per share.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We regularly assess risks from cybersecurity threats, monitor our information systems for potential vulnerabilities, and test those systems pursuant to our cybersecurity policies, processes, and practices, which are integrated into our overall risk management program. To protect our information systems from cybersecurity threats, we use various security tools that are designed to help identify, escalate, investigate, resolve, and recover from security incidents in a timely manner. Our board of directors assesses risks based on probability and potential impact to key business systems and processes as part of our overall risk management program overseen by the board of directors. Risks that are considered high are incorporated into our overall risk management program. We collaborate with third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes and to assist in the identification, verification, and validation of cybersecurity risks, as well as to support associated mitigation plans when necessary. We have also developed a third-party cybersecurity risk management process to conduct due diligence on external entities, including those that perform cybersecurity services. Cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected our Company, including our business strategy, results of operations, or financial condition. Refer to the risk factor captioned "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." in Part I, Item 1A. "Risk Factors" for additional details regarding cybersecurity risks and potential impacts on our business.

Governance

Our board of directors oversees our risk management process, including as it pertains to cybersecurity risks, which focuses on the most significant risks we face in the short-, intermediate-, and long-term timeframe. Management is responsible for the operational oversight of company-wide cybersecurity strategy, policy, and standards across relevant departments to assess and help prepare us to address cybersecurity risks. Meetings of our board of directors include discussions and presentations from management regarding specific risk areas throughout the year, including, among others, those relating to cybersecurity threats, and reports from management on our enterprise risk profile on an annual basis. The board of directors reviews our cybersecurity risk profile with management on a periodic basis using key performance and/or risk indicators. These key performance indicators are metrics and measurements designed to assess the effectiveness of our cybersecurity program in the prevention, detection, mitigation, and remediation of cybersecurity incidents. We take a risk-based approach to cybersecurity and have implemented cybersecurity policies throughout our operations that are designed to address cybersecurity threats and incidents.

ITEM 2. PROPERTIES

Our 30,764 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 October 2031. Pursuant to the terms of the lease agreement, we may extend the lease for one additional periods of five years.

We also lease a 10,936 square foot facility located in Salt Lake City, Utah. This facility houses our Armor equipment. We occupy this facility pursuant to a lease that expires in October 2031.

We believe that our existing facilities are adequate for our current and projected needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

This item does not apply to our business.

PART II

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

Market Information

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

Holders of Record

As of December 31, 2024, we had approximately 163 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. RESERVED

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

SINTX Technologies is an advanced ceramics company formed in December 1996, focused on providing solutions in a variety of biomedical, technical, and antipathogenic applications. We have grown from focusing primarily on the research, development and commercialization of medical devices manufactured with silicon nitride to becoming an advanced ceramics company engaged in diverse fields, including biomedical, technical and antipathogenic applications. This diversification enables us to focus on our core competencies which are the manufacturing, research, and development of products comprised from advanced ceramic materials for external partners. We seek to connect with new customers, partners and manufacturers to help them realize the goal of leveraging our expertise in advanced ceramics to create new, innovative products across these sectors.

SINTX Core Business

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.

Revenue

Our product revenue is derived from the manufacture and sale of products. These revenue sources include coatings, materials, and components for aerospace and medical device markets, toll processing services, and government contracts and grants. 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 we secure opportunities to manufacture third party products with silicon nitride, and as we continue to introduce new products into the market.

We derive grant and contract revenue from awards provided by governmental agencies. The goal of these grants and contracts is ultimately to develop revenue producing products.

Cost of Revenue

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

Gross Profit

Our gross profit measures our product revenue relative to our cost of revenue.

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 medical devices, industrial and ceramic armor products, product candidates for antipathogenic 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, 2024 Compared to the Year Ended December 31, 2023

The following table sets forth, for the periods indicated, our results of operations for the years ended December 31, 2024 and 2023 (dollars, in thousands):

	Year Ended December 31,			
	2024	2023	$ Change	% Change
Product revenue	$ 1,246	$ 1,226	$ 20	2%
Grant and contract revenue	1,641	1,401	240	17%
Total revenue	2,887	2,627	260	10%
Costs of revenue	811	784	27	3%
Gross profit	2,076	1,843	233	13%
Operating expenses:				
Research and development	5,201	8,713	(3,512)	-40%
General and administrative	3,997	4,222	(225)	-5%
Sales and marketing	614	1,137	(523)	-46%
Armor exit costs	4,602	-	4,602	100%
Reduction in force	407	-	407	100%
Grant and contract expense	1,302	1,129	173	15%
Total operating expenses	16,123	15,201	922	6%
Loss from operations	(14,047)	(13,358)	(689)	5%
Other income (expense), net	3,023	5,099	(2,076)	-41%
Net loss before income taxes	(11,024)	(8,259)	(2,765)	33%
Provision for income taxes	-	-	-	-%
Net loss	$ (11,024)	$ (8,259)	$ (2,765)	33%

Product Revenue, Grant and Contract Revenue

Total product revenue remained relatively flat when comparing the years ended December 31, 2024 and 2023. During the year ended December 31, 2024, the Company grant and contract revenue increased $0.2 million or 17% as compared to the same period in 2023.

Costs of Revenue and Gross Profit

Cost of revenue remained relatively flat when comparing the years ended December 31, 2024 and 2023. Gross profit increased $0.2 million, or 13%, as compared to the same period in 2023. This increase was primarily attributed to an increase in grant and contract revenue and a shift in product mix to more profitable products.

Research and Development Expenses

Research and development expenses decreased $3.5 million, or -40%, as compared to the same period in 2023. This decrease was primarily attributable to a decrease in patent expenses, employee wages, product prototypes, and tooling expenses.

General and Administrative Expenses

General and administrative expenses decreased $0.2 million, or -5%, as compared to the same period in 2023. This decrease is primarily due to a decrease in employee wages and recruiting expenses.

Sales and Marketing Expenses

Sales and marketing expenses decreased $0.5 million, or -46%, as compared to the same period in 2023. This decrease was primarily attributable to a reduction in employee wages and an overall decrease in costs for outside consulting.

Armor Exit Costs

Armor exit costs increased $4.6 million, or 100%, as compared to the same period in 2023. This increase was primarily attributable to an increase in asset impairment costs at the SINTX Armor facility.

Reduction in Force Expenses

Reduction in force expenses increased $0.4 million, or 100%, as compared to the same period in 2023. This increase was primarily attributable to payroll expenses related to severance and accrued vacation payouts.

Grant and Contract Expenses

Grant and contract expenses increased $0.2 million, or 15%, as compared to the same period in 2023. This increase was primarily attributable to a general increase in grant and contract revenue when compared to the prior year.

Other Income (Expense), Net

Other income decreased $2.1 million, or -41%, as compared to the same period in 2023. This decrease was primarily due to a decrease in the change in the fair value of the derivative liabilities in the amount of $2.8 million, and a $0.1 million increase in gain on disposal of assets offset by $0.8 million in offering costs on derivative liabilities in 2023 with no corresponding amount in 2024.

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, 2024 and 2023, the Company incurred a net loss of $11.0 million and $8.3 million, respectively, and used cash in operations of $8.6 million and $14.1 million, respectively. The Company had an accumulated deficit of $281.7 million and $270.7 million as of December 31, 2024 and 2023, respectively. We will require substantial future capital in order to continue operating our business, conduct research and development and regulatory clearance and approval activities necessary to bring our products to market, and 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 our product candidates.

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, decrease expenses and/ raise additional funding. 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. 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 20, 2025, entered into a private placement transaction pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors for aggregate gross proceeds of $5.0 million, before deducting fees to the placement agent and other expenses payable by the Company in connection with the Private Placement. The Company intends to use the net proceeds from the Private Placement for general corporate purposes and working capital. H.C. Wainwright & Co. ("Wainwright"), acted as the exclusive placement agent for the Private Placement, which closed on February 25, 2025. As part of the Private Placement, the Company issued (i) 1,171,189 shares of the Company's common stock, par value $0.01 per share ("Common Stock"), (ii) pre-funded warrants to purchase 278,098 shares of Common Stock (the "Pre-Funded Warrants") with an exercise price of $0.0001 per share, and (iii) warrants to purchase 1,449,287 shares of Common Stock (the "Common Warrants," together with the Pre-Funded Warrants, the "Warrants") (the Warrants, together with the Shares and Warrant Shares (as defined below), the "Securities") with an exercise price of $3.32 per share. The purchase price per share of Common Stock and the associated Common Warrant was $3.45 and the purchase price per Pre-Funded Warrant and associated Common Warrant was $3.4499. The Common Warrants are exercisable immediately and expire five-and one-half years from issuance. The Pre-Funded Warrants are exercisable immediately and terminate when exercised in full.

On February 2, 2024, the Company closed on a public offering of 80,000 units, with each unit consisting of one share of its common stock, or one pre-funded warrant to purchase one share of its common stock, one Class E Warrant with each warrant entitled to purchase one share of common stock, and one Class F Warrant with each warrant entitled to purchase one share of common stock. Each unit was sold at a public offering price of $50.00 resulting in gross proceeds to the Company of $4 million before deducting offering fees and expenses. The Class E and Class F Warrants were immediately exercisable at a price of $50.00 per share. The Class E Warrants expire five years from the date of issuance and the Class F Warrants expire eighteen months from the date of issuance. Of the $4.0 million of gross proceeds, approximately $0.6 million were allocated to common stock and prefunded warrants ($0.5 million net of offering costs) and approximately $3.4 million were allocated to derivative liabilities (with approximately $0.5 million of cash offering costs and $0.1 million of agent warrant offering costs recorded as derivative expense).

On February 10, 2023, the Company closed on a public offering of 10,750 units, with each unit consisting of one share of common stock, or one pre-funded warrant to purchase one share of its common stock, one Class C Warrant to purchase one share of common stock, and one half of one Class D Warrant with each whole Class D Warrant entitling the holder to purchase one share of common stock. Gross proceeds, before deducting offering expenses, totaled approximately $12.0 million. Of the $12.0 million of gross proceeds, approximately $5.4 million were allocated to common stock and prefunded warrants ($4.8 million net of offering costs) and approximately $6.7 million were allocated to derivative liabilities (with approximately $0.7 million of cash offering costs and $0.1 million of agent warrant offering costs recorded as derivative expense).

On March 26, 2024, the Company closed on a public offering of 142,000 shares of the Company's common stock, (the "March 26 Offering"). Each Share was sold at a public offering price of $9.40. The aggregate proceeds to the Company from the March 26 Offering were approximately $1.3 million before deducting placement agent fees and other estimated offering expenses payable by the Company.

On April 5, 2024, the Company closed on a public offering of 358,000 shares of the Company's common stock, (the "April 5 Offering"). Each Share was sold at a public offering price of $4.20. The aggregate proceeds to the Company from the April 5 Offering were approximately $1.5 million before deducting placement agent fees and other offering expenses payable by the Company.

On October 17, 2022, the Company completed a rights offering of units consisting of convertible preferred stock and common stock warrants, resulting in gross proceeds to the Company of approximately $4.7 million, after deducting expenses relating to the offering, including dealer-manager fees and expenses,

On February 25, 2021, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with Maxim Group LLC (the "Agent"), as sales agent, as amended on January 10, 2023 and October 12, 2023 , pursuant to which the Company could offer and sell shares of the Company's common stock, par value $0.01 pershare (the "Shares"), initially up to an aggregate offering price of $15,000,000, from time to time in an at-the-market public offering.

On March 22, 2024, the company suspended sales under the ATM Agreement and terminated the continuous offering. On July 11, 2024, the Company filed a Prospectus Supplement with the SEC adjusting the amount available for sale under the ATM Agreement to $3.1 million and shortly thereafter begin offering and selling Shares under the ATM Agreement to the public. During the year ended December 31, 2024, 602,357 Shares were sold under the ATM Agreement for gross proceeds of approximately $3.7 million. Because the Company is subject to General Instruction I.B.6 of Form S-3, it is restricted from selling securities in a public primary offering with a value exceeding one-third of its public float (the market value of our common stock held by our non-affiliates) in any 12-month period so long as its public float remains below $75.0 million. As of December 31, 2024, there was no capacity to offer and sell Shares under the ATM Agreement.

On June 11, 2024, the Company received formal notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company has evidenced compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). The Company remains subject to a "Mandatory Panel Monitor," as that term is defined in Listing Rule 5815(d)(4)(B), for a period of one year from June 11, 2024. If, within the one-year period, the Company fails to satisfy the minimum $1.00 closing bid price threshold for 30 consecutive business days, Nasdaq will issue a delist determination rather than provide the Company with a grace period to regain compliance with the Bid Price Rule. In that event, the Company would have the opportunity to request a new hearing to address the deficiency.

