

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

or

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

For the transition period from _____ to _____

Commission file number: 001-34951

Xtant Medical Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	20-5313323
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
664 Cruiser Lane Belgrade, Montana	59714
(Address of Principal Executive Offices)	(Zip Code)
(406) 388-0480	
(Registrant's Telephone Number, Including Area Code)	

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.000001 per share	XTNT	NYSE American LLC

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

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

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 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 Act). Yes No

The aggregate market value of the common stock held by non-affiliates as of June 30, 2022 was approximately \$7.0 million (based on the closing price of the Company's common stock on the last business day of the Company's most recently completed second fiscal quarter, as reported on the NYSE American).

The number of shares of the Company's common stock, \$0.000001 par value, outstanding as of March 3, 2023 was 108,897,048.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (“Exchange Act”), and are subject to the safe harbor created by those sections. For more information, see “*Cautionary Statement Regarding Forward-Looking Statements*.”

As used in this report, the terms “we,” “us,” “our,” “Xtant,” “Xtant Medical,” and the “Company” mean Xtant Medical Holdings, Inc. and our consolidated wholly-owned subsidiaries, unless the context indicates another meaning.

We own various unregistered trademarks and service marks, including our corporate logo. Solely for convenience, the trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the owner of such trademarks and trade names will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies. We include our website address throughout this report for reference only.

The information contained on or connected to our website is not incorporated by reference into this report.

We are a “smaller reporting company” as that term is defined in Rule 12b-2 promulgated under the Exchange Act. Accordingly, this report reflects the scaled reporting requirements of smaller reporting companies as set forth in Regulation S-K, promulgated under the Exchange Act.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our forward-looking statements include, but are not limited to, statements regarding our “expectations,” “hopes,” “beliefs,” “intentions,” or “strategies” regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should” and “would,” as well as similar expressions, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking.

A forward-looking statement is neither a prediction nor a guarantee of future events or circumstances and those future events or circumstances may not occur. You should not place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-K. The forward-looking statements contained in this Form 10-K are based on currently available operating, financial and competitive information and our current expectations and beliefs concerning future developments and their potential effects on us. These forward-looking statements involve a number of risks, uncertainties, or assumptions, many of which are beyond our control, which may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the “Part I. Item 1.A. *Risk Factors*” section of this Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We are including this cautionary statement to make applicable and take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws.

PART I

Item 1. Business

Overview

Xtant Medical Holdings, Inc. is a global medical technology company focused on the design, development, and commercialization of a comprehensive portfolio of orthobiologics and spinal implant fixation systems to facilitate spinal fusion in complex spine, deformity, and degenerative procedures. Our products are used by orthopedic spine surgeons and neurosurgeons to treat a variety of spinal disorders in the cervical, thoracolumbar, and interbody spine.

We promote and sell our products in the United States through independent distributors and stocking agents, supported by direct employees. We have an extensive distribution channel of commissioned independent agents and stocking agents in the United States representing some or all of our products. We also maintain a national accounts program to enable our agents to gain access to independent health delivery network hospitals and through group purchasing organizations (“GPOs”). We have biologics contracts with major GPOs, as well as extensive access to integrated delivery networks (“IDNs”) across the United States for both our biologics and spine hardware products. We promote and sell our products internationally through distribution partners in Canada, Mexico, South America, Australia, and certain Pacific region countries.

We have focused and intend to continue to focus primarily on four key growth initiatives: (1) introduce new products; (2) expand our distribution network; (3) penetrate adjacent markets; and (4) leverage our growth platform with technology and strategic acquisitions. While the intent of these four key growth initiatives is to increase our future revenues, no assurance can be provided that we will be successful in implementing these growth initiatives or increasing our future revenues.

Industry and Market Overview

The orthopedic biomaterials market consists of materials that are organic, inorganic or synthetic in nature. These materials are implanted or applied in or near the indicated bone to aid in healing, encourage bone tissue augmentation, compensate in areas where bone tissue is depleted, and restore structure to allow for repair. These materials are often used as substitutes to autograft materials, which are taken from a harvest site in the patient to patch or repair the wounded or unhealthy site.

Fixation is often instrumental in allowing the body to heal and regenerate tissue. Fixation provides the constructive support necessary for reestablishing stability, by immobilizing the regenerative site, and relieving stress. Fixation also can help hold the biomaterial in place in order to achieve a better outcome. Examples of fixation products can include, but are not limited to, plates, screws, pins, rods, spacers, and staples. Fixation products may be made from various metals and polymer materials.

Our Orthobiologics Products

Our biomaterial products include OsteoSponge, OsteoSponge SC, OsteoSelect DBM putty, OsteoSelect Plus DBM putty, OsteoWrap, and our line of 3Demin products, as described below, as well as other allografts:

- OsteoSponge is a form of demineralized bone matrix (“DBM”) made from 100% human bone. Derived from trabecular (cancellous) bone, OsteoSponge is designed to provide a natural scaffold for cellular in-growth and expose bone-forming proteins to the healing environment. The malleable properties of OsteoSponge enable it to conform to, and fill, most defects. OsteoSponge’s unique mechanical and osteoconductive properties in tandem with its osteoconductive potential make OsteoSponge an ideal bone graft for use in various orthopedic practices including spine, neurology, cranial/maxillofacial, trauma, plastic/reconstruction and general procedures where new bone growth is needed.

- OsteoSelect DBM Putty is designed to be easily molded into any shape and compressed into bony voids. We have validated a low-dose, low-temperature gamma sterilization process designed to provide maximum osteoinductive potential while still affording device level sterility.
- OsteoSelect PLUS DBM Putty combines the exceptional cohesive characteristics of OsteoSelect DBM Putty with demineralized cortical chunks. OsteoSelect PLUS is designed to deliver differentiated handling properties and ensure patient safety through validated, terminal sterilization. Each lot of OsteoSelect PLUS DBM is tested for osteoinductivity *in vivo* prior to being released.
- 3Demin is a family of allografts that maximizes osteoconductivity and the osteoinductive potential of human bone. They consist of 100% demineralized cortical bone with excellent, malleable handling characteristics, and are distributed as a sterile allograft. Our 3Demin products are easily hydrated with any biocompatible liquid, making them an ideal option for various bone grafting applications. They are most commonly used in spinal fusion procedures.
- OsteoFactor is a uniquely processed allograft that contains retained growth factors found within the endosteum layer of allograft bone. Unlike the various growth factor-based products on the market today, OsteoFactor is not limited to a single growth factor but contains a wide array of naturally occurring proteins and peptides that support bone formation and remodeling.
- OsteoVive Plus is a growth factor enriched cellular bone matrix created through a proprietary processing method. The combination of viable cells, growth factors and DBM fibers results in an allograft containing higher concentrations of growth factors than other cellular allografts.

We also process and distribute (i) sports allografts which are processed specifically for anterior and posterior cruciate ligament repairs, anterior cruciate ligament reconstruction and meniscal repair, (ii) milled spinal allografts which are comprised of cortical bone milled to desired shapes and dimensions, and (iii) traditional allografts for multi-disciplinary applications including orthopedics, neurology, podiatry, oral/maxillofacial, genitourinary and plastic/reconstructive.

Our Spinal Implant Products

We offer a comprehensive line of products that are used to treat a variety of spinal and sacroiliac conditions, including trauma, degeneration, deformity and tumor, including use of minimally invasive surgery techniques. Some of our key spinal implant product lines include:

Cervical Products

- The Certex Spinal Fixation System consists of screws, hooks, rods, and cross connectors. It is intended to promote fusion of the subaxial cervical spine and cervico-thoracic junction (C3 – T3 inclusive).
- The Spider Cervical Plating System consists of simple, single step locking with 3 forms of locking feedback providing confidence in Spider System construct and performance.

Thoracolumbar Products

- The Axle Interspinous Fusion System is a fully modular interspinous device matched to the patient's individual anatomy and available in multiple implantable configurations.
- The Silex Sacroiliac Joint Fusion System is a sacroiliac fixation system which actively compresses across the SI joint. Sacroiliac dysfunction is increasingly recognized as a frequent contributor to chronic low back pain.
- The Xpress Minimally Invasive Pedicle Screw System combines minimally invasive functionality to the most common lumbar fixation procedures — pedicle screw fixation.
- The Fortex Pedicle Screw System consists of titanium alloy bone screws, rods, cross-connectors and associated instruments. The system is indicated for attachment to the pedicles of the thoracic, lumbar, and sacral spine.

Interbody Products

- Calix is a family of PEEK interbody spacers and precision instruments for both cervical and thoracolumbar applications. Calix PC is a frictional titanium plasma-coated PEEK implant that provides additional biomechanical performance and end-plate visualization.
- The Axle-X Interspinous Fusion System is an internal fixation device for spinal surgery in the non-cervical spine (T1 – S1 inclusive). It is a minimally invasive, modular interspinous fusion system with angled spikes that allows for adequate L5 – S1 engagement and other variations in patient anatomy. The Axle-X Interspinous Fusion System is designed to provide spinal stability for lumbar fusion procedures, including the treatment of degenerative disc disease, spinal tumors and trauma.
- The Irix-C Cervical Integrated Fusion System consists of an integrated titanium ring, surrounded by an outer PEEK ring and two screws. It is intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for the treatment of degenerative disc disease.
- The Irix-A Lumbar Integrated Fusion System consists of an integrated titanium ring, surrounded by an outer PEEK ring and three screws. It is intended for spinal fusion procedures at one or two contiguous levels of the lumbosacral spine (L2 – S1 inclusive) in skeletally mature patients for the treatment of degenerative disc disease.

Interlaminar Stabilization Products

- The Coflex device is a single-piece, U-shaped, titanium implant intended for the treatment of moderate to severe lumbar spinal stenosis in conjunction with decompression. It provides minimally invasive, motion preserving stabilization.
- The CoFix implant allows minimally invasive, segmental stabilization after microsurgical decompression and serves to support posterior fusion as an alternative to fixation with pedicle screws. It is intended for use on all levels of the lumbar spine for back pain and intervertebral disc-related pain due to degenerative processes of the lumbar spine with the occurrence of instability.

Sales and Marketing

We distribute our products in the United States through an extensive distribution network of commissioned independent sales agents and stocking agents. As of December 31, 2022, we had over 300 independent sales agents and stocking agents. We also maintain a national accounts program to enable our agents to gain access to IDN hospitals and through GPOs. We have biologics contracts with major GPOs, including Vizient, Premier, and HealthTrust Purchasing Group, as well as extensive access to IDNs across the United States for both biologics and spine hardware systems.

Our international footprint includes distribution partners in Canada, Mexico, South America, Australia, and certain Pacific region countries. We do not have any operations in or sales to Europe.

Donor Procurement

Xtant's mission with respect to donor procurement is: "Honoring the gift of donation, by helping our patients live as full, and complete a life as possible."

In furtherance of our mission, we have agreements with multiple recovery agencies, and we continue to explore options to expand our network for access to donor tissue in anticipation of increased demand for our biologics products. We expect to be able to continue to build our network for donor tissue as our processing capabilities and sales increase.

Competition

There are various public and private organizations that offer both fixation and orthobiologics to their customers. Our primary competitors include Medtronic plc, Johnson and Johnson, Zimmer Biomet Holdings, Inc., Stryker Corporation, Nuvasive, Inc., Bioventus Inc., Globus Medical, Inc., Surgalign Holdings, Inc., SeaSpine Holdings Corporation, OrthoFix Medical Inc., Alphatec Holdings, Inc., as well as dozens of privately-owned companies. We also compete with tissue banks that do not offer spinal fixation products, such as AlloSource International, Inc., LifeNet Health, and MTF Biologics.

Intellectual Property

We rely upon patents, trademarks, trade secrets and other proprietary rights to maintain and improve our competitive position. We review third-party proprietary rights, including patents and patent applications, as available, to develop an effective intellectual property strategy, avoid infringement of third-party proprietary rights, identify licensing opportunities and monitor the intellectual property owned by others.

We protect our proprietary rights through a variety of methods. As a condition of employment, we generally require employees to execute an agreement relating to the confidential nature of and company ownership of proprietary information and assigning intellectual property rights to us. We generally require confidentiality agreements with vendors, consultants, and others who may have access to proprietary information. We generally limit access to our facilities and review the release of company information in advance of public disclosure. There can be no assurances, however, that confidentiality agreements with employees, vendors, and consultants will not be breached, adequate remedies for any breach would be available, or competitors will not discover or independently develop our trade secrets. Litigation also may be necessary to protect trade secrets or techniques we own.

Patents

Although we believe that, in the aggregate, our patents are valuable, and patent protection is beneficial to our business and competitive positioning, our patent protection will not necessarily deter or prevent competitors from attempting to develop similar products. There can be no assurances that our patents will provide competitive advantages for our products or that competitors will not challenge or circumvent these rights. In addition, there can be no assurances that the United States Patent and Trademark Office (“USPTO”) or foreign patent offices will issue any of our pending patent applications. The USPTO and foreign patent offices may deny or require a significant narrowing of the claims in our pending patent applications and the patents issuing from such applications. Any patents issuing from the pending patent applications may not provide us with significant commercial protection. We could incur substantial costs in proceedings before the USPTO or foreign patent offices, including opposition and other post-grant proceedings. These proceedings could result in adverse decisions as to the patentability, priority of our inventions, and the narrowing or invalidation of claims in issued patents. Additionally, the laws of some of the countries in which our products are or may be sold may not protect our intellectual property to the same extent as the laws in the United States or at all.

Our policy is to file patent applications in the United States and other countries when we believe it is commercially advantageous to do so. We do not consider our business to be materially dependent upon any individual patent. As of December 31, 2022, our biologics patent portfolio includes 13 issued patents in the US and 6 pending US patent applications, and our fixation portfolio includes 51 issued patents in the US and one pending US patent application. We expect that additional patent applications will be filed and prosecuted as inventions are discovered, technological improvements and processes are developed, and specific applications are identified. There can be no assurance that we will be able to obtain final approval of any patents.

Trademarks

We have registered, and continue to seek registration, of trademarks and continuously monitor and aggressively pursue users of names and marks that potentially infringe upon our registered trademarks. We currently own the following registered trademarks: OsteoSponge®, OsteoVive®, OsteoWrap®, OsteoLock®, BacFast®, OsteoSelect®, Elutia®, OsteoSTX®, hMatrix®, 3Demin®, BACTERINSE®, Circle of Life®, Coflex® and CoFix™. Under the X-spine name, we own the following registered trademarks: SILEX®, X-SPINE®, IRIX®, CAPLESS®, CERTEX®, CALIX®, H-GRAFT®, SPIDER, X90®, HYDRAGRAFT®, BUTREX®, FORTEX®, AXLE®, FIXCET®, XTANT®, Capless® and X-spine’s square design logo.

Trade Secrets and Other Proprietary Rights

To safeguard our proprietary knowledge and technology, we rely upon trade secret protection and non-disclosure/confidentiality agreements with employees, consultants and third-party collaboration partners with access to our confidential information. Although we believe our proprietary technology has value, because of rapid technological changes in the medical industry, we also believe that proprietary protection is of less significance than factors such as the intrinsic knowledge and experience of our management, advisory board, consultants and personnel and their ability to identify unmet market needs and to create, invent, develop and market innovative and differentiated products.

Government Regulation

We are registered with the U.S. Food and Drug Administration (“FDA”) as a manufacturer of human cellular and tissue products (“HCT/Ps”) as well as medical devices, and we are an accredited member in good standing of the American Association of Tissue Banks (“AATB”). We meet all licensing requirements for the distribution of HCT/Ps in states with licensing requirements, including Florida, California, Delaware, Illinois, Louisiana, Maryland, Oregon, and New York. Our industry is highly regulated, and we cannot predict the impact of future regulations on either us or our customers.

Our fixation products and instrumentation systems are regulated as medical devices and therefore are subject to extensive regulation by the FDA, as well as by other domestic and international regulatory bodies. These regulations govern multiple activities that Xtant and our suppliers, licensors and partners perform and will continue to perform. These regulated activities include product design and development, testing, manufacturing, labeling, storage, safety, premarket clearance, advertising and promotion, product marketing, sales and distribution, post-market surveillance and post-market adverse event reporting. All products currently marketed by Xtant are regulated as HCT/Ps and/or have received 510(k) clearances.

Human Tissue

Human tissue product regulations are designed to ensure that sound, high quality practices are followed to prevent the introduction, transmission or spread of communicable disease. Among other things, the regulations require that companies that recover, process, store, label, package or distribute HCT/Ps register with the FDA. In addition, regulations provide criteria that must be met for donors to be eligible to donate tissues and is referred to as the “Donor Eligibility” rule. Regulations also govern the processing and distribution of the tissues and are often referred to as the “Current Good Tissue Practices” (“cGTP”) regulations.

An HCT/P is regulated solely under section 361 of the Public Health Service Act (“PHSA”) and 21 CFR Part 1271 if it meets the following four criteria:

- 1) The HCT/P is minimally manipulated;
- 2) The HCT/P is intended for homologous use only;
- 3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article (with limited exceptions); and
- 4) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function and: is for autologous use; is for allogeneic use in a first-degree or second-degree blood relative; or is for reproductive use.

Several of our products, including OsteoSponge and OsteoWrap, are regulated as HCT/Ps and are therefore subject to the following regulatory requirements under section 361 of the PHSA and 21 CFR Part 1271:

- **Registration and Listing:** Establishments that engage in the manufacture of HCT/Ps are required to register annually with the FDA and list their HCT/Ps. New establishments are required to register and list their HCT/Ps within 5 days after beginning operations.

- Donor Eligibility: HCT/P establishments must screen donors for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases and communicable disease risks associated with xenotransplantation, as well as test donors for relevant communicable disease agents.
- Good Tissue Practices: HCT/P establishments must comport with the regulatory requirements for preventing the introduction, transmission, or spread of communicable disease. These regulations cover facilities, environmental control, equipment, supplies and reagents, recovery, processing and process controls, labeling controls, storage, receipt, predistribution shipment, and distribution of HCT/Ps.
- Adverse Reaction Reporting: Establishments are required to investigate any adverse reaction involving a communicable disease related to an HCT/P that the manufacturer made available for distribution. The regulatory criteria call for reporting such adverse reactions involving a communicable disease if it is fatal, life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention, including hospitalization.
- Inspections: The FDA has broad post-market and regulatory enforcement powers. HCT/P manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the cGTP regulations.
- Violative Product: Upon an FDA finding that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of applicable regulations; the HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or an establishment is in violation of applicable regulations, the FDA may issue an order that the HCT/Ps be recalled, destroyed or retained, take possession of and/or destroy the violative HCT/Ps, or serve upon the establishment an order to cease manufacturing.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions such as warning or untitled letters, injunctions, or other action.

There are many HCT/P products that must undergo regulatory review and licensure by the FDA. The approval process for a Biologics License Application (“BLA”) includes a rigorous review of the safety and efficacy of the biological product. Successful applications typically require testing and validation through a series of clinical and non-clinical studies taking place over multiple years of product development. We refer to all of our HCT/P products as biologics.

Medical Devices

The Center for Devices and Radiological Health regulates the clearance and approval of conventional medical devices, such as our spinal hardware, as well as some of the HCT/Ps that are also regulated as medical devices, such as our OsteoSelect DBM putty. In the United States, medical devices are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending pre-market approval applications (“PMAs”), issuance of warning letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

Under the FDCA, medical devices are classified into one of three classes based on the risk associated with the device and the level of control necessary to provide a reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed.

Most Class I devices and a minority of Class II devices are completely exempt from premarket review by the FDA. Most Class II devices and a minority of Class I devices require 510(k) clearance. Devices that pose the highest risk, including life sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device or a “pre-amendment” Class III device in commercial distribution before May 28, 1976 for which PMA applications are not required, are placed in Class III requiring PMA approval. A novel device is placed in Class III by default, but it may be eligible to be placed in Class I or Class II via “de novo” classification if it can be shown to pose only low to moderate risk with appropriate regulatory controls.

The PMA approval pathway requires proof of the safety and effectiveness of the device to the FDA’s satisfaction. The 510(k) clearance pathway is much less burdensome and time-consuming than the PMA approval pathway. The de novo pathway has an enhanced burden compared to the 510(k) clearance pathway, but is much less burdensome than a PMA approval process.

Under the 510(k) clearance pathway, the applicant must submit to the FDA a premarket notification demonstrating that the medical device is substantially equivalent to a legally marketed predicate device. A predicate device may be a previously 510(k) cleared device, Class II de novo device, or a pre-amendment device (unless the FDA has issued a regulation calling for PMA applications for this device type). To be substantially equivalent, the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and be shown to be equally safe and effective and not raise different questions of safety and effectiveness than the predicate device.

After the FDA accepts the 510(k) premarket notification, it begins a substantive review. By statute, the FDA is required to complete its review within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, typically ranging from three to nine months or more, and clearance is never assured. The FDA’s 510(k) review generally compares a proposed device to a predicate device with respect to intended use and technology. The information necessary to show substantial equivalence will depend on the differences between the proposed device and the predicate device, which may include bench, animal, and/or clinical studies. The discussion of what data is needed is sometimes conducted in a voluntary process called the pre-submission process whereby companies meet with the FDA to discuss the data needed for clearance.

If the FDA finds the applicant’s device is substantially equivalent to the predicate device, it will send a letter to the applicant stating that fact. This allows the applicant’s device to be commercially distributed in the United States. Otherwise, the applicant must fulfill the much more rigorous premarketing requirements of the PMA approval process or seek reclassification of the device through the de novo process.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require reclassification through the de novo process or a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer’s decision not to seek a new 510(k) clearance, the agency may require the manufacturer to seek 510(k) clearance, de novo classification, or PMA approval. The FDA can also require a manufacturer to cease marketing and/or recall the modified device until 510(k) clearance, de novo classification, or PMA approval is obtained.

Another procedure for obtaining marketing authorization for a medical device is the “de novo classification” procedure. Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III, regardless of the level of risk they pose. Additionally, in response to a 510(k) premarket notification, if the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the de novo process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

The advantage of the de novo classification is that it generally requires less data than a PMA. The disadvantage is that it may require more data than a 510(k) and most often will include human clinical data. A request for de novo classification also has a longer review time. If the de novo application is denied, the device remains in Class III and PMA approval may be required before the device may be legally marketed in the United States. The FDA is increasingly moving devices with slightly different proposed indication statements or different technological features off the 510(k) path and onto the de novo path, resulting in more time and expense for the company.

A device not eligible for 510(k) clearance or de novo classification must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The cost of preparing and submitting a PMA is substantial and a PMA application must provide extensive preclinical and clinical trial data and also detailed information about the device and its components regarding, among other things, device design, manufacturing and labeling. Under federal law, the submission of most PMAs is additionally subject to a substantial annually adjusted application user fee. Satisfaction of FDA PMA requirements typically takes years, and the actual time required may vary substantially based upon the type, complexity, and novelty of the device or disease. In the future, Xtant may decide to strategically commercialize products in the United States that would require a PMA, but there are no plans to do so at the present time.

After a medical device enters commercial distribution, numerous regulatory requirements continue to apply. These include:

- The FDA's Quality System Regulation ("QSR") requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- Labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of devices for uncleared, unapproved or off-label uses;
- Advertising and promotion requirements;
- Restrictions on sale, distribution or use of a device;
- The potential for new 510(k) clearances for certain modifications to previously 510(k) cleared devices;
- Medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- Medical device correction and removal reporting regulations, which require that manufacturers report to the FDA their field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA;
- Recall requirements, including a mandatory recall, if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- An order of repair, replacement or refund;
- Device tracking requirements; and
- Post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions such as: warning letters, fines, injunctions, consent decrees and civil penalties; unanticipated expenditures, repair, replacement, refunds, recall or seizure of our devices; operating restrictions, partial suspension or total shutdown of manufacturing; the FDA's refusal of our requests for 510(k) clearances, de novo classification, or premarket approvals of new devices, new intended uses or modifications to existing devices; the FDA's refusal to issue certificates to foreign governments needed to export devices for sale in other countries; and withdrawing 510(k) clearances, de novo marketing authorization, or premarket approvals that have already been granted; and criminal prosecution.

International Regulation

Many foreign countries have regulatory bodies and restrictions similar to the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval in a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA approval and the related requirements may differ. Some third-world countries accept CE Certificates of Conformity or FDA clearance or approval as part of applications of approval for marketing of medical devices in their territory. Other countries, including Brazil, Canada, Australia and Japan, require separate regulatory filings.

Healthcare Fraud and Abuse

Healthcare fraud and abuse laws apply to Xtant's business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded healthcare programs. The Federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal health care programs, such as by Medicare or Medicaid. The concerns that the Anti-Kickback Statute addresses are multiple, but primary among them are, first, that the federal government pays/reimburses health care providers for the true acquisition cost of goods and services provided to patients served by government programs. The government does not want, for example, health care providers obtaining manufacturer discounts which are not disclosed to the government on cost report forms submitted for reimbursement to the government. The government wants to be the beneficiary of such discounts. Second, for that reason, the government wants transparency in the billing process which discloses such discounts to the government. Third, the government does not want purchasing, prescription or referral decisions for medical devices biased by economics unrelated to the best choices for a patient.

The Federal Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. Remunerative relationships with physicians in which manufacturers give health care providers gifts or pay for entertainment, sporting events, trips or other perquisites, may be viewed as an attempt to buy loyalty to the manufacturer's products. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs as well as any third-party payors, including commercial insurers. Further, federal legislation, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively "PPACA"), among other things, clarified the intent requirements of the Federal Anti-Kickback Statute and the federal criminal statutes governing healthcare fraud. Specifically, a person or entity can be found to have violated the statutes without actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA amended the Social Security Act to provide 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 or federal civil money penalties statute. Amendments to the Federal False Claims Act provide that a violation of the Federal Anti-Kickback Statute is also a violation of the Federal False Claims Act, subjecting healthcare entities to treble damages and mandatory penalties for each false claim or statement.

Additionally, the civil Federal False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. The purpose of the Federal False Claims Act is to prevent manufacturers from causing or inducing inappropriate prescriptions leading to an inappropriate government reimbursement. It often comes into play where a manufacturer suggests or assists a health care provider to bill for an off-label, uncovered use. It also can occur when the reimbursement advice given by a manufacturer results in inappropriate reimbursement claims from "upcoding," miscoding, "stretched" coding, the use of inappropriate modifiers or inappropriate care settings. These behaviors can result in the government paying for products or procedures that should not be reimbursed by the federal government. The manufacturer must be truthful and not misleading in the reimbursement advice it gives to customers.

Actions under the Federal False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the Federal False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the Federal False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare companies throughout the country for a wide variety of Medicare billing practices, as well as federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, and has obtained multi-million and multi-billion dollar settlements under the Federal False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and suppliers' compliance with the healthcare reimbursement rules and fraud and abuse laws.

The Federal Physician Payments Sunshine Act imposes annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians. Device manufactures are also required to collect information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives for reporting to the Centers for Medicare & Medicaid Services ("CMS"). A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

Our operations are also subject to the U.S. Foreign Corrupt Practices Act ("FCPA"). We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded United States corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in certain foreign jurisdictions.

Coverage and Reimbursement

Xtant's currently approved products are commonly treated as general supplies utilized in spinal and orthopedic surgery and if covered by third-party payors, are paid for as part of the surgical procedure. Accordingly, healthcare providers in the United States generally rely on third-party payors, principally private insurers and governmental payors such as Medicare and Medicaid, to cover and reimburse all or part of the cost of a spine surgery in which Xtant products are used. Sales volumes and fees for Xtant products will continue to depend in large part on the availability of coverage and reimbursement from such third-party payors. Third-party payors perform analyses on new technologies to determine if they are medically necessary before providing coverage for them. These third-party payors may still deny reimbursement on covered technologies if they determine that a device used in a procedure was not used in accordance with the payor's coverage policy. Particularly in the United States, third-party payors continue to carefully review, and increasingly challenge, the prices charged for procedures and medical products.

In the United States, a large percentage of insured individuals receive their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use Xtant products.

The overall escalating cost of medical products and services has led to, and will likely continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. Government or private third-party payors cannot be guaranteed to cover and reimburse the procedures using Xtant products in whole or in part in the future or that payment rates will be adequate. In addition, it is possible that future legislation, regulation or coverage and reimbursement policies of third-party payors will adversely affect the demand for Xtant products or the ability to sell them on a profitable basis.

Internationally, reimbursement and healthcare payment systems vary substantially from country to country and include single-payor, government-managed systems as well as systems in which private payors and government managed systems exist side-by-side. Xtant's ability to achieve market acceptance or significant sales volume in international markets will be dependent in large part on the availability of reimbursement for procedures performed using company products under the healthcare payment systems in such markets. A number of countries may require Xtant to gather additional clinical data before recognizing coverage and reimbursement for its products.

ISO Certification

Xtant is an International Organization for Standardization (“ISO”) certified organization. To obtain ISO 13485:2016 certification, an organization must demonstrate its ability to provide medical devices that consistently meet applicable customer and regulatory requirements. The primary objective of ISO 13485:2016 is to facilitate harmonized medical device regulatory requirements for quality management systems. All requirements of ISO 13485:2016 are specific to organizations providing medical devices, regardless of the type or size of the organization. The certification assures our customers and partners of our commitment to quality, and in the quality of our innovative products and processes. Additionally, we believe that our ISO 13485:2016 certification may offer new markets and business opportunities for our products in the global marketplace.

Human Capital

Mission, Quality Policy and Core Values

Our Mission is to “honor the gift of donation, by allowing our patients to live as full, and complete a life as possible.” Through an effective quality system, we prioritize our commitment to our patients and donor families.

- We aim to improve the quality of life for our patients by designing, manufacturing and distributing medical devices and human tissues for transplant that are safe, effective and meet the needs of our customers.
- We honor the gift of donation by enhancing our core competencies and maximizing utilization of the gift.

Our Mission and quality policy reflect our core values of:

- Respect for the individual,
- Responsiveness to our customers, and
- Responsibility to our stakeholders.

Employees

As of December 31, 2022, Xtant had 135 employees, 134 of whom were full time employees, and of whom 63 were in operations, 21 were in sales and marketing, 3 in research and development and engineering, 16 in regulatory and quality affairs, and 23 were in administrative functions. In addition, we utilize various outsourced services to manage normal business cycles. None of our employees are covered by a collective bargaining agreement and management considers its relations with employees and service partners to be good.

Code of Conduct

Each employee agrees to follow our Code of Conduct, which is on our corporate website, and covers a wide range of business practices and procedures. Recognizing that our Code of Conduct may not address every situation our employees may encounter, other resources exist to assist our employees in their decision-making, including our management team, training and a hotline pursuant to which employees can ask questions or report issues on an anonymous basis.

Employee Safety, Health and Wellness

We are committed to maintaining a safe workplace and promoting the health and wellness of our employees. We have an employee Health & Safety Committee that is comprised of employees and recommends improvements in furtherance of employee health and safety. We also have implemented multiple safety programs and regularly perform safety hazard evaluations within our manufacturing facility. We publish a quarterly Safety Standard newsletter that reiterates our commitment to safety, highlights actions we have taken and intend to take to improve employee safety, and provides practical advice to employees to keep them and their families safe. Throughout the COVID-19 pandemic, our employees have been our first and foremost focus as we implemented a number of measures to provide a safe work environment, including social distancing and remote work schedules.

With respect to health and wellness, we provide our employees a variety of flexible and convenient health and wellness programs designed to support their physical and mental health. These include, among others, medical, dental and vision coverage, health savings and flexible spending accounts, flexible work schedules, family leave and care resources, and an employee assistance program. With respect to COVID-19, we have encouraged our employees to get a COVID-19 vaccine by sharing information on the vaccines and where to obtain one.

Compensation and Benefits

We provide competitive compensation and benefits to attract and retain superior talent and to give our employees the tools to succeed both on and off the job. In addition to salaries, our compensation and benefits, typically include annual bonuses; commission programs; a 401(k) plan with employer matching opportunities; tuition assistance; and company-sponsored short-term and long-term disability, life and accidental death and dismemberment insurance, among others.

Employee Engagement

We provide all employees with the opportunity to anonymously share their opinions and feedback directly with senior management and human resources. Submissions are analyzed to enhance the employee experience, promote retention, drive change, and leverage the overall success of our organization.

Employee Development and Training

We recognize that successful execution of our strategy is dependent on attracting, developing and retaining top talent in all areas of the business. We have a robust learning management system platform that includes several modules for employee development and training. In addition, we have a professional development policy intended to promote professional development opportunities and provide support to employees who want to increase the effectiveness of their performance in their current position. We encourage employees to obtain skills, knowledge and abilities which may improve their opportunities for career advancement within our Company and the purpose of our professional development policy is to provide our employees with the requirements for approval, time off, and reimbursement for employee training and professional development activities.

Diversity, Equity and Inclusion

We strive to create a diverse workplace in which all employees feel respected, valued and empowered to reach their full potential. We define diversity as the range of human differences, including but not limited to race, ethnicity, gender, gender identity, sexual orientation, age, social class, physical ability or attributes, religious or ethical values system, national origin, and political beliefs.

Community Engagement

Throughout the year, we encourage our employees to engage in community outreach programs and we sponsor various community organizations in the Belgrade, Montana area. As a company, we work closely with the Donate Life Community to support our industry and promote the gift of donation. We have been an active sponsor for the Donate Life Rose Parade event since 2012 and sponsor a donor family and select employees to attend that event each year.

