

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2020

or

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

For the transition period from _____ to _____
 Commission file 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 [X]

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

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

Indicate by check mark whether the registrant has submitted electronically 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 [X] 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

[X] Smaller reporting company
Emerging growth company

[X]
[]

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

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

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

The aggregate market value of the common stock held by non-affiliates as of June 30, 2020 was \$3.5 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 February 22, 2021 was 77,818,396.

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, 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.

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.

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. Our response since the onset of COVID-19 has been undertaken with the objective of positioning Xtant for long-term success by:

- Implementing a series of cost-saving actions intended to preserve capital and restructure our operations;
- Identifying and implementing specific operational procedural changes to return yields on biological products to realign with our mission of, “Honoring the gift of donation by allowing our patients to live as full a life as possible”;
- Re-engineering business processes in bioprocessing and inventory management systems to support current and future commercial activities; and
- Restructuring our credit facility to dramatically reduce the amount of our indebtedness and cost to service our debt, which should make it easier for us to refinance or replace this debt in the future, as well as facilitate easier access to capital markets for investment in our growth initiatives.

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. It provides the constructive support necessary for reestablishing stability, by immobilizing the regenerative site, and relieving stress. Fixation can also 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, and may be made from various metals and polymer materials.

How We Compete

We believe the following allow us to compete in the marketplace:

- *Broad Portfolio of Products:* We have a comprehensive portfolio of products that address a broad array of spinal pathologies, anatomies and surgical approaches in the complex spine and minimally invasive surgery (“MIS”) markets. To protect company innovative technologies and techniques, we maintain and plan to continue to grow our intellectual property portfolio.
- *Customer Service:* Responding quickly and efficiently to the needs of patients, surgeons and hospitals is central to our corporate culture and critical to our success. Our supply chain and customer service teams work together to make sure that the right product and instrumentation is in the right place at the right time. Through such vertically integrated processes, we strive to meet the changing needs of our customers.
- *National Distribution Network:* Xtant has built a distribution channel function calling on orthopedic surgeons, neuro surgeons, their staff and the hospital administrators that support them. We have an extensive distribution channel of commissioned independent agents and stocking agents in the United States that represent some or all of Xtant’s products.
- *GPO Access:* We 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 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. Upon compressing the allograft, OsteoSponge springs back to fill the void. 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.
- OsteoSponge SC is a form of OsteoSponge designed to fill bony defects in the subchondral region of joints.
- 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. Every production batch of OsteoSelect is tested for osteoinductive bone growth characteristics allowing us to make that unique marketing claim.
- 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. OsteoSelect PLUS is indicated as a bone void filler and bone graft substitute in the pelvis, extremities, and posterolateral spine.

- OsteoWrap is 100% human cortical bone demineralized through a proprietary process to make the graft flexible while maintaining allograft integrity. This product has various applications in orthopedic, neurological, trauma, oral/maxillofacial and reconstructive procedures. OsteoWrap is designed to wrap around non-union fractures to assist with fusion or be used in conjunction with a hardware plate system. Additionally, this product is intended to provide the surgeon with superior handling characteristics as the allograft can be easily sized using surgical scissors or a scalpel and is designed to withhold sutures or staples for fixation.
- 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.

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. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patient anatomy. 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. Self-drilling screws preserve cancellous bone for secure screw purchase. If drilling is desired, instruments offer optional drill guides and drill bits. A full sweep of 15° angulation can be achieved with Spider System variable screws.

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.

Sales and Marketing

We distribute our products in the United States through an extensive distribution network of commissioned 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.

Donor Procurement

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. 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."

Competition

There are various public and private organizations that offer both fixation and orthobiologics to their customers. The market is dominated by large competitors, including Medtronic plc, Johnson and Johnson, Zimmer Biomet Holdings, Inc., Stryker Corporation, Nuvasive, Inc., and Globus Medical, Inc. Together, we believe these large competitors have approximately 80% market share. We compete with these larger competitors and several others, including 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.

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 an outstanding claim of patent infringement litigation which we are analyzing. In addition, we were recently subject to patent infringement litigation that we settled in February 2020. There can be no assurances that we do not infringe any patents or other proprietary rights. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages, license fees or royalties to such party and/or cease production, marketing, and distribution of those products. Litigation also may be necessary to defend infringement claims of third parties or to enforce patent rights we hold or to protect trade secrets or techniques we own.

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, 2020, our fixation patent portfolio includes 51 issued patents globally, and our biologics patent portfolio includes 19 issued patents globally and 4 patent applications pending. 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®, and Circle of Life®. 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. There can be no assurance, however, that these measures will adequately protect against the unauthorized disclosure or use of confidential information, or that third parties will not be able to independently develop similar technology. Additionally, there can be no assurance that any agreements concerning confidentiality and non-disclosure will not be breached, or if breached, that we will have an adequate remedy to protect us against losses. 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 products have been regulated by the FDA since 1993. These 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 because they meet these four criteria. The FDA's Tissue Reference Group confirmed this in non-binding recommendations provided to us.

Products that are regulated solely under Section 361 of the PHSA and 21 CFR Part 1271 are subject to the following regulatory requirements:

- 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 do not meet the criteria to be classified solely under Section 361 of the PHSA and 21 CFR Part 1271 and therefore 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

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory which is: (i) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (iii) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. The Center for Devices and Radiological Health governs 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.

Generally, a de novo application contains a device description, indications for use statement, proposed labeling, data/performance testing (e.g., bench testing and/or clinical study data), the proposed classification, and a risk/benefit analysis. The risk/benefit analysis is the key element of a de novo petition and typically includes a summary of the benefits of the device, a summary of the known and potential risks, any risk mitigations, and an explanation of whether the benefits outweigh the risks. The applicant must also outline special controls, which can include data and labeling requirements that subsequent applicants under the new device classification regulation must follow to obtain a 510(k) clearance.

The timing for review of a de novo application is less certain than a 510(k). As a practical matter, de novo marketing authorization often ranges from a year or more, and marketing authorization is never assured. If the FDA authorizes the de novo petition, the device may be legally marketed and used as a predicate device for future 510(k) submissions. If the de novo application is denied, the device remains in Class III and a PMA approval may be required before the device may be legally marketed in the United States.

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. 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. 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.

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. There is sometimes advisory panel review of the clinical data. The FDA typically conducts a pre-approval inspection of the manufacturer's facilities and may also inspect the clinical trial documentation. The FDA will not approve the device unless compliance is shown with Quality System Regulation (“QSR”) requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. During the review period, the FDA may also request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

By statute, the FDA has 180 days to review a filed PMA application, although the review more often occurs over a significantly longer period of time. If its evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter. An approvable letter usually contains a number of conditions that must be met in order to secure a final approval of the PMA application. When and if these conditions have been fulfilled to the satisfaction of the FDA, the FDA will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in this approval letter, if any. If the FDA's evaluation of a PMA application or the relevant manufacturing facilities is not favorable, the FDA will deny approval of the PMA application or issue a not approvable letter.

Even after approval of a PMA, new PMA applications or PMA supplements may also be required for modifications to any approved device, including modifications to the manufacturing processes, device labeling and device design, based on the findings of post-approval studies. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

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

- The FDA's QSR, which requires 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.

In light of extensive new legislation in Europe, specifically the new European Medical Device Regulation (“MDR”), we ceased selling products in the European Union (“EU”) during the third quarter of 2020 after concluding that the cost to maintain our regulatory approvals and sell our products in the EU, especially in light of this extensive new legislation, exceeded the benefits of doing business there for Xtant. Our revenues from sales of our products in the EU during 2020 were only \$0.2 million.

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. Recent 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 False Claims Act amendments in 2009 and 2010 expanded the scope of the liability for health care entities generally to potentially reach violations of regulatory duties, such as good manufacturing practices. There have been large settlements in the life sciences arena related to FDA regulatory violations for promotional activities and good manufacturing practice.

Even in instances where a company may have no actual liability, the Federal False Claims Act private citizen provisions (qui tam) allow the filing of Federal False Claims Act actions under seal and impose a mandatory duty on the United States Department of Justice to investigate such allegations. Most private citizen actions are declined by the Department of Justice or dismissed by federal courts. However, the investigation costs for a company can be significant and material even if the allegations are without merit.