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

The Board of Directors, together with management, is performing an ongoing evaluation of the Company's business strategy and focus. On August 1, 2024, the board of directors appointed Eric Olson to the office of Chief Executive Officer and President to lead the evaluation process.

The Company has implemented a change in strategic emphasis to advancements in the medical device sector. Historically engaged in both industrial and biomedical applications, SINTX is prioritizing the development and commercialization of innovative medical devices, leveraging our expertise in advanced ceramics and biomaterials. Such a renewed focus would align with a commitment to improving patient outcomes through the creation of products designed for surgical, orthopedic, and other specialized medical applications. We would concentrate our resources on high-growth areas within the healthcare sector where our proprietary materials and technologies—such as silicon nitride—provide a distinct competitive advantage due to their unique strength, durability, and biocompatibility.

Through this transformation, SINTX's aim would be to deliver meaningful innovations to the medical community. Our current research and development pipeline is centered on medical-grade devices that incorporate antimicrobial properties, enhanced imaging capabilities, and durability under physiological conditions, which are critical for orthopedic implants, spinal fusion devices, and other surgical tools. If we transition away from industrial applications, we anticipate this strategic shift will enable us to better serve the medical sector, address critical unmet needs, and position SINTX as a leading provider in the medical device market. By focusing on partnerships and collaborations with healthcare institutions and industry leaders, SINTX is positioned to expand its footprint in the medical device sector and drive shareholder value through sustainable, high-impact innovations, however, such a transition has not been approved by the Board of Directors, nor can such approval or successful transition be assured.

On August 8, 2024, the Board of Directors approved a plan to implement a Company-wide reduction in the workforce. This decision is part of the Company's ongoing strategic review of its operations aimed at improving operational efficiency and reducing costs. The reduction in force reduced the number of employees of the Company from 40 to 23. During the year ended December 31, 2024, the Company recorded expenses of approximately $407,000 associated with the reduction in workforce.

On August 12, 2024, the Board of Directors of the Company approved a plan to cease efforts to make the armor plant operational. This decision was made to streamline operations and focus on core business areas that align with the Company's long-term strategic goals. The armor plant has not been fully operational since the acquisition of the armor equipment in July 2021 and has been completely shut down since October 2023 due to the malfunctioning of the sintering furnace. In connection with this decision the Company incurred an impairment charge of approximately $4.6 million during the year ended December 31, 2024. This charge primarily relates to the write-down of certain long-lived assets associated with the armor plant to their estimated fair value.

The Company's insurance carrier has determined that a covered loss occurred when the sintering furnace malfunctioned, and coverage is available for the Company's repair of the sintering furnace. However, the Company's efforts to fully repair the damaged furnace continue to be delayed. Management will work with the insurance company to continue to fund the repair of the furnace. When the furnace is fully repaired, management intends to sell the furnace, and related equipment, to a third party. However, the full repair and sale of the furnace, and related equipment, cannot be assured. Therefore, in the calculation of the $4.6 million impairment charge, management has assumed no proceeds will be received from a potential sale of the furnace and related equipment.

Sale of TA&T

On February 19, 2025, we entered into an Entity Acquisition Agreement (the "Agreement") with Tethon Corporation ("Tethon"), pursuant to which the Company sold to Tethon all of the issued and outstanding shares of Technology Assessment and Transfer, Inc. ("TA&T"), a wholly owned subsidiary of the Company, in exchange for the assumption by Tethon of the outstanding liabilities of TA&T (the "Sale").

Based on the decrease in expenditures from the reduction in force, sale of TA&T and the increase in cash on February 20, 2025, SINTX management has determined that there is no uncertainty of the Company's ability to continue as a going concern through at least March 19, 2026 and further analysis of this matter is not deemed necessary for the year ended December 31, 2024.

Cash Flows

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

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (8,642)	$ (14,115)
Net cash used in investing activities	(194)	(501)
Net cash provided by financing activities	9,094	11,711
Net cash provided (used)	$ 258	$ (2,905)

Net Cash Used in Operating Activities

Net cash used in operating activities was $8.6 million in 2024, compared to $14.1 million used in 2023, a decrease of $5.5 million. The decrease in the net loss from operations, and related non-cash add backs to the net loss, was $3.4 million from 2024 when compared to 2023. The decrease in cash used for operating activities during 2024 was primarily due to the $3.4 million mentioned above plus changes in the movement of working capital items during 2024 as compared to the same period in 2023 as follows: a $0.9 million decrease in cash used in accounts receivable, a $0.7 million decrease in cash used for prepaids, a $0.6 million decrease for inventory, a $0.4 million decrease in cash used in other liabilities, and a $0.2 million decrease in cash used for payments on operating lease liability, all offset by a $0.7 million increase in cash used in accounts payable and accrued liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.2 million during 2024, compared to $0.5 million used in investing activities during the same period in 2023, a decrease of $0.3 million. The decrease in cash used in investing activities during 2024 was primarily due to a $0.5 million increase in proceeds from notes receivable, offset by $0.2 million increase in purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $9.1 million during 2024, compared to $11.7 million provided by financing activities during the same period in 2023, a decrease of $2.6 million. This decrease was primarily attributable to a decrease in proceeds from issuance of warrant derivative liabilities of $3.3 million, an increase in payments on debt of $0.2 million, offset by a $0.9 million increase in proceeds from issuance of common stock.

Indebtedness

Business Loan

On July 20, 2021, TA&T, entered into a Loan Authorization and Agreement in the amount of approximately $350,000 (the "Business Loan"). The Company made a one-time $35,000 buy down payment when acquiring the loan. The Business Loan bore interest at a rate of 3.75% per annum. The Business Loan was secured by a general security interest in all of the assets of TA&T. The Business Loan contained other standard provisions that are customary of loans of this type. The business loan was paid in full during the first quarter of 2024 and there was no outstanding balance at December 31, 2024.

Insurance Premium Finance Arrangements

In March 2024, in connection with securing Director and Officer professional liability insurance, the Company entered into a Premium Finance Arrangement to extend the premium payment out for a period of 10 months. The Company paid a total of $40,000 up front toward the insurance premium and financed approximately $238,000. The Company will make 10 equal payments under the terms of the Premium Finance Agreement. The Premium Finance Agreement bears interest at an annual percentage rate of 8.510%. The Director and Officer professional liability insurance debt was paid in full during the fourth quarter of 2024 and there was no outstanding balance at December 31, 2024.

In June 2024, in connection with securing commercial liability insurance, the Company entered into a Premium Finance Arrangement to extend the premium payment out for a period of 10 months. The Company paid a total of $26,000 up front toward the insurance premium and financed approximately $117,000. The Company will make 10 equal payments under the terms of the Premium Finance Agreement. The Premium Finance Agreement bears interest at an annual percentage rate of 8.75%. As of December 31, 2024, there was an outstanding balance of $32,000.

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

We have not entered into any transactions since January 1, 2021 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.

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.

Seasonality and Backlog

Our business is generally not seasonal in nature. The majority of our product revenue is derived from the manufacture and sale of spinal fusion products, used in the treatment of spine disorders, to CTL Medical. We also retained CTL Medical to act as our exclusive broker to offer for sale, and sell, our manufacturing services to third party developers of spinal implants and spinal devices that incorporate silicon nitride technology, which has a remaining term of 3-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, 2024. There have been no material changes to those policies for the year ended December 31, 2024. 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.

New Accounting Pronouncement, Not Yet Adopted

The Company has reviewed all 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 aerospace components and 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, 7 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.

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. Contact 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 employee 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 Credit Losses Doubtful Accounts

Financial assets, which potentially subject the Company to credit losses, consist primarily of receivables. We measure expected credit losses of financial assets based on historical loss and other information available to management using type of receivable (commercial, grants or contracts, retainage, or other) and different aging categories (less than 90 days past due, over 90 days past due, over 180 days past due, and financially troubled customers). These expected credit losses are recorded to an allowance for credit losses valuation account that is deducted from receivables to present the net amount expected to be collected on the financial asset on the consolidated balance sheet. Management believes that the historical loss information it has compiled is a reasonable basis on which to determine expected credit losses for trade receivables held as of December 31, 2024, because the composition of the trade receivables as of that date is consistent with that used in developing the historical credit-loss percentages (i.e., the similar risk characteristics of its customers and its lending practices have not changed significantly over time).

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 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, 2024. As explained above, the Company sold most intangible assets that had a carrying value, 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.

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, 2024 and 2023, 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

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, 2024. Based on this evaluation, the Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2024, 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, 2024. 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, 2024, the Company's internal control over financial reporting was effective.

There were no changes in our internal control over financial reporting that occurred during 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2024, none of our directors or officers adopted or terminated a "Rule 10-b5-1 trading arrangement" or "non-Rule 10-b5-1 trading arrangement" as each term is identified in Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

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.

Name	Age	Positions
B. Sonny Bal, M.D.	62	Chairman of the Board of Directors
David W. Truetzel	68	Director
Jeffrey S. White	71	Director
Eric A. Stookey	54	Director
Mark Froimson, M.D.	64	Director
Eric Olson	61	Director, President and Chief Executive Officer

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:

Class III Directors— continuing directors with a term expiring at the 2026 annual meeting of stockholder.

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. 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 was 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.

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 2025 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, Paranet, LLC, an IT services provider and ScholarPath, Inc. an educational software platform. 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 Director — continuing director with a term expiring at the 2027 annual meeting of stockholders.

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.

Eric Olson has served as the Company's Chief Executive Officer and President since August 2024 and as a member of the Board of Directors since November 2024. Prior to being appointed as Chief Executive Officer and President, from June 2022 to August 2024, Mr. Olson, age 61, served as Founder, Chief Executive Officer and Board Member of Foresite Innovations, LLC, a private healthcare innovation and development holding company. From January 2016 to June 2022, Mr. Olson was the founder, President, Chief Executive Officer and Board Member of Predictive Biotech, Inc., which developed the first human stem cell and tissue product (HCT/P) derived from the perinatal tissue. Prior to joining Predictive Biotech, Mr. Olson was the President and Chief Executive Officer for Cupertino based Skeletal Kinetics from December 2014 to January 2016. This Colson & Associates company developed and commercialized synthetic bone substitute products for Orthopedic and Spinal applications. From February 2012 to September 2014, Mr. Olson served as Chief Executive Officer and President and a member of the board of directors of SINTX Technologies (formerly Amedica Corporation). Mr. Olson began his career with London-based Smith & Nephew and has worked in Senior Sales and Marketing leadership roles with Johnson & Johnson, Medtronic and Wright Medical. He earned Bachelor of Science Degrees in Behavioral Science and Health Administration from The University of Utah and completed a Master's level Hospital Administration Internship Program at the same institution.

Executive Officers

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

Name	Age	Position
Eric Olson.	61	President and Chief Executive Officer, Principal Financial Officer
Gregg Homigblum	62	Chief Strategy Officer

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

Eric Olson has served as the Company's Chief Executive Officer and President since August 2024 and as a member of the Board of Directors since November 2024. Prior to being appointed as Chief Executive Officer and President, from June 2022 to August 2024, Mr. Olson, age 61, served as Founder, Chief Executive Officer and Board Member of Foresite Innovations, LLC, a private healthcare innovation and development holding company. From January 2016 to June 2022, Mr. Olson was the founder, President, Chief Executive Officer and Board Member of Predictive Biotech, Inc., which developed the first human stem cell and tissue product (HCT/P) derived from the perinatal tissue. Prior to joining Predictive Biotech, Mr. Olson was the President and Chief Executive Officer for Cupertino based Skeletal Kinetics from December 2014 to January 2016. This Colson & Associates company developed and commercialized synthetic bone substitute products for Orthopedic and Spinal applications. From February 2012 to September 2014, Mr. Olson served as Chief Executive Officer and President and a member of the board of directors of SINTX Technologies (formerly Amedica Corporation). Mr. Olson began his career with London-based Smith & Nephew and has worked in Senior Sales and Marketing leadership roles with Johnson & Johnson, Medtronic and Wright Medical. He earned Bachelor of Science Degrees in Behavioral Science and Health Administration from The University of Utah and completed a Master's level Hospital Administration Internship Program at the same institution.

Gregg Honigblum has served as the Company's Chief Strategy Officer since November 2024. Prior to being appointed as Chief Strategy Officer, from December 2023 to November 2024 Mr. Honigblum served as a Managing Director for FNEX Capital, LLC, a global leader in Private Securities transaction and investment banking. From June 2021 to December 2023 Mr. Honigblum served as a Managing Director for Westlake Securities, an investment banking firm focused on growth, merger and acquisitions, and capital raising services for middle market companies. From August 2016 to December 2023 Mr. Honigblum was a co-founder and Director for HealthGrowth Capital, LLC specializing in providing capital, strategic advisory services, and a Group Purchasing Organization Platform with large wholesale pharmaceutical distributors. He earned a Bachelor of Arts degree in Economics from the University of Texas at Austin. Mr. Honigblum holds Series 7, 24, and 63 securities licenses.