Corporate Information

We began operations in 1998 as a spin out of the Center for Biofilm Engineering at Montana State University, or the CBE, and incorporated as “Bacterin, Inc.” in the state of Montana in January 2000. Through a series of transactions and corporate events, we eventually became Bacterin International Holdings, Inc., a Delaware corporation (“Bacterin”). Bacterin’s common stock traded on the NYSE Amex, now known as the NYSE American, under the ticker symbol “BONE.” On July 31, 2015, we acquired all of the outstanding capital stock of X-spine Systems, Inc. (“X-spine”) for approximately \$60 million in cash, repayment of approximately \$13 million of X-spine debt, and approximately 4.24 million shares (0.4 million shares post reverse split) of Xtant common stock. As a result of this transaction, X-spine became a wholly owned subsidiary of Bacterin International Holdings, Inc. and we immediately then changed our corporate name to “Xtant Medical Holdings, Inc.” Soon thereafter, we formed a new wholly owned subsidiary, Xtant Medical, Inc., to facilitate the integration of Bacterin and X-spine. On October 15, 2015, our common stock began trading on the NYSE MKT, now known as the NYSE American, under the ticker symbol “XTNT.”

Controlled Company Status

As a result of debt restructuring transactions completed in 2018 and 2020, OrbiMed Royalty Opportunities II, LP (“Royalty Opportunities”) and ROS Acquisition Offshore LP (“ROS”), which are funds affiliated with OrbiMed Advisors LLC (“OrbiMed”), collectively own approximately 67.2% of our outstanding common stock as of December 31, 2022. Because more than 50% of the combined voting power of all of our outstanding common stock is beneficially owned by OrbiMed, we are a “controlled company” as defined in section 801(a) of the NYSE American Company Guide. As such, we are exempt from certain NYSE American rules requiring our Board of Directors to have a majority of independent members, a compensation committee composed entirely of independent directors and a nominating committee composed entirely of independent directors.

Available Information

We make available, free of charge and through our Internet website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (“SEC”). Reports filed with the SEC also may be viewed at www.sec.gov. We include our website throughout this report for reference only. The information contained on or connected to our website is not incorporated by reference into this report.

Item 1A. Risk Factors

Our business and an investment in our common stock are subject to a variety of risks. The following risk factors describe some of the material factors that could have a material adverse effect upon our business, financial condition, results of operations, and the market price for our common stock. Many of these events are outside of our control. If any of these risks actually occur, our business, financial condition or results of operations may be materially adversely affected. In such case, the market price of our common stock could decline and investors in our common stock could lose all or part of their investment.

Risk Factors Summary

This summary is not complete and should be read in conjunction with the risk factors set forth below.

Risks Related to Our Business

- Biologics products are inherently difficult and time-consuming to manufacture. We have experienced and could continue to experience manufacturing issues, which could negatively impact our business and results of operations.
- Prolonged inflation and supply chain disruptions could result in delayed product launches, lost revenue, higher costs and decreased profit margins.
- COVID-19 has adversely affected our business, operating results and financial condition.
- We may not be able to compete successfully because we are smaller and have fewer financial resources and less ability to invest in the development of new products.
- If we are unable to innovate, develop, introduce and market new products and technologies, our business may be negatively affected.
- Our private label and OEM business involves risks and may be subject to significant fluctuation.
- Our growth and inventory initiatives involve risks.
- Our biologics business is dependent on the availability of human donors and negative publicity could reduce demand for our biologics products and impact the supply of available donor tissue.
- We are highly dependent on the continued availability of our facilities.
- We may be subject to product liability litigation that could be expensive.
- Our quarterly operating results are subject to substantial fluctuations.
- We have completed business combinations in the past, including our recent acquisition of the Coflex and CoFix product lines, which involve risks and may do so in the future.
- We operate in some markets outside the United States that expose us to additional risks.
- Our ability to deduct interest is limited.

Risks Related to Governmental Regulation

- Our business is subject to extensive governmental regulation, including product approvals and clearances and healthcare fraud and abuse laws, false claims laws, and physician payment transparency laws.
- Governmental regulation could restrict the use of our tissue products or our procurement of tissue.
- Outside of the United States, our medical devices must comply with the laws and regulations of the foreign countries in which they are marketed, and compliance may be costly and time-consuming.
- Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.
- Our manufacturing operations are required to comply with the FDA's and other governmental authorities' laws and regulations regarding the manufacture and production of medical devices.

- Even if our products are cleared or approved by regulatory authorities, they could be subject to restrictions or withdrawal from the market.
- The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits.
- If our products cause or contribute to a death or serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations and likely litigation.
- Any future product recall or voluntary market withdrawal of a product due to defects, enhancements and modifications or other reasons could adversely affect our business and operating results.

- If we or our suppliers fail to comply with regulations pertaining to human cells, tissues, and cellular and tissue-based products or are deemed to be biological products requiring approval of a BLA prior to being marketed, these products could be subject to withdrawal from the market or other enforcement action.
- Loss of AATB accreditation would have a material adverse effect on us.
- Federal regulatory reforms may adversely affect our ability to sell our products and our business.
- Product pricing is subject to regulatory control, which could impact our revenue and other operating results.
- Our revenues depend upon prompt and adequate coverage and reimbursement from public and private insurers and national health systems.

Risks Related to Our Reliance on Third Parties

- Substantially all of our revenue is conducted through independent distributors and sales agents who we do not control.
- We depend on third-party suppliers for products, components and raw materials.

Risks Related to Human Capital Management

- Our business is dependent on a sufficient number of qualified workers, and competition for such talent is intense.
- We have limited staffing and are dependent upon key employees.

Risks Related to Our Outstanding Indebtedness, Need for Additional Financing and Financial Condition

- We have incurred significant losses, expect to continue to incur losses and may need additional financing to satisfy our anticipated future liquidity requirements.
- We have indebtedness that we may be unable to refinance or extend the maturity date of and which may substantially limit our ability to conduct and invest in our business.

Risks Related to Intellectual Property

- We could be required to pay damages or prevented from selling our products due to intellectual property lawsuits.
- We may not be able to obtain or protect our proprietary rights relating to our products which may cause us to lose market share to our competitors and be unable to operate our business profitably.

Risks Related to Our Information Technology, Cybersecurity and Data Protection

- We are dependent on various information technology systems, and failures of, interruptions to, or unauthorized tampering with those systems could have a material adverse effect on our business.

Risks Related to Our Controlled Company Status

- We are a “controlled company” within the meaning of the NYSE American rules since OrbiMed funds own a significant percentage of our common stock. As such, they have the right to designate a majority of our Board of Directors, and are able to exert significant control over our Company and management.

Risks Related to Our Common Stock

- Shares of our common stock are equity securities and subordinate to our outstanding indebtedness.
- The market price of our common stock is extremely volatile.
- We may issue additional common stock resulting in dilution, and the sale or availability for sale of our common stock could adversely affect the market price of our common stock.
- Our common stock may be delisted if we do not comply with the NYSE American continued listing requirements.
- Anti-takeover provisions may discourage or prevent a change in control.

- Our Amended and Restated Certificate of Incorporation (“Charter”) authorizes us to issue and designate shares of our preferred stock without stockholder approval and designates the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders.
- We have never paid dividends and do not expect to do so in the foreseeable future.

General Risk Factors

- We are subject to several other general risk factors, including risk regarding worldwide economic instability and social unrest; climate change; changes in accounting standards; public company requirements; securities litigation and environmental, social and governance practices scrutiny.

Risks Related to Our Business

Biologics products are inherently difficult and time-consuming to manufacture. We have experienced and could continue to experience manufacturing issues, which could negatively impact our business and results of operations.

Biologics products are inherently difficult and time-consuming to manufacture. Our products are manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials. Other production constraints, including the number of processors we are able to hire, the number of clean rooms available in our facilities, and our ability to automate certain processes by implementing labor saving technology also affect the speed and extent of our production. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. A shortage of the number of processors or clean rooms or inadequate levels of automation may cause us to be unable to operate at full production, which has in the past and could continue to negatively impact our business and results of operations. For example, as a result of the labor shortage we experienced in 2022, we were unable to operate at full capacity from time to time, which caused us to pass on certain revenue opportunities we otherwise may have been able to pursue. To try to mitigate this issue in the future, we have made certain operational changes and continue to implement processes that are intended to automate certain tasks. No assurance can be provided that these measures will be successful.

Prolonged inflation and supply chain disruptions could result in delayed product launches, lost revenue, higher costs and decreased profit margins.

A majority of our products are manufactured and sold inside of the United States, which increases our exposure to domestic inflation and fuel price increases. Recent inflationary pressures stemming from supply chain disruptions and increased demand have resulted in increased fuel, raw material and other costs which, if they continue for a prolonged period, may adversely affect our results of operations. In order to combat high levels of inflation, the Federal Reserve raised its target range for the federal funds rate seven times in 2022, representing a cumulative 425 basis point increase. As of December 31, 2022, the target range for the federal funds rate was 4.25% to 4.50%. Additionally, the Federal Reserve has indicated that it is likely to continue to raise the rate to a peak level of 4.60% in 2023 in order continue its efforts to curtail high inflation. However, there is no guarantee that these interest rate increases will slow inflation, and we may continue to be adversely impacted by high levels of inflation. Additionally, we have experienced shortages in certain raw materials, suppliers have been unable to meet delivery schedules due to excess demand and labor shortages, and lead times have lengthened throughout our supply chain. Our efforts to mitigate supply chain weaknesses may not be successful or may have unfavorable effects. For example, efforts to purchase raw materials in advance for product manufacturing may result in increased storage costs or excess supply. If our costs rise due to continuing significant inflationary pressures or supply chain disruptions, we may not be able to fully offset such higher costs through price increases. In addition, delays in obtaining materials from our suppliers could delay product launches or result in lost opportunities to sell our products due to their unavailability. Increased costs and decreased product availability due to supply chain issues could adversely impact our revenue and/or gross margin, and could thereby harm our business, financial condition, and results of operations.

Our business, operating results and financial condition have been and may continue to be materially adversely affected by the COVID-19 pandemic.

At the onset of, and at various times during, the COVID-19 pandemic, hospitals and other medical facilities have cancelled or deferred elective procedures, diverted resources to patients suffering from infections and limited access for non-patients, including our direct and indirect sales representatives. Additionally, hospitals and other medical facilities have experienced high levels of staff turnover resulting from layoffs, employee burnout and the reallocation of nurses to COVID-19 care, particularly during surges in COVID-19 cases. Because of these circumstances, surgeons and their patients have deferred, and may continue to defer, procedures in which our products otherwise would be used. These circumstances have negatively impacted, and may continue to negatively impact, the number of elective procedures being conducted and the ability of our employees, independent sales representatives and distributors to effectively market and sell our products, which has had and will likely continue to have a material adverse effect on our revenues. During the first quarter of 2022, spine and other surgery procedure volumes were negatively impacted in many of our key markets, due to cancellations and/or postponements of procedures as a result of hospitalizations of COVID-19 patients, restrictions on elective procedures and staffing shortages in our key markets, which negatively impacted our first quarter 2022 revenues. This reduction in elective procedures and staffing subsided beginning in the second quarter and the during the remainder of 2022, but could reoccur if there is another wave or sustained resurgence of COVID-19 cases and hospitalizations.

COVID-19 also has caused, and may continue to cause, adverse effects on general commercial activity and the global economy and supply chain, disrupting our ability to obtain raw materials, components and products. The pandemic has also adversely affected, and may continue to adversely affect, our distributors, independent sales representatives, customers, contract manufacturers and suppliers and their respective businesses, which, in turn, have adversely affected, and may continue to adversely affect, our business and operations. Although we continue to monitor the impact of COVID-19 on our business, operations and financial results, the full extent to which COVID-19 will continue to impact our business will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 variants, actions taken to contain or treat the impact of COVID-19, the availability, acceptance and effectiveness of vaccines, future resurgences of the virus and its variants, the level of any government restrictions, patient capacity at hospitals and healthcare systems, and the willingness and ability of patients to seek care and treatment due to safety concerns or financial hardship. If our revenues do not recover to pre-COVID-19 levels, we may be required to incur impairment charges to our long-lived assets and goodwill and write-off excess inventory, which would likely adversely affect our future operating results. COVID-19 also heightens the risks in certain of the other risk factors described in this Form 10-K.

Many competitive products exist, and we expect more will be developed. Our operating results have suffered during the past few years due to intense competition and we may not be able to compete successfully because we are smaller and have fewer financial resources and less ability to invest in the development of new products.

The markets for our products are highly competitive and subject to rapid and profound technological change. Our success depends, in part, on our ability to maintain a competitive position in the development of technologies and products for use by our customers. Many of the companies developing or marketing competitive products enjoy several competitive advantages over us, including greater financial and human resources for product development and sales and marketing; greater name recognition; established relationships with surgeons, hospitals and third-party payors; broader product lines and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and established sales and marketing and distribution networks. Our competitors may develop and patent processes or products earlier than us, obtain regulatory clearances or approvals for competing products more rapidly than us, develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive or acquire technologies and technology licenses complementary to our products or advantageous to our business, which could adversely affect our business and operating results. Not all of our sales and other personnel have non-compete agreements. We also compete with other organizations in recruiting and retaining qualified sales and management personnel, which may exacerbate the effects of the labor shortages we are currently experiencing, as described above. If our competitors are more successful than us in these matters, we may be unable to compete successfully against our existing or future competitors. Our industry has been subject to increasing consolidation. Consolidation in our industry not involving our Company could result in existing competitors increasing their market share through business combinations and result in stronger competitors, which could have a material adverse effect on our business, financial condition, and operating results. We may be unable to compete successfully in an increasingly consolidated industry and cannot predict with certainty how industry consolidation will affect our competitors or us.

If we are unable to innovate, develop, introduce and market new products and technologies, we may experience a decrease in market share or revenue if our products become obsolete, and our business and operating results would suffer.

Due to lack of funding, our research and development efforts and ability to develop new products have suffered during the past several years. We may be unable to compete effectively with our competitors unless we can keep up with existing or new products and technologies in the markets in which we compete. If we do not continue to innovate, develop, introduce and market new products and technologies, or if those products and technologies are not accepted, we may not be successful. Moreover, research and development efforts require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or innovation and our current and recent annual operating plans have not provided for any significant investment in new products. Demand for our products also could change in ways we may not anticipate due to evolving customer needs, changes in customer health insurance coverage, changing demographics, slow industry growth rates, declines in our markets, the introduction of new products and technologies, evolving surgical philosophies, and evolving industry standards, among others. Additionally, our competitors' new products and technologies may beat our products to market, may be more effective or less expensive than our products, or may render our products obsolete. It is also important that we carefully manage our introduction of new and enhanced products and technologies. If potential customers delay purchases until new or enhanced products are available, it could negatively impact our revenue. Our new products and technologies also could reduce demand for or render our existing products obsolete and thus adversely affect sales of our existing products and lead to increased expense for excess and obsolete inventory.

Our private label and OEM business, which we expect to account for an increasing percentage of our revenue, involves risks and may be subject to significant fluctuation on a product to product basis from period to period since our customers could decide to use other OEMs.

We expect an increasing portion of our future revenues to be derived from our private label and original equipment manufacturer, or OEM, business. This expectation is based on our plan to focus on expanding this business. We may not be successful, however, in retaining or expanding our private label and OEM business. Our private label and OEM business, although not subject to commissions, involves lower gross margins which, if this business increases as a percentage of our revenue, will put pressure on our future gross margins. In addition, our private label and OEM business involves other additional risks. For example, we generally do not have long-term supply agreements covering this business so our customers could periodically decide to use other OEMs based on cost, quality, delivery time, production capacities, competitive and regulatory considerations or other factors. Thus, revenues from our private label and OEM customers and the products we provide them are subject to significant fluctuation on a product to product basis from period to period. The success of our private label and OEM business is dependent upon the success of our private label and OEM customers in creating demand for and selling the products that we manufacture for them. If our private label and OEM business significantly increases, we may experience difficulties in staffing our manufacturing facility and meeting demand.

Our growth initiatives designed to increase our revenue and scale may not be successful and involve risks.

During 2021 and 2022, we focused primarily on four key growth initiatives: (1) introduce new products; (2) expand our distribution network; (3) penetrate adjacent markets; and (4) leverage our growth platform with technology and strategic acquisitions. We intend to continue to pursue these key growth initiatives in 2023. While the intent of these four key growth initiatives is to increase our future revenues, no assurance can be provided that we will be successful in implementing these growth initiatives or increasing our future revenues. Also our key growth initiatives involve risks, including effects on our product sales mix, which may adversely affect our gross margins and operating results. For example, a decrease in sales of our hardware products typically reduces our gross margins. In addition, margins vary among our biologics products, so the current trend towards our fiber-based products as opposed to our cancellous-based products may also reduce our future gross margins.

Our inventory initiatives designed to increase production of our more popular biologics products may not be successful.

We are currently focused on increasing production of our more popular biologics products by adding more cleanroom space and taking certain other actions. Some of these initiatives are costly to implement and may not be successful. No assurance can be provided that we will be successful in implementing our inventory initiatives or that they will lead to increased revenues.

Our biologics business is highly dependent on the availability of human donors. Any disruptions could cause our customers to seek alternative providers or technologies and harm our business and operating results.

Our mission is, “honoring the gift of donation, by allowing our patients to live as full, and complete a life as possible.” Accordingly, our biologics business is highly dependent on our ability to obtain donor cadavers as the raw material for many of our biologics products. The availability of acceptable donors is relatively limited, and we compete with many other companies for this limited availability. The availability of donors is also impacted by regulatory changes, AATB requirements, general public opinion of the donor process and our reputation for our handling of the donor process. In addition, due to seasonal changes in the mortality rates, some scarce tissues are at times in short supply. A disruption in the supply of this crucial raw material could have significant consequences for our revenue, operating results and continued operations.

Negative publicity concerning methods of tissue recovery and screening of donor tissue in our industry could reduce demand for our biologics products and impact the supply of available donor tissue.

Media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our biologics products. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to the transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of technologies incorporating human tissue. In addition, such negative publicity could cause the families of potential donors to become reluctant to agree to donate tissue to for-profit tissue processors.

We are highly dependent on the continued availability of our facilities and would be harmed if they were unavailable for any prolonged period of time.

Any failure in the physical infrastructure of our facilities or services could lead to significant costs and disruptions that could reduce our revenues and harm our business, reputation and financial results. We are highly reliant on our Belgrade, Montana facilities. Any natural or man-made event that impacts our ability to utilize these facilities could have a significant impact on our operating results, reputation and ability to continue operations. The regulatory process for approval of facilities is time-consuming and our ability to rebuild facilities would take a considerable amount of time and expense and cause a significant disruption in service to our customers. Further, the FDA or some other regulatory agency could identify deficiencies in future inspections of our facilities or our supplies that could disrupt our business and harm our operating results.

We may be party to product liability litigation that could be expensive, and our insurance coverage may not be adequate in a catastrophic situation.

The manufacture and sale of medical devices and biologics expose us to significant risk of product liability claims, which are made against us from time to time. We may incur material liabilities relating to product liability claims, including product liability claims arising out of the use of our products, if the liabilities exceed or are not covered under our insurance program. No assurance can be provided that any amounts that we may be required to pay to resolve such matters in the future will be within our insurance limits.

We also could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues, or heightened regulatory scrutiny that would warrant a recall of some of our products. Product liability lawsuits and claims, safety alerts and product recalls, regardless of their ultimate outcome, could result in decreased demand for our products, injury to our reputation, significant litigation and other costs, substantial monetary awards to or costly settlements with patients, product recalls, loss of revenue, increased regulatory scrutiny, and the inability to commercialize new products or product candidates, and otherwise have a material adverse effect on our business and reputation and on our ability to attract and retain customers.

Our quarterly operating results are subject to substantial fluctuations, and you should not rely on them as an indication of our annual or future results.

Our quarterly revenue and operating results have varied and in the future may vary significantly, and period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indications of our annual results or future performance. Any shortfalls in revenue or earnings from levels expected by industry analysts or investors, as a result of such quarterly fluctuations or otherwise, could have an immediate and significant adverse effect on the market price of our common stock in any given period. Our quarterly operating results may vary significantly due to a combination of factors, many of which are beyond our control. These factors include, among others:

- demand for our products;
- the effect of labor and staffing shortages at hospitals and other medical facilities on the number of elective procedures in which our products are used as well as global and local labor shortages and loss of personnel;
- the effect of inflation, increased interest rates and other recessionary indicators and supply chain disruptions;
- the impact of COVID-19 on the number of elective procedures and our business and operating results;
- the level of competition;
- the number, timing, and significance of new products and product introductions and enhancements by us and our competitors;
- our ability to develop, introduce, and market new and enhanced versions of our products on a timely basis;
- the timing of or failure to obtain regulatory clearances or approvals for our products;
- changes in pricing policies by us and our competitors;
- changes in the treatment practices of our customers;
- changes in independent sales representative or distributor relationships and sales force size and composition;
- the timing of material expense- or income-generating events and the related recognition of their associated financial impact;
- the number and mix of products sold in the quarter and the geographies in which they are sold;
- the number of selling days;
- the availability and cost of components and materials;
- the timing of orders and shipments;
- ability to obtain reimbursement for our products and the timing of patients' use of their calendar year medical insurance deductibles;
- work stoppages or strikes in our industry;
- changes in FDA and foreign governmental regulatory policies, requirements, and enforcement practices;
- changes in accounting standards, policies, estimates, and treatments;
- restructuring, impairment, and other special charges;
- costs associated with pending and any future litigation;

- variations in cost of sales due to the amount and timing of excess and obsolete inventory charges and manufacturing variances;
- income tax fluctuations and changes in tax rules;
- general economic, social and other external factors; and
- increases of interest rates, which can increase the cost of borrowings under our credit agreements and generally affect the level of economic activity.

We have completed acquisitions and business combinations in the past and our current business strategy includes targeted strategic acquisitions in the future. Acquisitions and business combinations are risky and may harm our business, reputation, operating results and financial condition.

We have completed acquisitions and business combinations in the past, including our recent acquisition of Surgalign SPV, Inc. (“Surgalign SPV”), and may complete acquisitions and business combinations in the future, especially since one of our key growth initiatives is to add depth to our product offerings through targeted strategic acquisitions. Our ability to complete acquisitions and business combinations will depend, in part, on the availability of suitable candidates at acceptable prices, terms, and conditions; our ability to compete effectively for acquisition candidates; and the availability of capital and personnel to complete such acquisitions and run the acquired business effectively. Any acquisition or business combination could impair our business, reputation, operating results and financial condition. The benefits of an acquisition or business combination may take more time than expected to develop or integrate into our operations, and we cannot guarantee that previous or future acquisitions or business combinations will, in fact, produce any benefits. Acquisitions and business combinations may involve a number of risks, the occurrence of which could adversely affect our business, reputation, operating results and financial condition, including:

- diversion of management’s attention;
- disruption to our existing operations and plans;
- inability to effectively manage our expanded operations;
- difficulties or delays in integrating and assimilating information and financial systems, operations, manufacturing processes and products of an acquired business or other business venture or in realizing projected efficiencies, growth prospects, cost savings, and synergies;
- inability to successfully integrate or develop a distribution channel for acquired product lines;
- potential loss of key employees, customers, distributors, or sales representatives of the acquired businesses or adverse effects on existing business relationships with suppliers, customers, distributors, and sales representatives;
- adverse impact on overall profitability if our expanded operations do not achieve the financial results projected in our valuation models;
- reallocation of amounts of capital from other operating initiatives and/or an increase in our leverage and debt service requirements to pay acquisition purchase prices or other business venture investment costs, which could in turn restrict our ability to access additional capital when needed or pursue other important elements of our business strategy;
- infringement by acquired businesses or other business ventures of intellectual property rights of others;

- violation of confidentiality, intellectual property and non-compete obligations or agreements by employees of an acquired business or lack of or inadequate formal intellectual property protection mechanisms in place at an acquired business;
- inaccurate assessment of additional post-acquisition investments, undisclosed, contingent or other liabilities or problems, unanticipated costs associated with an acquisition, and an inability to recover or manage such liabilities and costs;
- incorrect estimates made in the accounting for acquisitions and incurrence of non-recurring charges; and
- write-off of significant amounts of goodwill or other assets as a result of deterioration in the performance of an acquired business or product line, adverse market conditions, changes in the competitive landscape, changes in laws or regulations that restrict activities of an acquired business or product line, or as a result of a variety of other circumstances.

In addition, effective internal controls are necessary for us to provide reliable and accurate financial reports and to effectively prevent fraud. The integration of acquired businesses may result in our systems and controls becoming increasingly complex and more difficult to manage. We devote significant resources and time to comply with the internal control over financial reporting requirements of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”). However, we cannot be certain that these measures will ensure that we design, implement, and maintain adequate control over our financial processes and reporting in the future, especially in the context of acquisitions of other businesses, regardless of whether such acquired business was previously privately or publicly held. Any difficulties in the assimilation of acquired businesses into our control system could harm our operating results or cause us to fail to meet our financial reporting obligations. Also, some acquisitions, such as our recent acquisition of Surgalign SPV, may require the consent of the lenders under our credit agreements with MidCap and /or the consent of Royalty Opportunities and ROS under the Investor Rights Agreement. We cannot predict whether such approvals would be forthcoming or the terms on which the lenders or these investors would approve future acquisitions. These risks, among others, could be heightened if we complete a large acquisition or other business combination or multiple transactions within a relatively short period of time.

Although our international business is not substantial, we do operate in some markets outside the United States that are subject to political, economic, and social instability and expose us to additional risks.

Although our revenue from outside the United States comprised only 1% of our total revenue for the year ended December 31, 2022, our international sales operations nevertheless expose us and our representatives, agents, and distributors to the following risks inherent in operating in foreign jurisdictions:

- the imposition of additional U.S. and foreign governmental controls or regulations on orthopedic implants and biologic products;
- withdrawal from or revision to international trade policies or agreements and the imposition or increases in import and export licensing and other compliance requirements, customs duties and tariffs, import and export quotas and other trade restrictions, license obligations, and other non-tariff barriers to trade;
- economic instability, including economic instability caused by COVID-19 and currency risk between the U.S. dollar and foreign currencies, in our markets;
- political instability, including instability related to the current conflict between Russia and Ukraine;
- a shortage of high-quality international salespeople and distributors;
- loss of any key personnel who possess proprietary knowledge or are otherwise important to our success in international markets;

- changes in third-party reimbursement policy that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate our reducing selling prices for our products;
- transportation delays and interruptions, including due to recent supply chain and shipping disruptions; and
- exposure to different legal and political standards.

Our ability to deduct interest is limited.

Our ability to deduct interest on indebtedness properly allocable to our trade or business (which excludes investment interest) is limited to an amount equal to the sum of (i) our business interest income during the taxable year and (ii) 30% of our adjusted taxable income for such taxable year. For taxable years beginning after 2021, our adjusted taxable income for purposes of computing the 30% limitation will be reduced by depreciation, amortization and depletion deductions thereby causing a more restrictive limitation than that which existed for taxable years beginning prior to 2022. Disallowed interest deductions may be carried forward indefinitely and treated as business interest paid or accrued in the succeeding taxable year.

A shift in performing more procedures in ambulatory surgical centers from hospitals would likely put pressure on the prices of our products and margins.

We anticipate that more outpatient eligible procedures may be performed in ambulatory surgery centers and that this trend will continue as a cost control measure within the healthcare system. Because ambulatory surgery center facility fee reimbursement is typically less than facility fee reimbursement for hospitals and due to surgeons' potential ownership interests in ambulatory surgery centers, we typically experience more pressure on the pricing of our products by ambulatory surgery centers than by hospitals, and the average price for which we sell our products to ambulatory surgery centers is less than the average prices we charge to hospitals. In addition, some surgeons may choose to use fewer implants due to their interest in the profitability of the ambulatory surgery center. An accelerated shift of procedures using our products to ambulatory surgery centers could adversely impact the average selling prices of our products and our revenues could suffer as a result.

Risks Related to Governmental Regulation

Our business is subject to extensive regulation, including requirements for regulatory clearances or approvals prior to commercial distribution of our products. If we fail to maintain regulatory clearances and approvals, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, packaging, content and language of instructions for use, and storage;
- clinical trials;
- product safety;
- premarket clearance and approval;
- marketing, sales and distribution (including making product claims);

- advertising and promotion;
- product modifications;
- recordkeeping procedures;
- reports of corrections, removals, enhancements, recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- complying with the federal law and regulations requiring Unique Device Identifiers (“UDI”) on devices and their labeling and also requiring the submission of certain information about each device to FDA’s Global Unique Device Identification Database (“GUDID”); and
- product import and export.

Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive either premarket clearance under Section 510(k) of the FDCA, a de novo classification or a PMA, from the FDA, unless an exemption applies. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

Most of our currently commercialized products have received premarket clearances under Section 510(k) of the FDCA. In the future, the FDA may determine that our products will require the more costly, lengthy and uncertain de novo or PMA processes. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could adversely affect our revenue. Although we do not currently market any devices under PMA and have not gone through the de novo classification process for marketing authorization, we cannot assure you that the FDA will not demand that we obtain a PMA or de novo classification prior to marketing or that we will be able to obtain 510(k) clearances with respect to future products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that our products meet the standard of “substantial equivalence” for a 510(k) or meet the standard for the FDA to grant a petition for de novo classification;
- we may not be able to demonstrate to the FDA’s satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies (bench and/or animal) and clinical trials may be insufficient to support clearance or approval in general or for specific, commercially desirable indications, where required;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA clearance or approval policies or the adoption of new regulations may require additional data.

In addition, even if we do obtain clearance or approval, the FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Any delay in, or failure to receive or maintain, clearances or approvals for our products under development could prevent us from generating revenue from these products or achieving profitability.

We are subject, directly and indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and physician payment transparency laws. Failure to comply with these laws may subject us to substantial penalties.

We are subject to federal and state healthcare laws and regulations pertaining to fraud and abuse, and physician payment transparency, including false claims laws, anti-kickback laws and physician self-referral laws. Many states require compliance with different types of pricing transparency requirements such as having a code of conduct, as well as reporting remuneration paid to health care professionals or entities in a position to influence prescribing behavior. Violations of these federal and state laws can result in criminal and/or civil punishment, including fines, imprisonment and, in the United States, exclusion from participation in government healthcare programs. Greater scrutiny of marketing practices in our industry has resulted in numerous government investigations, prosecutions and settlements by various government authorities and this industry-wide enforcement activity is expected to continue. If a governmental authority were to determine that we do not comply with these laws and regulations, the Company and our directors, officers and employees could be subject to criminal and civil penalties, including exclusion from participation in U.S. federal healthcare reimbursement programs.

Many of these healthcare laws inevitably influence company standards of conduct. Other laws tie into these standards as well, such as compliance with the advertising and promotion regulations under the FDCA, the U.S. Federal Anti-Kickback Statute, the Federal False Claims Act, the Federal Physician Payments Sunshine Act and other laws. We use many distributors and independent sales representatives in certain territories and thus rely upon their compliance with applicable laws and regulations, such as with the advertising and promotion regulations or similar laws under countries located outside the United States and other applicable federal, state or international laws. These laws include:

- the U.S. Federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce 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 the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the Federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, 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 U.S. Federal False Claims Act; this may constrain our marketing practices and those of our independent sales agencies, educational programs, pricing, bundling and rebate policies, grants for physician-initiated trials and continuing medical education, and other remunerative relationships with healthcare providers;
- federal false claims laws (such as the U.S. Federal False Claims Act) which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims seeking payment from Medicare, Medicaid or other federal-funded third-party payors that are false or fraudulent; this may impact the reimbursement advice we give to our customers as it cannot be inaccurate and must relate to on-label uses of our products;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;
- the Federal Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. We are also required to collect information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives for reporting to CMS;

- analogous state and foreign law equivalents of each of the above federal laws, such as state anti-kickback prohibitions and false claims prohibitions which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other and federal law in significant ways and may not have the same effect, thus complicating compliance efforts; and
- the Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information.

Certain of these laws have exceptions and "safe harbors" which if met may protect certain arrangements from liability. For example, certain financial payments that might otherwise implicate the Federal Anti-Kickback Statute will be permitted under the state if they are structured to comply with one of various statutory exceptions or regulatory safe harbors established by the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services. These safe harbors include, for example, the "Discount" safe harbor which allows manufacturers of goods covered by federal payor programs to provide discounts to their customers in the form of rebates, volume discounts and the like as long as those discounts meet the express requirements of the safe harbor. Other safe harbors under the Anti-Kickback Statute may also apply to consulting, teaching and other personal service arrangements we may have with physicians and marketing personnel. These safe harbors are technical in nature and failure to meet any element of a safe harbor will cause an arrangement to lose safe harbor protection. In addition, there may not be safe harbors or exceptions for every potential financial arrangement we may enter into and, and even if there are, no assurances can be given that any of our arrangements or relationships will meet an otherwise applicable safe harbor.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with customers, marketing personnel, physicians and other healthcare providers, some of whom have or may have ownership interests in the Company and recommend and/or use our products, could be subject to challenge under one or more of such laws. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, and distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In addition, state and federal healthcare regulations are constantly evolving. Existing laws and regulations are subject to new and sometimes more restrictive interpretations on a regular basis so that arrangements we believe to be legally compliant could be deemed to be non-compliant under new interpretations. Similarly, new federal and state health care laws and regulations are being adopted on a regular basis. While we endeavor to identify and comply with these new laws and regulations, it is possible that we may be unaware of new legal requirements or interpretations which could result in our violation of these laws and/or regulations.