Federal False Claims Act liability is potentially significant in the health industry because the statute, as adjusted for inflation, provides for treble damages and mandatory minimum penalties of \$11,665 to \$23,331 per false claim or statement. Because of the potential for large monetary exposure, health care companies resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages that may be awarded in litigation proceedings. They may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs to companies to ensure compliance.

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. Effective January 2021, device manufacturers 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”) in 2022. 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 of up to an aggregate of \$150,000 per year, and up to an aggregate of \$1.0 million per year for “knowing failures.” Manufacturers must submit reports by the 90th day of each calendar year. 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. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

If a governmental authority were to conclude that Xtant is not in compliance with applicable laws and regulations, Xtant and its officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare, Medicaid and other federal health care programs. Our United States operations are 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.

Employees

As of December 31, 2020, Xtant had 110 employees, all of whom were full time employees, and of whom 55 were in operations, 19 were in sales and marketing, 3 in research and development and engineering, 11 in regulatory and quality affairs, and 22 were in administrative functions. In addition, we make use of a varying number of 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.

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. At the close of business on July 31, 2015, we changed our corporate name to “Xtant Medical Holdings, Inc.” On August 6, 2015, 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.”

As a result of debt restructuring transactions completed during first quarter of 2018 and, more recently, during fourth quarter of 2020, as described in more detail under “Part II. Item 7. *Management’s Discussion and Analysis of Financial Condition and Results of Operations*” section of this Form 10-K, OrbiMed Royalty Opportunities II, LP (“Royalty Opportunities”), which is the sole holder of our outstanding indebtedness and lender under our credit facility, and ROS Acquisition Offshore LP (“ROS”), which are funds affiliated with OrbiMed Advisors LLC (“OrbiMed”), collectively own approximately 93.9% of our outstanding common stock as of December 31, 2020.

Our corporate headquarters and manufacturing facility are located at 664 Cruiser Lane, Belgrade, Montana 59714. Our telephone number is (406) 388-0480.

Controlled Company Status

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. 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 (“Exchange Act”), 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 Outstanding Indebtedness, Need for Additional Financing and Financial Condition

- We have a history of significant losses and will likely need additional financing to satisfy our anticipated future liquidity requirements.
- We have indebtedness that is scheduled to mature on December 31, 2021, which we may be unable to refinance or extend the maturity date.
- The terms of our Second A&R Credit Agreement give the lender sole discretion on our ability to access the additional \$5 million in term loans thereunder and impose substantial limitations on the operation of our business and covenant requirements we may be unable to achieve.
- The anticipated replacement of the LIBOR benchmark interest rate could affect our interest rates.

Risks Related to Our Business

- The COVID-19 pandemic 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 develop and market new products and technologies, our business may be negatively affected.
- Our biologics business is highly dependent on the availability of human donors.
- Negative publicity concerning methods of tissue recovery and screening of donor tissue 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 are subject to product liability litigation that could be expensive if it exceeds our insurance coverage.
- We have completed business combinations in the past which involve risks and may do so in the future.
- Our quarterly operating results are subject to substantial fluctuations and are not indicative of annual results.
- 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 FDA or other regulatory requirements pertaining to human tissue products, 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 our business.
- 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

- We have limited staffing and are dependent upon key employees and qualified personnel, and competition for such talent is intense, especially around Belgrade, Montana.

Risks Related to Intellectual Property

- We could be required to pay damages or prevented from selling our products due to intellectual property lawsuits.
- 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 may not be able to obtain or protect our proprietary rights relating to our products.

Risks Related to Our Information Technology, Cybersecurity and Data Protection

- We are dependent on various information technology systems, which are substantially outdated and in need of significant upgrades or conversion to a new enterprise resource planning system.

Risks Related to Our Controlled Company Status

- OrbiMed funds 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 our Company and management.
- We are a “controlled company” within the meaning of the NYSE American rules.

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 stock ownership dilution, and 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.
- 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.
- We are authorized to issue and designate shares of our preferred stock without stockholder approval.
- Our Amended and Restated Certificate of Incorporation (“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.

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

General Risk Factors

- Worldwide economic instability and social unrest could adversely affect our revenue, financial condition, or results of operations.
- 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.
- The requirements of being a public company may cause difficulties for our Company.
- We may be subject to securities litigation, which is expensive and could divert management attention.

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, 2020, we had an accumulated deficit of \$230.3 million. During the year ended December 31, 2020, we incurred a net loss of \$7.1 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; regulatory requirements and delays; 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 recently signed a securities purchase agreement with an investor for a \$20 milion private placement, which may not close as anticipated.

On February 22, 2021, we entered into a securities purchase agreement with a single healthcare-focused institutional investor pursuant to which we agreed to issue 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 in a private placement. The closing of this private placement is expected to occur on February 24, 2021, subject to the satisfaction of customary closing conditions. We expect to receive gross proceeds of approximately \$20 million, before deducting fees and other estimated offering expenses from the Private Placement, and expect to use the net proceeds from the Private Placement for working capital and other general corporate purposes. No assurance can be provided that the conditions to closing will be satisfied or that the closing of this private placement will occur as anticipated on February 24, 2021 or at all.

We may need additional financing to satisfy our anticipated future liquidity requirements, which financing may not be available on favorable terms 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 balance of approximately \$2.3 million as of December 31, 2020, together with anticipated cash flows from operations, the anticipated net proceeds from our pending private placement and existing credit availability under our Second Amended and Restated Credit Agreement with Royalty Opportunities and ROS, as amended (the "Second A&R Credit Agreement") which we expect to replace or extend prior to its December 31, 2021 maturity date, will be sufficient to meet our anticipated cash requirements through at least the end of February 2022. Although we have availability under our Second A&R Credit Agreement, our ability to obtain additional term loans under this facility is in the sole and absolute discretion of the lender. In addition, this credit facility expires December 31, 2021, and all of our indebtedness thereunder matures on such date. While we intend to extend the maturity date of or replace this facility prior to the maturity date, no assurance can be provided that we will do so on terms that are favorable to us or at all. In addition, we may require or we may seek additional funds to fund our future operations and business strategy prior to February 2022. 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 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. 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 Royalty Opportunities, the lender under our Second A&R Credit Agreement, and ROS and Royalty Opportunities, parties to an Investor Rights Agreement dated February 14, 2018 with the Company (the "Investor Rights Agreement"), and no assurance can be provided that Royalty Opportunities and ROS would provide such consent, which could limit our ability to raise additional financing.

We have indebtedness which matures on December 31, 2021. We may not be able to extend the maturity date of or replace our credit facility 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.

Although we completed a debt restructuring during 2020 that reduced the amount of our indebtedness, as of December 31, 2020, we still had \$15.6 million of principal outstanding under our credit facility, which matures on December 31, 2021. Although we believe that we will be able to refinance our outstanding indebtedness or extend the maturity date of that facility, 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, including amounts borrowed under our credit facility, 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 Second A&R Credit Agreement could 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 agreement, 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 Second A&R Credit Agreement 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 Second A&R Credit Agreement includes a number of significant financial and operating restrictions. For example, the agreement contains financial covenants that, among other things, require us to maintain a minimum liquidity covenant, as defined in the agreement, and contains provisions that restrict our ability, subject to specified exceptions, to, among other things:

- make loans and investments, including acquisitions and transactions with affiliates;
- create liens or other encumbrances on our assets;
- dispose of assets;
- enter into contingent obligations;
- comply with NYSE American rules and regulations;
- engage in mergers or consolidations; and
- pay dividends.

We may be unable to comply with these covenants, which could result in a default under the agreement. 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 lender, 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, the lender is also a party to an Investor Rights Agreement with us which further substantially limits the operation of our business and the ability of our management to conduct and invest in our business.

Our credit facility involves additional risks that may adversely affect our liquidity, results of operations, and financial condition.

Availability of additional term loans under the Second A&R Credit Agreement is based on the amount of our liquidity and revenue and is also subject to the sole and absolute discretion of the lender. As a result, our access to credit under the Second A&R Credit Agreement is subject to fluctuations depending on our financial results and projected cash balances as of any valuation date as well as the discretion of the lender. Our inability to borrow additional amounts under the credit facility if and when we need them may adversely affect our liquidity, results of operations, and financial condition.