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.

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 forty (40) times during the year ended December 31, 2024. 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 2024.

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 directors are Mark Froimson and Eric Olsen, and their terms will expire at the annual meeting of stockholders to be held in 2027.
- The Class II directors are David W. Truetzel and Eric A. Stookey, and their terms will expire at the 2025 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 2026.

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.

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 2024, 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 2024, 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 met one time as a separate committee in 2024, additionally, 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 2024 and 2023 fiscal years.

Name and Principal Position	Year	Salary	Bonus	Non-Equity Incentive Plan Compensation	Stock Awards	Option Awards	All Other Comp (1)	Total Compensation
Eric Olson..... Chief Executive Officer	2024	$ 135,962	$ 25,000	$ -	$ -	$ -	$ 33,632	$ 194,594
	2023	$ -	$ -	$ -	$ -	$ -	$ -	$ -
B. Sonny Bal..... Chief Executive Officer	2024	$ 253,788	$ 7,222	$ -	$ 7,716	$ 19,622	$ 152,303	$ 440,651
	2023	$ 412,692	$ 36,750	$ -	$ 14,772	$ 61,367	$ 11,730	$ 537,312
David O'Brien .... Chief Operating Officer	2024	$ 220,769	$ 5,510	$ -	$ 3,443	$ 9,821	$ 130,281	$ 369,824
	2023	$ 367,308	$ 23,681	$ -	$ 9,405	$ 41,735	$ 11,474	$ 453,602

(1) Amount reflects matching of 401(k) contributions paid by us, severance, vacation payouts, housing expenses, and commuting expenses, 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. The Board, on an annual basis, adopts an executive bonus payment plan that is designed to provide executive officers with annual incentive compensation based on the achievement of certain pre-established performance objectives. By utilizing a combination of objective and subjective performance factors critical to our success, this program incentivizes our executive officers to achieve results that benefit them and the Company. Performance factors include the achievement of predetermined financial performance objectives, adherence to financial discipline measures and achievement of business development, product development and long-term business stability. The Board may modify or re-weight the objectives during the course of the fiscal year, if necessary, to reflect changes in our business plan.

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, 2024:

Name	Number of Securities Underlying Unexercised Options (#)(1) Exercisable	Unexercisable	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 ($)
Sonny Bal	3	-(2)	$ 9,400	4/21/2030	-	$ -
	4	-(3)	38,600	3/2/2031	-	-
	4	-(4)	9,800	1/26/2032	-	-
	-	-	-		12	42
					-	-
David O'Brien	3	-(5)	9,400	4/21/2030	-	-
	3	-(6)	38,600	3/2/2031	-	-
	3	-(7)	9,800	1/26/2032	-	-
	-	-	-		8	27

(1) The options have not been, and may never be, exercised, and actual gains, if any, on exercise will depend on the value of the shares of common stock on the date of exercise.

(2) 28% of the stock option vests on the one-year anniversary of the date of the grant and 3% per month thereafter.

(3) 28% of the stock option vests on the one-year anniversary of the date of the grant and 3% per month thereafter.

(4) 28% of the stock option vests on the one-year anniversary of the date of the grant and 3% per month thereafter.

(5) 28% of the stock option vests on the one-year anniversary of the date of the grant and 3% per month thereafter.

(6) 28% of the stock option vests on the one-year anniversary of the date of the grant and 3% per month thereafter.

(7) 28% of the stock option vests on the one-year anniversary of the date of the grant and 3% per month thereafter.

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.

The Company also entered into a Change of Control Agreement (the "Change of Control Agreement") with Mr. Olson. Among other things, the Change in Control Agreement provides that upon the consummation of a change in control, all outstanding options, restricted stock and other such rights held by the executive 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 (i) payment consisting of a lump sum payment equal to one 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 and (ii) continued health insurance coverage under the Company's health plan for a period of 12 months following termination. "Change in control" is defined in the Change of Control Agreement as occurring upon: (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) 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; (iii) the approval by our stockholders of an agreement for the sale or disposition of all or substantially all of our assets; (iv) or a change in the composition of the Board of Directors whereby individuals who were members of the Board of Directors immediately prior to the agreement cease to constitute a majority of the Board of Directors. As defined in the 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 intentional misconduct that causes material harm to the Company, provided that such misconduct is not rectifiable or remains uncorrected after written notice and a 30-day cure period; (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 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 500 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 Change in Control 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. Under the Agreement, Mr. Olson's receipt of such severance payments is subject to his execution and delivery of a general release of claims in favor of the Company.

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, 2024 to each of our non-employee directors.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)(6)	Total ($)
Sonny Bal (1)	$ 16,667	$ -	$ -	$ 16,667
David W. Truetzel (2)	120,000	-	-	120,000
Jeffrey S. White (3)	40,000	-	-	40,000
Eric A. Stookey (4)	40,000	-	-	40,000
Mark Froimson (5)	$ 40,000	$ -	$ -	$ 40,000

(1) As of December 31, 2024 Mr. Bal had 15 option awards outstanding.

(2) As of December 31, 2024 Mr. Truetzel had 5 option awards outstanding.

(3) As of December 31, 2024 Mr. White had 5 option awards outstanding.

(4) As of December 31, 2024 Mr. Stookey had 5 option awards outstanding.

(5) As of December 31, 2024 Mr. Froimson had 4 option awards outstanding.

(6) The amounts in this column do not reflect compensation actually received by our non-employee directors nor do they reflect the actual value that will be recognized by the non-employee directors. Instead, the amounts reflect the aggregate grant date fair value computed in accordance with Accounting Standards Codification ("ASC") 718 of awards of stock options made to non-employee directors for the fiscal year ended December 31, 2024 but excludes an estimate for forfeitures. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model.

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 12 equal monthly installments of $3,333 each;
- $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 400 stock options upon appointment. Further, each non-employee member of the Board is awarded an option grant for 150 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, 2024 relating to all of our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-average Exercise Price of Outstanding Options, Warrants and Rights	(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	72[1]	$ 19,546[2]	333,706
Equity compensation plans not approved by Stockholders	-	-	-
Total	72[1]	$ 19,546[2]	333,706

(1) Includes options outstanding under our 2020 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 333,745 shares of common stock, which includes 25 shares that were forfeited or reacquired by the Company due to termination or cancellation of the awards and are now part of the total number of shares of common stock 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 is to be administered by the Committee, or in the board of director's sole discretion, 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.

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.

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.

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.

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.

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.

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, 2025 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, 2025, 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 2,515,179 shares issued and outstanding on March 1, 2025.

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.

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)	22	*
David W. Truetzel (2)	5	*
Jeffrey S. White (3)	5	*
Eric A. Stookey (4)	5	*
David O'Brien (5)	22	*
Mark Froimson, M.D. (6)	4	*
All executive officers and directors as a group (6 persons)	63	*

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

(1) Represents 7 shares of Common Stock and options to purchase 15 shares of Common Stock that are currently exercisable within 60 days of March 1, 2025.

(2) Represents options to purchase 5 shares of Common Stock that are currently exercisable within 60 days of March 1, 2025.

(3) Represents options to purchase 5 shares of Common Stock that are currently exercisable within 60 days of March 1, 2025.

(4) Represents options to purchase 5 shares of Common Stock that are currently exercisable within 60 days of March 1, 2025.

(5) Represents 7 shares of Common Stock, and options to purchase 15 shares of Common Stock that are currently exercisable within 60 days of March 1, 2025

(6) Represents options to purchase 4 shares of Common Stock that are currently exercisable within 60 days of March 1, 2025.

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

Transactions with Related Persons

We have not entered into any transactions since January 1, 2024 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.

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 ACCOUNTANT FEES AND SERVICES

The aggregate fees and expenses incurred from our principal accounting firm, Tanner LLC, for fiscal years ended December 31, 2024 and 2023, were as follows (in thousands):

	Year Ended December 31 , 2024	Year Ended December 31, 2023
Audit fees	$ 247,382	$ 209,666
Audit related fees	109,238	150,253
Total Fees	$ 356,620	$ 359,919

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.

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 (i.e. consents and comfort letters associated with offerings) and are not reported under "Audit Fees".

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 AND FINANCIAL STATEMENT SCHEDULES

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

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

(2) Consolidated Financial Statement Schedules

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

(3) Exhibits

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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
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
2.2+†	Asset Purchase Agreement by and among SINTX Technologies, Inc. and B4C, LLC, dated July 20, 2021.		Form 8-K (Exhibit 2.1)	7/26/21	001-33624
2.3†	Stock Purchase Agreement		Form 8-K (Exhibit 2.1)	7/6/22	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
3.1.7	Certificate of Designation of Series D Preferred Stock		Form 8-K (Exhibit 3.1)	10/17/22	001-33624

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
3.1.8	Certificate of Designation of Series E Preferred Stock		Form 8-K (Exhibit 3.1)	10/28/22	001-33624
3.1.9	Certificate of Amendment to the Restated Certificate of Incorporation of Sintx Technologies, Inc.		Form 8-K (Exhibit 3.1)	12/19/22	001-33624
3.1.10	Certificate of Amendment to the Restated Certificate of Incorporation of Sintx Technologies, Inc.		Form 8-K (Exhibit 3.1)	5/23/24	001-33624
3.2	Amended and Restated Bylaws of SINTX Technologies, Inc.		Form 8-K (Exhibit 3.1)	10/01/21	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	Form of Common Stock Warrant		Form S-1/A	1/15/20	333-234438
4.3	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
4.4	Warrant Issued to Maxim Group LLC on February 6, 2020		Form 8-K (Exhibit 4.1)	2/07/20	001-33624
4.5	Warrant Issued to Ascendiant Capital Markets, LLC on February 6, 2020		Form 8-K (Exhibit 4.2)	2/07/20	001-33624
4.6	Form of Indenture		Form S-3 (Exhibit 4.2)	3/25/19	333-230492
4.7	Dealer Manager Warrants issued to Maxim Group LLC on October 17, 2022		Form 8-K (Exhibit 4.1)	10/17/22	001-33624
4.8	Dealer Manager Warrants issued to Ascendiant Capital Markets, LLC on October 17, 2022		Form 8-K (Exhibit 4.2)	10/17/22	001-33624
4.9	Form of Class A Warrant		Form 8-K (Exhibit 4.3)	10/17/22	001-33624
4.10	Form of Class B Warrant		Form 8-K (Exhibit 4.4)	10/17/22	001-33624
4.11	Form of Class C Warrant		Form S-1 (Exhibit 4.13)	2/7/23	333-269475
4.12	Form of Pre-Funded Warrant		Form S-1 (Exhibit 4.14)	2/6/23	333-269475
4.13	Form of Class D Warrant		Form S-1 (Exhibit 4.15)	2/7/23	333-269475
4.14	Form of Placement Agent Warrant		Form S-1 (Exhibit 4.16)	2/6/23	333-269475
4.15	Warrant Agency Agreement		Form 8-K (Exhibit 4.5)	2/9/23	001-33624
4.16	Form of Pre-Funded Warrant		Form 8-K (Exhibit 4.1)	2/2/24	001-33624
4.17	Form of Class E Warrant		Form 8-K (Exhibit 4.2)	2/2/24	001-33624
4.18	Form of Class F Warrant		Form 8-K (Exhibit 4.3)	2/2/24	001-33624
4.19	Form of Placement Agent Warrant		Form 8-K (Exhibit 4.4)	2/2/24	001-33624

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
4.20	Form of Warrant Agency Agreement		Form 8-K (Exhibit 4.5)	2/2/24	001-33624
4.21	Form of Senior Indenture, to be entered into between the Registrant and the trustee designated therein		Form S-3 (Exhibit 4.14)	10/12/23	333-274951
4.22	Form of Subordinated Indenture, to be entered into between the Registrant and the trustee designated therein		Form S-3 (Exhibit 4.16)	10/12/23	333-274951
4.23	Description of Registrant's Securities	X			
10.1	Centrepointe Business Park Lease Agreement Net by and between the Registrant and Centrepointe Properties, LLC, dated as of April 21, 2009		Form S-1 (Exhibit 10.10)	11/8/13	333-192232
10.2	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	Exchange Agreement dated April 4, 2016, by and among SINTX Corporation and Riverside Merchant Partners, LLC		Form 8-K (Exhibit 10.2)	4/05/16	001-33624
10.6	Form of Warrant Amendment Agreement		Form S-1 (Exhibit 10.26)	4/26/18	333-223032
10.7	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
10.8	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
10.9	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
10.10	Guaranty between Amedica Corporation and Daniel Chon dated as of October 1, 2018.		Form 8-K (Exhibit 10.3)	10/5/18	001-33624
10.11	ROFN Security Agreement between Amedica Corporation and CTL Corporation dated as of October 1, 2018.		From 8-K (Exhibit 10.4)	10/5/18	001-33624
10.12	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
10.13	Form of Share Purchase Agreement		Form 8-K (Exhibit 99.1)	6/29/20	001-33624
10.14	Placement Agency Agreement		Form 8-K (Exhibit 99.2)	6/29/20	001-33624
10.15	Form of Share Purchase Agreement		Form 8-K (Exhibit 99.1)	7/20/20	001-33624
10.16	Placement Agency Agreement		Form 8-K (Exhibit 99.2)	7/20/20	001-33624