There is also an increasing trend toward more criminal prosecutions and compliance enforcement activities for noncompliance with the HIPAA and state data privacy laws as well as for data breaches involving protected health information ("PHI"). In the ordinary course of our business, we may receive PHI. If we are unable to comply with HIPAA or experience a data breach involving PHI, we could be subject to criminal and civil sanctions and incur substantial investigation, defense and remediation costs.

If our operations are found to violate any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and materially adversely affect our business, results of operations and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

U.S. governmental regulation could restrict the use of our tissue products or our procurement of tissue.

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the National Organ Transplant Act (“NOTA”), a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for “valuable consideration.” NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas in the United States, with the exception of removal and implantation, and receive payments for all such services. We make payments to certain of our clients and tissue banks for their services related to recovering allograft bone tissue on our behalf. If NOTA is interpreted or enforced in a manner which prevents us from receiving payment for services we render, or which prevents us from paying tissue banks or certain of our clients for the services they render for us, our business could be materially and adversely affected.

We are engaged through our marketing employees, independent sales agents and sales representatives in ongoing efforts designed to educate the medical community as to the benefits of our products, and we intend to continue our educational activities. Although we believe that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of our products, payments in connection with such education efforts are not exempt from NOTA’s restrictions and our inability to make such payments in connection with our education efforts may prevent us from paying our sales representatives for their education efforts and could adversely affect our business and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft bone tissue-based material which our processing technologies may generate. Assuming that NOTA applies to our processing of allograft bone tissue, we believe that we comply with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be adopted in the future which would call into question one or more aspects of our method of operations.

Outside of the United States, our medical devices must comply with the laws and regulations of the foreign countries in which they are marketed, and compliance may be costly and time-consuming. Failure to obtain and maintain regulatory approvals in jurisdictions outside the United States will prevent us from marketing our products in such jurisdictions.

We currently market, and intend to continue to market, our products outside the United States, with the exception of the EU. To market and sell our product in countries outside the United States, we must seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of those countries. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from country to country. We may not obtain regulatory approvals or certifications outside the United States on a timely basis, if at all. Clearance or approval by the FDA does not ensure approval or certification by regulatory authorities in other countries, and approval or certification by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Obtaining and maintaining foreign regulatory approvals, certifications or registrations are expensive, and we cannot be certain that we will receive or maintain regulatory approvals, certifications or registrations in any foreign country in which we currently or plan to market our products. For example, during 2020, we ceased selling products in the EU since the cost to maintain our regulatory approvals in the EU exceeded the benefit of doing business there. In addition, the regulatory approval process outside the United States may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant changes to a device's design, materials, chemical composition, energy source, or manufacturing process, or that would constitute a major change in its intended use, may require a new 510(k) clearance, a de novo classification, or possibly a PMA. Modifications to our products that were implemented without obtaining clearance or approval and for which FDA subsequently concludes that clearance or approval was required, may require us to recall or cease marketing the modified devices until clearance or approval is obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. To do that, a manufacturer must determine if a change/modification to labeling of the device is a "major" change to the intended use statement (previously cleared by the FDA) or if a physical change/modification to the device itself "could significantly affect safety or effectiveness." If the labeling change is major and/or the physical change significantly affects safety and effectiveness, the manufacturer must file for an additional 510(k) clearance, de novo classification, or PMA for those changes before the modified device can be lawfully marketed. If the Company concludes in its own self-determination that the changes do not meet either of the thresholds of "major" or "significantly affects," it may simply document those changes by way of an internal letter-to-file as part of the manufacturer's quality system recording keeping. However, the FDA can review a manufacturer's decision and may disagree. The FDA will normally review a decision made by a manufacturer in a letter-to-file during a routine plant inspection, which FDA targets to conduct every two years for high-risk (Class III) device manufacturers and certain low and moderate risk (Class I and II) device manufacturers. In such a review the FDA may determine that a new clearance or approval was required before the device was put into commercial distribution.

We have made modifications to our products in the past that we concluded did not require a new clearance or approval, and we may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. No assurance can be given that the FDA would agree with any of our decisions not to seek 510(k) clearance, de novo classification, or PMA approval. The issue of whether a product modification requires clearance or approval, as opposed to a "letter-to-file" documenting the change, is not always clear and companies rely on FDA guidance to assist in making such decisions.

If the FDA requires us to cease marketing and recall a modified device until we obtain a new 510(k) clearance, de novo classification, or PMA, our business, financial condition, operating results and future growth prospects could be materially and adversely affected. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Our manufacturing operations are required to comply with the FDA's and other governmental authorities' laws and regulations regarding the manufacture and production of medical devices, which is costly and could subject us to enforcement action.

We and certain of our third-party manufacturers and suppliers are required to comply with the FDA's current Good Manufacturing Practices ("cGMP") requirements and Quality System Regulations ("QSR"), which cover, among other things, the methods of documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We and certain of our suppliers also are subject to the regulations of foreign jurisdictions regarding the manufacturing process for our products marketed outside of the United States. The FDA enforces the QSR through periodic announced (routine) and unannounced (for cause or directed) inspections of manufacturing facilities. The failure by us or one of our third-party manufacturers or suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, disgorgement of profits, criminal and civil penalties;

- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance, de novo classification, or PMA approval of new products or modified products;
- withdrawing 510(k) clearances, de novo classifications, or PMAs that have already been granted;
- refusal to grant export certificates for our products; or
- criminal prosecution.

Any of these actions could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We also may be required to bear other costs or take other actions that may have a negative impact on our future revenue and other operating results. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

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

Any product that we market will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. Such oversight will cover, among other things, the product's design and manufacturing processes, our quality system and compliance with reporting requirements, our compliance with post-approval clinical data requirements, and our promotional activities related to our products.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in, among other things, changes to labeling, restrictions on such products or manufacturing processes, product corrections, removal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, withdrawal of regulatory clearance or approvals, delays in or refusals of new 510(k)s, de novo requests or PMA applications, untitled letters, warning letters, refusal to grant export certificates for our products, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in improper promotion of our products.

Our products currently marketed in the United States have been cleared through the FDA's 510(k) process for use under specific circumstances. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA. We believe that the specific surgical procedures for which our products are marketed fall within the general intended use of the surgical applications that have been cleared by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific indications/procedures until we obtain FDA clearance or approval for them. Use of a device outside of its cleared or approved indication is known as "off-label" use. We cannot prevent a surgeon from using our products for off-label use, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional activities, reimbursement advice or training of sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training or promotional or reimbursement materials or subject us to regulatory or enforcement actions, including, among other things, the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, a civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the Federal False Claims Act for which it might impose a civil fine and even pursue criminal action. In those possible events, our reputation could be damaged, and adoption of the products would be impaired. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

There may be increased risk of injury and product liability if surgeons attempt to use our products off-label, misuse our products or do not follow recommended user techniques and guidelines. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us. Furthermore, the use of our products for indications other than those indications for which our products have been cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients. Any of these events could harm our business and operating results.

If our products cause or contribute to a death or serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or one of our similar devices were to recur. Under the FDA's reporting regulations applicable to HCT/Ps, we are required to report all adverse reactions involving a communicable disease if it is fatal, life threatening, results in permanent impairment of a body function or permanent damage to body structure, or necessitates medical or surgical intervention, including hospitalization. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as mandatory recalls, destruction, cessation of manufacturing, inspection or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. We are currently subject to certain product liability litigation, which could harm our business, financial condition or results of operations, especially if this litigation requires payments in amounts that exceed our product liability insurance coverage.

Any future product recall or voluntary market withdrawal of a product due to defects, enhancements and modifications or other reasons would significantly increase our costs.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found or for other reasons. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our financial condition and results of operations. The FDA requires that certain recalls undertaken to reduce a risk to health be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If we or our suppliers fail to comply with regulations pertaining to human cells, tissues, and cellular and tissue-based products, these products could be subject to withdrawal from the market or other enforcement action.

Certain of our products are regulated as HCT/Ps. Section 361 of the PHS Act authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as “361” HCT/Ps are subject to requirements relating to registering facilities and listing products with the FDA; screening and testing for tissue donor eligibility; and current Good Tissue Practice (“cGTPs”), when processing, storing, labeling, and distributing HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting, among other applicable requirements and laws. The FDA regulations also have additional requirements that address sub-contracted tissue services, tracking, and donor records review. If a tissue-based product is considered human tissue, the FDA requirements focus on preventing the introduction, transmission and spread of communicable diseases. A product regulated solely as a 361 HCT/P is not required to undergo 510(k) premarket clearance, de novo classification or PMA.

The FDA may inspect facilities engaged in manufacturing 361 HCT/Ps and may issue untitled letters, warning letters, or otherwise authorize orders of retention, recall, destruction and cessation of manufacturing if the FDA has reasonable grounds to believe that an HCT/P or the facilities where it is manufactured are in violation of applicable regulations. There also are requirements relating to the import of HCT/Ps that allow the FDA to make a decision as to the HCT/Ps’ admissibility into the United States.

An HCT/P is eligible for regulation solely as a 361 HCT/P if it is: (i) minimally manipulated; (ii) intended for homologous use as reflected by labeling, advertising or other indications of the manufacturer’s objective intent; (iii) the manufacturer does not involve the combination of the HCT/P with another article, except for water, crystalloids or a sterilizing, preserving, or storage agent (not raising new clinical safety concerns for the HCT/P); and (iv) it does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function or, if it has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, it is intended for autologous use or allogeneic use in a first or second degree relative or for reproductive use. If any of these requirements are not met, then the HCT/P is also subject to applicable biologic, device, or drug regulation under the FDCA or the PHS Act. These biologic, device or drug HCT/Ps must comply with the requirements exclusively applicable to 361 HCT/Ps and, in addition, with requirements applicable to biologics under the PHS Act, or devices or drugs under the FDCA, including licensure, clearance or approval, as the case may be.

Over the course of several years, the FDA issued regulations that address manufacturer activities associated with HCT/Ps. The first requires that companies that manufacture HCT/Ps register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for regulation solely under Section 361 of the PHS Act and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FDCA or the biological product licensing provisions of the PHS Act. The second set of regulations provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the “Donor Eligibility” rule. The third rule governs the processing and distribution of the tissues and is often referred to as the cGTP rule. The cGTP rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission.

At the time they came into effect approximately 15 years ago, these regulations increased regulatory scrutiny within the industry in which we operate and have led to increased enforcement action which affects the conduct of our business. In addition, these regulations can increase the cost of tissue recovery activities. The FDA periodically inspects tissue processors to determine compliance with these requirements. Allegations of violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of 21 CFR Part 1271 that we are required to comply with, although there can be no assurance that we will be deemed by FDA to be in compliance. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and our compliance with those aspects of the cGTP regulations that regulate those functions are dependent upon the actions of these independent entities. If our suppliers fail to comply with applicable requirements, our products and our business could be negatively affected. If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of regulatory actions, or enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

In addition, the FDA could disagree with our conclusion that one or more of our HCT/Ps meet the criteria for marketing solely under Section 361 of the PHS Act, and therefore that one or more of the HCT/Ps require licensure, approval or clearance of a marketing application. The FDA could conclude that the tissue is more than minimally manipulated, that the product is intended for a non-homologous use, that the product is combined with another article, or that the product has a systemic effect or is dependent on the metabolic activity of living cells for its primary function. The FDA could also determine that a modification to an HCT/P makes it ineligible for regulation solely as a 361 HCT/P. If the FDA were to draw these conclusions, it would likely require clinical studies conducted pursuant to an investigational new drug application ("IND") and the submission and licensure, approval or clearance of a marketing application in order for us to continue to market the product. Such an action by the FDA could cause negative publicity, decreased or discontinued product sales, and significant expense in obtaining required marketing licensure, approval or clearance.

Other regulatory entities with authority over our products and operations include state agencies enforcing statutes and regulations covering tissue banking. Regulations issued by Florida, New York, California and Maryland are particularly relevant to our business. Most states do not currently have tissue banking regulations. It is possible that others may make allegations against us or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations. Allegations like these could cause regulators or other authorities to take investigative or other action or could cause negative publicity for our business and the industry in which we operate.

Loss of AATB accreditation would have a material adverse effect on us.

We are accredited with the American Association of Tissue Banks, a private non-profit organization that accredits tissue banks and sets industry standards. Although AATB accreditation is voluntary and not required by law, as a practical matter, many of our customers would not purchase our products if we failed to maintain our AATB accreditation. Although we make every effort to maintain our AATB accreditation, the accreditation process is somewhat subjective and lacks regulatory oversight. There can be no assurance that we will continue to remain accredited with the AATB and any loss of our AATB accreditation would adversely affect our business and operating results.

Federal regulatory reforms may adversely affect our ability to sell our products and our business.

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

Our revenues depend upon prompt and adequate coverage and reimbursement from public and private insurers and national health systems.

The ability of healthcare providers to purchase our products depends in part on the extent to which reimbursement for the costs of such materials and related treatments is and will continue to be available from governmental health administration authorities, private health coverage insurers and other organizations. In the United States, healthcare providers who purchase our products generally rely on these third-party payors to pay for all or a portion of the cost of our products as a component of a single bundled payment amount for the procedures in which the products are used. Because there is often no separate third-party payor reimbursement to the provider for our products, the additional cost associated with purchasing our products can impact the provider's profit margin for delivering the treatment that includes are product as a component. If third-party payor reimbursement to providers for procedures involving our products is eliminated or reduced, some of our target customers may be unwilling to purchase our products and may choose to instead purchase less expensive alternatives from our competitors. In addition, third-party payors for hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, typically revise their coverage and payment policies, methodologies and amounts on an annual basis, which can result in noncoverage, stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of or reduction in reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on our products. Healthcare reform legislation at the federal and state levels could result in changes in coverage of and reimbursement for our products. Finally, our revenues also depend upon timely reimbursement data input from our independent agents. All of these factors could adversely affect our business.

Risks Related to our Reliance on Third Parties

Substantially all of our revenue is conducted through independent sales agents and distributors who we do not control.

Substantially all of our revenue is conducted through independent sales agents and distributors. Because the independent sales agent or distributor often controls the customer relationships within its territory (and, in certain countries outside the United States, the regulatory relationship), there is a risk that if our relationship with the independent sales agent or distributor ends, our relationship with the customer will be lost (and, in certain countries outside the United States, that we could experience delays in amending or transferring our product registrations). Also, because we do not control the independent sales agent or field sales agents of a distributor, there is a risk we will be unable to ensure that our sales processes, compliance, and other priorities will be consistently communicated and executed by the sales agent or distributor. If we fail to maintain relationships with our key independent sales agents and distributors or fail to ensure that our independent sales agent and distributors adhere to our sales processes, compliance, and other priorities, this could have an adverse effect on our operations. Changes to or turnover within our independent sales agent or distributor organization or transitions to direct selling models also could adversely affect our business if these transitions are not managed effectively. Further, independent sales agents and distributors of companies we have acquired may decide not to renew or may decide to seek to terminate, change and/or renegotiate their relationships with us. A loss of a significant number of our sales agent or distributors could have a material adverse effect on our business and results of operations.

One of our independent sales agents was associated with approximately 17% and 19% of our revenues during 2022 and 2021, respectively. In any one reporting period, this independent sales agent may contribute an even larger percentage of our revenues. We do not have a long-term agreement with this independent sales agent that requires this agent to continue selling our products on our behalf. While we anticipate that we would retain most of the sales associated with this independent sales agent in the event that we lose this independent sales agent, the loss of this independent sales agent and the agent's strong relationships with customers could adversely affect our revenues and other operating results.

In addition, our success is partially dependent upon our ability to retain and motivate our independent sales agents and distributors, and their representatives to sell our products in certain territories. They may not be successful in implementing our marketing plans. Some of our independent sales agents and distributors do not sell our products exclusively and may offer similar products from other companies. Our independent sales agents and distributors may terminate their contracts with us, may devote insufficient sales efforts to our products, or may focus their sales efforts on other products that produce greater commissions or revenues for them, which could have an adverse effect on our operations and operating results.

We depend on a limited number of third-party suppliers for products, components and raw materials and losing any of these suppliers, or their inability to provide us with an adequate supply of materials that meet our quality and other requirements or our failure to order a sufficient supply of products, components and raw materials, could harm our business and operating results.

Outside suppliers, some of whom are sole-source suppliers, provide us with products and raw materials and components used in manufacturing our orthobiologics and spinal implant products. We strive to maintain sufficient inventory of products, raw materials and components so that our production will not be significantly disrupted if a particular product, raw material or component is not available to us for a period of time, including as a result of a supplier's loss of its ISO or other certification, long required lead times, or other reasons, such as the supply chain and shipping disruptions experienced throughout 2021 and 2022. Despite our efforts, we sometimes experience an insufficient inventory of products, raw materials and/or components. If we fail to plan our procurement accordingly or are unable to obtain sufficient quantities of raw materials and components used in manufacturing our orthobiologics and spinal implant products that meet our quality and other requirements on a timely basis for any reason, we may not produce sufficient quantities of our products to meet market demand until a new or alternative supply source is identified and qualified and, as a result, we could lose customers, our reputation could be harmed, and our business could suffer. Furthermore, an uncorrected defect or supplier's variation in a component or raw material that is incompatible with our manufacturing, unknown to us, could harm our ability to manufacture products.

Although we believe there are alternative supply sources, replacing our suppliers may be impractical or difficult in many instances. For example, we could have difficulty obtaining similar products from other suppliers that are acceptable to the FDA or other foreign regulatory authorities. In addition, if we are required to transition to new suppliers for certain components or raw materials of our products, the use of components or materials furnished by these alternative suppliers could require us to alter our operations, and if we are required to change the manufacturer of a critical component of our products, we will have to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those systems.

Risks Related to Human Capital Management

Our business is dependent upon a sufficient number of qualified workers and competition for such talent is intense, especially around Belgrade, Montana, where the population is small and the labor market is tight. If we cannot attract and retain qualified personnel or if we must increase substantially our labor costs to attract and retain qualified personnel, the growth and success of our business, as well as our operating results and financial condition, may be adversely affected.

The population around Belgrade, Montana, where our headquarters and production facilities are located, is small, and as a result, there is a limited number of qualified personnel available in all functional areas, which has made it difficult for us to attract and retain the qualified personnel necessary for the development, operation and growth of our business. We have been further impacted by the recent labor shortage. Additionally, persistent inflation, which was especially high in Belgrade, Montana and surrounding areas during 2021 and 2022, has caused some members of the labor force to leave these areas in search of more affordable living arrangements, which has worsened our local labor shortage. Our ability to maintain our productivity at competitive levels and increase production in the future may be limited by our ability to employ, train and retain personnel necessary to meet our requirements. Companies in our industry, including us, are dependent upon an available labor pool of qualified employees. We compete for qualified personnel with other companies, academic institutions, governmental entities, and other organizations. A shortage in the labor pool of workers, which we believe currently exists in Belgrade, Montana, and which has worsened in the past year, has made it more difficult for us to attract and retain qualified personnel. We cannot be certain that we will be able to maintain an adequate qualified labor force necessary to operate efficiently and to support our growth strategy and operations. During 2022, these labor shortages contributed to production shortages and, from time to time, an inability for us to operate at full capacity. The tight labor market in the Belgrade, Montana, area also has required us to enhance our wages and benefit packages to attract a sufficient number of workers, and it is possible that these increased labor costs may not be effective in recruiting and retaining a sufficient number of qualified personnel. There can be no assurance that we will be successful in retaining our current personnel or in hiring or retaining a sufficient number of qualified personnel in the future. If we cannot attract and retain qualified personnel or if we must increase substantially our labor costs to attract and retain qualified personnel, the growth and success of our business, as well as our operating results and financial condition, will be adversely affected.

We have limited staffing and are dependent upon key employees.

Our success is dependent upon the efforts of a relatively small management team and staff. We have experienced a high level of employee turnover in past years, including members of our management team. We have employment arrangements in place with our executive and other officers, but none of these executive and other officers are bound legally to remain employed with Xtant for any specific term. We do not have key person life insurance policies covering our executive and other officers or any of our other employees. If key individuals were to leave Xtant, our business could be affected adversely if suitable replacement personnel are not recruited quickly.

Risks Related to Our Outstanding Indebtedness, Need for Additional Financing and Financial Condition

We have incurred significant losses, expect to continue to incur losses and may not achieve or sustain profitability.

We have a history of incurring net losses, and at December 31, 2022, we had an accumulated deficit of \$243.7 million. During the year ended December 31, 2022, we incurred a net loss of \$8.6 million. Our ability to achieve profitability will be influenced by many factors, including, among others, the level and timing of future revenues and expenditures; development, commercialization, market acceptance and availability and supply of our products; competing technologies and market developments; our ability to develop and introduce new products; regulatory requirements and delays; the strength of our relationships with our independent sales agents and distributors; and our ability to attract and retain key personnel. As a result, we may continue to incur operating losses for the foreseeable future. These losses will continue to have an adverse impact on our stockholders' equity, and we may never achieve or sustain profitability.

We may need additional financing to satisfy our anticipated future liquidity requirements, which financing may not be available on favorable terms, or at all, at the time it is needed and which could reduce our operational and strategic flexibility.

Although it is difficult for us to predict our future liquidity requirements, we believe that our cash and cash equivalents and restricted cash balance of approximately \$20.5 million as of December 31, 2022, together with existing credit availability under our Credit, Security and Guarantee Agreement (Term Loan), as amended (the "Term Credit Agreement"), and Credit, Security and Guaranty Agreement (Revolving Loan), as amended (the "Revolving Credit Agreement" and, together with the Term Credit Agreement, the "Credit Agreements"), with MidCap Financial Trust ("MidCap"), in its capacity as agent, will be sufficient to meet our anticipated cash requirements through at least the end of March 2024. Although we have availability under our Term Credit Agreement, our ability to obtain additional term loans under this agreement is in the sole and absolute discretion of MidCap and the lenders. Additionally, although we have availability under our Revolving Credit Agreement, the availability of such funds is determined based on a borrowing base equal to percentages of certain accounts receivable and inventory. These credit facilities have a maturity date of May 1, 2026, and all of our indebtedness thereunder matures on such date. We may require or we may seek additional funds to fund our future operations and business strategy prior to March 2024. Accordingly, there is no assurance that we will not need or seek additional funding at any time. We may elect to raise additional funds even before we need them if market conditions for raising additional capital are favorable. We may seek to raise additional funds through various sources, such as equity and debt financings, additional debt restructurings or refinancings, or through strategic collaborations, license agreements or acquisition transactions. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This is particularly true if economic and market conditions deteriorate. Any failure by us to raise additional funds on terms favorable to us, or at all, could result in our inability to pay our expenses as they come due, limit our ability to expand our business operations, and harm our overall business prospects. If adequate funds are not otherwise available, we could be required to curtail operations significantly, including reducing our sales and marketing expenses, which could negatively impact product sales, delaying new product initiatives, and we could even be required to cease operations, liquidate our assets and possibly seek bankruptcy protection.

To the extent we raise additional financing through the sale of equity or convertible debt securities or the restructuring or refinancing of our outstanding debt, the interests of our current stockholders may be diluted, and the terms may include discounted equity purchase prices, warrant coverage, or liquidation or other preferences that adversely affect the rights of our current stockholders. If we issue common stock, we may do so at purchase prices that represent a discount to our trading price and/or we may issue warrants to purchasers, which could dilute our current stockholders. If we issue preferred stock, it could affect the rights of our stockholders or reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. Additional 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. Prior to raising additional equity or debt financing, we must obtain the consent of MidCap and ROS and Royalty Opportunities, and no assurance can be provided that MidCap, ROS or Royalty Opportunities would provide such consent, which could limit our ability to raise additional financing.

We have indebtedness which matures on May 1, 2026. We may not be able to extend the maturity date of or replace our Credit Agreements or generate enough cash flow from our operations to service our indebtedness, and we may incur additional indebtedness in the future, which could adversely affect our business, financial condition, and operating results.

As of December 31, 2022, we had \$15.4 million of principal outstanding under our Credit Agreements, which indebtedness matures on May 1, 2026. Although we believe that we will be able to refinance or pay off our outstanding indebtedness or extend the maturity date of that facility at the appropriate time, no assurance can be provided that we will do so on terms that are favorable to us or at all. Our ability to make payments on, and to refinance, our indebtedness, and our ability to fund planned capital expenditures, contractual cash obligations, known and unknown liabilities, research and development efforts, working capital, any future acquisitions and business combinations, and other general corporate purposes depends on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory, and other factors, some of which are beyond our control. If we do not generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to pay our indebtedness or to fund our liquidity needs, we may be forced to refinance all or a portion of our indebtedness on or before the maturity dates thereof, sell assets, reduce or delay capital expenditures, seek to raise additional capital, or take other similar actions. We may not be able to execute any of these actions on commercially reasonable terms or at all. Our ability to refinance our indebtedness will depend on our financial condition at the time, the restrictions in the instruments governing our indebtedness, the consent of our lender, and other factors, including market conditions. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would likely have an adverse effect, which could be material, on our business, financial condition, and operating results.

In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry, and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- restrict our ability to make strategic acquisitions, business combinations or dispositions or to exploit business opportunities;
- place us at a competitive disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts or raise financing for working capital, capital expenditures, contractual obligations, research and development efforts, acquisitions or business combinations, debt service requirements, execution of our business strategy, or other purposes.

Any of these factors could materially and adversely affect our business, financial condition, and operating results. In addition, we may incur additional indebtedness, and if we do, the risks related to our business and our ability to service our indebtedness would increase.

A failure to comply with the covenants and other provisions of our Credit Agreements may cause suspension or termination of the Credit Agreements and/or require the immediate repayment of our outstanding indebtedness. If we are at any time unable to generate sufficient cash flows from operations to service our indebtedness when payment is due, we may be required to attempt to renegotiate the terms of the Credit Agreements, seek to refinance all or a portion of the indebtedness, or obtain additional financing. There can be no assurance that we will be able to successfully renegotiate such terms, that any such refinancing would be possible, or that any additional financing could be obtained on terms that are favorable or acceptable to us.

The terms of our Credit Agreements substantially limit our ability to conduct and invest in our business, take advantage of business opportunities, and respond to changing business, market, and economic conditions.

Our Credit Agreements include a number of significant financial and operating restrictions. For example, the Credit Agreements require us to maintain net product revenue at or above minimum levels and to maintain a minimum liquidity threshold or a minimum adjusted EBITDA level, in each case at levels specified in the Credit Agreements. The Credit Agreements also contain provisions that restrict our ability, subject to specified exceptions, to, among other things:

- create, incur, assume, guarantee or otherwise become or remain directly or indirectly liable with respect to any debt, except for permitted debt;
- create, assume, incur or suffer to exist any contingent obligations, except for permitted contingent obligations;
- purchase, redeem, defease or prepay any principal of, premium, if any, interest or other amount payable in respect of any debt prior to its scheduled maturity;
- create, assume or suffer to exist any lien on our assets;
- declare, order, pay, make or set apart any sum for any distribution, except for permitted distributions;
- enter into or assume any agreement prohibiting the creation or assumption of any lien upon our properties or assets or create or otherwise cause or suffer to exist or become effective certain consensual encumbrances or restrictions of any kind;
- declare, pay, make or set aside any amount for payment in respect of subordinated debt;
- engage in mergers or consolidations;
- acquire, make, own, hold or otherwise consummate any investment, other than permitted investments;
- enter into certain transactions with affiliates;
- amend or otherwise modify any organizational documents; and
- make certain amendments or modifications to certain material contracts.

We may be unable to comply with these covenants, which could result in a default under the Credit Agreements. In addition, these provisions may limit our ability to conduct and invest in our business, take advantage of business opportunities, and respond to changing business, market, and economic conditions. In addition, they may place us at a competitive disadvantage relative to other companies that may be subject to fewer, if any, restrictions or may otherwise adversely affect our business. Transactions that we may view as important opportunities, such as significant acquisitions or business combinations, may be subject to the consent of the lenders, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction. In addition, our Investor Rights Agreement with ROS and Royalty Opportunities further substantially limits the operation of our business and the ability of our management to conduct and invest in our business.

Our Credit Agreements involve additional risks that may adversely affect our liquidity, results of operations, and financial condition.

Availability of additional term loans under the Term Credit Agreement is based solely on the discretion of MidCap and the lenders, and additional funds are for the purposes agreed to between us, the borrowers and the lenders in advance of the making of loans under this additional tranche. Availability of additional funds under the Revolving Credit Agreement is determined based on a borrowing base equal to percentages of certain accounts receivable and inventory of the borrowers in advance with a formula set forth in the Revolving Credit Agreement. As a result, our access to credit under the Credit Agreements is subject to the discretion of MidCap and the lenders as well as fluctuations to our accounts receivable and inventory. Our inability to borrow additional amounts under the Credit Agreements if and when we need them may adversely affect our liquidity, results of operations, and financial condition.

Our outstanding indebtedness under the Credit Agreements bears interest at variable rates, which subjects us to interest rate risk and could increase the cost of servicing our indebtedness. The impact of increases in interest rates, such as interest rate increases stemming from the Federal Reserve's recent and planned increases to the target range for the federal funds rate, could be more significant for us than it would be for some other companies because of the amount of our outstanding indebtedness, thereby affecting our profitability.

Upon the occurrence and during the continuance of an event of default under the Credit Agreements, MidCap may terminate its commitments to lend additional money thereunder and declare all amounts outstanding thereunder to be immediately due and payable. Subject to certain exceptions, amounts outstanding under the Credit Agreements are secured by a senior first priority security interest in substantially all existing and after-acquired assets of our Company and each borrower. Accordingly, under certain circumstances, MidCap could seek to enforce security interests in our assets securing our indebtedness under the Credit Agreements, including restricting our access to collections on our accounts receivable. Any acceleration of amounts due under our Credit Agreements or the exercise by MidCap of its rights under the security documents, would have a material adverse effect on us.

We may be unable to meet financial or other covenant requirements in our Credit Agreements, and we may be unable to successfully negotiate waivers to cure any covenant violations.

Our Credit Agreements contain representations, warranties, fees, affirmative and negative covenants, substantial operating covenants, and default provisions. A breach of any of these covenants could result in a default under the agreements. Upon the occurrence and during the continuance of an event of default under the Credit Agreements, MidCap could elect to declare all amounts outstanding under the credit facility to be immediately due and payable and suspend or terminate all commitments to extend further credit. If MidCap accelerates the repayment of borrowings, we may not have sufficient assets to repay our indebtedness. Also, should there be an event of default, or should we need to obtain waivers following an event of default, we may be subject to higher borrowing costs and/or more restrictive covenants in future periods. In addition, to secure the performance of our obligations under the Credit Agreements, we pledged substantially all of our assets, including our intellectual property, to MidCap and the lenders. Our failure to comply with the covenants under the Credit Agreements could result in an event of default, the acceleration of our debt and the loss of our assets.

Risks Related to Intellectual Property

If we lose any future intellectual property lawsuits, a court could require us to pay significant damages or prevent us from selling our products.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Legal proceedings, regardless of the outcome, could drain our financial resources and divert the time and effort of our management. If we lose this litigation or any other similar legal proceedings of which we may become subject, a court could require us to pay significant damages to third parties, indemnify third parties from loss, require us to seek licenses from third parties, pay ongoing royalties, redesign our products, or prevent us from manufacturing, using, selling, offering for sale, or importing our products. While we do not believe that any of our products infringe any valid claims of patents or other proprietary rights held by others, we have been subject to patent infringement claims in the past. There can be no assurances that we do not infringe any patents or other proprietary rights. In addition to being costly, protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors and be unable to operate our business profitably.

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements, and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not completely protect our rights. For example, competitors may be able to design around some of our intellectual property rights to develop competing but non-infringing technologies. In addition, we cannot be assured that any of our pending patent applications will issue. The U.S. Patent and Trademark Office (or an applicable foreign intellectual property office) may deny or require a significant narrowing of the claims in its pending patent applications and the patents issuing from such applications. Any patents issuing from pending patent applications may not provide us with significant commercial protection or sufficient commercial protection to prevent competitors from utilizing similar but non-infringing technologies. We could incur substantial costs in proceedings before the U.S. Patent and Trademark Office. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. In addition, the laws of some of the countries in which our products are or may be sold may not protect our intellectual property to the same extent as U.S. laws or at all. We also may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries. Additionally, patents and certain other intellectual property rights are not perpetual, and third parties will be able to utilize the subject rights upon expiration.

In addition, we hold licenses from third parties that are necessary to utilize certain technologies used in the design and manufacturing of some of our products. The loss of such licenses could prevent us from manufacturing, marketing, and selling these products, which could harm our business. If we, or the other parties from whom we would license intellectual property, fail to obtain and maintain adequate patent or other intellectual property protection for intellectual property used in our products, or if any protection is reduced or eliminated, others could use the intellectual property used in our products, resulting in harm to our competitive business position.