Our outstanding indebtedness under the credit facility 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 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. In the event of a default under our Second A&R Credit Agreement, the lender may terminate its commitments to lend additional money under the credit facility and declare all amounts outstanding thereunder to be immediately due and payable. If an event of default occurs and is continuing under the Second A&R Credit Agreement, the lender thereunder may elect to increase the rates at which interest accrues. Subject to certain exceptions, amounts outstanding under the credit facility 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, the lender could seek to enforce security interests in our assets securing our indebtedness under the credit facility, including restricting our access to collections on our accounts receivable. Any acceleration of amounts due under our Second A&R Credit Agreement or the exercise by the lender thereto 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 Second A&R Credit Agreement, and we may be unable to successfully negotiate waivers to cure any covenant violations.

Our Second A&R Credit Agreement contains representations, warranties, fees, affirmative and negative covenants, including a minimum liquidity covenant and substantial operating covenants, and default provisions. A breach of any of these covenants could result in a default under the agreement. Upon the occurrence and during the continuance of an event of default under the Second A&R Credit Agreement, the lender could elect to declare all amounts outstanding under the credit facility to be immediately due and payable and terminate all commitments to extend further credit. If the lender 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 Second A&R Credit Agreement, we pledged substantially all of our assets, including our intellectual property, to the lender. Our failure to comply with the covenants under the Second A&R Credit Agreement could result in an event of default, the acceleration of our debt and the loss of our assets.

The anticipated replacement of the LIBOR benchmark interest rate could affect interest rates under our Second A&R Credit Agreement, which may adversely impact our business, operating results and financial condition.

In July 2017, the Financial Conduct Authority announced its intention to cease sustaining the London Interbank Offered Rate (“LIBOR”), which is widely used as a reference for setting the interest rates on loans, by the end of 2021. In April 2018, the New York Federal Reserve Bank began publishing its alternative rate, the Secured Overnight Financing Rate (“SOFR”), which is calculated using short-term repurchase agreements backed by Treasury securities. In early 2019, the Alternative Reference Rates Committee proposed that SOFR be utilized as the replacement for LIBOR. However, there is still uncertainty as to whether and when SOFR or another alternative rate will be adopted as the replacement for LIBOR. On November 30, 2020 the ICE Benchmark Administration announced its intention to extend from December 31, 2021 to June 20, 2023 the date most U.S. LIBOR rates (including the LIBO Rate as defined in the Second A&R Credit Agreement) would cease being computed and announced.

If LIBOR ceases to exist before our Second A&R Credit Agreement is terminated, we may need to renegotiate this agreement, since borrowings thereunder are indexed to the LIBO Rate, as such term is defined in the agreement and if such LIBO Rate is not determinable the interest rate will equal the interest rate in effect for immediately preceding Interest Period, as such term is defined in the agreement. This may increase or otherwise affect interest rates under our Second A&R Credit Agreement. We are evaluating the potential impact of the eventual replacement of LIBOR, including the possibility of SOFR as the dominant replacement. However, we are not able to predict whether LIBOR will cease to be available after June 30, 2023, whether SOFR will become a widely accepted benchmark in place of LIBOR, or what the impact of such a transition may be on our business, results of operations and financial condition.

Risks Related to Our Business

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

The COVID-19 pandemic has caused business closures, severe travel restrictions and the implementation of social distancing measures. 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 distributors and independent sales representatives. Because of the COVID-19 pandemic, 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. In addition, even after the easing of such restrictions such that governmental orders no longer prohibit or recommend against performing such procedures, patients may continue to defer such procedures out of concern of being exposed to COVID-19 or for other reasons.

The COVID-19 pandemic has also caused adverse effects on general commercial activity and the global economy, which has led to an economic slowdown and recession and could cause other unpredictable events, any of which could adversely affect our business, operating results or financial condition. The adverse effect of the pandemic on the broader economy also will likely negatively affect demand for procedures using our products, both in the near- and long-term. No assurance can be provided that our revenues will ever return to pre-COVID-19 levels. In addition, as a result of this negative effect on our economy, one or more of our distributors, independent sales representatives, customers, contract manufacturers and suppliers may experience financial distress, cancel, postpone or delay orders, be unable to perform under a contract, file for bankruptcy protection, go out of business, or suffer disruptions in their business or we may need to offer special payment terms or relief to our distributors, independent sales representatives and customers. Accordingly, we believe we are exposed to heightened credit risk as a result of the pandemic. This could adversely impact our ability to manufacture and provide products and otherwise operate our business, as well as increase our costs and expenses.

The decline in our revenues and adverse impact of the pandemic on our other operating results could impact our debt covenants under our credit facility and our ability to access funding thereunder or refinance that debt or extend its maturity date. We may need to borrow funds from alternative sources, such as other lenders and institutions or government agencies. There can be no guarantee that such borrowing will be available or available on favorable terms or without restrictions that may otherwise impair our operating flexibility. The COVID-19 pandemic has also led to and could continue to lead to severe disruption and volatility in the global capital markets, which could increase our cost of future capital and adversely affect our ability to access the capital markets in the future.

The foregoing and other continued disruptions to our business as a result of COVID-19 have resulted, and could continue to result, in a material adverse effect on our business, operating results, financial condition, prospects and the trading price of our common stock throughout 2021. The full extent to which the COVID-19 pandemic 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, the availability and effectiveness of vaccines, actions that federal, state and local governmental or regulatory agencies take in response to COVID-19, and other actions to contain it or treat its impact. The COVID-19 pandemic 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 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. 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 develop and market new products and technologies, we may experience a decrease in demand for our products, or our products could 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 introduce 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, 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 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 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, 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 have pending 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. We are currently involved in pending product liability litigation. While we believe these matters will be covered under our product liability insurance, no assurance can be provided that any amounts required to be paid to resolve these or any future matters 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. We currently carry product liability insurance; however, our insurance coverage may not be adequate, and our business could suffer material adverse consequences due to product liability claims.

We have completed acquisitions and business combinations in the past and may complete them 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 the acquisition of X-spine Systems, Inc. in 2015, and may complete acquisitions and business combinations in the future. 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. 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 may require the consent of the lender under our credit facility 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 lender or these investors would approve such 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.

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 impact of COVID-19 on our business or 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 distributor or independent sales representative 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, commodity prices, and manufacturing variances;
- income tax fluctuations and changes in tax rules;
- general economic, social and other external factors, such as the COVID-19 pandemic; and
- increases of interest rates, which can increase the cost of borrowings under our credit facility, and generally affect the level of economic activity.

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.

Operations in countries outside of the United States accounted for approximately 2% of our total revenue for the year ended December 31, 2020 and are accompanied by certain financial and other risks. Our international sales operations expose us and our representatives, agents, and distributors to risks inherent in operating in foreign jurisdictions. These risks include, among others:

- 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;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- the imposition of U.S. or international sanctions against a country, company, person, or entity with whom we do business that would restrict or prohibit continued business with that country, company, person, or entity;
- new or enhanced trade restrictions and restrictions on the activities of foreign agents, representatives and distributors;
- economic instability, including economic instability caused by the COVID-19 pandemic and currency risk between the U.S. dollar and foreign currencies, in our markets;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- scrutiny of foreign tax authorities, which could result in significant fines, penalties, and additional taxes being imposed upon us;
- difficulties in managing and staffing international operations and increases in infrastructure costs including legal, tax, accounting, and information technology;
- international pricing pressures;
- 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;
- unexpected changes in foreign regulatory requirements;
- differing local product preferences and product requirements and increased costs of customizing products for foreign countries;
- changes in tariffs and other trade restrictions, particularly related to the exportation of our biologic products;
- difficulties in protecting, enforcing and defending intellectual property rights;
- foreign currency exchange controls that might prevent us from repatriating cash;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- transportation delays and interruptions;
- national and international conflicts, including foreign policy changes, social unrest, acts of war or terrorist acts;
- complex data privacy requirements and labor relations laws; and
- exposure to different legal and political standards.

In addition, during the third quarter of 2020, we ceased selling products in the EU after concluding that the cost to maintain our regulatory approvals and sell our products in the EU, especially in light of extensive new legislation, exceeded the benefits of doing business there for Xtant. Our revenues from sales of our products in the EU during 2020 were only \$0.2 million and while we believe the anticipated costs to exit the EU will not be significant, no assurance can be provided that the actual costs involved will not exceed our anticipated costs.