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.17	Form of Share Purchase Agreement		Form 8-K (Exhibit 99.1)	8/6/20	001-33624
10.18	Placement Agency Agreement		Form 8-K (Exhibit 99.2)	8/6/20	001-33624
10.19	Form of Indenture		Form S-3 (Exhibit 4.18)	10/2/20	333-249267
10.20	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
10.21	2020 Equity Incentive Plan		Defn 14a Proxy Statement	7/10/2020	001-33624
10.22	Form of Warrant Agency Agreement between SINTX Technologies, Inc. and American Stock Transfer & Trust Company, LLC		Form 8-K (Exhibit 10.1)	10/17/22	001-33624
10.23	Amendment to Equity Distribution Agreement, dated as of January 10, 2023 by and between SINTX Technologies, Inc., and Maxim Group LLC		Form 8-K (Exhibit 10.1)	1/13/23	
10.24	Form of Securities Purchase Agreement		Form 8-K (Exhibit 10.1)	2/9/23	001-33624
10.25	Form of Placement Agent Agreement		Form S-1 (Exhibit 10.25)	2/6/23	333-269475
10.26	Form of Securities Purchase Agreement		Form 8-K (Exhibit 10.1)	2/2/24	001-33624
10.27	Form of Placement Agency Agreement		Form 8-K (Exhibit 10.2)	2/2/24	001-33624
10.28	Form of Stock Purchase Agreement		Form 8-K (Exhibit 10.1)	3/26/24	001-33624
10.29	Form of Placement Agency Agreement		Form 8-K (Exhibit 10.2)	3/26/24	001-33624
10.30	Form of Stock Purchase Agreement		Form 8-K (Exhibit 10.1)	4/4/24	001-33624
10.31	Form of Placement Agency Agreement		Form 8-K (Exhibit 10.2)	4/4/24	001-33624
19	Insider Trading Policy	X			
21.1	List of Subsidiaries	X			
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			
97	SINTX Technologies, Inc. Clawback Policy		Form 10-K (Exhibit 97)	3/27/24	001-33624
101 SCH	Inline XBRL Taxonomy Extension Schema Document (A)	X			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (A)	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (A)	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (A)	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (A)	X			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Management contract of compensatory plan or arrangement

\+ Schedules and exhibits to this Exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

† A portion of this Exhibit has been omitted as it contains information that (i) is not material and (ii) would be competitively harmful if publicly disclosed.

(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.

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 19, 2025

/s/ Eric Olson

Eric Olson
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 19, 2025

/s/ Eric Olson

Eric Olson., Director

Date: March 19, 2025

/s/ B. Sonny Bal

B. Sonny Bal, M.D., Director

Date: March 19, 2025

/s/ David W. Truetzel

David W. Truetzel, Director

Date: March 19, 2025

/s/ Jeffrey S. White

Jeffrey S. White, Director

Date: March 19, 2025

/s/ Eric A. Stookey

Eric A. Stookey, Director

Date: March 19, 2025

/s/ Mark Froimson

Mark Froimson, M.D., Director

As of and For the Years ended December 31, 2024 and 2023

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of
SINTX Technologies, Inc.

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, 2024 and 2023, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, 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 and 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 the underlying data used by the Company in its analysis, and evaluating management's specialist.

/s/ TANNER LLC

(PCAOB ID 270)
We have served as the Company's auditors since 2017
Lehi, Utah
March 18, 2025

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

	As of December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 3,598	$ 3,340
Account and other receivables, net of allowance totaling 61 and 72 respectively	196	685
Prepaid expenses and other current assets	465	539
Inventories	502	888
Other current assets	10	80
Total current assets	4,771	5,532
Inventories, net	465	333
Property and equipment, net	922	4,826
Intangible assets, net	16	21
Operating lease right of use asset	3,159	4,094
Other long-term assets	80	559
Total assets	$ 9,413	$ 15,365
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 299	$ 636
Accrued liabilities	986	1,404
Current portion of long-term debt	32	46
Derivative liabilities	208	304
Current portion of operating lease liability	456	512
Other current liabilities	1	4
Total current liabilities	1,982	2,906
Operating lease liability, net of current portion	3,537	3,687
Total liabilities	5,519	6,593
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; 19 and 26 shares issued and outstanding of December 31, 2024 and December 31, 2023 respectively.	-	-
Convertible preferred stock Series C, $0.01 par value, 130,000,000 total shares authorized inclusive of all series of preferred; 50 shares issued and outstanding as of both December 31, 2024 and 2023.	-	-
Convertible preferred stock Series D, $0.01 par value, 130,000,000 total shares authorized inclusive of all series of preferred; 180 shares issued and outstanding as of both December 31, 2024 and 2023.	-	-
Common stock, $0.01 par value, 250,000,000 shares authorized; 1,342,853 and 26,603 shares issued and outstanding as of December 31, 2024 and 2023, respectively.	13	-
Additional paid-in capital	285,619	279,486
Accumulated deficit	(281,738)	(270,714)
Total stockholders' equity	3,894	8,772
Total liabilities and stockholders' equity	$ 9,413	$ 15,365

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

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

	Years Ended December 31,	
	2024	**2023**
Product revenue	$ 1,246	$ 1,226
Grant and contract revenue	1,641	1,401
Total revenue	2,887	2,627
Costs of revenue	811	784
Gross profit	2,076	1,843
Operating expenses:		
Research and development	5,201	8,713
General and administrative	3,997	4,222
Sales and marketing	614	1,137
Armor exit costs	4,602	-
Reduction in force	407	-
Grant and contract expenses	1,302	1,129
Total operating expenses	16,123	15,201
Loss from operations	(14,047)	(13,358)
Other income (expenses):		
Interest expense	(29)	(2)
Interest income	107	135
Gain (loss) on the disposal of assets	(19)	17
Change in fair value of derivative liabilities	3,475	5,718
Offering costs of derivative liabilities	(550)	(786)
Other income (expense)	39	17
Total other income (expense), net	3,023	5,099
Net loss before income taxes	(11,024)	(8,259)
Provision for income taxes	-	-
Net loss	(11,024)	(8,259)
Deemed dividend related to beneficial conversion feature on convertible preferred stock	-	(26)
Net loss attributable to common stockholders	$ (11,024)	$ (8,285)
Net loss per share – basic and diluted		
Basic – net loss	$ (14.87)	$ (442.08)
Basic – deemed dividend and accretion of a discount on conversion of preferred stock	-	(1.39)
Basic – attributable to common stockholders	$ (14.87)	$ (443.47)
Diluted – net loss	$ (15.19)	$ (623.28)
Diluted - deemed dividend and accretion of a discount on conversion of preferred stock	-	(1.19)
Diluted – attributable to common stockholders	$ (15.19)	$ (624.47)
Weighted average common shares outstanding:		
Basic	741,250	18,682
Diluted	744,782	21,786

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

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

	Preferred Stock		Common Stock		Paid-In	Accumulated	Total
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2022	283	$ -	2,711	$ -	$ 268,159	$ (262,455)	$ 5,704
Stock based compensation	-	-	1	-	291	-	291
Common stock issued for cash, net of cash fees	-	-	15,462	-	4,794	-	4,794
Prefunded warrants issued for cash, net of cash fees	-	-	-	-	383	-	383
Extinguishment of derivative liability upon exercise of warrant	-	-	-	-	5,753	-	5,753
Issuance of common stock from the exercise of prefunded warrants for cash	-	-	850	-	-	-	-
Issuance of common stock from the cashless exercise of warrants	-	-	7,468	-	-	-	-
Redemption of preferred stock	(1)	-	-	-	(2)	-	(2)
Issuance of agent warrants	-	-	-	-	108	-	108
Issuance of common stock from the conversion of preferred stock	(26)	-	9	-	-	-	-
Deemed dividend related to the conversion of preferred stock	-	-	-	-	(26)	-	(26)
Deemed dividend related to the conversion of preferred stock	-	-	-	-	26	-	26
Round up shares issued in reverse split	-	-	102	-	-	-	-
Net loss	-	-	-	-	-	(8,259)	(8,259)
Balance as of December 31, 2023	256	-	26,603	-	279,486	(270,714)	8,772
Stock based compensation	-	-	14	-	82	-	82
Common stock issued for cash, net of cash fees	-	-	1,119,357	11	5,644	-	5,655
Prefunded warrants issued for cash, net of cash fees	-	-	-	-	406	-	406
Extinguishment of derivative liability upon exercise of warrant	-	-	-	-	1	-	1
Issuance of common stock from the exercise of warrants for cash	-	-	63,079	1	1	-	2
Redemption of preferred stock	(7)	-	1,833	-	-	-	-
Round up shares issued in reverse split	-	-	131,967	1	(1)	-	-
Net loss	-	-	-	-	-	(11,024)	(11,024)
Balance as of December 31, 2024	249	$ -	1,342,853	$ 13	$ 285,619	$ (281,738)	$ 3,894

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

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

	Years Ended December 31,	
	2024	**2023**
Cash flow from operating activities		
Net loss	$ (11,024)	$ (8,259)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	842	907
Amortization of right of use asset	537	745
Amortization of intangible assets	5	5
Impairment of Armor	4,602	-
Stock based compensation	82	291
Change in fair value of derivative liabilities	(3,475)	(5,610)
Loss (gain) on disposal of equipment	18	(17)
Credit loss expense (recoveries)	(1)	63
Changes in operating assets and liabilities:		
Account and other receivables	490	(420)
Prepaid expenses and other assets	482	(264)
Inventories	72	(485)
Accounts payable and accrued liabilities	(756)	(12)
Other liabilities	(2)	(370)
Payments on operating lease liability	(514)	(689)
Net cash used in operating activities	(8,642)	(14,115)
Cash flows from investing activities		
Purchase of property and equipment	(690)	(530)
Proceeds from the sale of property and equipment	20	29
Proceeds from notes receivable, net of imputed interest	476	-
Net cash used in investing activities	(194)	(501)
Cash flows from financing activities		
Proceeds from issuance of warrant derivative liabilities	3,366	6,650
Proceeds from issuance of common stock and prefunded warrants, net of cash fees	6,075	5,177
Proceeds from issuance of common stock in connection with exercise of warrants	2	-
Redemption of preferred stock Series E	-	(2)
Principal payment on debt	(349)	(114)
Net cash provided by financing activities	9,094	11,711
Net increase (decrease) in cash and cash equivalents	258	(2,905)
Cash and cash equivalents at beginning of year	3,340	6,245
Cash and cash equivalents at end of year	$ 3,598	$ 3,340

	Years Ended December 31,	
	2024	**2023**
Noncash investing and financing activities		
Reduction of derivative liability upon exercise of warrants	$ 1	$ 5,753
Right of use asset for amended lease liability – increase	-	2,504
Right-of-use assets and assumption of operating lease liability	-	114
Issuance of common stock for the cashless exercise of warrants	-	15
Issuance of prefunded warrants	-	2
Right of use asset for amended lease liability – decrease	307	(89)
Debt issued for prepaid insurance	335	-
Agent warrant offering cost allocated to equity	13	-
Supplemental cash flow information		
Cash paid for interest	$ 29	$ 21

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

1. Organization and Summary of Significant Accounting Policies

The consolidated financial statements include the accounts of SINTX Technologies, Inc. ("SINTX") and its wholly-owned subsidiaries, SINTX Armor, Inc. ("SINTX Armor") and Technology Assessment and Transfer, Inc. (TA&T), which are collectively referred to as "we" or "the Company". SINTX is an advanced ceramics company formed in December 1996, focused on providing solutions in a variety of diverse fields, including biomedical, technical, and antipathogenic applications. SINTX is a company that has grown over time from focusing on the research and development of silicon nitride for use in human interbody implants to becoming an advanced ceramics company engaged in many different fields. The core strength of the Company is the manufacturing, research, and development of advanced ceramics for external partners. The Company presently manufactures subtractive and additive forms of various ceramic and ceramic composite materials including silicon nitride and carbide, zirconia and alumina. SINTX has also become expert in developing proprietary powders, compounds, resins, and filaments for use in additive manufacturing along with production of finished individual components in its Salt Lake City and Maryland facilities. The SINTX Salt Lake City facility is registered with the FDA, is cGMP and ANVISA RDC 665 compliant, as well as being ISO 9001:2015, ISO 13485:2016 certified, and ASD9100D certified. The Company's products are primarily sold in the United States.