We seek to protect our trade secrets, know-how, and other unpatented proprietary technology, in part, with confidentiality agreements with our employees, independent distributors, and consultants. We cannot be assured, however, that the agreements will not be breached, adequate remedies for any breach would be available, or our trade secrets, know-how, and other unpatented proprietary technology will not otherwise become known to or independently developed by our competitors.

We may not be able to obtain or protect our proprietary rights relating to our products without resorting to costly and time-consuming litigation.

We may not be able to obtain, maintain and protect certain proprietary rights necessary for the development and commercialization of our products or product candidates. Our commercial success will depend in part on obtaining and maintaining patent protection on our products, successfully asserting these patents against competitors employing infringing technology, and successfully defending these patents against third-party challenges. Even if our patents cover a competing technology, a competitor may not accede to our demands to cease and desist or license our patent rights, which will then require us to pursue costly and time-consuming litigation. Even if we were successful in any such litigation, a court may not issue an injunction, or the infringing competitor may alter its technology to no longer infringe. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions of medical device and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the scope and breadth of patent claims that may be afforded to other companies' patents. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights. Such suits that we may need to defend extend beyond suits by our competitors and may include patent assertion entities, which acquire and assert patents as a means to generate income, due to the expensive nature of patent litigation. In the ordinary course of litigation, attorney fees are not recoverable.

In addition to the risks involved with patent protection, we also face the risk that our competitors will infringe on our trademarks. Any infringement could lead to a likelihood of confusion and could result in lost sales. Similarly, while we are cautious to avoid infringing the rights of third parties, we cannot control a third party asserting its trademarks against us. There can be no assurance that we will prevail in any claims we make to protect our intellectual property, or in defense of any claims brought against us.

Future protection for our proprietary rights is uncertain which may impact our ability to successfully compete in our industry. The degree of future protection for our proprietary rights is uncertain. We cannot ensure that:

- we were the first to make the inventions covered by each of our patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors will be valid and enforceable;
- any patents issued to us or our collaborators will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- any of our patent or other intellectual property rights in the U.S. and the technologies embodied therein will provide or be subject to similar or any protection in foreign markets;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on our business rights; or
- the measures we rely on to protect the intellectual property underlying our products will be adequate to prevent third parties from using our technology, all of which could harm our ability to compete in the market.

Risks Related to Information Technology, Cybersecurity and Data Protection

We are dependent on various information technology (“IT”) systems, and failures of, interruptions to, or unauthorized tampering with those systems could have a material adverse effect on our business.

We rely extensively on IT systems to conduct business. These systems include, but are not limited to, ordering and managing materials from suppliers, converting materials to finished products, invoicing and shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, and providing data security and other processes necessary to manage our business. During 2022, we implemented a significant upgrade to our enterprise resource planning system. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate for this on a timely basis, we may suffer interruptions in our ability to manage operations. Increased global cybersecurity vulnerabilities, threats and more sophisticated and targeted cybersecurity attacks pose a risk to the security of our systems and networks and those of our customers, suppliers, independent sales agents, distributors and third-party service providers, and the confidentiality, availability and integrity of any underlying information and data. Work from home arrangements may increase cybersecurity risks related to phishing, malware, and other similar cybersecurity attacks. We have programs, processes and technologies in place to prevent, detect, contain, respond to and mitigate security related threats and potential incidents. We undertake considerable ongoing improvements to our IT systems in order to minimize vulnerabilities, in accordance with industry and regulatory standards. Because the techniques used to obtain unauthorized access change frequently and can be difficult to detect, anticipating, identifying or preventing these intrusions or mitigating them if and when they occur may be challenging. During 2021, one of our employees was the victim of phishing scheme and as a result we paid three fraudulent invoices. Although the amount involved was immaterial, management brought the matter to the attention of the Audit Committee of the Board of Directors and immediately implemented a remediation plan in response thereto. Despite the remediation plan, no assurance can be provided that we will not become subject to another or similar attack, especially when our cybersecurity protection is dependent at least to some extent on the lack of human error. Additionally, on February 9, 2022, the SEC proposed new rules related to cybersecurity risk management, which may further increase our regulatory burden and the cost of compliance in such events.

Our IT systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards. We also outsource certain elements of our IT systems to third parties that, as a result of this outsourcing, could have access to certain confidential information and whose systems may also be vulnerable to these types of attacks or disruptions. There can be no assurance that our protective measures or those of these third parties will prevent or detect security breaches that could have a significant impact on our business, reputation, operating results and financial condition. The failure of these systems to operate or integrate effectively with other internal, customer, supplier or third-party service provider systems and to protect the underlying IT system and data integrity, including from cyber-attacks, intrusions or other breaches or unauthorized access of these systems, or any failure by us to remediate any such attacks or breaches, may also result in damage to our reputation or competitiveness, delays in product fulfillment and reduced efficiency of our operations, and could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, operating results and financial condition. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Risks Related to Our Controlled Company Status

Funds affiliated with OrbiMed own a significant percentage of our common stock, have the right to designate a majority of our Board of Directors, and are able to exert significant control over matters subject to stockholder approval, preventing other stockholders and new investors from influencing significant corporate decisions.

ROS and Royalty Opportunities collectively owned approximately 67% of our outstanding common stock as of December 31, 2022. We are party to an Investor Rights Agreement with ROS and Royalty Opportunities under which they are permitted to nominate a majority of the directors and designate the chairperson of our Board of Directors at subsequent annual meetings, as long as they maintain an ownership threshold in our Company of at least 40% of our then outstanding common stock. If ROS and Royalty Opportunities are unable to maintain this ownership threshold, the Investor Rights Agreement contemplates a reduction of nomination rights commensurate with their ownership interests. In addition, under the Investor Rights Agreement, for so long as the ownership threshold is met, we must obtain the approval of a majority of our common stock held by ROS and Royalty Opportunities to proceed with the following actions: (i) issue new securities; (ii) incur over \$250,000 of debt in a fiscal year; (iii) sell or transfer over \$250,000 of our assets or businesses or our subsidiaries in a fiscal year; (iv) acquire over \$250,000 of assets or properties in a fiscal year; (v) make capital expenditures over \$125,000 individually, or \$1,500,000 in the aggregate during a fiscal year; (vi) approve our annual budget; (vii) hire or terminate our chief executive officer; (viii) appoint or remove the chairperson of our Board of Directors; and (ix) make loans to, investments in, or purchase, or permit any subsidiary to purchase, any stock or other securities in another entity in excess of \$250,000 in a fiscal year. As long as the ownership threshold is met, we may not increase the size of our Board of Directors beyond seven directors without the approval of a majority of the directors nominated by ROS and Royalty Opportunities. The Investor Rights Agreement also grants ROS and Royalty Opportunities the right to purchase from us a pro rata amount of any new securities that we may propose to issue and sell.

Because of their significant share ownership and control, OrbiMed has the ability to exert substantial influence or actual control over our management and affairs and over substantially all matters requiring action by our stockholders and Board of Directors, including amendments to our Charter, Third Amended and Restated Bylaws (“Bylaws”), election and removal of directors, the appointment of management, future issuances of our common stock or other securities, payment of dividends, if any, on our common stock, the incurrence or modification of indebtedness by us, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions, as well as certain day-to-day decisions involved in operating our business, such as annual operating plans, capital expenditures and other investments in our business. The interests of OrbiMed may not necessarily in all cases be aligned with management’s views on the operation of our business or the interests of our other stockholders. In addition, OrbiMed and their affiliates may have an interest in pursuing acquisitions, divestitures and other transactions or not pursuing such transactions that, in their judgment, could enhance or reduce their investment, even though such transactions might involve risks to our other stockholders. For example, OrbiMed could cause us to make acquisitions that increase our indebtedness or cause us to sell revenue-generating assets. In addition, OrbiMed and their affiliates are able to determine the outcome of all matters requiring stockholder approval and are able to cause or prevent a change of control of our Company or a change in the composition of our Board of Directors and could preclude any acquisition of our Company. This concentration of voting control could deprive our other stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of our Company and ultimately might affect the market price of our common stock.

We are a “controlled company” within the meaning of the NYSE American rules and rely on exemptions from various corporate governance requirements that provide protection to stockholders of other companies.

We are a “controlled company” as defined in section 801(a) of the NYSE American Company Guide because more than 50% of the combined voting power of all of our outstanding common stock is beneficially owned by OrbiMed Advisors LLC. As a “controlled company,” we are exempt from certain NYSE American rules requiring our Board of Directors to have a majority of independent members, a compensation committee composed entirely of independent directors and a nominating committee composed entirely of independent directors. These independence standards are intended to ensure that directors who meet those standards are free of any conflicting interest that could influence their actions as directors. We rely on NYSE American’s controlled company exemptions and do not have a majority of independent directors on the Board of Directors, an independent nomination and governance committee or an independent compensation committee. Accordingly, our stockholders do not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the NYSE American rules.

Risks Related to Our Common Stock

Shares of our common stock are equity securities and are subordinate to our outstanding indebtedness.

Shares of our common stock are common equity interests. This means that our common stock will rank junior to any outstanding shares of our preferred stock that we may issue in the future or to the indebtedness under our Credit Agreements and any future indebtedness we may incur and to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding. Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our Board of Directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. In addition, our Credit Agreements preclude us from paying dividends. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to stockholders generally.

Our inability to comply with the continued listing requirements of the NYSE American could result in our common stock being delisted, which could affect its market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests to maintain the listing of our common stock on the NYSE American. If we do not maintain compliance with the continued listing requirements for the NYSE American within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). On October 5, 2020, we regained compliance with these continued listing requirements as a result of the completion of our August 2020 debt restructuring. No assurance can be provided that we will continue to comply with these continued listing requirements. If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

The market price of our common stock is extremely volatile, which may affect our ability to raise capital in the future and may subject the value of the investment of our stockholders to sudden decreases.

The market price for securities of medical device and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. The trading volume and prices of our common stock have been and may continue to be volatile and could fluctuate widely due to factors both within and beyond our control. During 2022, the sale price of our common stock ranged from \$0.46 to \$0.88 per share, and our daily trading volume ranged from 2 thousand to 328 thousand shares. Such volatility may be the result of broad market and industry factors. Future fluctuations in the trading price or liquidity of our common stock may harm the value of the investment of our stockholders in our common stock. Factors that may have a significant impact on the market price and marketability of our common stock include, among others:

- the terms of any potential future transaction(s) related to debt financing, debt restructuring or capital raising;
- our ability to make interest payments under our Credit Agreements;
- our observance of covenants under our Credit Agreements;
- announcements of technological innovations or new commercial products by us or our present or potential competitors;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with employees, suppliers, distributors, sales representatives and customers;
- acquisitions or divestitures;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;
- additions or departures of key personnel;
- sales of our equity securities by our significant stockholders or management or sales of additional equity securities by our Company;
- changes in securities analysts' recommendations;

- short selling;
- changes in health care policies and practices;
- the delisting of our common stock or halting or suspension of trading in our common stock by the NYSE American;
- economic, social and other external factors, such as COVID-19, supply chain disruptions, labor shortages and persistent inflation; and
- general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. These lawsuits often seek unspecified damages, and as with any litigation proceeding, one cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with any such lawsuits and our management's attention and resources could be diverted from operating our business as we respond to any such litigation. We maintain insurance to cover these risks for us and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages.

We may issue additional common stock resulting in stock ownership dilution.

From time to time, we issue equity securities to raise additional financing and in connection with debt restructurings. During 2022, we issued in a private placement approximately 20.3 million shares of common stock at a purchase price of \$0.48 per share and warrants to purchase approximately 5.1 million shares of common stock. Future dilution may occur due to additional future equity issuances and/or equity financing events by us, including any potential future restructuring of our outstanding indebtedness. In addition, we may raise additional capital through the sale of equity or convertible debt securities, which would further dilute the ownership interests of our stockholders. As of December 31, 2022, we had outstanding warrants to purchase approximately 12,187,470 shares of our common stock, stock options to purchase 3,347,819 shares of our common stock and restricted stock unit awards covering 3,612,433 shares of our common stock under the Xtant Medical Holdings, Inc. Second Amended and Restated 2018 Equity Incentive Plan, options to purchase 12,845 shares of our common stock under our prior equity compensation plan, and 7,443,895 shares available for issuance under the Xtant Medical Holdings, Inc. Second Amended and Restated 2018 Equity Incentive Plan. If these or any future warrants, options or restricted stock units are exercised or otherwise converted into shares of our common stock, our stockholders will experience additional dilution.

The sale or availability for sale of substantial amounts of our common stock or other equity securities could adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock or a preferred stock in the public market, or the perception that these sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through equity offerings in the future. We cannot predict what effect, if any, market sales of securities beneficially owned by OrbiMed or any other stockholder or the availability of these securities for future sale will have on the market price of our common stock.

Anti-takeover provisions in our organizational documents and agreements may discourage or prevent a change in control, even if a sale of the Company could be beneficial to our stockholders, which could cause our stock price to decline and prevent attempts by our stockholders to replace or remove our current management.

Several provisions of our Charter and Bylaws and our Investor Rights Agreement could make it difficult for our stockholders to change the composition of our Board of Directors, preventing them from changing the composition of management. In addition, several provisions of our Charter and Bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable. These provisions include:

- We have shares of common stock and preferred stock available for issuance without stockholder approval. The existence of unissued and unreserved common stock and preferred stock may enable the 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.
- Shares of our common stock do not have cumulative voting rights in the election of directors, so our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors.
- Special meetings of the stockholders may be called only by the Board of Directors, the chair of the Board of Directors or the chief executive officer.
- The Board of Directors may adopt, alter, amend or repeal our Bylaws without stockholder approval.
- Unless otherwise provided by law, any newly created directorship or any vacancy occurring on the Board of Directors for any cause may be filled by the affirmative vote of a majority of the remaining members of the Board of Directors even if such majority is less than a quorum, and any director so elected shall hold office until the expiration of the term of office of the director whom he or she has replaced or until his or her successor is elected and qualified.
- The affirmative vote of the holders of at least two-thirds of the voting power of the then outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class, is required to amend or repeal the provisions of our Charter related to the amendment of our Bylaws, the Board of Directors and our stockholders as well as the general provisions of our Charter.
- Stockholders must follow advance notice procedures to submit nominations of candidates for election to the Board of Directors at an annual or special meeting of our stockholders, including director election contests subject to the SEC's universal proxy rules, and must follow advance notice procedures to submit other proposals for business to be brought before an annual meeting of our stockholders.
- Unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware, subject to certain limitations, will be the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising under any provision of the General Corporation Law of the State of Delaware ("DGCL"), our Charter or our Bylaws, or (iv) any action asserting a claim governed by the internal-affairs doctrine.
- The Investor Rights Agreement includes director nomination rights, which provide that so long as the Ownership Threshold (as defined in the Investor Rights Agreement) is met, Royalty Opportunities and ROS are entitled to nominate such individuals to the Board of Directors constituting a majority of the directors. In addition, under the Investor Rights Agreement, so long as the Ownership Threshold is met, certain matters require the approval of Royalty Opportunities and ROS to proceed with such a transaction, including without limitation, the sale, transfer or other disposition of our assets or businesses or our subsidiaries with a value in excess of \$250,000 in the aggregate during any fiscal year (other than sales of inventory or supplies in the ordinary course of business, sales of obsolete assets (excluding real estate), sale-leaseback transactions and accounts receivable factoring transactions).
- The Letter Agreement between us and Mr. Stavros Vizirgianakis includes director nomination rights, which terminate on the earlier of (i) the date on which Mr. Vizirgianakis ceases to hold at least 75% of the shares of common stock purchased by him in our 2022 private placement, (ii) the second anniversary of the date of the second closing of our 2022 private placement, or (iii) upon written notice of Mr. Vizirgianakis to us.

These anti-takeover provisions could substantially impede the ability of our stockholders to benefit from a change in control and, as a result, could materially adversely affect the market price of our common stock and the ability of our stockholders to realize any potential change-in-control premium.

Our Board of Directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our Charter authorizes our Board of Directors, without the approval of our stockholders, to issue up to 10 million shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our Charter, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these series of preferred stock may be senior to or on parity with our common stock, which may reduce its value.

Our Charter designates the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit the ability of our stockholders to obtain a favorable judicial forum for disputes with us.

Our Charter provides that the Court of Chancery of the State of Delaware will be the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising under any provision of the DGCL, or (iv) any action asserting a claim governed by the internal-affairs doctrine. Stockholders in our Company will be deemed to have notice of and have consented to the provisions of our Charter related to choice of forum. The choice of forum provision in our Charter may limit the ability of our stockholders to obtain a favorable judicial forum for disputes with us.

Notwithstanding the foregoing, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and Section 22 of the Securities Act of 1933, as amended (the “Securities Act”), creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act, the Securities Act, or any other claim for which the federal courts have exclusive jurisdiction.

We have never paid dividends and do not expect to do so in the foreseeable future.

We have not declared or paid any cash dividends on our common stock. The payment of dividends in the future will be dependent on our earnings and financial condition and on such other factors as our Board of Directors considers appropriate. Unless and until we pay dividends, stockholders may not receive a return on their shares of our common stock. There is no present intention by our Board of Directors to pay dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our Credit Agreements preclude us from paying dividends. As a result, appreciation, if any, in the market price of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

General Risk Factors

Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations.

The health of the global economy, and the credit markets and the financial services industry in particular, as well as the stability of the social fabric of our society, affects our business and operating results. For example, the credit and financial markets may be adversely affected by the current conflict between Russia and Ukraine and measures taken in response thereto. If the credit markets are not favorable, we may be unable to raise additional financing when needed or on favorable terms. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions, such as the lingering economic impacts of COVID-19, continuing supply chain disruptions, labor shortages and persistent inflation, and measures taken in response thereto, including recent interest rate increases, could also adversely impact our suppliers' ability to provide us with materials and components, which may negatively impact our business. As with our customers and vendors, these economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

Climate change, or legal, regulatory or market measures to address climate change, may materially adversely affect our financial condition and business operations.

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our future operations from natural disasters and extreme weather conditions, such as hurricanes, tornadoes, wildfires or flooding. Concern over climate change could result in new legal or regulatory requirements designed to report, reduce or mitigate the effects of greenhouse gases, as well as more stringent regulation of water rights. For example, during 2022, the SEC proposed new climate disclosure rules, which, if adopted, would require new climate related disclosure in SEC filings, including certain climate-related metrics and greenhouse gas emissions data, information about climate-related targets and goals, transition plans, if any, and extensive attestation requirements. In addition to requiring public companies to quantify and disclose direct emissions data, the new rules also would require disclosure of climate impact arising from the operations and uses by the company's business partners and contractors and end-users of the company's products and/or services. We are currently assessing the impact of the new rules, if adopted as proposed, but at this time, we cannot predict the costs of implementation or any potential adverse impacts resulting from the new rules if adopted. However, we may incur increased costs relating to the assessment and disclosure of climate-related risks and increased litigation risks related to disclosures made pursuant to the new rules, either of which could materially and adversely affect our future results of operations and financial condition. Additionally, inconsistency of regulations at the state level in the states in which we operate may affect the costs of compliance with such legal or regulatory requirements.

In addition, public company stockholders are increasingly sensitive to the climate change impacts and mitigation efforts of companies, are increasingly seeking enhanced disclosure on the risks, challenges, governance implications, and financial impacts of climate change faced by companies and are demanding that companies take a proactive approach to addressing perceived environmental risks, including risks associated with climate change, relating to their operations. Adverse publicity or climate-related litigation that impacts us could have a negative impact on our business.

Changes in accounting standards, policies, or assumptions utilized in determining accounting estimates could adversely affect our financial statements, including our operating results and financial condition.

In preparing our consolidated financial statements in conformity with U.S. generally accepted accounting principles ("GAAP"), we must make decisions that impact our results of operations and/or financial condition. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, we apply judgments based on our understanding and analysis of the relevant circumstances, historical experience, and expert valuations, as appropriate. As a result, actual amounts could differ from those estimated at the time our consolidated financial statements are prepared. Our critical accounting estimates are described later in this report under Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. In addition, various authoritative accounting or regulatory entities, including the Financial Accounting Standards Board ("FASB"), and the SEC may amend, expand, and/or eliminate the financial accounting or reporting standards that govern the preparation of our consolidated financial statements or could reverse their previous interpretations or positions on how various financial accounting and/or reporting standards should be applied. We disclose the impact of accounting pronouncements that have been issued but not yet adopted within our Annual and Quarterly Reports on Form 10-K and Form 10-Q, respectively. However, we do not provide an assessment of proposed accounting pronouncements, as such proposals are subject to change through the exposure process and therefore, we cannot meaningfully assess their effects on our consolidated financial statements. Future changes to accounting standards could modify the accounting policies and procedures that are currently utilized in the preparation of our consolidated financial statements. Such changes may be difficult to predict and implement and could materially, or otherwise, impact how we prepare and report our consolidated financial statements, results of operations, and financial condition.

The requirements of being a public company, including compliance with the reporting requirements of the Exchange Act and the requirements of the Sarbanes-Oxley Act and the NYSE American, may strain our resources and divert management's attention, and we may be unable to comply with these requirements in a timely or cost-effective manner.

As a public company, we are subject to the reporting requirements of the Exchange Act and the corporate governance standards of the Sarbanes-Oxley Act and the NYSE American. These requirements place a strain on our management, systems and resources and we will continue to incur significant legal, accounting, insurance and other expenses. The Exchange Act requires us to file annual, quarterly and current reports with respect to our business and financial condition within specified time periods and to prepare a proxy statement with respect to our annual meeting of stockholders. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. The NYSE American requires that we comply with various corporate governance requirements. To maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting and comply with the Exchange Act and NYSE American requirements, significant resources and management oversight are required. This may divert management's attention from other business concerns and lead to significant costs associated with compliance, which could have a material adverse effect on us and the market price of our common stock. Furthermore, as we grow our business both organically and through acquisitions, our disclosure controls and procedures and internal control over financial reporting will become more complex, and we may require significantly more resources to ensure that these controls and procedures remain effective.

These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors or its committees or as our executive officers. Advocacy efforts by stockholders and third parties may also prompt even more changes in governance and reporting requirements. We cannot predict or estimate the amount of additional costs we may incur or the timing of these costs. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Scrutiny and evolving expectations from customers, regulators, investors, and other stakeholders with respect to our environmental, social and governance practices may impose additional costs on us or expose us to new or additional risks.

Public companies are facing scrutiny from customers, regulators, investors, and other stakeholders related to their environmental, social and governance ("ESG") practices and disclosure. Investor advocacy groups, investment funds and influential investors are also focused on these practices, especially as they relate to the environment, climate change, health and safety, supply chain management, diversity, labor conditions and human rights, both in our own operations and in our supply chain. Increased ESG-related compliance costs could result in material increases to our overall operational costs. Our ESG practices may not meet the standards of all of our stakeholders and advocacy groups may campaign for further changes. A failure, or perceived failure, to adapt to or comply with regulatory requirements or to respond to investor or stakeholder expectations and standards could negatively impact our business and reputation and have a negative impact on the trading price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters and manufacturing facility are located at 664 Cruiser Lane, Belgrade, Montana 59714. We also have two other facilities on the Montana campus, located at 600 Cruiser Lane, Belgrade, Montana 59714, and at 732 Cruiser Lane, Belgrade, Montana 59714. All our properties are leased.

We lease an approximately 14,000 square foot facility at 664 Cruiser Lane, Belgrade, Montana, which runs through October 2025. This building is an FDA registered facility with a Class 10,000 (ISO 7) environmentally controlled area. The validated manufacturing areas and laboratory facilities located in this facility provide processing, final packaging and testing space to manufacture medical devices pursuant to FDA, GMP regulations, and ISO 13485:2003. The facility is registered with the FDA for device design, device manufacture, and contract manufacture, as well as for screening, testing, storing, and distributing biological tissues. We also lease approximately 17,700 square feet in a building located at 600 Cruiser Lane, Belgrade, Montana. This space includes six Class 100 (ISO 5) clean rooms, a fully equipped diagnostics laboratory, microbiology laboratory and testing laboratory. We lease the building under a ten-year operating lease which runs through October 2025 and has a ten-year renewal option. We also lease approximately 21,000 square feet in a building located at 732 Cruiser Lane, Belgrade, Montana, where one Class 1,000 (ISO 6) clean room is located, which runs through October 2025.

Item 3. Legal Proceedings

Our legal proceedings are discussed in Note 11 – Commitments and Contingencies in the notes to our consolidated financial statements in this Form 10-K.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed on the NYSE American under the ticker symbol "XTNT."

Holders of Record

As of March 3, 2023, we had 170 holders of record.

Dividends

We have not paid any cash dividends and do not expect to do so in the foreseeable future. In addition, our credit agreements with MidCap preclude us from paying dividends.

Recent Sales of Unregistered Securities

We did not sell any unregistered equity securities of our Company during the quarter ended December 31, 2022, other than the issuance of shares of our common stock and warrants in connection with our private placement, as reported in a Current Report on Form 8-K as filed with the SEC on October 11, 2022.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any shares of our common stock or other equity securities of our Company during the quarter ended December 31, 2022.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. The following discussion should be read in conjunction with our consolidated financial statements and accompanying notes included in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed in the "Cautionary Statement Regarding Forward-Looking Statements" and under the heading "Part I. Item 1A. Risk Factors."

Business Overview

We develop, manufacture and market regenerative medicine products and medical devices for domestic and international markets. Our products serve the specialized needs of orthopedic and neurological surgeons, including orthobiologics for the promotion of bone healing, implants and instrumentation for the treatment of spinal disease. We promote our products in the United States through independent distributors and stocking agents, supported by direct employees.

We have an extensive sales channel of independent commissioned agents and stocking distributors in the United States representing some or all of our products. We also maintain a national accounts program to enable our agents to gain access to integrated delivery network hospitals ("IDNs") and through group purchasing organizations ("GPOs"). We have biologics contracts with major GPOs, as well as extensive access to IDNs across the United States for both biologics and spine hardware systems. While our focus is the United States market, we promote and sell our products internationally through stocking distribution partners in Canada, Mexico, South America, Australia, and certain Pacific region countries.

We have focused and intend to continue to focus primarily on four key growth initiatives: (1) introduce new products; (2) expand our distribution network; (3) penetrate adjacent markets; and (4) leverage our growth platform with technology and strategic acquisitions. While the intent of these four key growth initiatives is to increase our future revenues, no assurance can be provided that we will be successful in implementing these growth initiatives or increasing our future revenues.

Acquisition of Coflex and CoFix Product Lines

On February 28, 2023, we entered into an Equity Purchase Agreement (the "Equity Purchase Agreement") with Surgalign SPV, Inc. ("Surgalign SPV"), a Delaware corporation and wholly owned subsidiary of Surgalign Spine Technologies, Inc., a Delaware corporation ("Seller"), Seller and Surgalign Holdings, Inc., a Delaware corporation, pursuant to which we purchased all of the issued and outstanding shares of common stock of Surgalign SPV, which shares constitute all of the outstanding equity of Surgalign SPV, for an aggregate purchase price of \$17.0 million in cash. The closing contemplated by the Equity Purchase Agreement occurred on February 28, 2023 (the "Closing").

Immediately prior to the Closing, Seller and its affiliates transferred and assigned to Surgalign SPV, a privately held, newly formed entity, certain intellectual property, contractual rights and other assets related to the design, manufacture, sale and distribution of its Coflex and CoFix products in the United States (the "Coflex Business"). The Coflex and CoFix products have been approved by the U.S. Food and Drug Administration for the treatment of moderate to severe lumbar spinal stenosis in conjunction with decompression and provide minimally invasive, motion preserving stabilization.

For additional information regarding the acquisition of Surgalign SPV, refer to Note 17 – Subsequent Events in the consolidated financial statements in this Form 10-K.

Impact of COVID-19

At the onset of, and at various times during, the COVID-19 pandemic, hospitals and other medical facilities have cancelled or deferred elective procedures, diverted resources to patients suffering from infections, and limited access for non-patients, including our direct and indirect sales representatives. Because of these circumstances, surgeons and their patients have deferred, and may continue to defer, procedures in which our products otherwise would be used. In addition, many facilities that specialize in procedures in which our products are used have experienced, and may continue to experience, staffing shortages, temporary closures, and/or reduced operating hours. These circumstances have negatively impacted, and may continue to negatively impact, the number of elective procedures being conducted and the ability of our employees, independent sales representatives and distributors to effectively market and sell our products, which has had and may continue to have a material adverse effect on our revenues. During the first quarter of 2022, spine and other surgery procedure volumes were negatively impacted in many of our key markets, due to cancellations and/or postponements of procedures as a result of hospitalizations of COVID-19 patients, restrictions on elective procedures and staffing shortages in our key markets, which negatively impacted our first quarter 2022 revenues. This reduction in elective procedures and staffing shortages subsided beginning in the second quarter and during the remainder of 2022, but could reoccur if there is another wave or sustained resurgence of COVID-19 cases and hospitalizations.

COVID-19 also has caused and may continue to cause adverse effects on general commercial activity and the global economy and supply chain, disrupting our ability to obtain raw materials, components and products. COVID-19 has also adversely affected, and may continue to adversely affect, our distributors, independent sales representatives, customers, contract manufacturers and suppliers and their respective businesses, which in turn, have adversely affected, and may continue to adversely affect, our business and operations. Although we continue to monitor the impact of COVID-19 on our business, operations and financial results, the full extent to which COVID-19 will continue to impact our business during 2023 will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 variants, actions taken to contain or treat the impact of COVID-19, the availability, acceptance and effectiveness of vaccines, future resurgences of the virus and its variants, the level of any government restrictions, patient capacity at hospitals and healthcare systems, and the willingness and ability of patients to seek care and treatment due to safety concerns or financial hardship. If our revenues do not recover to pre-COVID-19 pandemic levels, we may be required to incur impairment charges to our long-lived assets and goodwill and write-off excess inventory, which would likely adversely affect our future operating results.

Results of Operations

Comparison of Years Ended December 31, 2022 and December 31, 2021

The following table sets forth our results of operations for 2022 and 2021 (dollars in thousands):

	Year Ended December 31,			
	2022		2021	
	Amount	% of Revenue	Amount	% of Revenue
Revenue				
Orthopedic product sales	\$ 57,958	100.0%	\$ 55,146	99.8%
Other revenue	11	0.0%	117	0.2%
Total Revenue	57,969	100.0%	55,263	100.0%
Cost of Sales				
Cost of Sales	25,832	44.6%	22,773	41.2%
Gross Profit	32,137	55.4%	32,490	58.8%
Operating Expenses				
General and administrative	15,462	26.7%	14,449	26.1%
Sales and marketing	22,515	38.8%	21,025	38.0%
Research and development	915	1.6%	870	1.6%
Total Operating Expenses	38,892	67.1%	36,344	65.7%
Loss from Operations	(6,755)	(11.7)%	(3,854)	(7.0)%
Other Expense				
Interest expense	(1,692)	(2.9)%	(995)	(1.8)%
Interest income	31	0.1%	—	0.0%
Total Other Expense	(1,661)	(2.9)%	(995)	(1.8)%

Net Loss from Operations Before Provision for Income Taxes	<u>(8,416)</u>	<u>(14.5)%</u>	<u>(4,849)</u>	<u>(8.8)%</u>
Provision for Income Taxes Current and Deferred	<u>(69)</u>	<u>(0.1)%</u>	<u>—</u>	<u>(0.0)%</u>
Net Loss	<u>\$ (8,485)</u>	<u>(14.6)%</u>	<u>\$ (4,849)</u>	<u>(8.8)%</u>

Revenue

Total revenue for the year ended December 31, 2022 increased 5% to \$58.0 million compared to \$55.3 million for the prior year. This is attributed primarily to revenue from new products introduced during 2021, specifically OsteoVive® Plus and OsteoFactor™.

Cost of Sales

Cost of sales consists primarily of manufacturing cost, product purchase costs and depreciation of surgical instruments. Cost of sales also includes reserves for estimated excess inventory, inventory on consignment that may be missing and not returned, and reserves for estimated missing and damaged consigned surgical instruments. Cost of sales increased by 13%, or \$3.0 million, to \$25.8 million for the year ended December 31, 2022 from \$22.8 million for the year ended December 31, 2021. This is primarily due to additional expense of \$1.0 million related to increased reserve expense for excess and obsolete inventory and additional salaries and wages expense of \$0.9 million, with the remaining increase relating primarily to higher sales levels.

Gross profit as a percentage of sales decreased to 55.4% for the year ended December 31, 2022 compared to 58.8% for the year ended December 31, 2021. Of this decrease, 280 basis points were due to higher production costs and 180 basis points resulted from increased charges for excess and obsolete inventory.

General and Administrative

General and administrative expenses consist primarily of personnel costs for corporate employees, cash-based and stock-based compensation related costs and corporate expenses for legal, accounting and other professional fees, as well as occupancy costs. General and administrative expenses increased 8%, or \$1.1 million, to \$15.5 million for the year ended December 31, 2022 compared to \$14.4 million for the year ended December 31, 2021. This increase is primarily attributable to additional expense of \$0.6 million related to various compensation plans, additional expense of \$0.4 million related to product registrations and costs related to ERP system upgrades of \$0.4 million, partially offset by legal settlement expenses of \$0.6 million during the prior year.