Our ability to deduct interest is limited.

Under the Tax Cuts and Jobs Act, 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. Disallowed interest deductions are carried forward indefinitely and treated as business interest paid or accrued in the succeeding taxable year.

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 U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”), a de novo classification or a Premarket Approval, 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. Effective January 2021, 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 in 2022;
- 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. No assurance can be provided that the costs involved in exiting the EU will not exceed our anticipated costs. 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. The FDA revised its guidance regarding when a change to a cleared device requires a new 510(k) clearance in October 2017. This guidance is more burdensome in terms of assessing and documenting whether a new 510(k) should be submitted.

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 human cells and tissue and cellular and tissue-based products, 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 December 2018, we initiated a Class 2 recall of our Calix Lumbar Spine Implant System. Although there were no device related adverse events reported for this product, and we worked with the FDA on the recall and closed it out in 2019, any future recall announcement could negatively affect our sales and harm our reputation with customers. 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 ongoing FDA or other regulatory authority requirements pertaining to human tissue products, these products could be subject to withdrawal from the market or other enforcement action.

The FDA has statutory authority to regulate HCT/Ps. HCT/Ps consist of articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient, including allograft-based products. The FDA and other regulatory authorities have been working to establish more comprehensive regulatory frameworks for allograft-based, tissue-containing products, which are frequently derived from cadaveric tissue. Certain of our products are regulated as HCT/Ps and are not marketed pursuant to the FDA's medical device regulatory authority, and therefore are not subject to FDA clearance or approval. Although we have not obtained premarket approval for these HCT/P products, they are nonetheless subject to regulatory oversight.

Section 361 of the PHSA 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; current Good Tissue Practices, or cGTP, when processing, storing, labeling and distributing HCT/Ps, including required labeling information; stringent recordkeeping; and adverse event reporting. 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. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to 361 HCT/Ps and, in addition, with requirements applicable to biologics under the PHS, or devices or drugs under the FDCA, including licensure, clearance or approval.

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 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. 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 "Current Good Tissue Practices" rule. The "Current Good Tissue Practice" 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 to recipients.

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 Current Good Tissue Practices 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 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, 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 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.

Procurement of certain human organs and tissue for transplantation, including allograft tissue we may use in future products, is subject to federal regulation under National Organ Transplant Act. NOTA prohibits the acquisition, receipt, or other transfer of certain human organs, including bone and other human tissue, for valuable consideration within the meaning of NOTA. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human organs. For any future products implicating NOTA's requirements, we would reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they would provide to us. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our services, thereby negatively impacting our future revenue and profitability. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our operating results. Further, in the future, if NOTA is amended or reinterpreted, we may not be able to pass these expenses on to our customers and, as a result, our business could be adversely affected.

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.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to sell our products and our business.

Product pricing is subject to regulatory control, which could impact our revenue and other operating results.

The pricing of our products may become subject to control by the government and other third-party payors. The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. In most foreign markets, the pricing of certain diagnostics and prescription pharmaceuticals are subject to governmental control. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control, though it is unclear which proposals will ultimately become law, if any. Changes in prices, including any mandated pricing, 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.

Political, economic and regulatory influences are subjecting the healthcare industry, including the medical device industry, in the United States to fundamental change. 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 distributors and sales agents who we do not control.

Substantially all of our revenue is conducted through distributors and independent sales agents. Because the independent 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 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 field sales agents of a distributor or independent sales agent, 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 distributor or sales agent. If we fail to maintain relationships with our key distributors and independent sales representatives or fail to ensure that our distributors and independent sales agent 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 distributor and independent sales agent organization or transitions to direct selling models also could adversely affect our business if these transitions are not managed effectively. Further, independent distributors and sales agents 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 distributors or agents could have a material adverse effect on our business and results of operations.

In addition, our success is partially dependent upon our ability to retain and motivate our distributors, independent sales agencies, and their representatives to sell our products in certain territories. They may not be successful in implementing our marketing plans. Some of our distributors and independent sales agencies do not sell our products exclusively and may offer similar products from other companies. Our distributors and independent sales agencies 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 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. Despite our efforts, we sometimes experience an insufficient inventory of products, raw materials and/or components. At the end of 2019 and beginning of 2020, we experienced a supply issue with certain of our biologics and hardware products. 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

We have limited staffing and are dependent upon key employees. In addition, 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.

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.

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 and growth of our business. 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, 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. A 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.

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 are currently subject to a patent infringement claim and were recently subject to patent infringement litigation which we settled in February 2020. There can be no assurances that we do not infringe any patents or other proprietary rights. In November 2020, we received a letter from a third party's legal counsel claiming that some of our products, including the Butrex Plating System, Spider Plating System, Aranax Plating System and Irix Fusion System, infringe a patent held by the third party and offering to discuss settlement terms. Because this matter is in early stages and because of the complexity of the claims, we cannot estimate the possible loss or range of loss, if any, associated with its resolution. However, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition or results of operations. 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. Our reliance on IT systems increased as work from home arrangements were necessitated by the COVID-19 pandemic. 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. In addition, we have grown in part through strategic business combinations and acquisitions. As a result of these transactions, we may face risks due to implementation, modification, or remediation of the IT controls, procedures, and policies at the acquired businesses.

In addition, 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. 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.

Our current enterprise resource planning (“ERP”) system is substantially outdated and in need of a substantial upgrade or conversion to a new ERP system.

Although we recently made upgrades to our ERP system, it is still substantially outdated and in need of significant additional upgrades or conversion to a new ERP system. Implementing new or upgraded systems carries substantial risk, including failure to operate as designed, failure to properly integrate with our systems, potential loss of data or information, cost overruns, implementation delays, and disruption of operations. Third-party vendors are also relied upon to design, program, maintain, and service the ERP system. Any failures of these vendors to properly deliver their services could have a material adverse effect on our business. In addition, any disruptions or malfunctions affecting our ERP system implementation plan could cause critical information upon which we rely to be delayed, defective, corrupted, inadequate, or inaccessible. We may experience difficulties in our business operations, or difficulties in operating our business under these systems, either of which could disrupt our operations, including our ability to timely invoice customers, ship and track product orders, project inventory requirements, manage our supply chain, effectively manage customer accounts receivable and pay suppliers within terms and otherwise adequately service our customers, and could lead to increased costs and other difficulties. In the event we experience significant disruptions as a result of the implementation or upgrade of new systems or otherwise, we may not be able to fix our systems in an efficient and timely manner. We may not realize the benefits we anticipate should all or part of the ERP system upgrade implementation process prove to be ineffective. Accordingly, such events may disrupt or reduce the efficiency of our entire operations and have a material adverse effect on our operating results and cash flows.

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 93.9% of our outstanding common stock as of December 31, 2020. Royalty Opportunities is also the lender under our Second A&R Credit Agreement and holds all of the outstanding indebtedness thereunder.

In addition, we are party to an Investor Rights Agreement with Royalty Opportunities and ROS 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 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.

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, Second 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 or position as our creditor, 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 Second A&R Credit Agreement 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 Second A&R Credit Agreement precludes 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 recent 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 2020, the sale price of our common stock ranged from \$0.55 to \$3.50 per share, and our daily trading volume ranged from zero to 112.3 million 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 Second A&R Credit Agreement;
- our observance of covenants under our Second A&R Credit Agreement;
- 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 the COVID-19 pandemic; 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.

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, 2020, we had outstanding warrants to purchase approximately 421,278 shares of our common stock, stock options to purchase 2,176,272 shares of our common stock and restricted stock unit awards covering 2,503,698 shares of our common stock under the Xtant Medical Holdings, Inc. Amended and Restated 2018 Equity Incentive Plan, options to purchase 14,620 shares of our common stock under our prior equity compensation plan, and 3,507,165 shares available for issuance under the Xtant Medical Holdings, Inc. 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 chairman of the Board or the chief executive officer.
- The Board of Directors may adopt, alter, amend or repeal our Second Amended and Restated 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 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 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 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 of Xtant 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, 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 assets or business of the Company or its 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).

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 to us or our stockholders by any of our directors, officers, or other employees, (iii) any action asserting a claim against us arising under the Delaware General Corporation Law (“DGCL”) or (iv) any action asserting a claim against us that is 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.