The Company has historically been focused on building revenue generating opportunities in three business industries - antipathogenic, technical, and biomedical – connecting with current and new customers, partners and manufacturers to help realize the goal of leveraging expertise in high-tech ceramics to create new, innovative opportunities across these sectors.

The Company's initial focus was the development and commercialization of products made from silicon nitride for use in spinal fusion and hip and knee replacement applications. SINTX believes it is the first and only manufacturer to use silicon nitride in medical applications primarily focused on spine fusion therapies. Since then, we have developed other medical device applications for our silicon nitride technology as well as utilized our expertise in the use of ceramic materials in other applications. In July 2021, the Company acquired the equipment and obtained certain proprietary know-how rights with the intention of developing, manufacturing, and commercializing protective armor from boron carbide and a composite material of silicon carbide and boron carbide for military, law enforcement and civilian uses. The armor plant has not been fully operational since the acquisition and the Company incurred an impairment charge of approximately $4.6 million during the year ended December 31, 2024. In June 2022, the Company acquired TA&T, a nearly 40-year-old business with a mission to transition advanced materials and process technologies from a laboratory environment to commercial products and services.

Basis of Presentation and Principles of Consolidation

These consolidated financial statements have been prepared by management in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC") and include all assets and liabilities of the Company.

Reverse Stock Split

On May 28, 2024, the Company effected a 1 for 200 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.

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, 2024 and 2023, the Company incurred a net loss of $11.0 million and $8.3 million, respectively, and used cash in operating activities of $8.6 million and $14.1 million, respectively. The Company had an accumulated deficit of $281.7 million and $270.7 million as of December 31, 2024 and 2023, respectively. We will require substantial future capital in order to continue operating our business, conduct research and development and regulatory clearance and approval activities necessary to bring our products to market, and 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 our product candidates.

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, decrease expenses and raise additional funding. Whether and when the Company can attain profitability and positive cash flows from operations or obtain additional financing is uncertain.

On February 25, 2021, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with Maxim Group LLC (the "Agent") as sales agent, as amended on January 10, 2023 and October 12, 2023, pursuant to which the Company could offer and sell shares of the Company's common stock, par value $0.01 per share (the "Shares"), initially up to an aggregate offering price of $15,000,000, from time to time in an at-the-market public offering. On March 22, 2024, the Company suspended sales under the ATM Agreement and terminated the continuous offering. On July 11, 2024, the Company filed a Prospectus Supplement with the SEC adjusting the amount available for sale under the ATM Agreement to $3.1 million and shortly thereafter begin offering and selling Shares under the ATM Agreement to the public. During the year ended December 31, 2024, 602,357 Shares were sold under the ATM Agreement for gross proceeds of approximately $3.7 million. Because the Company is subject to General Instruction I.B.6 of Form S-3, it is restricted from selling securities in a public primary offering with a value exceeding one-third of its public float (the market value of our common stock held by our non-affiliates) in any 12-month period so long as its public float remains below $75.0 million. As of December 31, 2024, there was no capacity to offer and sell Shares under the ATM Agreement.

On February 10, 2023, the Company closed on a public offering of 10,750 units, with each unit consisting of one share of common stock, or one pre-funded warrant to purchase one share of its common stock, one Class C Warrant to purchase one share of common stock, and one half of one Class D Warrant with each whole Class D Warrant entitling the holder to purchase one share of common stock. Gross proceeds, before deducting offering expenses, totaled approximately $12.0 million. Of the $12.0 million of gross proceeds, approximately $5.4 million were allocated to common stock and prefunded warrants ($4.8 million net of offering costs) and approximately $6.7 million were allocated to derivative liabilities (with approximately $0.7 million of cash offering costs and $0.1 million of agent warrant offering costs recorded as derivative expense).

On February 2, 2024, the Company closed on a public offering of 80,000 units, with each unit consisting of one share of its common stock, or one pre-funded warrant to purchase one share of its common stock, one Class E Warrant with each warrant entitled to purchase one share of common stock, and one Class F Warrant with each warrant entitled to purchase one share of common stock. Each unit was sold at a public offering price of $50.00 resulting in gross proceeds to the Company of $4 million before deducting offering fees and expenses. The Class E and Class F Warrants were immediately exercisable at a price of $50.00 per share. The Class E Warrants expire five years from the date of issuance and the Class F Warrants expire eighteen months from the date of issuance. Of the $4.0 million of gross proceeds, approximately $0.6 million were allocated to common stock and prefunded warrants ($0.5 million net of offering costs) and approximately $3.4 million were allocated to derivative liabilities (with approximately $0.5 million of cash offering costs and $0.1 million of agent warrant offering costs recorded as derivative expense).

On March 26, 2024, the Company closed on a public offering of 142,000 shares of the Company's common stock, (the "March 26 Offering"). Each Share was sold at a public offering price of $9.40. The aggregate proceeds to the Company from the March 26 Offering were approximately $1.3 million before deducting placement agent fees and other estimated offering expenses payable by the Company.

On April 5, 2024, the Company closed on a public offering of 358,000 shares of the Company's common stock, (the "April 5 Offering"). Each Share was sold at a public offering price of $4.20. The aggregate proceeds to the Company from the April 5 Offering were approximately $1.5 million before deducting placement agent fees and other offering expenses payable by the Company.

On February 20, 2025, the Company entered into a private placement transaction with certain institutional and accredited investors for aggregate gross proceeds of $5.0 million, before deducting fees to the placement agent and other expenses payable by the Company in connection with the Private Placement. As part of the Private Placement, the Company issued 1,171,189 shares of the Company's common stock, par value $0.01 per share ("Common Stock"), pre-funded warrants to purchase 278,098 shares of Common Stock (the "Pre-Funded Warrants") with an exercise price of $0.0001 per share, and warrants to purchase 1,449,287 shares of Common Stock (the "Common Warrants," together with the Pre-Funded Warrants, the "Warrants") (the Warrants, together with the Shares and Warrant Shares (as defined below), the "Securities") with an exercise price of $3.32 per share. The purchase price per share of Common Stock and the associated Common Warrant was $3.45 and the purchase price per Pre-Funded Warrant and associated Common Warrant was $3.4499. The Common Warrants are exercisable immediately and expire five-and one-half years from issuance. The Pre-Funded Warrants are exercisable immediately and terminate when exercised in full.

On June 11, 2024, the Company received formal notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company has evidenced compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). The Company remains subject to a "Mandatory Panel Monitor," as that term is defined in Listing Rule 5815(d)(4)(B), for a period of one year from June 11, 2024. If, within the one-year period, the Company fails to satisfy the minimum $1.00 closing bid price threshold for 30 consecutive business days, Nasdaq will issue a delist determination rather than provide the Company with a grace period to regain compliance with the Bid Price Rule. In that event, the Company would have the opportunity to request a new hearing to address the deficiency.

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

The Board of Directors, together with management, is performing an ongoing evaluation of the Company's business strategy and focus. On August 1, 2024, the board of directors appointed Eric Olson to the office of Chief Executive Officer and President to lead the evaluation process. The Board of Directors also entered into an engagement agreement with Ascendiant Partners to evaluate strategic transactions including, but not limited to, acquisitions, strategic partnerships, sell of business divisions, and reverse merger opportunities.

An option being evaluated is a change in strategic emphasis to advancements in the medical device sector. Historically engaged in both industrial and biomedical applications, SINTX would prioritize the development and commercialization of innovative medical devices, leveraging our expertise in advanced ceramics and biomaterials. Such a renewed focus would align with a commitment to improving patient outcomes through the creation of products designed for surgical, orthopedic, and other specialized medical applications. We would concentrate our resources on high-growth areas within the healthcare sector where our proprietary materials and technologies—such as silicon nitride—provide a distinct competitive advantage due to their unique strength, durability, and biocompatibility.

Through this transformation, SINTX's aim would be to deliver meaningful innovations to the medical community. Our current research and development pipeline is centered on medical-grade devices that incorporate antimicrobial properties, enhanced imaging capabilities, and durability under physiological conditions, which are critical for orthopedic implants, spinal fusion devices, and other surgical tools. If we transition away from industrial applications, we anticipate this strategic shift will enable us to better serve the medical sector, address critical unmet needs, and position SINTX as a leading provider in the medical device market. By focusing on partnerships and collaborations with healthcare institutions and industry leaders, SINTX is positioned to expand its footprint in the medical device sector and drive shareholder value through sustainable, high-impact innovations, however, such a transition has not been approved by the Board of Directors, nor can such approval or successful transition be assured.

SINTX Technologies has initiated discussions with the leaseholder for our Centerpointe location in Salt Lake City, Utah to explore options for reducing the Company's overall lease liability. This action aligns with our broader strategy to streamline operating expenses and the option to reallocate resources towards growth initiatives in the medical device sector. While these discussions reflect our commitment to financial optimization, there can be no assurance that negotiations will lead to a reduction in the existing lease liability. The outcome of these discussions remains uncertain, and SINTX will continue to evaluate additional measures to manage long-term obligations in alignment with our strategic objectives.

On August 8, 2024, the Board of Directors approved a plan to implement a Company-wide reduction in the workforce. This decision is part of the Company's ongoing strategic review of its operations aimed at improving operational efficiency and reducing costs. The reduction in force reduced the number of employees of the Company from 40 to 23. During the year ended December 31, 2024, the Company recorded expenses of approximately $0.4 million associated with the reduction in workforce.

On August 12, 2024, the Board of Directors of the Company approved a plan to cease efforts to make the armor plant operational. This decision was made to streamline operations and focus on core business areas that align with the Company's long-term strategic goals. The armor plant has not been fully operational since the acquisition of the armor equipment in July 2021 and has been completely shut down since October 2023 due to the malfunctioning of the sintering furnace. In connection with this decision the Company incurred an impairment charge of approximately $4.6 million during the year ended December 31, 2024. This charge primarily relates to the write-down of certain long-lived assets associated with the armor plant to their estimated fair value.

The Company's insurance carrier has determined that a covered loss occurred when the sintering furnace malfunctioned, and coverage is available for the Company's repair of the sintering furnace. However, the Company's efforts to fully repair the damaged furnace continue to be delayed. Management will work with the insurance company to continue to fund the repair of the furnace. When the furnace is fully repaired, management intends to sell the furnace, and related equipment, to a third party. However, the full repair and sale of the furnace, and related equipment, cannot be assured. Therefore, in the calculation of the $4.6 million impairment charge, management has assumed no proceeds will be received from a potential sale of the furnace and related equipment.

Based on the decrease in expenditures from the reduction in force, sale of TA&T and the increase in cash on February 20, 2025, SINTX management has determined that there is no uncertainty of the Company's ability to continue as a going concern through at least March 19, 2026 and further analysis of this matter is not deemed necessary for the year ended December 31, 2024.

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, 2024, the most significant estimate relates to derivative liabilities relating to common stock warrants.

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, 2024, three commercial customers and government agencies represent 54% of the Company's total revenues and 32% of the Company's total accounts receivable as of and for the year ended December 31, 2024.

Revenue Recognition

The Company derived its product revenue primarily from the sale of aerospace components and spinal fusion products. The aerospace components are key ceramic aircraft engine components sold to a leading manufacturer of aerospace components and systems whom the Company has entered into a 10-year, long-term agreement. The spinal fusion products are used in the treatment of spine disorders and sold to CTL Medical, with whom the Company signed a 10-year exclusive sales agreement in October 2018. The Company also records revenue from grants, contracts, and awards provided by government agencies. 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. Contact 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 employs 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 of products at the time the product is shipped.

Revenues from grants, contracts, and awards provided by governmental agencies are recorded based upon the terms of the specific agreements, which generally provide that revenue is earned when the allowable costs specified in the applicable agreement have been incurred or a milestone has been met. Cash received from federal grants, contracts, and awards can be subject to audit by the grantor and, if the examination results in a disallowance of any expenditure, repayment could be required. The duration of the government grants, contracts, and awards varies by government entity as well as phase level. The general duration period during 2024 was 2.3 years.