Sales and Marketing

Sales and marketing expenses consist primarily of sales commissions, personnel costs for sales and marketing employees, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. Sales and marketing expenses increased 7%, or \$1.5 million, to \$22.5 million for the year ended December 31, 2022 compared to \$21.0 million for the year ended December 31, 2021. The year-over-year increase included additional independent agent commissions expense of \$1.1 million resulting from higher sales and a greater mix of independent agent sales and additional expense of \$0.2 million associated with tradeshows and related travel.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new product technologies. Research and development expenses were \$0.9 million for each of the years ended December 31, 2022 and 2021.

Interest Expense

Interest expense for the year ended December 31, 2022 increased \$0.7 million to \$1.7 million as compared to \$1.0 million for the year ended December 31, 2021. This increase resulted from our debt refinancing in May 2021, prior to which no interest expense related to our debt instruments was incurred during 2021. We expect interest expense to increase in future periods compared to the comparable prior year periods in light of current rising interest rates. We expect that our annualized interest expense will increase approximately \$0.1 million for every 75 basis points of increase to the reference rate associated with our credit agreements before adjusting for principal payments.

Liquidity and Capital Resources

Working Capital

Since our inception, we have financed our operations through primarily operating cash flows, private placements of equity securities and convertible debt, debt facilities, common stock rights offerings, and other debt transactions. The following table summarizes our working capital as of December 31, 2022 and December 31, 2021 (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	\$ 20,507	\$ 18,387
Accounts receivable, net	10,853	7,154
Inventories	17,285	17,945
Total current assets	49,318	44,330
Accounts payable	3,490	2,615
Accrued liabilities	5,496	4,349
Line of credit	3,379	3,620
Current portion of long-term debt	2,333	—
Total current liabilities	15,218	11,077
Net working capital	34,100	33,253

Our increase in cash and cash equivalents was due primarily to net proceeds from our 2022 private placement of common stock and warrants, partially offset by net cash used in operations.

On August 25, 2022, we issued in the first tranche of a private placement with several accredited investors approximately 14.1 million shares of our common stock at a purchase price of \$0.48 per share and warrants to purchase approximately 3.5 million shares of our common stock. The warrants have an exercise price of \$0.48 per share, subject to customary anti-dilution, but not price protection, adjustments, are immediately exercisable and expire on the five-year anniversary of the date of issuance. We received net cash proceeds of approximately \$6.3 million, after deducting fees and other estimated offering expenses, from the first tranche of this private placement. The closing of the second tranche of the private placement occurred on October 7, 2022, at which we sold an additional approximately 6.2 million shares of our common stock and warrants to purchase approximately 1.6 million shares of common stock for an aggregate purchase price of \$3.0. The warrants issued at the second closing are identical to the warrants issued at the first closing and also expire on the five-year anniversary of the first closing. We expect to use the net proceeds from this private placement for working capital and other general corporate purposes.

Cash Flows

Net cash used in operating activities for the year ended December 31, 2022 was \$5.3 million compared to \$0.4 million provided by operating activities for the year ended December 31, 2021. This increase in net cash used in operating activities relates primarily to the increase in net loss, partially offset by the effects of changes in operating assets and liabilities.

Net cash used in investing activities for the years ended December 31, 2022 and 2021 was \$1.6 million and \$1.9 million, respectively, primarily representing purchases of property and equipment.

Net cash provided by financing activities was \$9.0 million for the year ended December 31, 2022, which was primarily attributable to \$9.3 million of proceeds from the private placement of common stock and common stock warrants, net of issuance costs. Net cash provided by financing activities was \$17.5 million for the year ended December 31, 2021, which was primarily attributable to \$18.4 million of proceeds the private placement of common stock and common stock warrants, net of issuance costs.

Current and Prior Credit Facilities

On May 6, 2021, the Company, as guarantor, and our subsidiaries, as borrowers (collectively, the “Borrowers”), entered into a Credit, Security and Guaranty Agreement (Term Loan) (the “Term Credit Agreement”) and Credit, Security and Guaranty Agreement (Revolving Loan) (the “Revolving Credit Agreement” and, together with the Term Credit Agreement, the “Credit Agreements”) with MidCap Financial Trust, in its capacity as agent (“MidCap”).

The Term Credit Agreement provides for a secured term loan facility (the “Term Facility”) in an aggregate principal amount of \$12.0 million (the “Term Loan Commitment”), which was funded to the Borrowers immediately, and an additional \$5.0 million tranche available solely at the discretion of MidCap and the lenders, for the purposes agreed to between the Company, the Borrowers and the lenders in advance of the making of loans under such additional tranche. The Revolving Credit Agreement provides for a secured revolving credit facility (the “Revolving Facility,” and, together with the Term Facility, the “Facilities”) under which the Borrowers may borrow up to \$8.0 million (such amount, the “Revolving Loan Commitment”) at any one time, the availability of which is determined based on a borrowing base equal to percentages of certain accounts receivable and inventory of the Borrowers in accordance with a formula set forth in the Revolving Credit Agreement. All borrowings under the Revolving Facility are subject to the satisfaction of customary conditions, including the absence of default, the accuracy of representations and warranties in all material respects and the delivery of an updated borrowing base certificate.

The Facilities have a maturity date of May 1, 2026 (the “Maturity Date”). Beginning in June 2023, the Company is required to make monthly principal payments of approximately \$0.3 million on the Term Facility through the Maturity Date. Each of the Borrowers, and the Company, as guarantor, are jointly and severally liable for all of the obligations under the Facilities on the terms set forth in the Credit Agreements. The Borrowers’ obligations, and the Company’s obligations as a guarantor, under the Credit Agreements are secured by first-priority liens on substantially all of their assets, including, without limitation, all inventory, equipment, accounts, intellectual property and other assets of the Company and the Borrowers.

The proceeds of the Term Facility and Revolving Facility were used to pay transaction fees in connection with the Facilities and to pay in full all outstanding indebtedness and accrued interest under the Company’s prior credit facility, which is described below. As of December 31, 2022, the Company had \$3.4 million outstanding and \$4.6 million of availability under the Revolving Facility. On October 27, 2022, the Credit Agreements were amended to transition the reference rate from LIBOR to term SOFR. The term SOFR reference rate was applied to amounts outstanding and draws that took place on or after the November 1, 2022.

The loans and other obligations pursuant to the Credit Agreements bear interest at a per annum rate equal to the sum of the SOFR rate, as such term is defined in the Credit Agreements, plus 0.11%, plus the applicable margin of 7.00% in the case of the Term Credit Agreement, and 4.50% in the case of the Revolving Credit Agreement, subject in each case to a floor of 1.00%. As of December 31, 2022, the effective rate of the Term Facility, inclusive of amortization of debt issuance costs and accretion of the final payment, was 13.20%, and the effective rate of the Revolving Facility was 8.74%.

The Credit Agreements contain affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants that, among other things, limit or restrict the ability of the Borrowers, subject to negotiated exceptions, to incur additional indebtedness and additional liens on their assets, engage in mergers or acquisitions or dispose of assets, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. In addition, the Credit Agreements require the Borrowers and the Company to maintain net product revenue at or above minimum levels and to maintain a minimum adjusted EBITDA and a minimum liquidity, in each case at levels specified in the Credit Agreements.

On March 7, 2022, the Credit Agreements were amended to, among other things, (i) provide for a waiver of compliance with respect to the Company's minimum adjusted EBITDA requirement if and so long as the Company's liquidity (as specifically defined in the Credit Agreements) is in excess of \$14 million and there is not otherwise an event of default under the Credit Agreements, commencing with the next delivery of the compliance certificate required under the Credit Agreements, and (ii) re-set the date certain fees payable in connection with optional prepayments are determined to the date the amendment was executed and consequently extend such fees' original expiration. In addition, the exit fees were increased by 25 basis points. As of December 31, 2022, we were in compliance with all covenants under the Credit Agreements.

On February 28, 2023, in connection with the acquisition of Surgalign SPV, the Term Credit Agreement was amended pursuant to an Amendment No. 3 to Credit, Security and Guarantee Agreement (Term Loan) ("Term Amendment No. 3") to provide approximately \$5.0 of funding for such acquisition. In addition to the Term Amendment No. 3., we entered into an Amendment No. 3 to Credit, Security and Guarantee Agreement (Revolving Loan) (together with the Term Amendment No. 3, the "Amendments No. 3"), which amends the Revolving Credit Agreement. Additionally, the Amendments No. 3 (i) re-set the date certain fees payable in connection with optional prepayments under the Term Credit Agreement and the Revolving Credit Agreement are determined to the date the amendments were executed and consequently extended such fees' original expiration and (ii) increased the minimum amount of interest payable under the Term Credit Agreement and the Revolving Credit Agreement from 1% to 2.5%.

On May 6, 2021, contemporaneously with the execution and delivery of the Credit Agreements, that certain Second Amended and Restated Credit Agreement, dated March 29, 2019, among the Company, the Borrowers, Royalty Opportunities and ROS, as subsequently amended, which was scheduled to mature on December 31, 2021, was terminated in accordance with the terms thereof and all outstanding amounts were repaid by the Borrowers to OrbiMed Royalty Opportunities II, LP in its role as sole lender thereunder.

Cash Requirements

We believe that our \$20.5 million of cash and cash equivalents as of December 31, 2022, together with amounts available under the Facilities, will be sufficient to meet our anticipated cash requirements through at least March 2024 despite the use of \$12.0 million of cash subsequent to the end of the year in connection with the acquisition of Surgalign SPV. However, we may require or seek additional capital to fund our future operations and business strategy prior to March 2024. Accordingly, there is no assurance that we will not need or seek additional financing prior to such time.

We may elect to raise additional financing even before we need it if market conditions for raising additional capital are favorable. We may seek to raise additional financing through various sources, such as equity and debt financings, additional debt restructurings or refinancings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This is particularly true if economic and market conditions deteriorate.

To the extent that we raise additional capital through the sale of equity or convertible debt securities or the restructuring or refinancing of our debt, the interests of our current stockholders may be diluted, and the terms may include discounted equity purchase prices, warrant coverage, liquidation or other preferences or rights that would adversely affect the rights of our current stockholders. If we issue common stock, we may do so at purchase prices that represent a discount to our trading price and/or we may issue warrants to the purchasers, which could further dilute our current stockholders. If we issue preferred stock, it could adversely affect the rights of our stockholders or reduce the value of our common stock. In particular, specific rights or preferences granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. Additional 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. Prior to raising additional equity or debt financing, we may be required to obtain the consent of the Agent under our Credit Agreements and/or ROS and Royalty Opportunities under our Investor Rights Agreement with them, and no assurance can be provided that they would provide such consent, which could limit our ability to raise additional financing and the terms thereof. In addition, the investors in our 2022 private placement have certain participation rights with respect to certain future equity offerings for capital raising purposes.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is included in Note 1 to our consolidated financial statements in “Item 8. Financial Statements and Supplementary Data.”

Critical Accounting Estimates

All of our significant accounting policies and estimates are described in Note 1 to our consolidated financial statements in “Item 8. Financial Statements and Supplementary Data.” Certain of our more critical accounting estimates require the application of significant judgment by management in selecting the appropriate assumptions in determining the estimate. By their nature, these judgments are subject to an inherent degree of uncertainty. We develop these judgments based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers, and information available from other outside sources, as appropriate. Actual results may differ from these estimates under different assumption conditions.

We believe that the following financial estimates are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recorded in our consolidated financial statements for all periods presented. Our management has discussed the development, selection, and disclosure of our most critical financial estimates with the Audit Committee of the Board of Directors and with our independent registered public accounting firm. The judgments about those financial estimates are based on information available as of the date of our financial statements. Those financial estimates include:

Goodwill and Intangible Assets

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, instead they are tested for impairment annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. We conduct our impairment test on an annual basis and review the analysis assumptions on a quarterly basis. We test goodwill for impairment at the reporting unit level, which is an operating segment or one level below an operating segment, referred to as a component. A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and segment management regularly reviews the operating results of that component.

We chose December 31 to assess our annual goodwill for any impairment in order to closely align with the timing of our annual planning process. In testing goodwill for impairment we perform a quantitative impairment test, including computing the fair value of the reporting unit and comparing that value to its carrying value. If the fair value is less than its carrying value, then the goodwill is determined to be impaired. In the event that goodwill is impaired, an impairment charge to earnings would become necessary. There was no impairment of goodwill recorded in 2022 or 2021.

We evaluate other intangible assets whenever current events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability for assets to be held and used is based on our projection of the undiscounted future operating cash flows of the underlying assets. To the extent such projections indicate that future undiscounted cash flows are not sufficient to recover the carrying amounts of related assets, a charge might be required to reduce the carrying amount to equal estimated fair value. We did not have a triggering event in 2022 or 2021.

Inventory Valuation

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the specific identification method and includes materials, labor and overhead. We calculate an inventory reserve for estimated obsolescence and excess inventory based on historical usage and sales, as well as assumptions about anticipated future demand for products. A significant sustained decrease in demand could result in an increase in the amount of excess inventory quantities on hand. Additionally, our industry is characterized by regular new product development and introductions that could result in an increase in the amount of obsolete inventory quantities on hand due to cannibalization of existing products. Our estimates for excess and obsolete inventory are reviewed and updated on a quarterly basis. Our estimates of anticipated future product demand may prove to be inaccurate in which case we may be required to incur charges for excess and obsolete inventory. Increases in our inventory reserves result in a corresponding expense, which is recorded to cost of sales. We believe the total reserve at December 31, 2022 is adequate.

Accounts Receivable and Allowances

Accounts receivable represents amounts due from customers for which revenue has been recognized. Normal terms on trade accounts receivable are net 30 days, and some customers are offered discounts for early pay. We perform credit evaluations when considered necessary, but generally do not require collateral to extend credit.

The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing receivables. We determine the allowance based on factors such as historical collection experience, customers' current creditworthiness, customer concentration, age of accounts receivable balance, general economic conditions that may affect a customer's ability to pay, and management judgment. In addition, we include provision for current expected credit loss based on historical collection experience adjusted for current economic conditions affecting collectability. Actual customer collections could differ from our estimates. Account balances are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Provisions to the allowance for doubtful accounts are charged to expense. We do not have any off-balance sheet credit exposure related to our customers.

Deterioration in the financial condition of any key customer or a significant slowdown in the economy could have a material negative impact on our ability to collect a portion or all of our accounts receivable. We believe that an analysis of historical trends and our current knowledge of potential collection issues provide us with sufficient information to establish a reasonable estimate for an allowance for doubtful accounts. However, since we cannot predict with certainty future changes in the financial stability of our customers, our actual future losses from uncollectible accounts may differ from our estimates. In the event we determined that a smaller or larger uncollectible accounts reserve is appropriate, we would record a credit or charge, as applicable, to bad debt expense in the period that we made such a determination. We believe our allowance for doubtful accounts at December 31, 2022 of \$0.5 million is adequate.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business and do not include any adjustments relating to the recoverability or classification of assets or the amounts of liabilities that might result from the outcome of these uncertainties. Our ability to continue as a going concern, realize the carrying value of our assets and discharge our liabilities in the ordinary course of business is dependent upon a number of factors, including, the level and timing of future revenues and expenditures; development, commercialization and market acceptance of our products; competing technologies and market developments; regulatory requirements and delays; and ability to attract and retain key personnel.

Management's evaluation of going concern was conducted as part of its discussions with and the review by the Board of Directors of our 2023 Annual Operating Plan. Management believes that our \$20.5 million of cash and cash equivalents as of December 31, 2022, together with amounts available under the Facilities, will be sufficient to meet our anticipated cash requirements through at least March 2024.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

This Item 7A is inapplicable to Xtant as a smaller reporting company.

Item 8. Financial Statements and Supplementary Data**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Xtant Medical Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Xtant Medical Holdings, Inc. (the “Company”) as of December 31, 2022 and 2021 and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the years in the two-year period ended December 31, 2022; and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The Company’s management is responsible for these financial statements. 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) (the “PCAOB”) and are required to be independent with respect to the Company in accordance with 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 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 critical audit matters 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 accounts or disclosures to which it relates.

Valuation of Inventory

Critical Audit Matter Description

As explained in Note 1 to the consolidated financial statements, the Company reviews the components of its inventory on a quarterly basis for estimated obsolescence and excess inventory and adjusts inventory to its net realizable value as necessary. Net inventory at December 31, 2022 totaled \$17.3 million.

Auditing management's calculation of estimated excess and obsolete inventory involved a high degree of auditor judgment due to the sensitivity of significant assumptions. Such assumptions include product life cycle, sales forecasts, and timing of competitors introducing new or enhanced products.

The impact of competition and the continuing impact of the COVID-19 pandemic on the sales forecast further increased the difficulty in auditing the reasonableness of management's estimates and assumptions and required a significant amount of audit effort.

How the Critical Audit Matter Was Addressed in the Audit

Our procedures related to management's forecasts of product demand used to record the excess and obsolete inventories reserve included the following, among others:

- Gained an understanding of the Company's internal control over developing its excess and obsolete inventories reserve to identify the types of potential misstatement, assessed the factors that affect the risks of material misstatement, and designed further audit procedures.
- Evaluated the appropriateness and consistency of management's methods and assumptions used in developing their estimate of the excess and obsolete inventory reserve, which included consideration of reserve trends by product category and the impact of changes in inventory management processes on the estimate.
- Evaluated the appropriateness of specified inputs supporting management's estimate, including the age of on-hand inventory items; historic inventory trends; historic write-off activity; and revenue forecasts, including the Company's ability to forecast sales by comparing prior period sales forecasts to actual amounts, taking into consideration the COVID-19 pandemic impact on current and future demand through sensitivity analysis.
- Developed an independent expectation of the excess and obsolete inventory reserve using historical inventory activity and compared our independent expectation to the amount recorded in the financial statements.

/s/ Plante & Moran, PLLC

We have served as the Company's auditor since 2011.

Denver, Colorado

March 7, 2023

XTANT MEDICAL HOLDINGS, INC.
Consolidated Statements of Operations
(In thousands, except number of shares and per share amounts)

	Year Ended December 31,	
	2022	2021
Revenue		
Orthopedic product sales	\$ 57,958	\$ 55,146
Other revenue	11	117
Total Revenue	<u>57,969</u>	<u>55,263</u>
Cost of Sales	<u>25,832</u>	<u>22,773</u>
Gross Profit	32,137	32,490
Operating Expenses		
General and administrative	15,462	14,449
Sales and marketing	22,515	21,025
Research and development	915	870
Total Operating Expenses	<u>38,892</u>	<u>36,344</u>
Loss from Operations	(6,755)	(3,854)
Other Expense		
Interest expense	(1,692)	(995)
Interest income	31	—
Total Other Expense	<u>(1,661)</u>	<u>(995)</u>
Net Loss from Operations Before Provision for Income Taxes	(8,416)	(4,849)
Provision for Income Taxes Current and Deferred	<u>(69)</u>	<u>—</u>
Net Loss	<u>\$ (8,485)</u>	<u>\$ (4,849)</u>
Net loss per share:		
Basic	\$ (0.09)	\$ (0.06)
Dilutive	\$ (0.09)	\$ (0.06)
Shares used in the computation:		
Basic	94,085,197	85,456,175
Dilutive	94,085,197	85,456,175

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.
Consolidated Balance Sheets
(In thousands, except number of shares and par value)

	<u>As of December 31, 2022</u>	<u>As of December 31, 2021</u>
ASSETS		
Current Assets:		
Cash and cash-equivalents	\$ 20,298	\$ 18,243
Restricted cash	209	144
Trade accounts receivable, net of allowance for credit losses of \$515 and \$552, respectively	10,853	7,154
Inventories	17,285	17,945
Prepaid and other current assets	673	844
Total current assets	<u>49,318</u>	<u>44,330</u>
Property and equipment, net	5,785	5,212
Right of use asset, net	1,380	1,258
Other assets	197	287
Intangible assets, net	344	400
Goodwill	<u>3,205</u>	<u>3,205</u>
Total Assets	<u>\$ 60,229</u>	<u>\$ 54,692</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,490	\$ 2,615
Accrued liabilities	5,496	4,349
Current portion of lease liability	458	462
Current portion of finance lease obligations	62	31
Line of credit	3,379	3,620
Current portion of long-term debt	<u>2,333</u>	<u>—</u>
Total current liabilities	<u>15,218</u>	<u>11,077</u>
Long-term Liabilities:		
Lease liability, net	972	842
Financing lease obligations, net	181	103
Long-term debt, plus premium and less issuance costs	<u>9,687</u>	<u>11,787</u>
Total Liabilities	<u>26,058</u>	<u>23,809</u>
Commitments and Contingencies (Note 11)		
Stockholders' Equity:		
Preferred stock, \$0.000001 par value; 10,000,000 shares authorized; no shares issued and outstanding	<u>—</u>	<u>—</u>
Common stock, \$0.000001 par value; 300,000,000 shares authorized; 108,874,803 shares issued and outstanding as of December 31, 2022 and 300,000,000 shares authorized; 87,068,980 shares issued and outstanding as of December 31, 2021	<u>—</u>	<u>—</u>
Additional paid-in capital	277,841	266,068
Accumulated deficit	<u>(243,670)</u>	<u>(235,185)</u>
Total Stockholders' Equity	<u>34,171</u>	<u>30,883</u>
Total Liabilities & Stockholders' Equity	<u>\$ 60,229</u>	<u>\$ 54,692</u>

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.
Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except number of shares)

	Common Stock		Additional Paid-In- Capital		Accumulated Deficit		Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2020	77,573,680	\$ —	\$ 244,850	\$ (230,336)	\$ 14,514		
Private placement of common stock, net of issuance costs of \$1,926	8,888,890	—	12,831	—	12,831		
Warrants issued in connection with the private placement	—	—	5,243	—	5,243		
Warrants issued in connection with the private placement to placement agents	—	—	351	—	351		
Common stock issued on vesting of restricted stock units	782,596	—	—	—	—		
Gain on debt extinguishment	—	—	785	—	785		
Withholding of common stock upon vesting of restricted stock units	(176,186)	—	(201)	—	(201)		
Stock-based compensation	—	—	2,209	—	2,209		
Net loss	—	—	—	(4,849)	(4,849)		
Balance at December 31, 2021	<u>87,068,980</u>	<u>\$ —</u>	<u>\$ 266,068</u>	<u>\$ (235,185)</u>	<u>\$ 30,883</u>		
Private placement of common stock, net of issuance costs of \$436	20,305,429	—	7,681	—	7,681		
Warrants issued in connection with the private placement	—	—	1,628	—	1,628		
Common stock issued on vesting of restricted stock units	1,500,394	—	—	—	—		
Stock-based compensation	—	—	2,464	—	2,464		
Net loss	—	—	—	(8,485)	(8,485)		
Balance at December 31, 2022	<u>108,874,803</u>	<u>\$ —</u>	<u>\$ 277,841</u>	<u>\$ (243,670)</u>	<u>\$ 34,171</u>		

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2022	2021
Operating activities:		
Net loss	\$ (8,485)	\$ (4,849)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,292	1,332
Non-cash interest	233	147
Non-cash rent	4	9
Gain on sale of fixed assets	(93)	(86)
Stock-based compensation	2,464	2,209
Provision for reserve on accounts receivable	243	45
Provision for excess and obsolete inventory	1,812	839
Changes in operating assets and liabilities:		
Trade accounts receivable	(3,941)	(319)
Inventories	(1,152)	2,624
Prepaid and other assets	261	(67)
Accounts payable	875	(332)
Accrued liabilities	1,146	(1,113)
Net cash (used in) provided by operating activities	<u>(5,341)</u>	<u>439</u>
Investing activities:		
Purchases of property and equipment	(1,764)	(2,115)
Proceeds from sale of fixed assets	205	225
Net cash used in investing activities	<u>(1,559)</u>	<u>(1,890)</u>
Financing activities:		
Borrowings on line of credit	54,229	36,361
Repayments on line of credit	(54,470)	(36,492)
Payments on financing leases	(50)	(50)
Proceeds from issuance of common stock, net of issuance costs	9,311	18,426
Payment of taxes from withholding of common stock on vesting of restricted stock units	—	(201)
Costs associated with refinancing	—	(136)
Payments on long-term debt	—	(411)
Net cash provided by financing activities	<u>9,020</u>	<u>17,497</u>
Net change in cash and cash equivalents and restricted cash	2,120	16,046
Cash and cash equivalents and restricted cash at beginning of year	18,387	2,341
Cash and cash equivalents and restricted cash at end of year	<u>\$ 20,507</u>	<u>\$ 18,387</u>
Reconciliation of cash and cash equivalents and restricted cash reported in the consolidated balance sheets		
Cash and cash equivalents	\$ 20,298	\$ 18,243
Restricted cash	209	144
Total cash and cash equivalents and restricted cash reported in the consolidated balance sheets	<u>\$ 20,507</u>	<u>\$ 18,387</u>

See notes to audited consolidated financial statements.

Notes to Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Xtant Medical Holdings, Inc., formerly known as Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiaries, are jointly referred to herein as “Xtant” or the “Company”). The terms “we,” “us” and “our” also refer to Xtant.

All intercompany balances and transactions have been eliminated in consolidation.

Xtant products serve the combined specialized needs of orthopedic and neurological surgeons, including orthobiologics for the promotion of bone healing, implants and instrumentation for the treatment of spinal disease, tissue grafts for the treatment of orthopedic disorders to promote healing following spine, cranial and foot surgeries and the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries.

Since March 2020, the COVID-19 pandemic has caused business closures, severe travel restrictions and implementation of social distancing measures. At the onset of the COVID-19 pandemic, hospitals and other medical facilities cancelled or deferred elective procedures, diverted resources to patients suffering from infections and limited access for non-patients, including our direct and indirect sales representatives. Because of COVID-19, surgeons and their patients have been, and may continue to be, required, or are choosing, to defer procedures in which our products otherwise would be used, and many facilities that specialize in the procedures in which our products otherwise would be used have experienced temporary closures or reduced operating hours. These circumstances have negatively impacted, and may continue to negatively impact, the ability of our employees, independent sales representatives and distributors to effectively market and sell our products, which has had and will likely continue to have a material adverse effect on our revenues.

At December 31, 2022, the Company had cash and cash equivalents of \$20.5 million, and an accumulated deficit of \$243.7 million and has incurred significant losses in the current and prior periods.

Management’s evaluation of going concern was conducted as part of its discussions with the Xtant Board of Directors’ review of the 2023 Annual Operating Plan. Management believes that our \$20.5 million of cash and cash equivalents as of December 31, 2022, together with amounts available under our line of credit, will be sufficient to meet our anticipated cash requirements through at least March 2024.

Investor Rights Agreement

We are party to an Investor Rights Agreement with ROS Acquisition Offshore (“ROS”) and OrbiMed Royalty Opportunities II, LP (“Royalty Opportunities”), which are funds affiliated with OrbiMed Advisors LLC (“OrbiMed”). Under the Investor Rights Agreement, Royalty Opportunities and ROS are permitted to nominate a majority of the directors and designate the chairperson of our Board of Directors at subsequent annual meetings, as long as they maintain an ownership threshold in our Company of at least 40% of our then outstanding common stock (the “Ownership Threshold”). If Royalty Opportunities and ROS are unable to maintain the Ownership Threshold, the Investor Rights Agreement contemplates a reduction of nomination rights commensurate with our ownership interests. In addition, for so long as the Ownership Threshold is met, we must obtain the approval of a majority of our common stock held by Royalty Opportunities and ROS to proceed with the following actions: (i) issue new securities; (ii) incur over \$250,000 of debt in a fiscal year; (iii) sell or transfer over \$250,000 of our assets or businesses or our subsidiaries in a fiscal year; (iv) acquire over \$250,000 of assets or properties in a fiscal year; (v) make capital expenditures over \$125,000 individually, or \$1.5 million in the aggregate during a fiscal year; (vi) approve our annual budget; (vii) hire or terminate our chief executive officer; (viii) appoint or remove the chairperson of our Board of Directors; and (ix) make, loans to, investments in, or purchase, or permit any subsidiary to purchase, any stock or other securities in another entity in excess of \$250,000 in a fiscal year. As long as the Ownership Threshold is met, we may not increase the size of our Board of Directors beyond seven directors without the approval of a majority of the directors nominated by Royalty Opportunities and ROS.

The Investor Rights Agreement grants Royalty Opportunities and ROS the right to purchase from us a pro rata amount of any new securities that we may propose to issue and sell. The Investor Rights Agreement may be terminated (a) upon the mutual written agreement of all the parties, (b) upon our written notice, ROS or Royalty Opportunities if the ownership percentage of our then outstanding common stock of ROS and Royalty Opportunities is less than 10%, or (c) upon written notice of ROS and Royalty Opportunities.

Concentrations and Credit Risk

The Company's accounts receivables are from a variety of health care organizations and distributors throughout the world. No single customer accounted for more than 10% of our revenue or accounts receivable in the fiscal years 2022 or 2021. Management believes that all significant credit risks have been identified at December 31, 2022.

Use of Estimates

The preparation of the financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period. Estimates and assumptions relating to receivables, inventories, goodwill, deferred income tax assets and liabilities, lease obligations and corresponding right-of-use asset, fair value of long-term debt, stock option grants and other equity awards are made at the end of each reporting period by management. Actual results could differ from those estimates.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity date of three months or less to be cash equivalents. Cash equivalents are recorded at cost, which approximates market value. At times, the Company maintains deposits in financial institutions in excess of federally insured limits.

Cash and cash equivalents classified as restricted cash on our condensed consolidated balance sheets are restricted as to withdrawal or use under the terms of certain credit agreements. The December 31, 2022 balance included lockbox deposits that are temporarily restricted due to timing at the period end. The lockbox deposits are applied against our line of credit the next business day.

Trade Accounts Receivable

Accounts receivable represents amounts due from customers for which revenue has been recognized. Normal terms on trade accounts receivable are net 30 days, and some customers are offered discounts for early pay. The Company performs credit evaluations when considered necessary, but generally does not require collateral to extend credit.

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, customers' current creditworthiness, customer concentration, age of accounts receivable balance, general economic conditions that may affect a customer's ability to pay, and management judgment. In addition, we include provision for current expected credit loss based on historical collection experience adjusted for current economic conditions affecting collectability. Actual customer collections could differ from estimates. Account balances are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Provisions to the allowance for doubtful accounts are charged to expense. The Company does not have any off-balance sheet credit exposure related to its customers.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the specific identification method and includes materials, labor and overhead. The Company calculates an inventory reserve for estimated obsolescence and excess inventory based on historical usage and sales, as well as assumptions about future demand for its products. These estimates for excess and obsolete inventory are reviewed and updated on a quarterly basis. Increases in the inventory reserves result in a corresponding expense, which is recorded to cost of sales.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to seven years for computers and equipment and five years for surgical instruments. Leasehold improvements are depreciated over the shorter of their estimated useful life or the remaining term of the lease. Repairs and maintenance are expensed as incurred.

Intangible Assets

Intangible assets with estimable useful lives are amortized over their respective estimated useful lives to their estimated residual values and reviewed for impairment whenever events or circumstances indicate their carrying amount may not be recoverable. Intangible assets include trademarks and patents and include costs to acquire and protect Company patents. Intangible assets are carried at cost less accumulated amortization. The Company amortizes these assets on a straight-line basis over their estimated useful lives.

Other Assets

Other assets consist of the short-term and the long-term portion of prepaid expenses and security deposits.

Long-Lived Asset Impairment

Long-lived assets, including property and equipment and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets.

Goodwill

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a business combination and determined to have indefinite useful lives are not amortized, instead they are tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. The Company conducts its impairment test on an annual basis and reviews the assumptions on a quarterly basis. We test goodwill for impairment at the reporting unit level, which is an operating segment or one level below an operating segment, referred to as a component. A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and segment management regularly reviews the operating results of that component.

Revenue Recognition

In the United States, we generate most of our revenue from independent commissioned sales agents. We consign our orthobiologics products to hospitals and consign or loan our spinal implant sets to the independent sales agents. The spinal implant sets typically contain the instruments, disposables, and spinal implants required to complete a surgery. Consigned sets are managed by the sales agent to service hospitals that are high volume users for multiple procedures. We ship replacement inventory to independent sales agents to replace the consigned inventory used in surgeries. Loaned sets are returned to the Company's distribution center, replenished, and made available to sales agents for the next surgical procedure.

For each surgical procedure, the sales agent reports use of the product by the hospital and, as soon as practicable thereafter, ensures that the hospital provides a purchase order to the Company. Revenue is recognized upon utilization of product.

Additionally, the Company sells product directly to domestic and international stocking resellers, original equipment manufacturer resellers and private label resellers. Upon receipt and acceptance of a purchase order from a stocking reseller, the Company ships product and invoices the reseller. The Company recognizes revenue when the control is transferred upon shipment or upon delivery, based on the contract terms and legal requirements, and the transfer of title and risk of loss occurs. There is generally no customer acceptance or other condition that prevents the Company from recognizing revenue in accordance with the delivery terms for these sales transactions. In the normal course of business, the Company accepts returns of product that have not been implanted. Product returns are not material to the Company's consolidated statements of operations. The Company accounts for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. The Company's policy is to record revenue net of any applicable sales, use, or excise taxes. Payment terms are generally net 30 days from invoice date and some customers are offered discounts for early pay.