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 Second A&R Credit Agreement 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, 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, any economic crisis, such as the recession caused by the COVID-19 pandemic, 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.

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 actuarial 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”), Public Company Accounting Oversight Board (“PCAOB”), 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, increase our costs 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.

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 August 2023 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 January 2024.

In addition to our facilities in Belgrade, Montana, we lease office space of approximately 300 square feet located at 6160 Summit Drive North, Suite 450, Brooklyn Center, Minnesota.

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 February 22, 2021, we had 178 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 Second A&R Credit Agreement precludes 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, 2020, other than the issuance of shares of our common stock in connection with our debt restructuring as reported in a Current Report on Form 8-K as filed with the SEC on October 1, 2020 and the issuance of shares of our common stock upon the exercise of warrants held by ROS and Royalty Opportunities as reported in a Current Report on Form 8-K as filed with the SEC on November 19, 2020.

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, 2020.

Item 6. Selected Financial Data

This Item 6 is inapplicable to Xtant as a smaller reporting company.

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 IDN hospitals and through 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.

While we focused on improving our balance sheet and operational efficiencies in 2020, we remain committed to continuing to develop and release new products, expand our marketing programs, including reengaging with our distribution network, and pursue operational improvements intended to assist us in our overall commercial performance. During 2020, we took several actions in furtherance of these objectives, including:

- Completing a debt restructuring, as detailed below, which dramatically reduced our indebtedness and cost to service our debt, which should make it easier for us to refinance or replace this debt in the future, as well as facilitate easier access to capital markets for investment in our growth initiatives;
- Executing an agreement with one of the largest GPOs in the country, which will give us access to a strategically important new customer base; and
- Launching the Matriform Si for spinal fusion procedures, which expanded our biologics portfolio offering and increased our footprint in the United States orthopedic bone graft substitute market.

Recent Debt Restructuring

On August 7, 2020, we entered into a Restructuring and Exchange Agreement (the "Restructuring Agreement") with OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP, pursuant to which the parties thereto agreed, subject to the terms and conditions set forth therein, to take certain actions as set forth therein and as described below (collectively, the "Restructuring Transactions") in furtherance of a restructuring of our outstanding indebtedness under the Second A&R Credit Agreement with Royalty Opportunities and ROS.

The primary purpose of the Restructuring Transactions was to improve our capital structure by reducing the amount of our indebtedness and cost to service our debt, which should make it easier for us to refinance or replace this debt in the future, as well as facilitate easier access to capital markets for investment in our growth initiatives. The Restructuring Transactions also allowed us to regain compliance with the NYSE American continued listing standards, which we achieved on October 5, 2020. The Restructuring Transactions included, among others:

- an amendment to our Charter to increase the number of authorized shares of our common stock from 75 million to 300 million, which occurred on October 1, 2020;
- the exchange by the Company of shares of our common stock for approximately \$40.8 million of the aggregate outstanding principal amount under the Second A&R Credit Agreement, as well as, without duplication, approximately \$21.1 million of the outstanding amount of PIK Interest (as defined in the Second A&R Credit Agreement) (such loans and PIK Interest, the “Exchanging Loans”), plus all other accrued and unpaid interest on the Exchanging Loans outstanding as of the closing date, at an exchange price of \$1.07 per share, representing the average closing price of our common stock over the 10 trading days immediately prior to the parties entering into the Restructuring Agreement, and resulting in the issuance of approximately 57.8 million shares of common stock (the “Share Issuance”), which occurred on October 1, 2020;
- the execution of an amendment to the Second A&R Credit Agreement by the parties thereto to change certain provisions therein, including extinguishing loans in an aggregate principal amount equal to the Exchanging Loans outstanding thereunder together with all accrued and unpaid interest thereon, paying a portion of the prepayment fee payable thereunder in respect of the Exchanging Loans with proceeds of additional loans under the Second A&R Credit Agreement, with the remaining portion of the prepayment fee exchanged for an additional 0.9 million shares of our common stock, reducing the amount of credit availability thereunder, decreasing the interest rate and eliminating certain financial covenants, which occurred on October 1, 2020; and
- the launch by the Company of a rights offering to allow our stockholders to purchase up to an aggregate of \$15 million of our common stock at the same price per share as the \$1.07 per share exchange price used to exchange the Exchanging Loans into our common stock as part of the Share Issuance (the “Rights Offering”), which commenced on November 5, 2020 and expired on December 4, 2020 and resulted in the issuance of 712,646 shares of our common stock and gross proceeds of \$0.8 million.

Following completion of these Restructuring Transactions, the remaining principal balance of our outstanding debt totals \$15.6 million.

As a result of the completion of the debt restructuring, on October 5, 2020 we received notification from NYSE Regulation that we had regained compliance with all of the continued listing standards of the NYSE American, including in particular the requirement under NYSE American Company Guide Section 1003(a)(iii) that requires a listed issuer to maintain stockholders’ equity of at least \$6 million if it has reported losses from continuing operations, and/or net losses, in its five most recent fiscal years.

Recent Development -- Private Placement

On February 22, 2021, we entered into a securities purchase agreement with a single healthcare-focused institutional investor (the “Investor”) pursuant to which we agreed to issue 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”) in a private placement (the “Private Placement”). The closing of the Private Placement is expected to occur on February 24, 2021, subject to the satisfaction of customary closing conditions. We expect to receive gross proceeds of approximately \$20 million before deducting fees and other estimated offering expenses from the Private Placement. We expect to use the net proceeds from the Private Placement for working capital and other general corporate purposes.

The Investor Warrant will have an exercise price of \$2.25 per share, subject to customary anti-dilution, but not price protection, adjustments, and will be immediately exercisable and expire on the five-year anniversary of the date of issuance.

Under the terms of the Securities Purchase Agreement, we agreed that in the event we propose to offer and sell shares of our common stock or certain common stock equivalents to non-strategic investors primarily for capital raising purposes, we would provide the Investor the right, but not the obligation, to participate in such offering in an amount of up to 25% of the securities offered in such offering. This participation right will expire upon the earlier of 12 months after the closing of the Private Placement or upon the occurrence of certain change in control events.

We also agreed, under the terms of the Securities Purchase Agreement, to enter into a registration rights agreement (the “Registration Rights Agreement”) with the Investor pursuant to which we will agree to prepare and file a registration statement (the “Resale Registration Statement”) with the SEC within 45 days of the closing date for purposes of registering the resale of the shares of common stock issued to the Investor and the shares of common stock issuable upon exercise of the Investor Warrant. We will

also agree to use our reasonable best efforts to cause the Resale Registration Statement to be declared effective by the SEC within 60 calendar days of the closing of the Private Placement (75 calendar days in the event the registration statement is reviewed by the SEC). If we fail to meet the specified filing deadlines or keep the Resale Registration Statement effective, subject to certain permitted exceptions, we will be required to pay liquidated damages to the Investor.

In connection with the Private Placement, we entered into a placement agent agreement with A.G.P./Alliance Global Partners (the “Placement Agent”) pursuant to which the Placement Agent is serving 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 certain percentage of the aggregate gross proceeds from the 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 Private Placement, or 444,444 shares of our common stock (the “Placement Agent Warrant”). The Placement Agent Warrant will have an exercise price of \$2.8125 per share, subject to customary anti-dilution, but not price protection, adjustments and will be immediately exercisable and expire on the five-year anniversary of the date of issuance.

Impact of the COVID-19 Pandemic

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 the COVID-19 pandemic, 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. In addition, even after the easing of such restrictions such that governmental orders no longer prohibit or recommend against performing such procedures, patients may continue to defer such procedures out of concern of being exposed to coronavirus or for other reasons. It is uncertain if our revenues will ever return to pre-COVID-19 levels.

The COVID-19 pandemic has also caused adverse effects on general commercial activity and the global economy, which has led to an economic recession and could cause other unpredictable events, any of which could adversely affect our business, operating results or financial condition. The adverse effect of the pandemic on the broader economy also will likely negatively affect demand for procedures using our products, both in the near- and long-term. This could cause one or more of our distributors, independent sales representatives, customers, contract manufacturers and suppliers to experience financial distress, cancel, postpone or delay orders, be unable to perform under a contract, file for bankruptcy protection, go out of business, or suffer disruptions in their business. This could impact our ability to manufacture and provide products and otherwise operate our business, as well as increase our costs and expenses.