Grant, contract, and award receivables relate to allowable amounts expended or otherwise incurred or earned in connection with the terms of a grant, contract, or award and for which reimbursement has not yet taken place. As of December 31, 2024, government grants, contracts, and awards accounted for approximately $0.1 million in accounts receivable. To be eligible to receive moneys from government agencies the Company must meet commitments as outlined in the grant, contract, and award agreements.

Costs of Revenue

The expenses that are included in costs of revenue associated with product sales 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. Inventory that is not expected to be utilized within 12 months of December 31, 2024, and 2023, respectively is recorded as long term.

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.

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 Credit Losses

Financial assets, which potentially subject the Company to credit losses, consist primarily of receivables. We measure expected credit losses of financial assets based on historical loss and other information available to management using type of receivable (commercial, grants or contracts, retainage, or other) and different aging categories (less than 90 days past due, over 90 days past due, over 180 days past due, and financially troubled customers). These expected credit losses are recorded to an allowance for credit losses valuation account that is deducted from receivables to present the net amount expected to be collected on the financial asset on the consolidated balance sheet. Management believes that the historical loss information it has compiled is a reasonable basis on which to determine expected credit losses for trade receivables held as of December 31, 2024, because the composition of the trade receivables as of that date is consistent with that used in developing the historical credit-loss percentages (i.e., the similar risk characteristics of its customers and its lending practices have not changed significantly over time).

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, 2024.

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.

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, 2024 and 2023.

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, 2024 and 2023, 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.

New Accounting Pronouncement, Not Yet Adopted

The Company has reviewed all 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.

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 shares of common stock 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 shares of common stock 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 0.2 million and 0.7 million shares of common stock as of December 31, 2024 and 2023, respectively.

Below are basic and diluted loss per share data for the year ended December 31, 2024, which are in thousands except for share and per share data:

	Basic Calculation	Effect of Dilutive Warrant Securities	Diluted Calculation
Numerator:			
Net loss	$ (11,024)	$ (291)	$ (11,315)
Deemed dividend and accretion of a discount	-	-	-
Net loss attributable to common stockholders	$ (11,024)	$ (291)	$ (11,315)
Denominator:			
Number of shares used in per common share calculations:	741,250	3,532	744,782
Net loss per common share:			
Net loss	$ (14.87)	$ (82.39)	$ (15.19)
Deemed dividend and accretion of a discount	-	-	-
Net loss attributable to common stockholders	$ (14.87)	$ (82.39)	$ (15.19)

Below are basic and diluted loss per share data for the year ended December 31, 2023, which are in thousands except for share and per share data:

	Basic Calculation	Effect of Dilutive Warrant Securities	Diluted Calculation
Numerator:			
Net loss	$ (8,259)	$ (5,320)	$ (13,579)
Deemed dividend and accretion of a discount	(26)	-	(26)
Net loss attributable to common stockholders	$ (8,285)	$ (5,320)	$ (13,605)
Denominator:			
Number of shares used in per common share calculations:	18,682	3,104	21,786
Net loss per common share:			
Net loss	$ (442.08)	$ (1,713.83)	$ (623.28)
Deemed dividend and accretion of a discount	(1.39)	-	(1.19)
Net loss attributable to common stockholders	$ (443.47)	$ (1,713.83)	$ (624.47)

2. Inventories

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

	As of December 31,	
	2024	2023
Raw materials	$ 629	$ 691
WIP	182	426
Finished goods	156	104
	$ 967	$ 1,221

Impairment of Armor inventories of $0.2 million was recorded during 2024 related to Armor exit costs, and is included in Armor exit costs in the statement of operations.

3. Property and Equipment

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

	As of December 31,	
	2024	2023
Manufacturing and lab equipment	$ 2,220	$ 5,597
Leasehold improvements	968	2,034
Software and computer equipment	664	751
Furniture and equipment	118	136
	3,970	8,518
Less: accumulated depreciation	(3,048)	(3,692)
	$ 922	$ 4,826

Depreciation expense for 2024 and 2023 was approximately $0.8 million and approximately $0.9 million, respectively. Impairment of property and equipment of $3.7 million was recorded during 2024 related to Armor exit costs, and is included in Armor exit costs in the statement of operations.

4. Intangible Assets

Intangible assets consisted of the following (in thousands):

	As of December 31,	
	2024	2023
Trademarks	$ 50	$ 50
Less: accumulated amortization	(34)	(29)
	$ 16	$ 21

Amortization expense for 2024 was approximately $5.0 thousand. Amortization expense for 2023 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, 2024 and 2023. 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, 2024 and 2023.

	Fair Value Measurements as of December 31, 2024 (in thousands)			
Description	**Level 1**	**Level 2**	**Level 3**	**Total**
Derivative liabilities				
Common stock warrants	$ -	$ -	$ 208	$ 208

	Fair Value Measurements as of December 31, 2023 (in thousands)			
Description	**Level 1**	**Level 2**	**Level 3**	**Total**
Derivative liabilities				
Common stock warrants	$ -	$ -	$ 304	$ 304

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, 2024 and 2023. 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, 2024 and 2023 (in thousands):

	Common Stock Warrants
Balance as of December 31, 2023	(5,126)
Issuance of derivatives	(6,650)
Exercise of warrants	5,753
Change in fair value	5,718
Other	1
Balance as of December 31, 2024	$ (304)
Issuance of derivatives	(3,366)
Exercise of warrants	1
Change in fair value	3,475
Other	(14)
Balance as of December 31, 2024	$ (208)

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, 2024, and 2023, 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, 2024 and 2023 were as follows:

	December 31, 2024	December 31, 2023
Weighted-average risk-free interest rate	4.12-4.35%	3.93-4.79%
Weighted-average expected life (in years)	0.10-4.09	1.10-4.12
Expected dividend yield	-%	-%
Weighted average expected volatility	140.0-210.0%	113.1%-125.7%

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):

	As of December 31,	
	2024	2023
Payroll and related expenses	$ 400	$ 610
Accrued payables	178	163
Other	408	631
	$ 986	$ 1,404

7. Debt

Business Loan

On July 20, 2021, TA&T entered into a Loan Authorization and Agreement in the amount of approximately $350,000 (the "Business Loan"). The Company made a one-time $35,000 buy down payment when acquiring the loan. The Business Loan bears interest at a rate of 3.75% per annum. The Business Loan is secured by a general security interest in all of the assets of TA&T. The business loan was paid in full during the first quarter of 2023 and there was no outstanding balance at December 31, 2024.

Related Party Debt

TA&T is obligated to repay certain personal loans made by the founders of TA&T to TA&T prior to SINTX's acquisition of TA&T (the "Personal Loans"). The total amount of the Personal Loans at June 30, 2022 was approximately $350,000. The Company agreed to repay the outstanding balance of the Personal Loans in (i) 24 equal monthly installments beginning September 1, 2022 and each month thereafter until paid in full as one prior owner's portion of the Personal Loans totaling $157,000, and (ii) for the other owner's portion of the Personal Loans totaling $193,000. The related party debt was paid in full during the third quarter of 2024 and there was no outstanding balance at December 31, 2024.

Insurance Premium Finance Arrangements

In March 2024, in connection with securing Director and Officer professional liability insurance, the Company entered into a Premium Finance Arrangement to extend the premium payment out for a period of 10 months. The Company paid a total of $40,000 up front toward the insurance premium and financed approximately $239,000. The Company will make 10 equal payments under the terms of the Premium Finance Agreement. The Premium Finance Agreement bears interest at an annual percentage rate of 8.510%. The Director and Officer professional liability insurance debt was paid in full during the fourth quarter of 2024 and there was no outstanding balance at December 31, 2024.

In June 2024, in connection with securing commercial liability insurance, the Company entered into a Premium Finance Arrangement to extend the premium payment out for a period of 10 months. The Company paid a total of $26,000 up front toward the insurance premium and financed approximately $117,000. The Company will make 10 equal payments under the terms of the Premium Finance Agreement. The Premium Finance Agreement bears interest at an annual percentage rate of 8.75%. As of December 31, 2024, there was an outstanding balance of $32,000.

8. Equity

2024 April Registered Offering

On April 5, 2024, the Company closed on a public offering 358,000 shares of the Company's common stock, (the "Offering"). Each Share was sold at a public offering price of $4.20. The aggregate proceeds to the Company from the Offering were approximately $1.5 million before deducting placement agent fees and other estimated offering expenses payable by the Company.

2024 March Registered Offering

On March 26, 2024, the Company closed on a public offering 142,000 shares of the Company's common stock, (the "Offering"). Each Share was sold at a public offering price of $9.40. The aggregate proceeds to the Company from the Offering were approximately $1.3 million before deducting placement agent fees and other estimated offering expenses payable by the Company.

2024 February Registered Offering

On February 2, 2024, the "Company closed on the public offering of 80,000 units consisting of (a)(i) 17,000 units (the "Common Units") to purchase shares (the "Unit Shares") of the Company's Common Stock, par value $0.01 per share (the "Common Stock") and (ii) 63,000 units (the "Pre-Funded Warrant Units" and together with the Common Units, the "Units") to purchase pre-funded warrants (the "Pre-Funded Warrants and each share of Common Stock underlying a Pre-Funded Warrant, a "Pre-Funded Warrant Share") to purchase up to 63,000 shares of Common Stock, (b) accompanying Class E warrants to purchase 80,000 shares of the Company's Common Stock (the "Class E Warrants"), and (c) accompanying Class F warrants to purchase 80,000 shares of the Company's Common Stock (the "Class F Warrants"). The aggregate proceeds to the Company from the Offering were approximately $4 million before deducting placement agent fees and other offering expenses payable by the Company. The offering was made pursuant to a securities purchase agreement (the "Purchase Agreement") with certain investors (the "Purchasers"), and a placement agency agreement dated as of January 31, 2024 (the "PAA") with Maxim Group LLC (the "Placement Agent"). Each Common Unit was sold at a public offering price of $50.00 and each Pre-Funded Warrant Unit was sold at a public offering price of $49.98. The Class E Warrants and the Class F Warrants are immediately exercisable (subject to the beneficial ownership cap at 4.99% or 9.99%) for one share of the Company's Common Stock at an exercise price of $50.00 per share. The Class E Warrants will expire five years from the date of issuance and the Class F Warrants will expire 18 months from the date of issuance. Each Pre-Funded Warrant is exercisable for one share of the Company's Common Stock at an exercise price of $0.0001 per share. The Pre-Funded Warrants are immediately exercisable (subject to the beneficial ownership cap at 4.99% or 9.99%) and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Company engaged Maxim Group LLC as the Company's sole placement agent for the Offering pursuant to the PAA. Pursuant to the PAA, the Company agreed to pay the Placement Agent a cash placement fee equal to 7.0% of the gross proceeds of the Offering, plus reimbursement of certain expenses and legal fees up to $100,000. The Company also agreed to issue up to 3,200 Common Stock purchase warrants to the Placement Agent (the "Placement Agent Warrants"). The Placement Agent Warrants are exercisable at an exercise price of $55.00. The Placement Agent Warrants will be exercisable beginning July 31, 2024, and will expire five years after the commencement of sales in the offering.

2023 Registered Offering

On February 10, 2023, the Company closed on a public offering of 10,750 units, with each unit consisting of one share of common stock, or one pre-funded warrant to purchase one share of its common stock, one Class C Warrant to purchase one share of common stock, and one half of one Class D Warrant with each whole Class D Warrant entitling the holder to purchase one share of common stock. Each unit was sold at a public offering price of $1,120.00. The Class C and Class D warrants each have a cashless exercise provision entitling the holders to surrender one Class C Warrant and receive 0.4 shares of common stock and on the surrender of one Class D Warrant the holder is entitled to receive 0.8 shares of common stock. The Class C Warrants expire five years from the date of issuance and the Class D Warrants expire three years from the date of issuance. The shares of common stock (or pre-funded warrants in lieu thereof) and accompanying warrants were only purchasable together in this offering but were issued separately and were immediately separable upon issuance. In addition, the company issued a total of 430 common stock warrants to the placement agent, Maxim Group, and the Company's financial advisor, Ascendiant Capital. Gross proceeds, before deducting offering expenses, totaled approximately $12.0 million. Of the $12.0 million of gross proceeds, approximately $5.4 million were allocated to common stock and prefunded warrants ($4.8 million net of offering costs) and approximately $6.7 million were allocated to derivative liabilities (with approximately $0.7 million of cash offering costs and $0.1 million of agent warrant offering costs recorded as derivative expense).