Disaggregation of revenue

The Company operates in one reportable segment with its net revenue derived primarily from the sale of orthobiologics and spinal implant products across North America. Sales are reported net of returns. No rebates, group purchasing organization fees or other customer allowances are present, and so are not relevant to net revenue determination. The following table presents revenues from these product lines for the years ended December 31, 2022 and 2021 (dollars in thousands):

	Year Ended December 31, 2022	Percentage of Total Revenue	Year Ended December 31, 2021	Percentage of Total Revenue
Orthobiologics	\$ 47,143	81%	\$ 42,259	77%
Spinal implant	10,815	19%	12,887	23%
Other revenue	11	0%	117	0%
Total revenue	<u>\$ 57,969</u>	<u>100%</u>	<u>\$ 55,263</u>	<u>100%</u>

Research and Development

Research and development costs, which are principally related to internal costs for the development of new products, are expensed as incurred.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net loss per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive shares of common stock outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Our diluted net loss per share is the same as basis earnings per share, as the effects of including 19,160,567 and 13,282,882 outstanding stock options, warrants and restricted stock units for the years ended December 31, 2022 and 2021, respectively, are anti-dilutive.

Fair Value of Financial Instruments

The carrying values of financial instruments, including trade accounts receivable, accounts payable, accrued liabilities and long-term debt, approximate their fair values based on terms and related interest rates.

The Company follows a framework for measuring fair value. The framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets.

Level 2: Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

Level 3: Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. During the years ended December 31, 2022 and 2021, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

(2) Receivables

The Company's provision for current expected credit loss is determined based on historical collection experience adjusted for current economic conditions affecting collectability. Actual customer collections could differ from estimates. Account balances are charged to the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Provisions to the allowance for credit losses are charged to expense. Activity within the allowance for credit losses was as follows for years ended December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Balance at January 1	\$ 552	\$ 653
Provision for current expected credit losses	243	45
Write-offs against allowance	(280)	(146)
	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
	\$ 515	\$ 552

(3) Inventories

Inventories consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	\$ 5,628	\$ 5,613
Work in process	798	571
Finished goods	10,859	11,761
	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
	\$ 17,285	\$ 17,945

(4) Property and Equipment, Net

Property and equipment, net are as follows (in thousands):

	December 31, 2022	December 31, 2021
Equipment	\$ 5,598	\$ 5,094
Computer equipment	1,043	751
Computer software	230	490
Leasehold improvements	4,105	3,849
Surgical instruments	11,266	11,424
Assets not yet in service	1,507	773
Total cost	<u>23,749</u>	<u>22,381</u>
Less: accumulated depreciation	(17,964)	(17,169)
	<u>\$ 5,785</u>	<u>\$ 5,212</u>

Depreciation expense related to property and equipment, including property under finance lease, for the years ended December 31, 2022 and 2021 was \$1.2 million and \$1.3 million, respectively.

(5) Goodwill and Intangible Assets

The results of the Company's annual goodwill impairment tests for the years ended December 31, 2022 and 2021 indicated that no goodwill impairment existed as of the test date.

The following table sets forth information regarding intangible assets (in thousands):

	December 31, 2022	December 31, 2021
Patents	\$ 807	\$ 847
Accumulated amortization	(463)	(447)
Net carrying value	<u>\$ 344</u>	<u>\$ 400</u>

Amortization expense was \$0.1 million for both of the years ended December 31, 2022 and 2021. The following is a summary of estimated future amortization expense for intangible assets as of December 31, 2022 (in thousands):

2023	\$ 54
2024	53
2025	52
2026	45
2027	40
Thereafter	100
Total	<u>\$ 344</u>

(6) Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Wages/commissions payable	\$ 4,464	\$ 3,184
Other accrued liabilities	1,032	1,165
Accrued liabilities	<u>\$ 5,496</u>	<u>\$ 4,349</u>

(7) Debt

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

	December 31, 2022	December 31, 2021
Amounts due under the Term Facility	\$ 12,000	\$ 12,000
Accrued end-of-term payments	216	83
Less: unamortized debt issuance costs	(196)	(296)
Less: current maturities	(2,333)	—
Long-term debt, less issuance costs	<u>\$ 9,687</u>	<u>\$ 11,787</u>

On May 6, 2021, the Company, as guarantor, and our subsidiaries, as borrowers (collectively, the “Borrowers”), entered into a Credit, Security and Guaranty Agreement (Term Loan) (the “Term Credit Agreement”) and Credit, Security and Guaranty Agreement (Revolving Loan) (the “Revolving Credit Agreement” and, together with the Term Credit Agreement, the “Credit Agreements”) with MidCap Financial Trust, in its capacity as agent (“MidCap”).

The Term Credit Agreement provides for a secured term loan facility (the “Term Facility”) in an aggregate principal amount of \$12.0 million (the “Term Loan Commitment”), which was funded to the Borrowers immediately, and an additional \$5.0 million tranche available solely at the discretion of MidCap and the lenders, for the purposes agreed to between the Company, the Borrowers and the lenders in advance of the making of loans under such additional tranche. The Revolving Credit Agreement provides for a secured revolving credit facility (the “Revolving Facility,” and, together with the Term Facility, the “Facilities”) under which the Borrowers may borrow up to \$8.0 million (such amount, the “Revolving Loan Commitment”) at any one time, the availability of which is determined based on a borrowing base equal to percentages of certain accounts receivable and inventory of the Borrowers in accordance with a formula set forth in the Revolving Credit Agreement. All borrowings under the Revolving Facility are subject to the satisfaction of customary conditions, including the absence of default, the accuracy of representations and warranties in all material respects and the delivery of an updated borrowing base certificate.

The Facilities have a maturity date of May 1, 2026 (the “Maturity Date”). Beginning in June 2023, the Company is required to make monthly principal payments of approximately \$0.3 million on the Term Facility through the Maturity Date. Each of the Borrowers, and the Company, as guarantor, are jointly and severally liable for all of the obligations under the Facilities on the terms set forth in the Credit Agreements. The Borrowers’ obligations, and the Company’s obligations as a guarantor, under the Credit Agreements are secured by first-priority liens on substantially all of their assets, including, without limitation, all inventory, equipment, accounts, intellectual property and other assets of the Company and the Borrowers.

The proceeds of the Term Facility and Revolving Facility were used to pay transaction fees in connection with the Facilities and to pay in full all outstanding indebtedness and accrued interest under the Company’s prior credit facility, which is described below. As of December 31, 2022, the Company had \$3.4 million outstanding and \$4.6 million of availability under the Revolving Facility. On October 27, 2022, the Credit Agreements were amended to transition the reference rate from LIBOR to term SOFR. The term SOFR reference rate was applied to amounts outstanding and draws that took place on or after the November 1, 2022.

The loans and other obligations pursuant to the Credit Agreements bear interest at a per annum rate equal to the sum of the SOFR rate, as such term is defined in the Credit Agreements, plus 0.11%, plus the applicable margin of 7.00% in the case of the Term Credit Agreement, and 4.50% in the case of the Revolving Credit Agreement, subject in each case to a floor of 1.00%. As of December 31, 2022, the effective rate of the Term Facility, inclusive of amortization of debt issuance costs and accretion of the final payment, was 13.20%, and the effective rate of the Revolving Facility was 8.74%.

The Credit Agreements contain affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants that, among other things, limit or restrict the ability of the Borrowers, subject to negotiated exceptions, to incur additional indebtedness and additional liens on their assets, engage in mergers or acquisitions or dispose of assets, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. In addition, the Credit Agreements require the Borrowers and the Company to maintain net product revenue at or above minimum levels and to maintain a minimum adjusted EBITDA and a minimum liquidity, in each case at levels specified in the Credit Agreements.

On March 7, 2022, the Credit Agreements were amended to, among other things, (i) provide for a waiver of compliance with respect to the Company's minimum adjusted EBITDA requirement if and so long as the Company's liquidity (as specifically defined in the Credit Agreements) is in excess of \$14 million and there is not otherwise an event of default under the Credit Agreements, commencing with the next delivery of the compliance certificate required under the Credit Agreements, and (ii) re-set the date certain fees payable in connection with optional prepayments are determined to the date the amendment was executed and consequently extend such fees' original expiration. In addition, the exit fees were increased by 25 basis points to 4.00% of the principal amount borrowed under the Term Facility. As of December 31, 2022, we were in compliance with all covenants under the Credit Agreements.

On February 28, 2023, in connection with the acquisition of Surgalign SPV, Inc. ("Surgalign SPV"), as described in Note 17, "*Subsequent Events*," the Term Credit Agreement was amended pursuant to an Amendment No. 3 to Credit, Security and Guarantee Agreement (Term Loan) ("Term Amendment No. 3") to provide approximately \$5.0 of funding for such acquisition. In addition to the Term Amendment No. 3., we entered into an Amendment No. 3 to Credit, Security and Guarantee Agreement (Revolving Loan) (together with the Term Amendment No. 3, the "Amendments No. 3"), which amends the Revolving Credit Agreement. Additionally, the Amendments No. 3 (i) re-set the date certain fees payable in connection with optional prepayments under the Term Credit Agreement and the Revolving Credit Agreement are determined to the date the amendments were executed and consequently extended such fees' original expiration and (ii) increased the minimum amount of interest payable under the Term Credit Agreement and the Revolving Credit Agreement from 1% to 2.5%.

On May 6, 2021, contemporaneously with the execution and delivery of the Credit Agreements, that certain Second Amended and Restated Credit Agreement (the "Second A&R Credit Agreement"), dated March 29, 2019, among the Company, the Borrowers, Royalty Opportunities and ROS, as subsequently amended, which was scheduled to mature on December 31, 2021, was terminated in accordance with the terms thereof and all outstanding amounts were repaid by the Borrowers to OrbiMed Royalty Opportunities II, LP in its role as sole lender thereunder.

(8) Equity

Private Placement

2022 Private Placement

On August 25, 2022, the Company closed the first tranche of a private placement (the "First Closing") with several accredited investors (the "Private Placement"). At the First Closing, the Company sold approximately 14.1 million shares of common stock of the Company and warrants to purchase approximately 3.5 million shares of common stock for an aggregate purchase price of approximately \$6.75 million. We received net cash proceeds of approximately \$6.3 million, after deducting fees and other offering expenses, from the First Closing.

The closing of the second tranche of the Private Placement (the "Second Closing") occurred on October 7, 2022. At the Second Closing, the Company sold an additional approximately 6.2 million shares of common stock of the Company and warrants to purchase approximately 1.6 million shares of common stock for an aggregate purchase price of approximately \$3.0 million.

The warrants, described in more detail in *Note (10), Warrants*, have an exercise price of \$0.48 per share, are subject to customary anti-dilution, but not price protection, adjustments, are immediately exercisable and expire on the five-year anniversary of the First Closing.

2021 Private Placement

On February 24, 2021, we issued in a private placement (the “2021 Private Placement”) to a single healthcare-focused institutional accredited investor (the “Investor”) 8,888,890 shares of our common stock at a purchase price of \$2.25 per share, and warrants to purchase up to 6,666,668 shares of our common stock (the “Investor Warrant”). We received net cash proceeds of approximately \$18.4 million, after deducting fees and other offering expenses, from the 2021 Private Placement.

The Investor Warrant, described in more detail in *Note (10), Warrants*, has an exercise price of \$2.25 per share, subject to customary anti-dilution, but not price protection, adjustments, is immediately exercisable and expires on the five-year anniversary of the date of issuance.

In connection with the 2021 Private Placement, we entered into a placement agent agreement with a placement agent (the “Placement Agent”) pursuant to which the Placement Agent served as our exclusive placement agent in connection with the Private Placement (the “Placement Agent Agreement”). Pursuant to the Placement Agent Agreement, we agreed to pay the Placement Agent a fee equal to a certain percentage of the aggregate gross proceeds from the 2021 Private Placement. In addition to the cash fee, we agreed to issue to the Placement Agent a warrant to purchase up to 5.0% of the shares sold to the Investor in the 2021 Private Placement, or 444,444 shares of our common stock (the “Placement Agent Warrant”). The Placement Agent Warrant, described in more detail in *Note (10), Warrants*, has an exercise price of \$2.8125 per share, subject to customary anti-dilution, but not price protection, adjustments, is immediately exercisable and expires on the five-year anniversary of the date of issuance.

(9) Stock-Based Compensation

Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan

On August 1, 2018, our stockholders approved the Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan at the 2018 annual meeting of stockholders of Xtant and on October 30, 2019 at our 2019 annual meeting of stockholders, our stockholders approved an amendment to increase the number of shares of common stock available thereunder by 1,500,000 shares. On October 27, 2020, at our 2020 annual meeting of stockholders, our stockholders approved an amendment to increase the number of shares of our common stock available for issuance under the 2018 Plan by an additional 5,550,308 shares. On October 26, 2022, at our 2022 annual meeting of stockholders, our stockholders approved an amendment to increase the number of shares of our common stock available for issuance under the 2018 Plan by an additional 8,500,000 shares (as amended, the “2018 Plan”). The 2018 Plan became effective immediately upon initial approval of the plan by our stockholders on August 1, 2018 and will expire on July 31, 2028, unless terminated earlier. The 2018 Plan replaced the Amended and Restated Xtant Medical Equity Incentive Plan (the “Prior Plan”) with respect to future grants of equity awards, although the Prior Plan continues to govern equity awards granted under the Prior Plan. The 2018 Plan permits the Board, or a committee thereof, to grant to eligible employees, non-employee directors, and consultants of the Company non-statutory and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, deferred stock units, performance awards, non-employee director awards, and other stock-based awards. The Board may select 2018 Plan participants and determine the nature and amount of awards to be granted. Subject to adjustment as provided in the 2018 Plan, the number of shares of our common stock available for issuance under the 2018 Plan is 16,858,055 shares, of which 7,443,895 shares remained available for grant as of December 31, 2022. Under the 2018 Plan, shares of our common stock related to awards granted under the plan that terminate by expiration, forfeiture, cancellation, or otherwise without the issuance of the shares become available again for grant under the plan.

Stock options granted under the 2018 Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The exercise price of all stock options granted under the 2018 Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. The 2018 Plan is administered by the Board. Stock options granted under the 2018 Plan are generally not transferable, vest in installments over the requisite service period, and are exercisable during the stated contractual term of the option only by the optionee.

Stock option activity, including options granted under the 2018 Plan and the Prior Plan was as follows:

	2022			2021		
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contract Term (years)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contract Term (years)
Outstanding at January 1	3,201,666	\$ 1.80		2,190,892	\$ 2.25	
Granted	602,123	0.64		1,012,083	1.27	
Cancelled or expired	(443,125)	2.39		(1,309)	345.82	
Outstanding at December 31	3,360,664	\$ 1.51	8.19	3,201,666	\$ 1.80	8.89
Exercisable at December 31	1,314,560	\$ 2.03	7.67	649,042	\$ 3.36	8.31

As of December 31, 2022, total compensation expense related to unvested employee stock options not yet recognized was \$1.8 million, which is expected to be allocated to expenses over a weighted-average period of 2.4 years. The weighted average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was \$0.55 and \$1.07, respectively. The estimated fair value of stock options granted is determined using the Black-Scholes-Merton method applied to individual grants. Key assumptions used to estimate the fair value of stock awards are as follows:

	Year Ended December 31,	
	2022	2021
Risk free interest rate	3.5%	0.97%
Dividend yield	0%	0%
Expected term	6.3 years	6.3 years
Expected volatility	112%	113%

Restricted stock unit activity for awards granted under the 2018 Plan was as follows:

	2022			2021		
	Shares	Weighted Average Fair Value at Grant Date Per Share		Shares	Weighted Average Fair Value at Grant Date Per Share	
		Share	Date Per Share		Share	Date Per Share
Outstanding at January 1	2,970,104	\$	1.39	2,503,698	\$	1.54
Granted	2,461,528	\$	0.55	1,249,002	\$	1.27
Vested	(1,500,394)	\$	1.26	(782,596)	\$	1.72
Cancelled	(318,805)	\$	1.32	—	\$	—
Outstanding at December 31	3,612,433	\$	0.88	2,970,104	\$	1.39

Total stock-based compensation expense recognized for employees and directors was \$2.5 million and \$2.2 million for the years ended December 31, 2022 and 2021, respectively, and was recognized as general and administrative expense. Total compensation expense related to unvested restricted stock units not yet recognized was \$2.7 million as of December 31, 2022, which is expected to be allocated to expenses over a weighted-average period of 2.2 years.

(10) Warrants

2022 Warrants

As noted in Note 8, “*Equity*,” on August 25, 2022, the Company issued warrants to purchase approximately 3.5 million shares of common stock. The Warrants meet all the requirements to be classified as equity awards in accordance with Accounting Standards Codification (“ASC”) No. 815-40. The number of shares of Company common stock issuable upon exercise of the Warrants is subject to standard and customary anti-dilution provisions for stock splits, stock dividends, or similar transactions. In addition, the Warrants include a buy-out right whereby the holders of such warrants may put the warrants back to the Company or its successor in the event of a purchase, tender or exchange offer accepted by 50% or more of the Company’s holders of common stock and not approved by the Company’s board of directors. The buy-out amount is equal to the Black-Scholes value of the warrants on the date the triggering transaction is consummated based on certain inputs as defined in the Warrant agreement. The consideration to be paid if the buy-out provision is triggered shall be in the same type or form of consideration that is being offered and paid to the holders of Company common stock in connection with the triggering transaction.

While the Warrants are classified as a component of equity, we were required to allocate the proceeds of the Private Placement between the shares of common stock and the Warrants issued based on their relative fair values. The fair value of the Warrants, \$0.47 per warrant, issued in connection with the Private Placement was determined using a Black Scholes model. Significant assumptions in the model included contractual term (5 years) and the estimated volatility factor of the Company’s stock (107%).

2021 Warrants

As noted in Note 8, “*Equity*,” on February 22, 2021, the Company issued the Investor Warrants and Placement Agent Warrants. The Investor and Placement Agent Warrants meet all the requirements to be classified as equity awards in accordance with ASC\ No. 815-40. The number of shares of Company common stock issuable upon exercise of the Investor Warrants and Placement Agent Warrants is subject to standard and customary anti-dilution provisions for stock splits, stock dividends, or similar transactions. In addition, the Investor Warrants include a buy-out right whereby the holders of such warrants may put the warrants back to the Company or its successor in the event of a purchase, tender or exchange offer accepted by 50% or more of the Company’s holders of common stock and not approved by the Company’s board of directors. The buy-out amount is equal to the Black-Scholes value of the warrants on the date the triggering transaction is consummated based on certain inputs as defined in the Investor Warrant agreement. The consideration to be paid if the buy-out provision is triggered shall be in the same type or form of consideration that is being offered and paid to the holders of Company common stock in connection with the triggering transaction.

While the Investor Warrants are classified as a component of equity, we were required to allocate the proceeds of the 2021 Private Placement between the shares of common stock and Investor Warrants issued based on their relative fair values. We utilized a lattice valuation model to determine the fair value of the Investor Warrants. The fair value of the Placement Agent Warrants issued in connection with the 2021 Private Placement was determined using a Black Scholes model. Significant assumptions in both models included contractual term (5 years) and the estimated volatility factor based on a weighted average of comparable published betas of peer companies (61%).

The following table summarizes our warrant activities for the years ended December 31, 2022 and 2021:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding as of January 1, 2021	421,278	\$ 10.80
Issued	7,111,112	2.29
Expired	(421,278)	10.80
Outstanding as of December 31, 2021	7,111,112	\$ 2.29
Issued	5,076,358	0.48
Outstanding as of December 31, 2022	12,187,470	\$ 1.53

(11) Commitments and Contingencies

Operating Leases

We currently lease three office facilities. These leases are under non-cancelable operating lease agreements with expiration dates in 2025. We have the option to extend certain leases to five or ten-year term(s) and we have the right of first refusal on any sale.

The Company records lease liabilities within current liabilities or long-term liabilities based upon the length of time associated with the lease payments. The Company records its long-term operating leases as right-of-use assets. Upon initial adoption, using the modified retrospective transition approach, no leases with terms less than 12 months have been capitalized to the consolidated balance sheet consistent with ASC 842. Instead, these leases are recognized in the consolidated statement of operations on a straight-line expense throughout the lives of the leases. No Company leases contain common area maintenance or security agreements.

We have made certain assumptions and judgments when applying ASC 842, the most significant of which is that we elected the package of practical expedients available for transition, which allow us to not reassess whether expired or existing contracts contain leases under the new definition of a lease, lease classification for expired or existing leases, and whether previously capitalized initial direct costs would qualify for capitalization under ASC 842. Additionally, we did not elect to use hindsight when considering judgments and estimates such as assessments of lessee options to extend or terminate a lease or purchase the underlying asset.

As of December 31, 2022, the weighted-average remaining lease term was 2.8 years. Lease expense related to operating leases was \$0.6 million for both of the years ended December 31, 2022 and 2021. The Company's lease agreements do not provide a readily determinable implicit rate nor is it available to the Company from its lessors. Instead, during the year ended December 31, 2022, the Company estimates the weighted-average discount rate for its operating leases to be between 5.64% and 7.05% to discount future cash flows to present value based on the incremental borrowing rate.

Future minimum payments as of December 31, 2022 under these long-term operating leases are as follows (in thousands):

2023	\$ 534
2024	559
2025	470
Total future minimum lease payments	1,563
Less: amount representing interest	(133)
Present value of obligations under operating leases	1,430
Less: current portion	(458)
Long-term operating lease obligations	\$ 972

Litigation

We may be subject to potential liabilities under government regulations and various claims and legal actions that are pending but we believe are immaterial at this time or may be asserted in the future from time to time.

These matters arise in the ordinary course and conduct of our business and may include, for example, commercial, product liability, intellectual property, and employment matters. We intend to continue to defend the Company vigorously in such matters and when warranted, take legal action against others. Furthermore, we regularly assess contingencies to determine the degree of probability and range of possible loss for potential accrual in our financial statements. An estimated loss contingency is accrued in our financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Based on our assessment, we have adequately accrued an amount for contingent liabilities currently in existence. We do not accrue amounts for liabilities that we do not believe are probable or that we consider immaterial to our overall financial position. Litigation is inherently unpredictable, and unfavorable resolutions could occur. As a result, assessing contingencies is highly subjective and requires judgment about future events. The amount of ultimate loss may exceed the Company's current accruals, and it is possible that its cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies.

Indemnifications

Our indemnification arrangements generally include limited warranties and certain provisions for indemnifying customers against liabilities if our products or services infringe a third-party's intellectual property rights. To date, we have not incurred any material costs as a result of such warranties or indemnification provisions and have not accrued any liabilities related to such obligations in the accompanying consolidated financial statements.

We have also agreed to indemnify our directors and executive officers for costs associated with any fees, expenses, judgments, fines, and settlement amounts incurred by any of these persons in any action or proceeding to which any of those persons is, or is threatened to be, made a party by reason of the person's service as a director or officer, including any action by us, arising out of that person's services as our director or officer or that person's services provided to any other company or enterprise at our request.

(12) Income Taxes

The Company's provision for income taxes differs from applying the statutory U.S. Federal income tax rate to income before taxes. The primary difference results from providing for state income taxes and from deducting certain expenses for financial statement purposes but not for federal income tax purposes.

The components of income (loss) before provision for income taxes consist of the following (in thousands):

	Year Ended December 31,	
	2022	2021
United States	\$ (8,416)	\$ (4,849)
Total	\$ (8,416)	\$ (4,849)

The components of the income tax provision are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Current:		
Federal	\$ —	\$ (51)
State	69	51
Total current	—	—
Deferred:		
Federal	—	—
State	—	—
Total deferred	—	—
Total provision for income taxes	\$ 69	\$ —

The reconciliation of income tax attributable to operations computed at the U.S. Federal statutory income tax rate of 21% to income tax expense is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Statutory Federal tax rate	\$ (1,767)	\$ (1,018)
Valuation allowance	1,510	315
State income taxes, net of Federal benefit	(323)	(110)
Attribute reduction related to Sec. 382	—	—
Change in state income tax rate	(22)	(33)
Gain on extinguishment of debt	—	165
Stock compensation adjustment and other reconciling items	640	557
Nondeductible executive compensation	31	124
Nondeductible meals and entertainment expense	—	—
 Total provision for income taxes	\$ 69	\$ —

Deferred tax components are as follows (in thousands):

	At December 31,	
	2022	2021
Deferred tax assets:		
Accrued liability for vacation	\$ 78	\$ 130
Accrued commissions and bonuses / compensation	320	284
Accrued contingencies	55	52
Amortization	22	27
Bad debt reserve	139	148
Capitalized R&D expenses	287	—
Charitable contributions carryforward	15	15
Lease liability	385	350
Interest expense	2,391	1,968
Inventory reserve	3,059	2,777
Net operating loss carryovers	13,721	13,164
Stock option compensation	677	783
UNICAP	76	74
Other	55	113
Total deferred tax assets	21,280	19,811
Deferred tax liabilities:		
Right of use asset	(372)	(338)
Prepays	(56)	(83)
Depreciation	(62)	(111)
Total deferred tax liabilities	(490)	(532)
 Valuation allowance	(20,790)	(19,279)
 Net deferred tax assets	\$ —	\$ —

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management does not believe it is more likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a valuation allowance equal to the net realizable deferred tax assets. The valuation allowance increased by \$1,510,691 in 2022 and by \$314,706 in 2021.

At December 31, 2022 and 2021, the Company had total domestic Federal and state net operating loss carryovers of approximately \$104.8 million and \$101.8 million, respectively. Federal net operating losses generated prior to 2018 and State net operating loss carryovers expire at various dates between 2023 and 2042. Federal net operating losses generated after 2017 have an indefinite carryforward and are only available to offset 80% taxable income beginning in 2021.

The Company has completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from the Company's formation through December 31, 2022. Based upon this study, the Company determined that an ownership change occurred during 2018. Accordingly, the Company reduced its deferred tax assets related to the federal NOL carryforwards that are anticipated to expire unused as a result of these ownership changes. These tax attributes were excluded from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate. Future ownership changes may further limit the Company's ability to utilize its remaining tax attributes. The 2019 through 2021 tax years remain open to examination by the Internal Revenue Service and various other state tax agencies. These taxing authorities have the authority to examine those tax years until the applicable statute of limitations expire.

The 2019 through 2021 tax years remain open to examination by the Internal Revenue Service and various other state tax agencies. These taxing authorities have the authority to examine those tax years until the applicable statute of limitations expire.

The Company did not recognize any material interest or penalties related to income taxes for the years ended December 31, 2022 and 2021.

(13) Employee Benefit Plans

We have a 401(k) plan for our employees. The 401(k) plan is a defined contribution plan covering substantially all of our employees. Employees are eligible to participate in the plan on the first day of any month after starting employment. Employees are allowed to contribute a percentage of their wages to the 401(k) plan, subject to statutorily prescribed limits and are subject to a discretionary employer match of 100% of their wage deferrals not in excess of 4% of their wages. The Company contributed \$0.4 million and \$0.3 million as part of the employer match program for the years ended December 31, 2022 and 2021, respectively.

(14) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
<i>Cash paid during the period for:</i>		
Interest	\$ 1,454	\$ 846
<i>Non-cash activities:</i>		
Fixed assets acquired under finance lease	\$ 159	\$ 163
Revaluation of lease liability and right of use asset	\$ 234	\$ —
Gain on extinguishment of Second A&R Credit Agreement	\$ —	\$ 785
Extinguishment of Second A&R Credit Agreement financed by line of credit	\$ —	\$ 3,755
Prepaid debt issuance costs	\$ —	\$ 75
Warrants issued in connection with the 2021 Private Placement to placement agents	\$ —	\$ 351

(15) Related Party Transactions

Royalty Opportunities, which owns approximately 16% of the Company's outstanding common stock, was the sole holder of our outstanding long-term debt and a party to the Second A&R Credit Agreement, which was terminated in connection with our debt refinancing described under Note 8, "Debt". In addition, as described in more detail under Note 1, "Business Description and Summary of Significant Accounting Policies," we are party to an Investor Rights Agreement and Registration Rights Agreement with Royalty Opportunities and ROS. Transactions between the Company and Royalty Opportunities and ROS are conducted under the provisions of the Second A&R Credit Agreement, the Prior Credit Agreement, the Investor Rights Agreement, and the Registration Rights Agreement, as noted above.

The Company was party to a Sublease Agreement wherein the Company leased from Cardialen, Inc., a portion of Cardialen's office space on a month-to-month. The rent was approximately \$1,000 per month. The agreement was terminated effective September 30, 2021. Because Jeffrey Peters was both a member of our Board of Directors and the Chief Executive Officer, President, and a director of Cardialen, this transaction qualified as a related party transaction.

All related party transactions are reviewed and approved by the Audit Committee or the disinterested members of the full Board.

(16) Segment and Geographic Information

The Company's management reviews our financial results and manages the business on an aggregate basis. Therefore, financial results are reported in a single operating segment: the development, manufacture and marketing of orthopedic medical products and devices.

The Company attributes revenues to geographic areas based on the location of the customer. Approximately 99% of revenue was in the United States for the years ended December 31, 2022 and 2021. Total revenue by major geographic area is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
United States	\$ 57,162	\$ 54,570
Rest of World	807	693
Total	\$ 57,969	\$ 55,263

(17) Subsequent Events

Acquisition of Coflex and CoFix Product Lines

On February 28, 2023, we entered into an Equity Purchase Agreement (the "Equity Purchase Agreement") with Surgalign SPV, a Delaware corporation and wholly owned subsidiary of Surgalign Spine Technologies, Inc., a Delaware corporation ("Seller"), Seller and Surgalign Holdings, Inc., a Delaware corporation, pursuant to which we purchased all of the issued and outstanding shares of common stock of Surgalign SPV, which shares constitute all of the outstanding equity of Surgalign SPV, for an aggregate purchase price of \$17.0 million in cash (the "Purchase Price"). The closing contemplated by the Equity Purchase Agreement occurred on February 28, 2023 (the "Closing").

Immediately prior to the Closing, Seller and its affiliates transferred and assigned to Surgalign SPV, a privately held, newly formed entity, certain intellectual property, contractual rights and other assets related to the design, manufacture, sale and distribution of its Coflex and CoFix products in the United States (the "Coflex Business"). The Coflex and CoFix products have been approved by the U.S. Food and Drug Administration for the treatment of moderate to severe lumbar spinal stenosis in conjunction with decompression and provide minimally invasive, motion preserving stabilization.

In conjunction with the Equity Purchase Agreement, on February 28, 2023, we entered into a Transition Services Agreement with Surgalign SVP and Seller, whereby Seller agreed to provide, or cause to be provided, to us on and after the effective date of the Equity Purchase Agreement, after giving effect to the Closing, certain transitional services related to the transition of the Coflex Business.

We funded the Purchase Price with cash on hand and approximately \$5.0 million of indebtedness incurred under our Term Credit Agreement, which was amended on February 28, 2023 pursuant to an Amendment No. 3 to Credit, Security and Guarantee Agreement (Term Loan) ("Term Amendment No. 3") to provide such funding. In addition to the Term Amendment No. 3, we entered into an Amendment No. 3 to Credit, Security and Guarantee Agreement (Revolving Loan) ("Revolving Amendment No. 3" and, together with the Term Amendment No. 3, the "Amendments No. 3"), which amends the Revolving Credit Agreement. Additionally, the Amendments No. 3 (i) re-set the date certain fees payable in connection with optional prepayments under the Term Credit Agreement and the Revolving Credit Agreement are determined to the date the amendments were executed and consequently extended such fees' original expiration and (ii) increased the minimum amount of interest payable under the Term Credit Agreement and the Revolving Credit Agreement from 1% to 2.5%.

We recorded the purchase of this acquisition using the acquisition method of accounting and, accordingly, recognized the assets acquired at their fair values as of the date of acquisition. No liabilities were assumed in connection with the acquisition. Because the Closing occurred on February 28, 2023, information necessary to complete the purchase accounting is not yet available.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management with the participation of our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2022. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2022, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior and executive management, we conducted an evaluation of our internal control over financial reporting based upon the framework Internal Control - Integrated Framework (2013) as outlined by COSO, the Committee of Sponsoring Organizations of the Treadway Commission. Our 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 accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of an evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Based on our evaluation under the framework Internal Control - Integrated Framework (2013), management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the fourth quarter ended December 31, 2022 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The table below sets forth certain information concerning our current directors and executive officers as of February 24, 2023. No family relationships exist among our directors or executive officers. We sometimes refer to the Board of Directors of Xtant as the “Board.”

Name	Age	Position	Director/Officer Since
Stavros Vizirgianakis	52	Chairman of the Board and Director	2022
Sean E. Browne	57	President and Chief Executive Officer and Director	2019
John Bakewell ⁽¹⁾	61	Director	2018
Michael Eggenberg ⁽²⁾	53	Director	2018
Robert McNamara ⁽¹⁾⁽²⁾	66	Director	2018
Matthew Rizzo ⁽²⁾	50	Director	2018
Kevin D. Brandt	57	Chief Commercial Officer	2018
Scott C. Neils	38	Chief Financial Officer	2022
Mark A. Schallenberger	37	Chief Operations Officer	2023

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

The business experience of each director and executive officer is summarized below.