The decline in our revenues and adverse impact on our other operating results could impact our debt covenants under our credit facility and our ability to access funding thereunder or refinance that debt or extend its maturity date. We may need to borrow funds from alternative sources, such as other lenders and institutions or government agencies. There can be no guarantee that such borrowing will be available or available on favorable terms or without restrictions that may otherwise impair our operating flexibility. The COVID-19 pandemic has also led to and could continue to lead to disruption and volatility in the global capital markets, which could increase our cost of future capital and adversely affect our ability to access the capital markets in the future.

In response to the COVID-19 pandemic, during the second quarter of 2020, we implemented a series of cost-saving actions intended to preserve capital to support our operations. These temporary cost-saving actions included:

- termination or furlough of 42% of our workforce;
- suspension in hiring most open positions;
- elimination of planned fiscal 2020 merit increases;
- institution of a temporary 20% base salary or wage reduction for all executive officers and employees;
- 20% reduction in non-employee director retainers for second quarter of 2020;
- suspension of future 401(k) plan matching contributions by the Company; and
- reduction in fiscal 2020 sales and marketing expenses and other discretionary spending.

Effective July 1, 2020, we reinstated the full base salaries and wages of all our employees and restored future 401(k) plan matching contributions.

COVID-19 has resulted and will likely continue to result in a material adverse effect on our business, operating results, financial condition, prospects and the trading price of our common stock in the near-term and beyond 2020. The full extent to which the COVID-19 pandemic 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, the actions to contain it or treat its impact, and the availability and effectiveness of vaccines.

Results of Operations

Comparison of Years Ended December 31, 2020 and December 31, 2019

The following table sets forth our results of operations for 2020 and 2019 (dollars in thousands):

	Year Ended December 31,			
	2020		2019	
	Amount	% of Revenue	Amount	% of Revenue
Revenue				
Orthopedic product sales	\$ 53,188	99.7%	\$ 64,516	99.7%
Other revenue	149	0.3%	166	0.3%
Total Revenue	53,337	100.0%	64,682	100.0%
Cost of Sales	18,945	35.5%	22,166	34.3%
Gross Profit	34,392	64.5%	42,516	65.7%
Operating Expenses				
General and administrative	13,503	25.3%	17,344	26.8%
Sales and marketing	20,983	39.4%	26,493	41.0%
Research and development	657	1.2%	932	1.4%
Total Operating Expenses	35,143	65.9%	44,769	69.2%
Loss from Operations	(751)	(1.4)%	(2,253)	(3.5)%
Other Income (Expense)				
Interest expense	(5,976)	(11.2)%	(5,772)	(8.9)%
Other income (expense)	—	(0.0)%	(98)	(0.2)%
Total Other Expense	(5,976)	(11.2)%	(5,870)	(9.1)%
Net Loss from Operations Before Provision for Income Taxes	(6,727)	(12.6)%	(8,123)	(12.6)%
Provision for Income Taxes				
Current and Deferred	(296)	(0.6)%	(98)	(0.1)%
Net Loss	\$ (7,023)	(13.2)%	\$ (8,221)	(12.7)%

Revenue

Total revenue for the year ended December 31, 2020 decreased 17.5% to \$53.3 million compared to \$64.7 million for the prior year. The decrease of \$11.3 million is largely attributed to the impact of COVID-19 and the sudden drop in elective procedures beginning in early March 2020.

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 decreased by 14.5%, or \$3.2 million, to \$18.9 million for the year ended December 31, 2020 from \$22.2 million for the year ended December 31, 2019. This reduction was due primarily to lower revenue during the year ended December 31, 2020 compared to the prior year, as previously discussed. Cost of sales as a percent of total revenue was 35.5% of revenue for the year ended December 31, 2020, compared to 34.3% for the prior year. This increase in cost of sales as a percent of total revenue is also primarily due to lower revenue during the year ended December 31, 2020 versus the prior year.

Gross profit as a percentage of sales decreased to 64.5% for the year ended December 31, 2020 compared to 65.7% for the year ended December 31, 2019. This reduction is primarily attributable to diminished economies of scale due to lower revenue, partially offset by reduced depreciation expense.

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 decreased 22.1%, or \$3.8 million, to \$13.5 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease is primarily attributable to lower legal and consulting fees of \$2.1 million, reduced legal settlement expenses of \$0.9 million, reduced field action expenses of \$0.5 million, reduced license fees of \$0.5 million, reduced executive recruiting fees of \$0.4 million and reduced salaries and wages of \$0.3 million during the year ended December 31, 2020. These decreases were offset partially by severance expense of \$0.7 million and additional stock-based compensation expense of \$0.6 million during the year ended December 31, 2020. The reduced salaries and wages were due to the reduction in headcount and the temporary 20% salary and wage decreases implemented during the second quarter of 2020 in response to the COVID-19 pandemic.

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 decreased 20.8%, or \$5.5 million, to \$21.0 million for the year ended December 31, 2020, compared to \$26.5 million for the year ended December 31, 2019. This decrease is primarily due to a \$3.1 million reduction in sales commissions due to lower revenues, reduced salaries and wages of \$1.5 million and lower travel expenses of \$0.5 million compared to the prior year.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new product technologies. Research and development expenses decreased \$0.3 million, or 29.5%, to \$0.7 million for the year ended December 31, 2020 from \$0.9 million for the year ended December 31, 2019. This decrease was due primarily to a reduction in research and development headcount in 2020 compared to 2019.

Interest Expense

Interest expense for the year ended December 31, 2020 increased \$0.2 million to \$6.0 million as compared to \$5.8 million for the year ended December 31, 2019. This increase was due to an amendment to our credit agreement in May 2020 which increased the effective interest rate of our outstanding debt prior the partial exchange of outstanding paid-in-kind interest and principal for shares of our common stock in connection with our October 1, 2020 debt restructuring. Concurrent with this debt restructuring, we incurred expense of \$0.7 million related to prepayment fees under our credit agreement. The debt restructuring transaction allowed us to forego \$2.0 million of interest expense which otherwise would have accrued during the remainder of the year ended December 31, 2020 under the terms of our credit agreement.

Income Tax Provision

Income tax provision for the year ended December 31, 2020 increased \$0.2 million to \$0.3 million as compared to \$0.1 million for the year ended December 31, 2019. This increase was due to certain states suspending the utilization of net operating losses as offsets to taxable income.

Liquidity and Capital Resources

Working Capital

Since our inception, we have historically financed our operations through operating cash flows, as well as the private placement of equity securities and convertible debt, an equity credit facility, a debt facility, a common stock rights offerings and other debt transactions.

The following table highlights several key measures of our working capital performance and debt levels (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	\$ 2,341	\$ 5,237
Accounts receivable, net	6,880	10,124
Inventories	21,408	16,101
Total current assets	31,365	32,246
Accounts payable	2,289	2,188
Accrued liabilities	6,120	6,625
Current portion of long-term debt	16,797	—
Total current liabilities	25,649	9,390
Net working capital	5,716	22,856
Long-term debt, net	—	76,244

On February 22, 2021, we entered into a securities purchase agreement with a single healthcare-focused institutional investor pursuant to which we agreed to issue 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 in a private placement. The closing of the Private Placement is expected to occur on February 24, 2021, subject to the satisfaction of customary closing conditions. We expect to receive gross proceeds of approximately \$20 million before deducting fees and other estimated offering expenses from the Private Placement. We expect to use the net proceeds from the Private Placement for working capital and other general corporate purposes.

Long-term debt, net consists of long-term debt due to the lender under the Second A&R Credit Agreement. Since the maturity of the indebtedness outstanding under our credit facility is December 31, 2021, all outstanding indebtedness is classified as current as of December 31, 2020. In addition, although the remaining principal balance of our outstanding debt totals \$15.6 million, the current portion of long-term debt as of December 31, 2020 was \$16.8 million reflecting the carrying value of the loans outstanding under the credit facility, which is equal to the undiscounted future cash payments and principal associated with the loans thereunder.

Cash Flows

Net cash used in operating activities for the year ended December 31, 2020 was \$0.7 million compared to \$0.4 million for the year ended December 31, 2019. This increase was due primarily to higher usage of cash from working capital to restore inventory levels to amounts necessary to support anticipated sales of certain higher-demand products, which was partially offset by collection of accounts receivable.