2021 Equity Distribution Agreement

On February 25, 2021, the Company entered into an Equity Distribution Agreement (as amended, the "2021 Distribution Agreement") with Maxim Group LLC ("Maxim"), pursuant to which the Company may sell from time to time, shares of the Company's common stock having an aggregate offering price of up to $15 million through Maxim, as agent. On October 12, 2023, the Company entered into an amendment to the Distribution Agreement, pursuant to which the expiration date of the Distribution Agreement was extended to the earlier of: (i) the sale of shares having an aggregate offering price of $15.0 million, (ii) the termination by either Maxim or the Company upon the provision of fifteen (15) days written notice, or (iii) February 25, 2025. No other changes were made to the terms of the Distribution Agreement. As of December 31, 2024, there have been 12,360 shares of common stock sold under the 2021 Distribution Agreement for gross proceeds of $1.0 million. As of December 31, 2024, the Company had no funds available for sale under the Distribution Agreement. Maxim may sell the Shares by any method permitted by law deemed to be an "at-the-market" offering (the "ATM") 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. 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 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. The Company currently has registered up to $3.1 million for sale under the Distribution Agreement, pursuant to the Registration Statement on Form S-3 (File No. 333-274951). On July 11, 2024, the Company filed a Prospectus Supplement with the SEC increasing the amount available for sale under the Distribution Agreement to $3.1 million. As of December 31, 2024, there have been 607,920 shares of common stock sold under the 2021 Distribution Agreement for gross proceeds of $4.1 million. Because the company's public float is less than $75 million, the Company is subject to General Instruction I.B.6 of Form S-3 which limits the amounts that we may sell under the registration statement over a 12-month period to an amount equal to or less than one-third of our public float. The shares of the Company's common stock to be sold under the Distribution Agreement will be sold and issued pursuant to the Form S-3, as amended, which was previously declared effective by the Securities and Exchange Commission, and the related prospectus and one or more prospectus supplements.

9. Stock-Based Compensation

A summary of the Company's outstanding stock option activity for the years ended December 31, 2024 and 2023 is as follows:

	December 31, 2024			
	Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Intrinsic Value
As of December 31, 2023	60	$ 21,954	6.9	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	(24)	3,861,275	-	-
Expired	(1)	891,768,343	-	-
As of December 31, 2024	35	$ 18,872	5.5	$ -
Exercisable at December 31, 2024	35	$ 24,292	6.1	$ -
Vested and expected to vest at December 31, 2024	10	$ 38,168	5.5	$ -

	December 31, 2023			
	Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Intrinsic Value
As of December 31, 2022	60	$ 46,804	7.9	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	-	-
As of December 31, 2023	60	$ 21,954	6.9	$ -
Exercisable at December 31, 2023	51	$ 52,298	7.0	$ -
Vested and expected to vest at December 31, 2023	49	$ 21,854	6.9	$ -

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.

Unrecognized stock-based compensation as of December 31, 2024, is as follows (in thousands):

	Unrecognized Stock-Based Compensation	Weighted Average Remaining of Recognition (in years)
Stock options	$ 2	0.0
Stock grants	8	1.2

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,	
	2024	2023
Federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(4.3)%	(5.0)%
Return to provision	0.0%	0.0%
Equity related expenses	(5.6)%	(12.5)%
Change in valuation allowance	30.9%	38.5%
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,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 57,763	$ 55,797
Stock-based compensation	3,192	3,171
Federal R&D credit	2,222	2,222
Impairment	1,148	-
Accrued expenses	53	121
Capitalized research expenses	3,145	3,083
Intangibles	237	292
Right of use asset/liabilities	32	26
Other	15	18
Total deferred tax assets	67,807	64,730
Deferred tax liabilities:		
Depreciation	(431)	(763)
Total deferred tax liabilities	(431)	(763)
Less valuation allowance	(67,376)	(63,967)
Net deferred tax liability	$ -	$ -

	December 31,	
	2024	2023
Pre-tax book income tax at statutory rate	$ (2,315)	$ (1,734)
State taxes, net of federal benefit	(482)	(414)
Return to provision	-	-
Equity related expenses	(614)	(1,036)
Change in valuation allowance	3,409	3,181
Other	2	3
Total income tax expense	$ -	$ -

As of December 31, 2024 and 2023, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $231.5 million and $223.6 million, respectively. The federal and state net operating loss carryforwards incurred prior to 2018 will expire from 2024 to 2037 unless previously utilized, and the federal and state net operating loss carryforwards incurred in 2018 and thereafter carry forward indefinitely. 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, 2024 and 2023, 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 $3.4 million and $3.2 million for the years ended December 31, 2024 and 2023, respectively.

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, 2024 and 2023.

13. Leases

The Company has entered into multiple operating leases from which it conducts its business.

SINTX

With respect to SINTX operations, the Company leases 30,764 square feet of office, warehouse and manufacturing space under a single operating lease. This lease expires in October 2031. The lease has one five-year extension option.

SINTX Armor

On August 19, 2021, the Company, on behalf of SINTX Armor, entered into an Industrial Lease Agreement (the "SINTX Armor Lease") pursuant to which the Company has agreed to lease approximately 10,936 square feet of office and manufacturing space from which SINTX Armor will conduct its operations. The term of the SINTX Armor Lease is 122 months through October 2031. Impairment of operating lease right-of-use assets of $0.7 million was recorded during 2024 related to Armor exit costs, and is included in Armor exit costs in the statement of operations.

TA&T

In connection with operation of its business, TA&T has entered into various leases for approximately 15,840 square feet of office and manufacturing space from which it conducts its research, development and manufacturing activities. The leases have various expiration dates ranging from April 30, 2024 through April 2030. See Note 14 for sale of TA&T subsequent to December 31, 2024.

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.

As of December 31, 2024, the operating lease right-of-use assets totaled approximately $3.2 million and the operating lease liability totaled approximately $4.0 million. Non-cash operating lease expense during the year ended December 31, 2024, totaled approximately $0.5 million. As of December 31, 2024, the weighted-average discount rate for the Company's operating lease was 8.8%.

Operating lease future minimum payments together with the present values as of December 31, 2024, are summarized as follows:

	December 31,
2025	$ 790
2026	748
2027	770
2028	794
2029	817
Beyond	1,424
Total future minimum lease payments	5,343
Less amounts representing interests	(1,350)
Present value of lease liability	3,993
Current-portion of operating lease liability	456
Long-term portion operating lease liability	$ 3,537

14. Subsequent Events

Sale of TA&T

On February 19, 2025, the Company entered into an Entity Acquisition Agreement with Tethon Corporation ("Tethon"), pursuant to which the Company sold to Tethon all of the issued and outstanding shares of TA&T in exchange for the assumption by Tethon of the outstanding liabilities of TA&T. The Agreement contains representations, warranties, covenants and indemnities by the parties customary for transactions of this type. The representations, warranties and covenants contained in the Agreement were made only for purposes of the Agreement and as of specified dates, were solely for the benefit of the parties to the Agreement and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the Agreement. The representations and warranties have been made for the purpose of allocating contractual risk between the parties to the Agreement instead of establishing these matters as facts and may be subject to a contractual standard of materiality different from what might be viewed as material to investors. Investors should not rely on the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the Company or Tethon. Moreover, information concerning the subject matter of the representations, warranties and covenants may change after the date of the Agreement, which subsequent information may or may not be fully reflected in public disclosures.

Capital Raise

On February 20, 2025, entered into a private placement transaction pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors for aggregate gross proceeds of $5.0 million, before deducting fees to the placement agent and other expenses payable by the Company in connection with the Private Placement. The Company intends to use the net proceeds from the Private Placement for general corporate purposes and working capital. H.C. Wainwright & Co. ("Wainwright"), acted as the exclusive placement agent for the Private Placement, which closed on February 25, 2025. As part of the Private Placement, the Company issued (i) 1,171,189 shares of the Company's common stock, par value $0.01 per share ("Common Stock"), (ii) pre-funded warrants to purchase 278,098 shares of Common Stock (the "Pre-Funded Warrants") with an exercise price of $0.0001 per share, and (iii) warrants to purchase 1,449,287 shares of Common Stock (the "Common Warrants," together with the Pre-Funded Warrants, the "Warrants") (the Warrants, together with the Shares and Warrant Shares (as defined below), the "Securities") with an exercise price of $3.32 per share. The purchase price per share of Common Stock and the associated Common Warrant was $3.45 and the purchase price per Pre-Funded Warrant and associated Common Warrant was $3.4499. The Common Warrants are exercisable immediately and expire five-and one-half years from issuance. The Pre-Funded Warrants are exercisable immediately and terminate when exercised in full.

EXHIBIT 4.23

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.

Exhibit 19

INSIDER TRADING POLICY

(as approved by the Board of Directors September 30, 2021)

SINTX Technologies, Inc. (the "Company") has adopted the following policy regarding trading by Company personnel in the Company's securities (the "Insider Trading Policy," or this "Policy"). This Policy applies to all Company personnel, including directors, officers, employees and consultants of the Company and its subsidiaries. This Policy also applies to certain family members, other members of a person's household and entities controlled by Company personnel, as described in Section IV below.

I. The Need for an Insider Trading Policy

This Policy has been developed:

- to educate all Company personnel as to the federal securities laws and the rules of the U.S. Securities and Exchange Commission (the "SEC") on insider trading in public company securities;
- to set forth requirements that apply to Company personnel and other persons covered by this Policy who seek to trade in the Company's securities;
- to protect the Company and its personnel from legal liability; and
- to preserve the reputation of the Company and its personnel for integrity and ethical conduct.

Because the Company is a public company, transactions in the Company's securities are subject to the federal securities laws and regulations adopted by the SEC. These laws and regulations make it illegal for an individual to buy or sell securities of the Company while aware of material non-public information. The SEC takes insider trading very seriously and devotes significant resources to uncovering the activity and to prosecuting offenders. Liability may extend not only to the individuals who trade while in possession of material non-public information but also to their "tippers," people who leak material non-public information to individuals who then trade based on that information. The Company and "controlling persons" of the Company may also be liable for violations by Company employees.

II. What is Material Non-Public Information?

Definition.

Material non-public information is any information (positive or negative) that:

- is not generally known to the public, and
- which, if publicly known, would likely affect either the market price of the Company's securities or a person's decision to buy, sell or hold the Company's securities.

Examples.

Common examples of information that will frequently be regarded as material include, but are not limited to:

- quarterly or annual earnings results;
- projections of future financial results;
- earnings or losses;
- news of a pending or proposed merger, acquisition or tender offer;
- news of a pending or proposed acquisition or disposition of a significant asset;
- news of a pending or proposed joint venture;
- a company restructuring;
- significant transactions with officers, directors or greater than 5% shareholders;
- financing transactions;
- changes in dividend policies, the declaration of a stock split or the offering of additional securities;
- establishment of a stock repurchase program;
- changes in pricing or cost structure of Company products or services;
- changes in management;
- changes in auditors or notification that the auditor's reports may no longer be relied upon;
- significant new products or discoveries;
- significant clinical or regulatory developments;
- pending or threatened significant litigation, or the resolution of such litigation;
- impending bankruptcy or financial liquidity problems;
- internal financial information which departs from what the market expects;
- the gain or loss of a significant customer or supplier, major contract, license, registration or collaboration;
- the entry, amendment or termination of a material contract; or
- other items that require the filing of a Current Report on Form 8-K with the SEC.

Hindsight.

In determining whether information is material, the SEC and other regulators will view the information after-the-fact with the benefit of hindsight. As a result, in determining whether any information is material, we will and you should carefully consider whether regulators and others might view the information as being material in hindsight, with the benefit of all relevant information that later becomes available. For example, if there is a significant change in the Company's stock price following release of certain information, that information will likely be determined to have been material when viewed with the benefit of hindsight.

In addition to addressing the relevant statutes and regulations in this area, we are adopting this Policy to avoid even the appearance of improper conduct on the part of anyone employed by or associated with the Company and certain related persons, not just members of senior management.

III. The Consequences of Insider Trading

The consequences of insider trading violations can be severe. For individuals who trade while in possession of material non-public information (or tip information to others) the sanctions may include:

- a civil penalty of up to three times the profit gained, or loss avoided;

- a criminal fine of up to $5 million (regardless of the size of the profit made on the trade); and
- incarceration for a term of up to 20 years.
- These penalties can apply even if you are not an officer of the Company or a member of the Board of Directors. Moreover, if an employee violates this Policy, you may also be subject to Company-imposed sanctions, including termination for cause.
- For the Company (as well as possibly any supervisory person) that fails to take appropriate steps to prevent illegal trading the sanctions may include:
    - a civil penalty of the greater of $1 million or three times the profit gained, or loss avoided as a result of the employee's violation; and
    - a criminal penalty of up to $25 million.
- If you are subject to an insider trading investigation, any of the above consequences, including an SEC investigation regardless of whether it results in prosecution, can tarnish the Company's or your reputation and irreparably damage your career.

IV. Our Policy

General Prohibition on Trading.