Stavros Vizirgianakis has served as a member of our Board since August 2022. Mr. Vizirgianakis was elected to the Board in connection with our private placement in August 2022. Mr. Vizirgianakis is the former Chief Executive Officer of Misonix, Inc., a medical device company that Bioventus Inc. acquired in 2021. Mr. Vizirgianakis has a distinguished career in the medical devices field having worked for United States Surgical Corporation as director of sales for sub-Saharan Africa and later Tyco Healthcare in the capacity of General Manager South Africa. In 2006, Mr. Vizirgianakis co-founded Surgical Innovations, which has become one of the largest privately owned medical device distributors in the African region, and now part of the Johannesburg Stock Exchange listed entity Ascendis Health. Mr. Vizirgianakis was Managing Director of Ascendis Medical from January 2014 through July 2016. Mr. Vizirgianakis served as the President and Chief Executive Officer of Misonix from September 2016 through October 2021. He also served on the board of Bioventus Inc. and Tenaxis Medical and is a strategic investor and advisor to numerous medical device startups and established companies in this field. Mr. Vizirgianakis has a Degree in Commerce from the University of South Africa. Mr. Vizirgianakis’s extensive experience as a senior executive of a publicly traded medical technology company, as well as his experience serving on the board of directors of other companies contributes valuable experience to our Board.

Sean E. Browne has served as our President and Chief Executive Officer since October 2019 and as a member of our Board since October 2019. Prior to this, Mr. Browne served as Chief Revenue Officer of CCS Medical, Inc., a provider of home delivery medical supplies, from September 2014 to June 2019. Prior to CCS Medical, Mr. Browne served as Chief Operating Officer of The Kini Group, an integrated cloud-based software analytics and advisory firm, from March 2013 to August 2014. From November 2007 to March 2016, Mr. Browne served as President and Chief Executive Officer and a director of Neuro Resource Group, a venture start-up medical device company that was sold to a strategic buyer. In other roles, Mr. Browne served as President, Miltex Surgical Instrument Division for Integra LifeSciences Holdings Corporation, a publicly held medical device company that acquired Miltex Holdings, Inc. Mr. Browne served as Vice President, Sales and Marketing of Esurg.com, an e-commerce company serving physician and ambulatory surgery markets. Prior to Esurg.com, Mr. Browne served as Senior Vice President, Health Systems Division of McKesson Corporation, a drug company, and prior to McKesson, served in various positions with increasing responsibility at Baxter Healthcare. Mr. Browne holds a Masters of Business Administration from the Kellogg School of Management at Northwestern University and a Bachelor of Science degree, with a major in Finance and minor in Statistics, from Boston University. We believe that Mr. Browne’s day-to-day operations experience as a result of his role as our President and Chief Executive Officer enable him to make valuable contributions to the Board of Directors. In addition, in his role as President and Chief Executive Officer, Mr. Browne provides unique insight into our business strategies, opportunities and challenges, and serves as the unifying element between the leadership and strategic direction provided by the Board of Directors and the implementation of our business strategies by management.

John Bakewell has served as a member of our Board since February 2018. He was initially elected to the Board in connection with our restructuring in February 2018. Mr. Bakewell is a strategic executive with more than 30 years of experience in senior executive roles and as a board member of several medical technology companies. He serves on the board of directors of Treace Medical Concepts, Inc. (NASDAQ: TMCI) and Neuronetics, Inc. (NASDAQ: STIM), both medical device companies, and Impulse Dynamics, Plc., a privately held medical device company. Mr. Bakewell most recently held the position of Chief Financial Officer of Exact Sciences Corporation (NASDAQ: EXAS), a molecular diagnostics company, and previously Chief Financial Officer of Lantheus Holdings, Inc. (NASDAQ: LNTH), a diagnostic medical imaging company. Mr. Bakewell has also served in Chief Financial Officer positions at Interline Brands, Inc., RegionalCare Hospital Partners, Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020, Cyberonics, Inc., now part of LivaNova PLC (NASDAQ: LIVN), Altra Energy Technologies, Inc. and ZEOS International, Ltd. He began his career in the public accounting profession, serving seven years, collectively, with Ernst & Young and KPMG Peat Marwick. Mr. Bakewell previously served on the board of directors of Entellus Medical, Inc., a public ENT-focused medical device company, until its acquisition by Stryker Corp.; ev3 Inc., a public endovascular medical device company, until its acquisition by Covidien plc; Keystone Dental, Inc., a private dental implant medical device company; and Corindus Vascular Robotics, Inc., a public cardiovascular robotics medical technology company and now a Siemens Healthineers company. Mr. Bakewell holds a Bachelor of Arts in Accounting from the University of Northern Iowa and is a certified public accountant (current status inactive). Mr. Bakewell's financial expertise and extensive managerial experience as a senior executive of several publicly traded medical technology companies, as well as his experience serving on the board of directors of other companies contributes valuable experience to our Board.

Michael Eggenberg has served as a member of our Board since February 2018. Mr. Eggenberg was initially elected to the Board in connection with our restructuring in February 2018. Mr. Eggenberg is a designee of Royalty Opportunities and ROS under the Investor Rights Agreement. Since December 2016, Mr. Eggenberg has been a Managing Director with OrbiMed Advisors LLC, a private equity and venture capital firm, focusing on healthcare royalty and structured finance investments. From May 2005 to December 2016, Mr. Eggenberg was with Fortress Investment Group LLC, a global investment manager, most recently as a Managing Director focused on special opportunities funds. Mr. Eggenberg previously held positions at CIT Group Inc., Wells Fargo Bank, N.A. and Bank of America, formerly NationsBank. Mr. Eggenberg received his BS in Finance and General Business from Drexel University. Mr. Eggenberg brings valuable experience in the life science industry and finance experience to the Board.

Robert McNamara has served as a member of our Board since February 2018. He has over 25 years experience in the medical device industry. Mr. McNamara was initially elected to the Board in connection with our restructuring in February 2018. He also serves as Audit Committee Chairman of Axonics, Inc. (AXNX) and as a board member of Alpha Teknova, Inc. (TKNO). From January 2013 to July 2016, Mr. McNamara served as Executive Vice President and from April 2012 to July 2016 as the Chief Financial Officer for LDR Holding Corporation, a publicly held medical device (spinal implants) company acquired by Zimmer Biomet Holdings, Inc. In addition, Mr. McNamara has previously served as the Senior Vice President and Chief Financial Officer for publicly traded medical device companies including Accuray Inc., a stereotactic radiation company focused on treating cancer using AI robotics, Somnus Medical Technologies Inc., a RF energy company focused on treating upper airway breathing disorders, and Target Therapeutics, Inc., a minimally invasive catheter and device company treating vascular diseases of the brain. Mr. McNamara has been a member of the board of directors of Northstar Neurosciences Inc. and is the former Mayor of Menlo Park, California. Mr. McNamara began his career in public accounting and is a certified public accountant (current status inactive). Mr. McNamara holds a Bachelor of Science in Accounting from the University of San Francisco and a Masters of Business Administration in Finance from The Wharton School at the University of Pennsylvania. Mr. McNamara brings valuable finance and accounting experience in the medical device industry to the Board.

Matthew Rizzo has served as a member of our Board since February 2018. Mr. Rizzo was initially elected to the Board in connection with our restructuring in February 2018. Mr. Rizzo is a designee of Royalty Opportunities and ROS under the Investor Rights Agreement. Since December 2021, Mr. Rizzo has served as a General Partner with OrbiMed Advisors LLC, a private equity and venture capital firm, and is focused on healthcare royalty and structured finance investments. From April 2010 to December 2021, Mr. Rizzo served as a Partner with OrbiMed Advisors LLC. From 2009 to 2010, Mr. Rizzo was a Senior Director in Business Development at Ikaria, a biotherapeutics company. From 2006 to 2009, Mr. Rizzo was Vice President at Fortress Investment Group LLC, a global investment manager, focused on healthcare investments in the Drawbridge Special Opportunities Funds. From 2001 to 2006, Mr. Rizzo was at GlaxoSmithKline, where he worked in business and commercial analysis. Mr. Rizzo received his MBA from Duke University and his BS from University at Buffalo. Mr. Rizzo brings valuable experience in the life science industry and finance experience to the Board.

Kevin D. Brandt has served as our Chief Commercial Officer since July 2018. From January 2017 to June 2018, Mr. Brandt served as Executive Vice President, Chief Commercial Officer – Domestic Direct of RTI Surgical, Inc., a surgical implant company. Mr. Brandt joined RTI as Vice President and General Manager, Emerging Technologies Commercialization in June 2012 and assumed additional responsibilities in January 2013 as head of RTI's direct spine business. Following the acquisition of Pioneer Surgical, from July 2013 to December 2016, Mr. Brandt assumed additional responsibility when he began overseeing all North American and Canadian spine hardware and spine biologics portfolios. Mr. Brandt has over 32 years of commercial leadership experience in the global orthopedic industry focusing on building sustainable growth and value. Mr. Brandt's expertise includes experience in sales, marketing, business development, mergers and acquisitions and integration leadership. Prior to joining RTI, Mr. Brandt held various senior leadership roles over an 18-year period in the orthopedic and spinal divisions at Stryker Corporation. In his most recent position at Stryker, he was President of Osteokinetics Corp. from January 2002 to June 2012. From June 2000 to December 2001, Mr. Brandt was Senior Director, US Spinal Sales, in which he was responsible for divesting and subsequently leading the Stryker Spine US Sales organization. Prior to joining Stryker, Mr. Brandt was a sales leader at Zimmer in a flagship office piloting a direct sales model from January 1990 to April 1994. Mr. Brandt earned a master's degree in business administration in corporate finance and investments with distinction from Adelphi University, a bachelor of science degree in business administration from New York Institute of Technology, and has taken executive education courses at the Wharton School of Business, US Naval Academy and the Gallup organization.

Scott C. Neils has served as our Chief Financial Officer since June 2022 and prior to that served as our Interim Chief Financial Officer from January 2022 to June 2022 and as our Controller from August 2019 until January 2022. Mr. Neils' has 15 years of experience focused on public accounting and corporate finance. In this role, Mr. Neils gained extensive experience managing our finance and accounting functions. Prior to joining Xtant, Mr. Neils served as Audit Senior Manager at Baker Tilly US, LLP (formerly Baker Tilly Virchow Krause, LLP), an advisory, tax and assurance firm, from November 2015 to August 2019. Prior to that position, Mr. Neils was at Grant Thornton LLP, an accounting and advisory organization, from September 2007 to November 2015, most recently as Audit Manager. Mr. Neils is a Certified Public Accountant. He holds a Bachelor of Science in Business in Accounting and a Master of Accountancy from the Carlson School of Management at the University of Minnesota.

Mark A. Schallenberger was appointed our Chief Operations Officer effective as of January 16, 2023. Prior to this, Mr. Schallenberger served as Chief Operations Officer of Surgenex LLC, a medical technology manufacturer, from June 2019 to January 2023. Prior to Surgenex, Mr. Schallenberger served as Senior Director of Marketing & Product Development of DCI Donor Services Tissue Bank, a tissue bank, from February 2016 to June 2019. Prior to DCI Donor Services Tissue Bank, Mr. Schallenberger served as various roles with increasing responsibility from September 2010 to February 2016 culminating with Director of Scientific Affairs with Xtant Medical Holdings, Inc. formerly Bacterin International Holdings, Inc. Mr. Schallenberger holds a Master of Science in Chemical Biology from The Scripps Research Institute and a Bachelor of Science degree in Chemistry from the University of Montana.

Controlled Company Status

We are a “controlled company” as defined in section 801(a) of the NYSE American Company Guide, and as such, we are exempt from certain NYSE American rules requiring our Board of Directors to have a majority of independent members, a compensation committee composed entirely of independent directors and a nominating committee composed entirely of independent directors. While we have a compensation committee, it is not comprised of a majority of independent directors. Since we do not have a nominating committee, the Board of Directors performs the functions of a nominating committee.

Investor Rights Agreement

We are party to an Investor Rights Agreement with OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP, which are funds affiliated with OrbiMed Advisors LLC. Under the Investor Rights Agreement, Royalty Opportunities and ROS are permitted to nominate a majority of the directors and designate the chairperson of our Board of Directors at subsequent annual meetings, as long as they maintain an ownership threshold in our Company of at least 40% of our then outstanding common stock. If Royalty Opportunities and ROS are unable to maintain the Ownership Threshold, as defined in the Investor Rights Agreement, the Investor Rights Agreement contemplates a reduction of nomination rights commensurate with our ownership interests. For so long as the Ownership Threshold is met, we must obtain the approval of a majority of our common stock held by Royalty Opportunities and ROS to proceed with the following actions: (i) issue new securities; (ii) incur over \$250,000 of debt in a fiscal year; (iii) sell or transfer over \$250,000 of our assets or businesses or our subsidiaries in a fiscal year; (iv) acquire over \$250,000 of assets or properties in a fiscal year; (v) make capital expenditures over \$125,000 individually, or \$1,500,000 in the aggregate during a fiscal year; (vi) approve our annual budget; (vii) hire or terminate our chief executive officer; (viii) appoint or remove the chairperson of our Board of Directors; and (ix) make, loans to, investments in, or purchase, or permit any subsidiary to purchase, any stock or other securities in another entity in excess of \$250,000 in a fiscal year. As long as the Ownership Threshold is met, we may not increase the size of our Board or Directors beyond seven directors without the approval of a majority of the directors nominated by Royalty Opportunities and ROS.

The Investor Rights Agreement grants Royalty Opportunities and ROS the right to purchase from us a pro rata amount of any new securities that we may propose to issue and sell. The Investor Rights Agreement may be terminated (a) upon the mutual written agreement of all the parties, (b) upon our written notice or the written notice of ROS or Royalty Opportunities if the ownership percentage of our then outstanding common stock of ROS and Royalty Opportunities is less than 10%, or (c) upon written notice of ROS and Royalty Opportunities.

Director Independence

The Board has affirmatively determined that John Bakewell and Robert McNamara are “independent directors,” as defined under the independence standards of the NYSE American.

Board Leadership Structure

Under the terms of the Investor Rights Agreement, Royalty Opportunities and ROS have the right to designate the Chairman of the Board and previously designated Jeffrey Peters, a former director, as Chairman of the Board. However, following waiver of this provision by Royalty Opportunities and ROS, Stavros Vizirgianakis was appointed Chairman of the Board in August 2022 in connection with our private placement. Accordingly, Mr. Vizirgianakis serves as Chairman of the Board. Sean E. Browne serves as our President and Chief Executive Officer. We believe this leadership structure is in the best interests of the Company and our stockholders and strikes the appropriate balance between the Chief Executive Officer’s responsibility for the strategic direction, day-to-day leadership, and performance of the Company and the Chairman of the Board’s responsibility to guide the overall strategic direction of the Company, provide oversight of our corporate governance and guidance to our Chief Executive Officer, and to set the agenda for and preside over Board meetings. We recognize that different leadership structures may be appropriate for companies in different situations and believe that no one structure is suitable for all companies. We believe that we are currently well-served by this leadership structure.

In connection with our August 2022 private placement, we entered into an agreement with Stavros Vizirgianakis, as the lead investor of the private placement, pursuant to which we agreed to provide Mr. Vizirgianakis certain director nomination rights. Pursuant to the terms of the agreement, we agreed to and expanded the size of the Board by one position and elected Mr. Vizirgianakis as a director to fill the vacancy created as a result of the increase, effective upon completion of the closing of the first tranche of securities in the private placement. In addition, we agreed to and elected Mr. Vizirgianakis as Chairman of the Board, effective upon completion of the first closing. The director nomination rights set forth in the agreement will terminate on the earlier of (i) the date on which Mr. Vizirgianakis ceases to hold at least 75% of the shares of our common stock purchased by him in the private placement; (ii) the second anniversary of the date of the second closing; or (iii) upon written notice of Mr. Vizirgianakis to the Company.

Board Committees

We currently maintain two Board committees, an Audit Committee and a Compensation Committee. We are a controlled company and have elected not to comply with the NYSE American corporate governance requirements, which require an independent nomination and governance committee and an independent compensation committee. We currently do not maintain a nomination and governance committee. While we maintain a Compensation Committee, it is not independent according to NYSE American corporate governance requirements.

The table below summarizes the current membership of each of our two standing board committees as of February 24, 2023. During a portion of 2022, we also maintained a Strategic Transactions Committee on which Mr. McNamara served as Chair and Messrs. Eggenberg and Rizzo served as members, but this committee was disbanded in August 2022.

Director	Audit Committee	Compensation Committee
John Bakewell	Chair	
Sean Browne		•
Michael Eggenberg	•	
Robert McNamara		Chair
Matthew Rizzo		•
Stavros Vizirgianakis		

Audit Committee

The organization and primary responsibilities of the Audit Committee are set forth in its charter, posted on our website at www.xtantmedical.com (click “Investors” and “Corporate Governance”), and include various matters with respect to the oversight of our accounting and financial reporting process and audits of our financial statements. The primary purposes of the Audit Committee include:

- to oversee the accounting and financial reporting processes of the Company and audits of the financial statements of the Company;
- to provide assistance to the Board with respect to its oversight of the following:
 - integrity of the Company’s financial statements and internal controls;
 - the Company’s compliance with legal and regulatory requirements;
 - the qualifications and independence of the Company’s independent registered public accounting firm; and
 - the performance of the Company’s internal audit function, if any, and independent registered public accounting firm.
- to prepare the report required to be prepared by the Audit Committee pursuant to the rules of the Securities and Exchange Commission.

The Audit Committee currently consists of Mr. Bakewell (Chair) and Mr. McNamara. The Audit Committee met five times during fiscal 2022. Under the NYSE American listing standards, all Audit Committee members must be independent directors and meet heightened independence requirements under the federal securities laws. In addition, all Audit Committee members must be financially literate, and at least one member must be financially sophisticated. Further, under SEC rules, the Board must determine whether at least one member of the Audit Committee is an “audit committee financial expert,” as defined by the SEC’s rules. The Board has determined that both Mr. Bakewell and Mr. McNamara are independent, financially literate, and sophisticated and qualify as “audit committee financial experts” in accordance with the applicable rules and regulations of the SEC.

Compensation Committee

The organization and responsibilities of the Compensation Committee are set forth in its charter, which is posted on our website at www.xtantmedical.com (click “Investors” and “Corporate Governance”). The primary purposes of the Compensation Committee include:

- recommending to the Board all compensation for the Company’s Chief Executive Officer and other executive officers;
- administering the Company’s equity-based compensation plans;
- reviewing, assessing, and approving overall strategies for attracting, developing, retaining, and motivating Company management and employees;
- overseeing the development and implementation of succession plans for the Chief Executive Officer and other key executive officers and employees;
- reviewing, assessing, and approving overall compensation structure on an annual basis; and
- recommending and leading a process for the determination of non-employee director compensation.

The Compensation Committee consists of Mr. McNamara (Chair), Mr. Eggenberg and Mr. Rizzo. The Compensation Committee met six times during fiscal 2022.

Director Nomination Process

Since we are not required under the NYSE rules to maintain a nominating committee and we do not have a nominating committee, the Board oversees our director nomination process. In identifying and evaluating candidates for membership on the Board, the Board may take into account all factors it considers appropriate, which may include strength of character, mature judgment, career specialization, relevant technical skills, diversity (including, but not limited to, gender, race, ethnicity, age, experience, and skills), and the extent to which the candidate would fill a present need on the Board. We do not have a formal diversity policy for directors. The Board identifies director candidates based on input provided by a number of sources, including Board members, stockholders, management, and third parties. The Board does not distinguish between nominees recommended by our stockholders and those recommended by other parties. Any stockholder recommendation must be sent to our Corporate Secretary at Xtant Medical Holdings, Inc., 664 Cruiser Lane, Belgrade, Montana 59714, and must include certain information concerning the nominee as specified in the Company’s Second Amended and Restated Bylaws. During the fourth quarter of 2022, we made no material changes to the procedures by which stockholders may recommend nominees to the Board.

Code of Ethics and Code of Conduct

We have adopted a Code of Ethics for the CEO and Senior Financial Officers as well as a Code of Conduct that applies to all directors, officers, and employees. Our corporate governance materials, including our Code of Ethics for the CEO and Senior Financial Officers and Code of Conduct, are available on our website at www.xtantmedical.com (click “Investors” and “Corporate Governance”). We intend to disclose on our corporate website any amendment to, or waiver from, a provision of our Code of Ethics for the CEO and Senior Financial Officers that applies to directors and executive officers and that is required to be disclosed pursuant to the rules of the SEC and the NYSE American.

Item 11. Executive Compensation

Executive Compensation

Summary Compensation Table

The table below provides summary information concerning all compensation awarded to, earned by, or paid to the individual that served as a principal executive officer (“PEO”) of the Company during the year ended December 31, 2022, the two most highly compensated executives other than the PEO for the year ended December 31, 2022.

Name and Principal Position	Year	Salary	Bonus ⁽¹⁾	Stock Awards ⁽²⁾	Option Awards ⁽³⁾	Non-Equity Incentive Plan Compensation ⁽⁴⁾	All Other Compensation ⁽⁵⁾	Total
Sean E. Browne <i>President and Chief Executive Officer</i>	2022	\$600,000	\$ —	\$ —	\$ —	\$ 416,400	\$ 44,162	\$ 1,060,562
Kevin D. Brandt <i>Chief Commercial Officer</i>	2022	415,000	\$ —	\$ 213,241	\$ —	\$ 144,005	\$ 6,250	\$ 778,496
Scott C. Neils ⁽⁶⁾ <i>Chief Financial Officer</i>	2021	408,615	\$ —	\$ 205,878	\$ 214,288	\$ 85,243	\$ 9,992	\$ 924,016
Scott C. Neils ⁽⁶⁾ <i>Chief Financial Officer</i>	2022	366,977	\$ —	\$ 188,646	\$ 60,028	\$ 124,342	\$ 26,540	\$ 766,533

- (1) We generally do not pay any discretionary bonuses or bonuses that are subjectively determined and did not pay any such bonuses to any named executive officers in 2022. Annual cash incentive bonus payouts based on performance against pre-established performance goals are reported in the “Non-equity incentive plan compensation” column.
- (2) Amounts reported represent the aggregate grant date fair value for restricted stock unit (“RSU”) awards computed in accordance with FASB ASC Topic 718. The grant date fair value is determined based on the per share closing sale price of our common stock on the grant date for 2022 and 2021.
- (3) Amounts reported represent the aggregate grant date fair value for option awards granted to each named executive officer computed in accordance with FASB ASC Topic 718. The grant date fair value is determined based on our Black-Scholes option pricing model. The table below sets forth the specific assumptions used in the valuation of each such option award:

Grant Date	Grant Date Fair Value Per Share	Risk Free Interest Rate	Expected Life	Expected Volatility	Expected Dividend Yield
01/15/2022	\$ 0.55	1.61%	6.25 years	112.60%	—
08/15/2021	1.27	0.97%	6.25 years	112.66%	—

- (4) Amounts reported represent payouts under our annual bonus plan and for each year reflect the amounts earned for that year but paid during the following year.
- (5) The table below provides information concerning amounts reported in the “All Other Compensation” column of the Summary Compensation Table for 2022 with respect to each named executive officer. Additional detail on these amounts is provided in the table below.

Name	401(k) Match	Commuting Expenses	Total
Sean E. Browne	\$ 12,200	\$ 31,962	\$ 44,162
Kevin D. Brandt	6,250	—	6,250
Scott C. Neils	11,798	26,540	38,338

- (6) Mr. Neils was appointed as our Interim Chief Financial Officer effective January 3, 2022 and our Chief Financial Officer effective June 1, 2022.

Executive Employment and Other Agreements

Employment Agreements

Effective October 7, 2019, we entered into an employment agreement with Sean E. Browne, our President and Chief Executive Officer, which provides for an annual base salary \$600,000 and a target annual bonus opportunity equal to 100% of his annual base salary. We agreed to reimburse his reasonable travel and business expenses. In addition, we agreed to grant him an option to purchase 329,044 shares of our common stock and an RSU unit award covering 329,044 shares of our common stock under the Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan, as amended (the “2018 Plan”), effective as of October 15, 2019, consistent with our equity grant policy. The total number of shares subject to these equity awards represented 5% of our then outstanding common stock. We also agreed to grant Mr. Browne additional stock options and RSU awards, in the same proportionate split, in the event OrbiMed (including its affiliates) converts any of our outstanding indebtedness into equity of the Company within five years. Accordingly, in response to the completion of our October 2020 debt restructuring, on November 15, 2020, we granted Mr. Browne an additional option to purchase 1,468,859 shares of our common stock and an RSU award covering 1,468,859 shares of our common stock. The terms of these awards are described under “Outstanding Equity Awards at Fiscal Year-End.” Our agreement with Mr. Browne also contains standard confidentiality, non-competition, non-solicitation and assignment of intellectual property provisions, as well as standard severance and change in control provisions, which are described under “—*Potential Payments upon Termination or Change in Control.*”

Effective July 9, 2018, we entered into an employment agreement with Kevin D. Brandt, our Chief Commercial Officer, which provided for an initial annual base salary of \$400,000 (which was subsequently increased to \$415,000 in April 2019) with a target annual bonus of 50% of his annual base salary, and a \$90,000 signing bonus, which was required to be paid back if Mr. Brandt terminated his employment with Xtant prior to the one-year anniversary of his hire date. In addition, the agreement provided for the grant of an RSU award covering 40,000 shares of our common stock, which will vest in full on July 9, 2021, the three-year anniversary date of Mr. Brandt’s hire date, assuming continued employment. The agreement also provides that Mr. Brandt is eligible to receive an annual equity award, subject to the approval of the Board, provided that the grant value of such equity award shall not be less than 50% of his annual base salary. Accordingly, on August 15, 2020, Mr. Brandt was granted an option to purchase 119,942 shares of our common stock and an RSU award covering 95,183 shares of our common stock, which are described under “Outstanding Equity Awards at Fiscal Year-End.” This agreement contains standard confidentiality, non-competition, non-solicitation, and assignment of intellectual property provisions, as well as standard severance and change in control provisions, which are described under “—*Potential Payments upon Termination or Change in Control.*”

Effective June 1, 2022, we entered into an employment agreement with Scott C. Neils, our Chief Financial Officer, which provides for an annual base salary \$400,000 and a target annual bonus opportunity equal to 50% of his annual base salary. For 2022, Mr. Neils’s bonus will be based on his earned salary for 2022 in light of his promotion to Interim Chief Financial Officer in January 2022 and his promotion to Chief Financial Officer on a non-interim basis effective June 1, 2022. Our agreement with Mr. Neils also contains standard confidentiality, non-competition, non-solicitation and assignment of intellectual property provisions, as well as standard severance and change in control provisions, which are described under “—*Potential Payments upon Termination or Change in Control.*”

Indemnification Agreements

We have entered into indemnification agreements with our executive officers that require us to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers to the fullest extent not prohibited by Delaware law.

401(k) Retirement Plan

We have a 401(k) plan for our employees. The 401(k) plan is a defined contribution plan covering substantially all of our employees. Employees are eligible to participate in the plan on the first day of any month after starting employment. Employees are allowed to contribute a percentage of their wages to the 401(k) plan, subject to statutorily prescribed limits and are subject to a discretionary employer match of 100% of their wage deferrals not in excess of 4% of their wages.

Outstanding Equity Awards at Fiscal Year-End

The table below provides information regarding unexercised option awards and unvested stock awards held by each of our named executive officers that remained outstanding at our fiscal year-end, December 31, 2022. All of the outstanding equity awards described below were granted under the 2018 Plan.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price	Option Expiration Date ⁽¹⁾	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares or Units of Stock that Have Not Vested ⁽²⁾
	Exercisable	Unexercisable				
Sean E. Browne	197,426 734,429	131,618(3) 734,430(5)	\$ 2.70 1.26	10/15/2029 11/15/2030	131,618(4) 734,430(6)	\$ 86,868 484,724
Kevin D. Brandt	30,770 30,395 59,971 62,349	— 10,132(8) 59,971(10) 137,370(12)	6.20 2.76 1.13 1.27	08/15/2028 08/15/2029 08/15/2030 08/15/2031	8,793(7) 47,592(9) 121,582(11) 410,079(13)	5,803 31,411 80,244 270,652
Scott C. Neils	15,381 30,048 —	5,127(14) 66,106(12) 109,164(16)	1.80 1.27 0.65	11/15/2029 08/15/2031 01/15/2032	58,594(9) 88,983(15) 251,895(13)	38,672 58,729 166,251

- (1) All options awards have a 10-year term, but may terminate earlier if the recipient's employment or service relationship with the Company terminates.
- (2) Based on the closing price of our common stock on December 31, 2022 (\$0.66), as reported by the NYSE American.
- (3) This stock option vests in nearly equal installments annually over a five-year period beginning on October 15, 2020. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if Mr. Browne dies.
- (4) This RSU award vests in nearly equal installments annually over a five-year period beginning on October 15, 2020. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if Mr. Browne dies.
- (5) This stock option vests in nearly equal installments annually over a four-year period beginning on October 15, 2021. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if Mr. Browne dies.

- (6) This RSU award vests in nearly equal installments annually over a four-year period beginning on October 15, 2021. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if Mr. Browne dies.
- (7) This RSU award vests in nearly equal installments annually over a four-year period beginning on August 15, 2020. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to 12 months following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (8) This stock option vests in nearly equal installments annually over a four-year period beginning on August 15, 2020. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (9) This RSU award vests in nearly equal installments annually over a four-year period beginning on August 15, 2021. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to 12 months following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (10) This stock option vests with respect to 25% of the shares on August 15, 2021 and with respect to the remaining 75% of such shares over the three-year period thereafter in 12 as nearly equal as possible quarterly installments. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (11) This RSU award vests in nearly equal installments annually over a four-year period beginning on August 15, 2022. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to 12 months following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (12) This stock option vests with respect to 25% of the shares on August 15, 2022 and with respect to the remaining 75% of such shares over the three-year period thereafter in 12 as nearly equal as possible quarterly installments. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (13) This RSU award vests in nearly equal installments annually over a four-year period beginning on August 15, 2023. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to 12 months following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (14) This stock option vests in nearly equal installments annually over a four-year period beginning on November 15, 2020. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (15) This RSU award vests in nearly equal installments annually over a four-year period beginning on January 15, 2023. In addition, this RSU award will vest in full immediately in the event that it is discontinued upon a change in control or up to 12 months following a change in control and a pro rata percentage will vest immediately if the executive dies.
- (16) This stock option vests with respect to 25% of the shares on January 15, 2023 and with respect to the remaining 75% of such shares over the three-year period thereafter in 12 as nearly equal as possible quarterly installments. In addition, this option will vest in full immediately in the event that it is discontinued upon a change in control or up to one year following a change in control and a pro rata percentage will vest immediately if the executive dies.

Xtant Medical Holdings, Inc. Second Amended and Restated 2018 Equity Incentive Plan

In 2022, the Board and the Company's stockholders approved and adopted the Xtant Medical Holdings, Inc. Second Amended and Restated 2018 Equity Incentive Plan (the "2018 Plan"). The purpose of the 2018 Plan is to advance the interests of the Company and our stockholders by enabling us to attract and retain qualified individuals to perform services, provide incentive compensation for such individuals in a form that is linked to the growth and profitability of our company and increases in stockholder value, and provide opportunities for equity participation that align the interests of participants with those of our stockholders.

The 2018 Plan replaced the Amended and Restated Xtant Medical Equity Incentive Plan (the "Prior Plan"). However, the terms of the Prior Plan, as applicable, continue to govern awards outstanding under the Prior Plan until exercised, expired, paid, or otherwise terminated or canceled.

The 2018 Plan permits the Board, or a committee or subcommittee thereof, to grant to eligible employees, non-employee directors, and consultants of the Company non-statutory and incentive stock options, stock appreciation rights, restricted stock awards, RSUs, deferred stock units, performance awards, non-employee director awards, and other stock-based awards. Subject to adjustment, the maximum number of shares of our common stock authorized for issuance under the 2018 Plan is 16,858,055 shares. To date, the Company has granted stock options, restricted stock and RSUs under the 2018 Plan. As of December 31, 2022, 7,443,895 shares of Xtant common stock remained available for issuance under the 2018 Plan.

Potential Payments upon Termination or Change in Control

Executive Employment Agreements

Under the terms of the employment agreements we have entered into with our named executive officers, if the executive's employment is terminated by the Company without "cause" (as defined in the agreement), the executive will be entitled to receive a severance payment equal to 12 months of his annual base salary, payable as salary continuation, reimbursement of COBRA payments for up to 12 months, and the prorated amount of any unpaid bonus for the calendar year in which his termination of employment occurs, if earned pursuant to the terms thereof. If the executive's employment is terminated by the Company without "cause" or by the executive for "good reason" in connection with or within 12 months after a "change in control" (as such terms are defined in the agreement), the executive's severance payment, as previously described, will be paid in one lump sum, and in the case of Mr. Brandt, will equal two times his base salary. To be eligible to receive these payments, the executive will be required to execute and not revoke a release of claims against the Company.

Equity Award Agreements

All equity awards held by our named executive officers have been granted under 2018 Plan. Under the terms of the 2018 Plan and the award agreements governing these awards, if an executive's employment or other service with the Company is terminated for cause, then all outstanding awards held by such executive will be terminated and forfeited. In the event an executive's employment or other service with the Company is terminated by reason of death, then:

- All outstanding stock options will vest and become exercisable immediately as to a pro rata percentage of the unvested portion of the option scheduled to vest on the next applicable vesting date, and the vested portion of the options will remain exercisable for a period of one year after the date of such termination (but in no event after the expiration date).
- The outstanding unvested RSU awards will vest and become immediately issuable as to a pro rata percentage of the unvested portion of the RSU awards scheduled to vest on the next applicable vesting date and the unvested portion of the RSU awards will terminate.