Net cash used in investing activities for the year ended December 31, 2020 was \$1.3 million, primarily representing purchases of property and equipment of \$1.5 million, partially offset by proceeds from sale of fixed assets of \$0.2 million. Net cash used in investing activities for the year ended December 31, 2019 was \$0.5 million, primarily representing purchases of property and equipment of \$0.9 million, partially offset by proceeds from sale of fixed assets of \$0.3 million.

Net cash used in financing activities was \$0.9 million during the year ended December 31, 2020 consisting primarily of \$1.0 million in costs associated with our debt restructuring and \$0.3 million in payments on long-term debt. These costs were partially offset by \$0.6 million in proceeds from our rights offering. Net cash used in financing activities was \$0.6 million for the year ended December 31, 2019 consisting primarily of \$0.5 million of payments on financing leases.

Cash Requirements

The outstanding indebtedness under the Second A&R Credit Agreement matures December 31, 2021. We believe that we will be able to refinance the outstanding indebtedness under the Second A&R Credit Agreement or extend the maturity date of that facility such that our \$2.3 million of cash and cash equivalents as of December 31, 2020, together with anticipated cash flows from operations, the anticipated net proceeds from the Private Placement and the \$5.0 million available at the lender's sole discretion under the Second A&R Credit Agreement, or comparable refinanced credit agreement, will be sufficient to meet our anticipated cash requirements through at least February 2022. While we intend to refinance our outstanding indebtedness or extend the maturity date of this facility, no assurance can be provided that we will do so on terms that are favorable to us or at all. In addition, we may require or seek additional capital to fund our future operations and business strategy prior to February 2022. 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 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 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 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 ROS and Royalty Opportunities, 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.

Second A&R Credit Agreement

In connection with our recent debt restructuring described above, on October 1, 2020, we entered into a Second Amendment to our Second A&R Credit Agreement (the "Second Amendment") with ROS and Royalty Opportunities, which among other things, provided for:

- Extinguishment of approximately \$61.9 million of principal and paid-in-kind interest outstanding on the loans in exchange for approximately 57.8 million shares of our common stock and the addition of a principal loan amount equal to prepayment fees associated with the loans not paid in cash or exchanged for shares of our common stock;
- Exchange of approximately \$0.9 million of prepayment fees associated amounts outstanding under the Second A&R Credit Agreement for approximately 0.9 million shares of our common stock;
- Elimination of the availability of additional draw loan advances and reduction of available additional term loans to \$5.0 million, the availability of which is in the sole and absolute discretion of the lender;
- Accrual of interest payable in cash for the remaining term of the Second A&R Credit Agreement at a rate per annum equal to the sum of (i) 7.00% plus (ii) the higher of (x) the LIBO Rate (as such term is defined in the Second A&R Credit Agreement) and (y) 1.00%; and
- Elimination of certain financial covenants.

In addition, as a result of the Second Amendment, Royalty Opportunities is now the sole holder of our outstanding indebtedness and the sole lender under the credit facility.

Long-term debt, plus premium and less issuance costs, consists of long-term debt due to the lender under the Second A&R Credit Agreement as of December 31, 2020 and 2019. Since the maturity date of the indebtedness outstanding under our credit facility is December 31, 2021, all outstanding indebtedness is classified as current as of December 31, 2020.

As a result of our recent debt restructuring, as previously described, we recorded a gain on restructuring totaling \$15.1 million. The gain represents the excess of the carrying value of our outstanding loans under the Second A&R Credit Agreement prior to the extinguishment of such debt in the debt restructuring transaction, \$80.3 million, over the sum of the fair value of the 57.8 million shares issued therewith, \$48.2 million, and \$17.1 million of undiscounted future cash payments associated with the Second Amendment.

The carrying value of loans outstanding under the Second A&R Credit Agreement is equal to the undiscounted future cash payments associated with the Second Amendment and principal associated with loans thereunder. Cash interest payments in connection with the Second A&R Credit Agreement will reduce the carrying value of associated loans, and accordingly, no interest expense related to cash interest payments will be recorded for the duration of the Second A&R Credit Agreement.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital expenditures or capital resources that are material to an investor in our shares.

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 2020 or 2019.

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 2020 or 2019.

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, 2020 of \$11.1 million 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, 2020 of \$0.7 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 2021 Annual Operating Plan. Management believes that we will be able to refinance the amounts outstanding under the Second A&R Credit Agreement or extend the date of its maturity such that our \$2.3 million of cash and cash equivalents as of December 31, 2020, together with the \$5.0 million in availability at the sole discretion of the lender under our Second A&R Credit Agreement, or comparable refinanced credit agreement, will be sufficient to meet our anticipated cash requirements and continue as a going concern through at least February 2022.

Although we have availability under our Second A&R Credit Agreement, this agreement is scheduled to terminate on December 31, 2021. Accordingly, we anticipate that we will need to refinance our outstanding indebtedness and obtain additional credit availability in the near future. No assurance can be provided that we will be able to do this on favorable terms or at all. We may elect to seek additional financing even before we need it if market conditions 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 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. 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 would be required to curtail operations significantly, including reducing our sales and marketing expenses and introduction of new products which could negatively impact product sales and we could even be required to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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

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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, 2020 and 2019 and the related statements of operations, stockholders’ equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The Company’s management is responsible for these financial statements. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits 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 consolidated 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accounting for the Debt Restructuring

Critical Audit Matter Description

As described in Notes 1 and 7 to the consolidated financial statements, the Company completed two debt modifications during 2020 resulting in warrants valued at \$1.9 million being added to equity balances in the second quarter as well as \$48.2 million worth of common shares issued in exchange for \$63.2 million of debt and a gain on partial extinguishment of that debt of \$15.1 million all recorded within equity in the fourth quarter. The first modification was accounted for as a debt modification and the second modification was accounted for as a partial extinguishment and modification of terms.

The recognition, measurement, and disclosure of the Company's debt modifications and partial extinguishment discussed above was considered especially challenging and required significant auditor judgment due to the complex determination by management of the appropriate assumptions and accounting guidance. The assumptions and accounting guidance included considerations of troubled debt restructuring, whether debt modification or extinguishment accounting was triggered; the calculation of effective interest rate in connection with that determination; equity or liability classification of warrants issued; the fair value of the warrants issued; the determination that the exchange option granted to the lenders was not a derivative and related analysis of trading volume in determining that the debt would not be readily convertible; and the treatment of all the related transaction costs.

How the Critical Audit Matter Was Addressed in the Audit

To test the accounting for the debt modifications and exchange of the Company's debt, including the issuance of warrants, we performed audit procedures that included the following, among others:

- Gained an understanding of the Company's internal control over financial reporting to identify the types of potential misstatement, assess the factors that affect the risks of material misstatement, and design further audit procedures.
- Evaluated management's accounting related to changes in the terms of its long-term debt, including the exchange of a portion of the debt to equity and the reasonableness of management's assumptions described above.
- Involved our valuation specialists to assist with the evaluation of methodologies used by the Company and significant assumptions included in the fair value estimates of the warrants issued. The most significant input was the value of the underlying stock price used in the Black-Scholes-Merton option pricing method.
- Evaluated management's analysis and conclusion regarding the classification of the warrants.
- Tested the use of a specific date for valuing the warrants used in the valuation model by performing a sensitivity analysis to test the reasonableness of the date chosen for the valuation based on stock prices on various dates and range of prices within those dates.