You and any Related Person (as defined below) may not buy or sell securities of the Company while in possession of material nonpublic information or engage in any other action to take advantage of, or pass on to others, that information, subject to the specific exceptions noted below in this Section IV under the caption "Exceptions for Certain Transactions."

Transactions by Family Members, Others in Your Household and Entities You Control.

The restrictions in this Policy also apply to "Related Persons", which are any of the following:

- immediate family members who reside with you;
- others living in your household (whether or not related to you);
- family members who do not reside with you but are otherwise dependent upon you for financial support (e.g., college students away at school);
- family members who do not live in your household but whose transactions in the Company's securities are directed by you or are subject to your influence or control (e.g., parents or children who consult with you before they trade in the Company's securities); and
- any entities that you influence or control, including any corporations, limited liability companies, partnerships or trusts.

SEC regulations specifically provide that any material non-public information about the Company communicated to any spouse, parent, child or sibling is considered to have been communicated under a duty of trust or confidence; and that any trading in the Company's securities by such family members while they are aware of such information may, therefore, violate insider trading laws and regulations. Company personnel are expected to be responsible for the compliance of all Related Persons with this Policy. This means that, to the extent such Related Persons of Company personnel intend to trade in the Company's securities, the Related Persons need to comply with the black-out periods and all other restrictions in this Policy. Furthermore, you should not participate in any investment club (i.e., groups of people who pool their money to make investments) that may invest in the Company's securities.

Other Companies' Non-public Information.

This Policy also applies with equal force to information relating to any other company, including our customers or suppliers, obtained by Company personnel during the course of their service to or employment by the Company. Specifically, no Company personnel who, in the course of work on behalf of the Company, learns of material non-public information about a company with which the Company does business may trade in the other company's securities until the information becomes public or is no longer material.

Personal or Independent Reasons Are Not Exceptions. Transactions in the Company's securities that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) are no exception. Even the appearance of an improper transaction must be avoided to preserve our reputation for adhering to the highest standards of conduct.

Policy Administrator.

This Policy shall be administered by the "Policy Administrator," who shall be the head of human resources, or such other person designated as such by the Company's Board of Directors.

When Information Becomes Public.

This Policy applies to material non-public information about the Company, which means that trading is permitted once the information becomes known to the public (unless some other Company policy or legal obligation restricts trading at that time). Because the Company's shareholders and the investing public should be afforded time to receive and absorb information, as a general rule you should not engage in any transactions until the beginning of the first business day after material information has been released. Thus, if an announcement is made before the market opens on a Monday, Tuesday generally would be the first day on which you may trade. If an announcement is made before the market opens on a Friday, Monday generally would be the first day on which you may trade. However, if the information released is complex, such as a major financing or other significant transaction, it may be necessary to allow additional time for the information to be absorbed by the investing public. In such circumstances, you will be notified by the Policy Administrator regarding a suitable waiting period before trading. In addition, we have established specified black-out periods, as described below.

Prohibited Trading Periods.

While it is never permissible to trade based on material non-public information, we are implementing the following procedures to help prevent inadvertent violations of this Policy and avoid even the appearance of an improper transaction (which could result, for example, where Company personnel engage in a trade while unaware of a pending major development).

Company Wide Black-Out Periods Applicable to All Company Personnel.

All Company personnel and Related Persons are prohibited from trading in any of the Company's securities during the following periods:

- from the time each such individual becomes aware of the material information (the black-out start times often vary), until the beginning of the first business day after the day the Company has made a public announcement of material information, including earnings releases, unless the information released is complex, in which case it may be necessary to extend this period and the Policy Administrator will notify you of any such extension of the black-out period; and
- during other specified periods when significant developments or announcements are anticipated, as notified by the Policy Administrator.

You will be notified by e-mail when you may not trade in the Company's securities during periods when significant developments or announcements are anticipated, in which event you will also be notified when trading restrictions are lifted. Of course, even during periods when trading is permitted, no one, including persons or entities who do not fall within the definition of Related Persons, should trade in the Company's securities if he or she possesses material non-public information.

Pre-Clearance of All Acquisitions, Sales and Other Transfers by Company Personnel.

In order to ensure compliance with this Policy and with any Section 16 reporting requirements, all transactions in the Company's securities (including acquisitions, sales, gifts and other transfers, whether or not for value), including the execution of Trading Plans (as defined below), by members of the Company's Board of Directors or any Company personnel or Related Persons must be pre-cleared by the Policy Administrator. If you are a member of one of the groups listed above and you contemplate a transaction in the Company's securities, you must contact the Policy Administrator or other designated individual prior to executing the transaction. The Policy Administrator will use his or her reasonable best efforts to provide approval or disapproval of the proposed transaction within two business days. You must wait until receiving pre-clearance to execute the transaction. Neither the Company nor the Policy Administrator shall be liable for any delays that may occur due to the pre-clearance process. If the transaction is pre-cleared by the Policy Administrator, it must be executed by the end of the second business day after receipt of pre-clearance. Notwithstanding receipt of pre-clearance of a transaction, if you become aware of material nonpublic information about the Company after receiving the pre-clearance but prior to the execution of the transaction, you may not execute the transaction. The responsibility for determining whether you are in possession of material non-public information rests with you**. If you are a Section 16 reporting person, promptly following execution of the transaction, but in no event later than the end of the first business day after the execution of the transaction, you must notify the Policy Administrator and provide details regarding the transaction sufficient to complete the required Section 16 filings.**

Please note that pre-clearance does not provide Company personnel with immunity from investigation or suit, for which it is the responsibility of the individual to comply with the federal securities regulations.

Exceptions for Certain Transactions.

(1) Gifts.

Bona fide gifts are not transactions that are subject to this Policy, unless the person making the gift (the donor) has reason to believe that the recipient of the gift intends to sell the Company's securities while the donor is in possession of material non-public information.

(2) Mutual Funds.

Transactions in mutual funds that are invested in the Company's securities are not transactions subject to this Policy.

(3) Transactions Involving Company Equity Plans.

Except as otherwise noted below, this Policy does not apply to the following transactions:

- Stock Option Exercises. This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's equity plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale of stock for the purpose of generating the cash needed to pay the exercise price and or taxes upon the exercise of an option.
- Restricted Stock Awards and Restricted Stock Unit Awards. This Policy does not apply to the vesting of restricted stock or restricted stock units, or the exercise of a tax withholding right pursuant to which a person elects to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock or restricted stock unit. This Policy does apply, however, to any market sale of restricted stock or shares received upon vesting of restricted stock units.
- Employee Stock Purchase Plan. This Policy does not apply to purchases of the Company's securities under the Company's employee stock purchase plan. This Policy does apply, however, to subsequent sales or other transfers of such securities.
- Other Transactions with the Company. Any other purchase of the Company's securities from the Company or sales of the Company's securities to the Company are not subject to this Policy.

(4) Rule 10b5-1 Trading Plans.

Notwithstanding the restrictions and prohibitions on trading in the Company's securities set forth in this Policy, persons subject to this Policy are permitted to effect transactions in the Company's securities pursuant to approved trading plans established under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("Trading Plans"), which may include transactions during the prohibited periods discussed above. Rule 10b5-1 requires that these transactions be made pursuant to a plan that was established while the person was not in possession of material non-public information, and the SEC requires that these plans not be entered into during any applicable Company-imposed black-out period. In order to comply with this Policy, the Company must pre-approve any such Trading Plan prior to its effectiveness. After a Trading Plan is approved, you must wait for a cooling-off period before the first trade is made under the Trading Plan, the length of which will be determined by the Policy Administrator. Once the Trading Plan is adopted, you must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the dates of the trades. The Trading Plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party. Any modification of a Trading Plan is the equivalent of entering into a new Trading Plan and cancelling the old Trading Plan. Company personnel seeking to establish, modify or cancel a Trading Plan should contact the Policy Administrator.

V. Individual Responsibility

Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in the Company's securities while in possession of material non-public information. You are responsible for making sure that he or she complies with this Policy, and that any Related Person, whose transactions are subject to this Policy, also comply with this Policy. In all cases, the responsibility for determining whether you are in possession of material non-public information rests with you, and any action on the part of the Company, the Policy Administrator or any other Company personnel pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You may be subject to legal penalties and disciplinary action by law enforcement officials and/or the Company for any conduct prohibited by this Policy or applicable securities laws, as described in Section III above.

Tipping Information to Others.

You may not disclose non-public information about the Company to others outside the Company who do not have an obligation to maintain the confidentiality of such information. If an outsider trades on such information, penalties for insider trading may apply in these situations whether or not you derive any monetary benefit from the other person's trading activities. Material non-public information is often inadvertently disclosed or overheard in casual, social conversations. Please take care to avoid such disclosures.

Prevention of Insider Trading by Others.

If you become aware of a potential insider trading violation, you must immediately advise our Policy Administrator and/or report the matter using the Company's anonymous whistleblower reporting procedures. You should also take steps, where appropriate, to prevent persons under your supervision and/or control from using material non-public information for trading purposes. Moreover, Company-imposed sanctions, including termination for cause, could result if an employee fails to comply with this Policy.

Confidentiality.

The unauthorized disclosure of internal information about the Company, whether or not for the purpose of facilitating improper trading in the Company's securities can cause serious problems for the Company. You should not discuss internal Company matters or developments (whether or not you think such information is material) with anyone outside of the Company (including, but not limited to, family, friends, business associates, investors and expert consulting firms), except as required in the performance of regular corporate duties. This prohibition applies specifically (but not exclusively) to inquiries about the Company that may be made by the financial press, investment analysts or others in the financial community and also includes posting material non-public information on any social media outlets such as Facebook, Twitter, etc. It is important that all such communications on behalf of the Company be made only through an authorized officer under carefully controlled circumstances. Unless you are expressly authorized to the contrary, if you receive any inquiries of this nature, you should decline comment and refer the inquirer to the head of investor relations or the CEO. Please review the Company's separate Regulation FD Policy, which governs all public communications with people outside the Company. Please also refer to the Company's Social Media Policy.

VI. Additional Prohibited Transactions

Because we believe it is generally improper and inappropriate for Company personnel to engage in short-term or speculative transactions involving the Company's securities, it is our policy that you and any Related Person not engage in any of the following activities, except in each case in limited circumstances with prior approval of the Policy Administrator:

- trading in any shares of Company common stock purchased in the open market and held for less than six months;
- short sales of the Company's securities;
- use of the Company's securities to secure a margin or other loan;
- transactions in straddles, collars or other similar risk reduction or hedging devices; and
- transactions in publicly-traded options relating to the Company's securities (i.e., options that are not granted by the Company).

VII. Post-Termination Transactions

This Policy will no longer apply after the termination of your service to the Company. However, if you are in possession of material non-public information when your service terminates, you may not trade in the Company's securities until that information has become public or is no longer material, and it would be prudent for you, if you are subject to a black-out period upon termination of service, to refrain from trading until those restrictions no longer apply to Company personnel. Note, if you are a Section 16 reporting person there may still be restrictions on your ability to trade in the Company's securities post-termination of employment.

VIII. Company Assistance

The Policy Administrator can respond to any questions about specific transactions or this Policy in general that you may have. Remember, however, the ultimate responsibility for adhering to this Policy and avoiding improper transactions rests with you. In this regard, please use your best judgment when considering a transaction in the Company's securities.

IX. Certifications

As a condition to employment, all employees will be required to certify their understanding of and intent to comply with this Policy. All members of the Company's Board of Directors are also required to certify their understanding of and intent to comply with this Policy at the time of appointment or subsequently as this Policy may be updated from time-to-time.

Certification Under Insider Trading Policy

The undersigned hereby certifies that he/she has read and understands, and agrees to comply with, the Company's Insider Trading Policy, a copy of which was distributed with this Certification.

Date: _____

Signature _____

Name: _____
(Please Print)

Title: _____

Date: April 2021

Exhibit 21.1

List of Subsidiaries

SINTX Armor, Inc., a Utah corporation.

Technology Assessment and Transfer, Inc., a Maryland corporation.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statements on Form S-1 (Nos. 333-223032, 333-234438, 333-266070, 333-269475 and 333-275137) and Form S-3 (Nos. 333-274951) and Form S-8 (Nos. 333-248846) of SINTX Technologies, Inc. (the Company) of our report dated March 18, 2025, 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, 2024.

/s/ Tanner LLC

Lehi, UT
March 18, 2025

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Eric Olson, 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 19, 2025

By: */s/ Eric Olson*
Eric Olson
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Eric Olson, 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 19, 2025

By: */s/ Eric Olson*
Eric Olson
Principal Financial Officer

Exhibit 32

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, 2024 (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 19, 2025

By: */s/ Eric Olson*

Eric Olson

Chief Executive Officer and Principal Financial Officer