In the event an executive's employment or other service with the Company is terminated by reason of disability, then:

- All outstanding stock options will remain exercisable to the extent exercisable on the termination date for a period of one year after the date of such termination (but in no event after the expiration date).
- All outstanding unvested RSU awards will terminate.

In the event an executive's employment or other service with the Company is terminated for any other reason, then:

- All outstanding stock options will remain exercisable to the extent exercisable on the termination date for a period of 90 days after the date of such termination (but in no event after the expiration date).
- All outstanding unvested RSU awards will terminate.

In addition, the equity award agreements governing the equity awards held by our named executive officers contain "change in control" provisions. Under the award agreements, without limiting the authority of the Compensation Committee to adjust awards, if a "change in control" of the Company (as defined in the 2018 Plan) occurs, then, unless otherwise provided in the award or other agreement, if an award is continued, assumed, or substituted by the successor entity, the award will not vest or lapse solely as a result of the change in control but will instead remain outstanding under the terms pursuant to which it has been continued, assumed, or substituted and will continue to vest or lapse pursuant to such terms. If the award is continued, assumed, or substituted by the successor entity and within one year following the change in control, the executive is either terminated by the successor entity without "cause" or, if the executive resigns for "good reason," each as defined in the award agreement, then the outstanding option will vest and become immediately exercisable as of the termination or resignation and will remain exercisable until the earlier of the expiration of its full specified term or the first anniversary of the date of such termination or resignation, and the outstanding RSU award will be fully vested and will be converted into shares of our common stock immediately thereafter. If an award is not continued, assumed, or substituted by the successor entity, then the outstanding option will be fully vested and exercisable, and the Compensation Committee will either give the executive a reasonable opportunity to exercise the option prior to the change in control transaction or will pay the difference between the exercise price of the option and the per share consideration paid to similarly situated stockholders. Under these conditions, the outstanding RSU award will be fully vested and will be converted into shares of our common stock immediately thereafter.

Director Compensation

Director Compensation Program

Our director cash compensation consists of an annual cash retainer paid to each non-employee director and an additional annual cash retainer paid to the Chairman of the Board, the Audit Committee Chair, and the Compensation Committee Chair and annual RSU equity grants.

The table below sets forth the annual cash retainers for 2022:

Description	Annual Cash Retainer
Non-Employee Director	\$ 50,000
Chairman of the Board Premium	32,500
Audit Committee Chair Premium	32,500
Compensation Committee Chair Premium	32,500

In addition, during a portion of 2022, we maintained a Strategic Transactions Committee on which Mr. McNamara served as Chair and received a pro rata portion of an annual cash retainer of \$25,000.

In 2021, we revised our non-employee director compensation program to provide for annual RSU equity grants, and accordingly, on August 15, 2022, each of our non-employee directors at that time received an RSU award valued at \$165,000 for 215,415 shares of our common stock. In connection with his appointment as a director of the Company, Mr. Vizirgianakis received an RSU award for 70,776 shares of our common stock on August 25, 2022 and, after approval by our stockholders of an increase in the number of shares available under the 2018 Plan, received an additional RSU award for 144,639 shares of our common stock on October 26, 2022. All of these RSU awards will vest on August 15, 2023, except for the RSU award granted to Mr. Peters, which was accelerated in connection with his departure from the Board.

Director Compensation Table for Fiscal 2022

The table below describes the compensation earned by our directors during fiscal 2022, other than Sean E. Browne, our President and Chief Executive Officer. Mr. Browne is not compensated separately for his service as a director, and his compensation is discussed under “Executive Compensation.”

Name	Fees Earned or Paid in Cash		Stock Awards ⁽¹⁾ (2)	Option Awards	All Other Compensation	Total
John Bakewell	\$ 82,500		\$ 112,016	\$ —	\$ —	\$ 194,516
Michael Eggenberg	50,000		112,016	—	—	162,016
Robert McNamara	98,796		112,016	—	—	210,812
Jeffrey Peters ⁽³⁾	62,247		112,016	—	—	174,263
Matthew Rizzo	50,000		112,016	—	—	162,016
Stavros Vizirgianakis	28,856		126,865	—	—	155,721

(1) The amount reported in the “Stock Awards” column represents the aggregate grant date fair value for the RSU awards granted to our non-employee directors in 2022. The grant date fair value for the RSU awards was determined based on the closing sale price of our common stock on the grant date.

(2) As of December 31, 2022, each non-employee director, other than Mr. Peters, held 215,415 unvested stock awards.

(3) Mr. Peters did not stand for re-election as a director at our annual stockholders meeting held on October 26, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Significant Beneficial Owners

The table below sets forth information as to beneficial owners that have reported to the SEC or have otherwise advised us that they are a beneficial owner, as defined by the SEC's rules and regulations, of more than 5% of our outstanding common stock.

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class ⁽¹⁾
Common Stock	OrbiMed Advisors LLC ⁽²⁾ 601 Lexington Avenue, 54 th Floor New York, NY 10022	73,114,592	67.1%
Common Stock	Altium Capital Management, LP ⁽³⁾ 152 West 57 th Street, Floor 20 New York, NY 10019	12,744,209 ⁽⁴⁾	11.7(4)%
Common Stock	Stavros Vizirgianakis ⁽⁵⁾ 664 Cruiser Lane Belgrade, MT 59714	7,224,924	6.6%

- (1) Percent of class is based on 108,897,048 shares of our common stock outstanding as of February 24, 2023.
- (2) Based in-part on information contained in a Schedule 13D/A filed with the SEC on August 30, 2022. Includes 56,004,974 shares of common stock held of record by ROS Acquisition Offshore LP ("ROS Acquisition"). OrbiMed Advisors LLC ("Advisors"), a registered investment adviser under the Investment Advisors Act of 1940, as amended, is the investment manager of ROS Acquisition. By virtue of such relationships, Advisors may be deemed to have voting and investment power with respect to the securities held by ROS Acquisition as noted above and as a result may be deemed to have beneficial ownership over such securities. Advisors exercises its voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the securities held by ROS Acquisition.

Also includes 17,109,618 shares of common stock held of record by OrbiMed Royalty Opportunities II, LP ("ORO II"). OrbiMed ROF II LLC ("ROF II") is the general partner of ORO II, and Advisors is the managing member of ROF II. By virtue of such relationships, Advisors and ROF II may be deemed to have voting and investment power with respect to the securities held by ORO II as noted above and as a result may be deemed to have beneficial ownership over such securities. Advisors exercises its voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the securities held by ORO II.
- (3) Based on information contained in a Schedule 13G filed with the SEC on February 14, 2023 and other information known to the Company. Altium Growth Fund, LP (the "Fund"), Altium Capital Management, LLC, and Altium Growth GP, LLC each have shared dispositive power and voting power over the shares. The Fund is the record and direct beneficial owner of the shares. Altium Capital Management, LP is the investment adviser of, and may be deemed to beneficially own the shares owned by the Fund. Altium Growth GP, LLC is the general partner of, and may be deemed to beneficially own the shares owned by the Fund. The number of shares consists of 6,246,291 shares of our common stock and 6,497,918 shares of our common stock issuable upon exercise of a warrant (the "Investor Warrant").
- (4) While the total number of shares of our common stock issuable upon exercise of the Investor Warrant is reflected in this table, the Fund is not permitted to exercise such Investor Warrant to the extent that such exercise would result in the Fund and its affiliates beneficially owning more than 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. The Fund has the right to increase this beneficial ownership limitation in its discretion on 61 days' prior written notice to us.
- (5) Based on information contained in a Schedule 13D filed with the SEC on September 6, 2022 and other information available to the Company. The number of shares consists of 5,779,940 shares of our common stock and 1,444,984 shares of our common stock issuable upon exercise of warrants.

Security Ownership of Management

The table below sets forth information relating to the beneficial ownership of our common stock as of February 24, 2023, by:

- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

The number of shares beneficially owned by each person is determined in accordance with the SEC's rules and regulations, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under the SEC's rules and regulations, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of February 24, 2023, through the exercise of any stock option, warrants, or other rights or the vesting of any RSU awards. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 108,897,048 shares of our common stock outstanding as of February 24, 2023. Shares of our common stock that a person has the right to acquire within 60 days of February 24, 2023, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

Title of Class	Name of Beneficial Owner	Amount and Nature of Beneficial Ownership ⁽¹⁾	Percent of Class
Common Stock	John Bakewell	233,131	*
Common Stock	Sean E. Browne	1,572,393	1.4%
Common Stock	Michael Eggenberg	—	—
Common Stock	Robert McNamara	231,394	*
Common Stock	Matthew Rizzo	—	—
Common Stock	Stavros Vizirgianakis ⁽²⁾	7,224,924	6.6%
Common Stock	Kevin D. Brandt	311,481	*
Common Stock	Scott C. Neils	139,575	*
Common Stock	All current executive officers and directors as a group (9 persons)	9,712,898	8.7%

* Less than 1% of outstanding shares of common stock.

(1) Includes for the persons listed below the following shares subject to options and RSUs held by that person that are currently exercisable or become exercisable within 60 days of February 24, 2023:

Name	Warrants	Options	RSUs
Sean E. Browne	—	931,855	—
Stavros Vizirgianakis	1,444,984	—	—
Kevin D. Brandt	—	195,955	—
Scott C. Neils	—	112,842	—
All current directors and executive officers as a group (9 persons)	1,444,984	1,240,652	—

(2) Based on information contained in a Schedule 13D filed with the SEC on September 6, 2022 and other information available to the Company. The number of shares consists of 5,779,940 shares of our common stock and 1,444,984 shares of our common stock issuable upon exercise of warrants.

Securities Authorized for Issuance under Equity Compensation Plans

The table below provides information about our common stock that may be issued under our equity compensation plans as of December 31, 2022.

Plan Category	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	6,973,097	\$ 1.51	7,443,895
Equity compensation plans not approved by security holders	—	—	—
Total	6,973,097	\$ 1.51	7,443,895

- (1) Amount includes 3,347,819 shares of our common stock issuable upon the exercise of stock options granted under the 2018 Plan, 12,845 shares of our common stock issuable upon the exercise of stock options granted under the Prior Plan and 3,612,433 shares of our common stock issuable upon the vesting of RSU awards granted under the 2018 Plan.
- (2) Not included in the weighted-average exercise price calculation are 3,970,105 RSU awards.
- (3) Amount includes 7,443,895 shares of our common stock remaining available for future issuance under the 2018 Plan. No shares remain available for grant under the Prior Plan since such plan has been terminated with respect to future grants.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Policies and Procedures for Review and Approval of Related Party Transactions

Pursuant to its charter, the Audit Committee reviews and approves all related party transactions and makes recommendations to the full Board regarding approval of such transactions, unless the Board specifically delegates this responsibility to the Compensation Committee. The Audit Committee reviewed the transactions described below and determined that they were fair, just, and reasonable to the Company and in the best interests of the Company and its stockholders.

Related Party Transactions

Below is a description of transactions that have occurred during the past two fiscal years, or any currently proposed transactions, to which we were or are a participant and in which:

- the amounts involved exceeded or will exceed the lesser of: \$120,000 or one percent (1%) of the average of our total assets at year end for the last two completed fiscal years; and
- a related person (including any director, director nominee, executive officer, holder of more than 5% of our common shares or any member of their immediate family) had or will have a direct or indirect material interest.

Investor Rights Agreement

We are party to an Investor Rights Agreement with OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP (“ROS”) pursuant to which Royalty Opportunities and ROS are permitted to nominate a majority of the directors and designate the chairperson of our Board of Directors at subsequent annual meetings, as long as they maintain an ownership threshold in our Company of at least 40% of our then outstanding common stock. If Royalty Opportunities and ROS are unable to maintain the Ownership Threshold, as defined in the Investor Rights Agreement, the Investor Rights Agreement contemplates a reduction of nomination rights commensurate with our ownership interests. For so long as the Ownership Threshold is met, we must obtain the approval of a majority of our common stock held by Royalty Opportunities and ROS to proceed with the following actions: (i) issue new securities; (ii) incur over \$250,000 of debt in a fiscal year; (iii) sell or transfer over \$250,000 of our assets or businesses or our subsidiaries in a fiscal year; (iv) acquire over \$250,000 of assets or properties in a fiscal year; (v) make capital expenditures over \$125,000 individually, or \$1,500,000 in the aggregate during a fiscal year; (vi) approve our annual budget; (vii) hire or terminate our chief executive officer; (viii) appoint or remove the chairperson of our Board of Directors; and (ix) make loans to, investments in, or purchase, or permit any subsidiary to purchase, any stock or other securities in another entity in excess of \$250,000 in a fiscal year. As long as the Ownership Threshold is met, we may not increase the size of our Board of Directors beyond seven directors without the approval of a majority of the directors nominated by Royalty Opportunities and ROS.

The Investor Rights Agreement grants Royalty Opportunities and ROS the right to purchase from us a pro rata amount of any new securities that we may propose to issue and sell. The Investor Rights Agreement may be terminated (a) upon the mutual written agreement of all the parties, (b) upon our written notice or the written notice of ROS or Royalty Opportunities if the ownership percentage of our then outstanding common stock of ROS and Royalty Opportunities is less than 10%, or (c) upon written notice of ROS and Royalty Opportunities.

Second Amended and Restated Credit Agreement

On March 29, 2019, the Company and our subsidiaries, Bacterin International, Inc., Xtant Medical, Inc. and X-spine Systems, Inc., entered into a Second Amended and Restated Credit Agreement with Royalty Opportunities and ROS (the “Second A&R Credit Agreement”), which Second A&R Credit Agreement was amended twice thereafter. On May 6, 2021, contemporaneously with the execution and delivery of new credit agreements with MidCap, the Second A&R Credit Agreement, as amended, was terminated in accordance with the terms thereof and all outstanding amounts were repaid by the borrowers to Royalty Opportunities in its role as sole lender thereunder. During the year ended December 31, 2021, the largest amount of principal outstanding under this credit facility was \$15.6 million, and as of December 31, 2021, the amount of principal outstanding was \$0.00. The Company paid \$1.2 million in interest under the credit facility and \$15.6 million in principal amount during the year ended December 31, 2021.

2021 Lock-Up Agreements

On February 24, 2021, we entered into lock-up agreements with each of our directors and executive officers, pursuant to the Securities Purchase Agreement, dated as of February 22, 2021, between us and the purchasers signatory thereto pursuant to which each such director and executive officer agreed to a lock-up on any sale or other disposition of our common stock, subject to certain exceptions. The lock-up period had a 90-day duration and expired on May 25, 2021.

Sublease Agreement

We were party to a sublease agreement with Cardialen, Inc., under which we leased a portion of Cardialen’s office space in Brooklyn Center, Minnesota. The sublease agreement was amended several times to change the amount of office space and monthly rent. Under the amended sublease agreement, we agreed to pay rent ranging from \$500 to \$1,350 per month for 2020, \$950 per month for 2021, \$975 per month for 2022 and \$1,000 per month thereafter through the expiration date of January 31, 2024. During 2021, we paid a total of \$7,600 to Cardialen under this lease agreement. This lease agreement has been terminated. Because Jeffrey Peters was both a member of our Board and the Chief Executive Officer, President, and a director of Cardialen, this transaction qualified as a related party transaction.

2022 Private Placement and Securities Purchase Agreement

On August 23, 2022, we entered into a securities purchase agreement (the “Securities Purchase Agreement”) with several accredited investors, including Stavros Vizirgianakis and his brother, pursuant to which we agreed to issue an aggregate of 20,305,429 shares of our common stock and warrants to purchase up to an aggregate of 5,076,358 shares of our common stock in a private placement (the “Private Placement”), at a per unit (each unit consisting of one share and a warrant to purchase 0.25 of a share) purchase price of \$0.48, which represented a 2.5% discount to the 10-day volume-weighted average price of our common stock ending August 19, 2022. The closing of the Private Placement was structured to occur in two tranches in order to comply with the continued listing requirements of the NYSE American, which requires stockholder approval of the sale, issuance, or potential issuance by listed companies of common stock (or securities convertible into common stock) at a price less than the greater of book or market value which equals 20% or more of outstanding common stock prior to the transaction.

On August 25, 2022, we closed the first tranche of the Private Placement (the “First Closing”). At the First Closing, we sold an aggregate of 14,060,315 shares and warrants to purchase an aggregate of 3,515,079 shares, for an aggregate purchase price of approximately \$6.75 million. Of these shares and warrants, we sold 3,515,079 shares and warrants to purchase 878,770 shares to Stavros Vizirgianakis in exchange for approximately \$1.7 million and sold 3,515,077 shares and warrants to purchase 878,769 shares to the brother of Stavros Vizirgianakis in exchange for approximately \$1.7 million.

Immediately after the execution of the Securities Purchase Agreement by the parties thereto, we obtained the written consent of Royalty Opportunities and ROS, the holders of an aggregate of 73,114,592 shares of our common stock as of August 23, 2022, representing greater than a majority of the outstanding shares of our common stock as of such date, for the approval of the issuance of Shares and Warrants at the second closing of the Private Placement (the “Second Closing”) pursuant to the continued listing requirements of the NYSE American and in accordance with applicable provisions of the Delaware General Corporation Law and our Second Amended and Restated Bylaws. The written consent of Royalty Opportunities and ROS was sufficient to approve the issuance of Shares and Warrants at the Second Closing. Therefore, no proxies or additional consents were solicited by us in connection with this issuance. Pursuant to Section 14(c) of the Exchange Act, and the rules and regulations promulgated thereunder, on September 9, 2022, we sent a definitive information statement to all holders of our common stock as of August 23, 2022 for the purpose of informing such stockholders of the written actions taken by Royalty Opportunities and ROS. The Second Closing occurred on October 7, 2022. At the Second Closing, we sold an aggregate of 6,245,114 shares and warrants to purchase an aggregate of 1,561,279 shares, for an aggregate purchase price of approximately \$3.0 million. Of these shares and warrants, we sold 2,264,861 shares and warrants to purchase 566,214 shares to Stavros Vizirgianakis in exchange for approximately \$1.1 million and sold 857,696 shares and warrants to purchase 214,425 shares to the brother of Stavros Vizirgianakis in exchange for approximately \$0.4 million.

2022 Lock-Up Agreements

Under the terms of the Securities Purchase Agreement, each of the accredited investors party thereto executed a lock-up agreement with the Company, pursuant to which each such investor agreed to a lock-up on any sale or other disposition of our common stock, subject to certain exceptions. The lock-up period had a three-month duration, except in the case of Stavros Vizirgianakis who agreed to a 12-month lock-up period.

Lead Investor Agreement

Under the terms of the Securities Purchase Agreement, we entered into an agreement with Stavros Vizirgianakis, as the lead investor of the Private Placement, pursuant to which we agreed to provide certain director nomination rights to Mr. Vizirgianakis. Pursuant to the terms of the agreement, we expanded the size of our Board by one position and elected Mr. Vizirgianakis as a director to fill the vacancy created as a result of the increase, effective upon completion of the First Closing. In addition, we elected Mr. Vizirgianakis as Chairman of the Board, effective upon completion of the First Closing. The director nomination rights set forth in the agreement will terminate on the earlier of (i) the date on which Mr. Vizirgianakis ceases to hold at least 75% of the shares of our common stock to be purchased by him in the Private Placement; (ii) the second anniversary of the date of the Second Closing; or (iii) upon written notice of Mr. Vizirgianakis to the Company.

2022 Registration Rights Agreement

Under the terms of the Securities Purchase Agreement, we entered into a Registration Rights Agreement with Stavros Vizirgianakis, his brother, and the other accredited investors party to the Securities Purchase Agreement, which required us, among other things, to file a shelf resale registration statement with the SEC within 60 days of the date of the First Closing for purposes of registering the resale of the shares of our common stock sold in the Private Placement and the shares of our common stock issuable upon exercise of the warrants and use our commercially reasonable best efforts to cause the shelf resale registration statement to become effective under the Securities Act of 1933, as amended, within 75 days of the date of the First Closing, subject to certain exceptions. We filed this registration statement on October 11, 2022 and it became effective on October 20, 2022.

Family Relationships

There are no family relationships between or among our directors, executive officers, or persons nominated or chosen by the Company to become directors or executive officers.

Director Independence

The Board has affirmatively determined that John Bakewell and Robert McNamara are “independent directors,” as defined under the independence standards of the NYSE American.

Item 14. Principal Accounting Fees and Services

Audit and Non-Audit Fees

Plante & Moran, PLLC (“Plante Moran”) served as the independent registered public accounting firm to audit our books and accounts for the fiscal years ended December 31, 2022 and 2021.

The table below presents the aggregate fees billed for professional services rendered by Plante Moran for the years ended December 31, 2022 and December 31, 2021.

	2022	2021
Audit fees	\$ 320,158	\$ 284,317
Audit-related fees	7,000	8,000
Tax fees	—	—
All other fees	—	—
Total fees	\$ 327,158	\$ 292,317

In the above table, “audit fees” are fees billed for services provided related to the audit of our annual financial statements, quarterly reviews of our interim financial statements, and services normally provided by the independent accountant in connection with statutory and regulatory filings or engagements for those fiscal periods. “Audit-related fees” are fees not included in audit fees that are billed by the independent accountant for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements. These audit-related fees also consist of the review of our registration statements filed with the SEC and related services normally provided in connection with statutory and regulatory filings or engagements. “Tax fees” are fees billed by the independent accountant for professional services rendered for tax compliance, tax advice, and tax planning. “All other fees” are fees billed by the independent accountant for products and services not included in the foregoing categories.

Pre-Approval Policy

It is the Audit Committee’s policy to approve in advance the types and amounts of audit, audit-related, tax, and any other services to be provided by our independent registered public accounting firm. In situations where it is not practicable to obtain full Audit Committee approval, the Audit Committee has delegated authority to the Chair of the Audit Committee to grant pre-approval of auditing, audit-related, tax, and all other services up to \$20,000. Any pre-approved decisions by the Chair are required to be reviewed with the Audit Committee at its next scheduled meeting. The Audit Committee approved 100% of all services provided by Plante Moran during 2022 and 2021.

PART IV

Item 15. Exhibit and Financial Statement Schedules

Financial Statements

Our consolidated financial statements are included in “Part II, Item 8. Financial Statements and Supplementary Data.”

Financial Statement Schedules

All financial statement schedules are omitted because they are inapplicable since we are a smaller reporting company.

Exhibits

The exhibits being filed or furnished with this report are listed below, along with an indication as to each management contract or compensatory plan or arrangement.

A copy of any exhibits listed or referred to herein will be furnished at a reasonable cost to any person who is a stockholder upon receipt from any such person of a written request for any such exhibit. Such request should be sent to: Scott Neils, Chief Financial Officer, Xtant Medical Holdings, Inc., 664 Cruiser Lane, Belgrade, MT 59714, Attn: Stockholder Information.

Exhibit No.	Description
2.1†	<u>Equity Purchase Agreement, dated February 28, 2023, by and among Xtant Medical Holdings, Inc, Surgalign SPV, Inc., Surgalign Spine Technologies, Inc., and Surgalign Holdings, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 1, 2023 (SEC File No. 001-34951) and incorporated by reference herein)</u>
3.1	<u>Amended and Restated Certificate of Incorporation of Xtant Medical Holdings, Inc. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 13, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
3.2	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Xtant Medical Holdings, Inc. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 31, 2019 (SEC File No. 001-34951) and incorporated by reference herein)</u>
3.3	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Xtant Medical Holdings, Inc., as amended (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 1, 2020 (SEC File No. 001-34951) and incorporated by reference herein)</u>
3.4	<u>Second Amended and Restated Bylaws of Xtant Medical Holdings, Inc. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 16, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.1	<u>Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.2	<u>Form of Common Stock Certificate (filed as Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>

Exhibit No.	Description
4.3	<u>Investor Rights Agreement dated February 14, 2018 by and among Xtant Medical Holdings, Inc., OrbiMed Royalty Opportunities II, LP, ROS Acquisition Offshore LP, Park West Partners International, Limited and Park West Investors Master Fund, Limited (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on February 16, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.4	<u>Registration Rights Agreement (for Common Stock underlying the Indenture Notes) dated January 17, 2017 by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed with the SEC on January 20, 2017 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.5	<u>Registration Rights Agreement (for Common Stock underlying the PIK Notes) dated January 17, 2017 by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.13 to the Registrant's Current Report on Form 8-K filed with the SEC on January 20, 2017 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.6	<u>Registration Rights Agreement (for Common Stock issued upon the exchange of the Notes and pursuant to the Private Placement) dated as of February 14, 2018 by and among Xtant Medical Holdings, Inc., OrbiMed Royalty Opportunities II, LP, ROS Acquisition Offshore LP, Telemetry Securities, L.L.C., Bruce Fund, Inc., Park West Investors Master Fund, Limited, and Park West Partners International, Limited (filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on February 16, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.7	<u>Registration Rights Agreement dated October 1, 2020 by and among Xtant Medical Holdings, Inc., OrbiMed Royalty Opportunities II, LP, and ROS Acquisition Offshore LP (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on October 1, 2020 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.8	<u>Registration Rights Agreement dated February 24, 2021 by and between Xtant Medical Holdings, Inc. and the investor party thereto (filed as Exhibit 4.4 to the Registrant's Registration Statement on Form S-3 filed with the SEC on April 6, 2021 (Sec File No. 333-255074) and incorporated by reference herein).</u>
4.9	<u>Registration Rights Agreement dated as of August 25, 2022 by and among Xtant Medical Holdings, Inc. and the investors party thereto (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 31, 2022 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.10	<u>Form of Investor Warrant (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.11	<u>Form of Placement Agent Warrant (filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.12	<u>Form of Warrant (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 24, 2022 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.1●	<u>Amended and Restated Xtant Medical Equity Incentive Plan (filed as Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015 (SEC File No. 001-34951) and incorporated by reference herein)</u>

Exhibit No.	Description
10.2●	<u>Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 3, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.3●	<u>Xtant Medical Holdings, Inc. Amended and Restated 2018 Equity Incentive Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 28, 2020 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.4●	<u>Xtant Medical Holdings, Inc. Second Amended and Restated 2018 Equity Incentive Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 28, 2022 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.5●	<u>Form of Employee Stock Option Award Agreement for use with the Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 3, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.6●	<u>Form of Employee Restricted Stock Unit Award Agreement for use with the Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on August 3, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.7●	<u>Form of Non-Employee Director Restricted Stock Unit Award Agreement for use with the Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.8●	<u>Form of Indemnification Agreement for Directors and Officers (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.9●	<u>Employment Agreement dated as of October 7, 2019 by and between Xtant Medical Holdings, Inc. and Sean E. Browne (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 7, 2019 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.10●	<u>Employment Agreement effective as of July 9, 2018 by and between Xtant Medical Holdings, Inc. and Kevin D. Brandt (filed as Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.11●	<u>Amended and Restated Employment Agreement effective as of August 8, 2019 by and between Xtant Medical Holdings, Inc. and Greg Jensen (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.12●	<u>Resignation Agreement and Release effective as of January 3, 2022 by and between Xtant Medical Holdings, Inc. and Greg Jensen (filed as Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.13●	<u>Employment Agreement effective as of June 1, 2022 by and between Xtant Medical Holdings, Inc. and Scott Neils (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 2, 2022 (SEC File No. 001-34951) and incorporated by reference herein)</u>

Exhibit No.	Description
10.14•	<u>Letter Agreement dated August 25, 2022 by and between Xtant Medical Holdings, Inc. and Stavros Vizirgianakis (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on August 31, 2022 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.15	<u>Restructuring and Exchange Agreement dated as of January 11, 2018 by and among Xtant Medical Holdings, Inc., OrbiMed Royalty Opportunities II, LP, ROS Acquisition Offshore LP, Bruce Fund, Inc., Park West Partners International, Limited, Park West Investors Master Fund, Limited, and Telemetry Securities, L.L.C. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 12, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.16	<u>Restructuring and Exchange Agreement dated as of August 7, 2020 by and among Xtant Medical Holdings, Inc., OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 10, 2020 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.17	<u>Securities Purchase Agreement dated as of February 14, 2018 by and among Xtant Medical Holdings, Inc., OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP. (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on February 16, 2018 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.18	<u>Securities Purchase Agreement dated February 22, 2021 by and between Xtant Medical Holdings, Inc. and the investor party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.19	<u>Placement Agent Agreement dated February 22, 2021 by and between Xtant Medical Holdings, Inc. and A.G.P/Alliance Global Partners (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.20	<u>Securities Purchase Agreement dated as of August 23, 2022 by and among Xtant Medical Holdings, Inc. and the investors party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 24, 2022 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.21	<u>Transition Services Agreement, dated February 28, 2023, by and among Surgalign SPV, Inc., Surgalign Spine Technologies, Inc., and Xtant Medical Holdings, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 1, 2023 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.22	<u>Credit, Security and Guaranty Agreement (Term Loan) dated as of May 6, 2021 by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 6, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>
10.23	<u>Credit, Security and Guaranty Agreement (Revolving Loan) dated as of May 6, 2021 by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on May 6, 2021 (SEC File No. 001-34951) and incorporated by reference herein)</u>

Exhibit No.	Description
10.24	<u>Amendment No. 1 to Credit, Security and Guaranty Agreement (Term Loan) dated as of March 7, 2022 by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.19 to the Registrant's Current Report on Form 8-K filed with the SEC on May 2, 2022 (SEC File No. 001-34951) and incorporated by reference herein).</u>
10.25	<u>Amendment No. 1 to Credit, Security and Guaranty Agreement (Revolving Loan) dated as of March 7, 2022 by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.20 to the Registrant's Current Report on Form 8-K filed with the SEC on May 2, 2022 (SEC File No. 001-34951) and incorporated by reference herein).</u>
10.26	<u>Amendment No. 2 to Credit, Security and Guaranty Agreement (Term Loan) dated as of October 27, 2022 by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (SEC File No. 001-34951) and incorporated by reference herein).</u>
10.27	<u>Amendment No. 2 to Credit, Security and Guaranty Agreement (Revolving Loan) dated as of October 27, 2022 by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (SEC File No. 001-34951) and incorporated by reference herein).</u>
10.28	<u>Amendment No. 3 to Credit, Security and Guaranty Agreement (Term Loan), dated as of February 28, 2023, by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Financial Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on March 1, 2023 (SEC File No. 001-34951) and incorporated by reference herein).</u>
10.29	<u>Amendment No. 3 to Credit, Security and Guaranty Agreement (Revolving Loan), dated as of February 28, 2023, by and among Xtant Medical, Inc., Bacterin International, Inc., X-spine Systems, Inc., and any additional borrower that hereafter becomes party thereto, Xtant Medical Holdings, Inc., and any additional guarantor that hereafter becomes party thereto, and MidCap Funding IV Trust, as agent, and the lenders from time to time party thereto (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on March 1, 2023 (SEC File No. 001-34951) and incorporated by reference herein).</u>
10.30*	<u>Commercial Lease dated as of February 1, 2012 by and between Cruiser Lane, LLC and Bacterin International Holdings, Inc.</u>
10.31*	<u>Addendum to Commercial Lease dated as of December 3, 2018 between Cruiser Lane, LLC and Bacterin International Holdings, Inc.</u>

Exhibit No.	Description
10.32*	<u>Addendum to Commercial Lease dated as of July 29, 2022 between Cruiser Lane, LLC and Bacterin International Holdings, Inc.</u>
10.33*	<u>Lease Agreement dated as of August 7, 2013 by and between McClellan Farm and Bacterin International, Inc.</u>
10.34*	<u>Triple Net Commercial Lease dated as of October 23, 2015 by and between Shep Does Stuff LLC and Bacterin International, Inc.</u>
21.1*	<u>Subsidiaries of the Registrant</u>
23.1*	<u>Consent of Independent Registered Public Accounting Firm, Plante & Moran, PLLC</u>
31.1*	<u>Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1**	<u>Certification of Chief Executive Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2**	<u>Certification of Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS*	Inline XBRL INSTANCE DOCUMENT (the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document)
101.SCH*	Inline XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	Inline XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF*	Inline XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	Inline XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	Inline XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

● Indicates a management contract or compensatory plan

* Filed herewith

** Furnished herewith

† All exhibits and schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.

Item 16. Form 10-K Summary

Optional disclosure, not included in this Annual Report on Form 10-K.

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.

XTANT MEDICAL HOLDINGS, INC.

March 7, 2023

By: /s/ Sean E. Browne

Name: Sean E. Browne

Title: President and Chief Executive Officer
(principal executive officer)

By: /s/ Scott Neils

Name: Scott Neils

Title: Chief Financial Officer
(principal financial and accounting 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 indicated on March 7, 2023.

Signature	Title
<u>/s/ Sean E. Browne</u> Sean E. Browne	President and Chief Executive Officer (principal executive officer)
<u>/s/ Scott Neils</u> Scott Neils	Chief Financial Officer (principal financial and accounting officer)
<u>/s/ John Bakewell</u> John Bakewell	Director
<u>/s/ Michael Eggenberg</u> Michael Eggenberg	Director
<u>/s/ Robert McNamara</u> Robert McNamara	Director
<u>/s/ Matthew Rizzo</u> Matthew Rizzo	Director
<u>/s/ Stavros Vizirgianakis</u> Stavros Vizirgianakis	Director