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 excess and obsolescence and adjusts inventory to its net realizable value as necessary. The excess and slow-moving inventory reserve at December 31, 2020 totaled \$11 million. Net inventory at December 31, 2020 totaled \$21 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 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 financial reporting 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 slow-moving 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; 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 slow-moving inventory reserve using historic 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

February 24, 2021

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

	Year Ended December 31,	
	2020	2019
Revenue		
Orthopedic product sales	\$ 53,188	\$ 64,516
Other revenue	149	166
Total Revenue	<u>53,337</u>	<u>64,682</u>
Cost of Sales	18,945	22,166
Gross Profit	<u>34,392</u>	<u>42,516</u>
Operating Expenses		
General and administrative	13,503	17,344
Sales and marketing	20,983	26,493
Research and development	657	932
Total Operating Expenses	<u>35,143</u>	<u>44,769</u>
Loss from Operations	<u>(751)</u>	<u>(2,253)</u>
Other Income (Expense)		
Interest expense	(5,976)	(5,772)
Other expense	—	(98)
Total Other Expense	<u>(5,976)</u>	<u>(5,870)</u>
Net Loss from Operations Before Provision for Income Taxes	<u>(6,727)</u>	<u>(8,123)</u>
Provision for Income Taxes		
Current and Deferred	<u>(296)</u>	<u>(98)</u>
Net Loss	<u>\$ (7,023)</u>	<u>\$ (8,221)</u>
Net loss per share:		
Basic	\$ (0.25)	\$ (0.63)
Dilutive	\$ (0.25)	\$ (0.63)
Shares used in the computation:		
Basic	28,499,847	13,163,931
Dilutive	28,499,847	13,163,931

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, 2020</u>	<u>As of December 31, 2019</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 2,341	\$ 5,237
Trade accounts receivable, net of allowance for credit losses of \$653 and \$500, respectively	6,880	10,124
Inventories	21,408	16,101
Prepaid and other current assets	736	784
Total current assets	<u>31,365</u>	<u>32,246</u>
Property and equipment, net	4,347	4,695
Right of use asset, net	1,690	2,100
Goodwill	3,205	3,205
Intangible assets, net	457	515
Other assets	402	394
Total Assets	<u>\$ 41,466</u>	<u>\$ 43,155</u>
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	\$ 2,289	\$ 2,188
Accrued liabilities	6,120	6,632
Current portion of lease liability	423	394
Finance lease obligations	20	176
Current portion of long-term debt	16,797	—
Total current liabilities	<u>25,649</u>	<u>9,390</u>
Long-term Liabilities:		
Lease obligation, net	1,303	1,726
Long-term debt, plus premium and less issuance costs	—	76,244
Total Liabilities	<u>26,952</u>	<u>87,360</u>
Commitments and Contingencies (note 11)		
Stockholders' Equity (Deficit):		
Preferred stock, \$0.000001 par value; 10,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$0.000001 par value; 300,000,000 shares authorized; 77,573,680 shares issued and outstanding as of December 31, 2020 and 75,000,000 shares authorized; 13,161,762 shares issued and outstanding as of December 31, 2019		
Additional paid-in capital	244,850	179,061
Accumulated deficit	(230,336)	(223,266)
Total Stockholders' Equity (Deficit)	<u>14,514</u>	<u>(44,205)</u>
Total Liabilities & Stockholders' Equity (Deficit)	<u>\$ 41,466</u>	<u>\$ 43,155</u>

See notes to audited consolidated financial statements.

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

	Common Stock		Additional Paid-In- Capital		Accumulated Deficit		Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at December 31, 2018	13,172,179	\$ —	\$ 171,273	\$ (215,045)	\$ (43,772)		
Stock-based compensation	—	—	515	—	—	515	
Forfeiture of restricted stock	(10,417)	—	—	—	—	—	
Debt extinguishment	—	—	7,264	—	—	7,264	
Issuance of warrant	—	—	9	—	—	9	
Net loss	—	—	—	(8,221)	—	(8,221)	
Balance at December 31, 2019	13,161,762	\$ —	\$ 179,061	\$ (223,266)	\$ (44,205)		
ASU 2016-13 cumulative effect adjustment	—	—	—	(47)	—	(47)	
Stock-based compensation	—	—	1,084	—	—	1,084	
Common stock issued on vesting of restricted stock units	144,878	—	—	—	—	—	
Issuance of warrant	—	—	1,862	—	—	1,862	
Debt exchange, net of exchange costs of \$1,058	58,754,394	—	62,175	—	—	62,175	
Issuance of common shares, net of issuance costs of \$143	712,646	—	620	—	—	620	
Exercise of warrants	4,800,000	—	48	—	—	48	
Net loss	—	—	—	(7,023)	—	(7,023)	
Balance at December 31, 2020	77,573,680	\$ —	\$ 244,850	\$ (230,336)	\$ 14,514		

See notes to audited consolidated financial statements.

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

	Year Ended December 31,	
	2020	2019
Operating activities:		
Net loss	\$ (7,023)	\$ (8,221)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,079	3,143
Non-cash interest	5,963	5,726
Non-cash rent	16	20
Gain on sale of fixed assets	(369)	(61)
Stock-based compensation	1,084	515
Provision for reserve on accounts receivable	307	513
Provision for excess and obsolete inventory	485	509
Changes in operating assets and liabilities:		
Trade accounts receivable	2,890	(647)
Inventories	(5,792)	692
Prepaid and other assets	40	204
Accounts payable	101	(4,278)
Accrued liabilities	(512)	1,472
Net cash used in operating activities	(731)	(413)
Investing activities:		
Purchases of property and equipment	(1,545)	(879)
Proceeds from sale of fixed assets	241	335
Net cash used in investing activities	(1,304)	(544)
Financing activities:		
Payments on financing leases	(156)	(455)
Payments on long-term debt	(315)	—
Costs associated with exchange of debt for common shares	(1,058)	—
Proceeds from issuance of common stock, net of issuance costs	620	—
Proceeds from exercise of common stock warrants	48	—
Costs associated with Second Amended and Restated Credit Agreement	—	(148)
Net cash used in financing activities	(861)	(603)
Net change in cash and cash equivalents	(2,896)	(1,560)
Cash and cash equivalents at beginning of year	5,237	6,797
Cash and cash equivalents at end of year	\$ 2,341	\$ 5,237

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, Xtant Medical, Inc., a Delaware corporation, Bacterin International, Inc., (“Bacterin”) a Nevada corporation, and X-Spine Systems, Inc. (“X-spine”), an Ohio corporation (Xtant Medical Inc., Bacterin and X-spine 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 the COVID-19 pandemic, 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, 2020, the Company had cash and cash equivalents of \$2.3 million, and an accumulated deficit of \$230.3 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 2021 Annual Operating Plan. Management believes that we will be able to refinance the amounts outstanding under our credit agreement or extend the maturity date, based on communications with the lender, such that our \$2.3 million of cash and cash equivalents as of December 31, 2020, together with the \$5.0 million available at the lender’s sole discretion under our credit agreement, or comparable refinanced credit agreement, will be sufficient to meet our anticipated cash requirements and continue as a going concern through at least February 2022.

Debt Restructuring

On August 7, 2020, we entered into a Restructuring and Exchange Agreement (the “Restructuring Agreement”) with OrbiMed Royalty Opportunities II, LP (“Royalty Opportunities”) and ROS Acquisition Offshore LP (“ROS”), pursuant to which the parties thereto agreed, subject to the terms and conditions set forth therein, to take certain actions as set forth therein and as described below (collectively, the “Restructuring Transactions”) in furtherance of a restructuring of the Company’s outstanding indebtedness under the Company’s Second Amended and Restated Credit Agreement with Royalty Opportunities and ROS, as amended (the “Second A&R Credit Agreement”).

The primary purpose of the Restructuring Transactions was to improve our capital structure by reducing the amount of our indebtedness and cost to service our debt, which should make it easier for us to refinance or replace this debt in the future, as well as facilitate easier access to capital markets for investment in our growth initiatives. The Restructuring Transactions also allowed us to regain compliance with the NYSE American continued listing standards, which we achieved on October 5, 2020. The Restructuring Transactions included, among others:

- an amendment to the Company’s Amended and Restated Certificate of Incorporation, as amended (“Charter”), to increase the number of authorized shares of our common stock from 75 million to 300 million (the “Charter Amendment”), which occurred on October 1, 2020;
- the exchange by the Company of shares of our common stock for approximately \$40.8 million of the aggregate outstanding principal amount under the Second A&R Credit Agreement, as well as, without duplication, approximately \$21.1 million of the outstanding amount of PIK Interest (as defined in the Second A&R Credit Agreement) (such loans and PIK Interest, the “Exchanging Loans”), plus all other accrued and unpaid interest on the Exchanging Loans outstanding as of the closing date, at an exchange price of \$1.07 per share, representing the average closing price of the common stock over the 10 trading days immediately prior to the parties entering into the Restructuring Agreement, and resulting in the issuance of approximately 57.8 million shares of common stock (the “Share Issuance”), which occurred on October 1, 2020
- the execution of an amendment to the Second A&R Credit Agreement by the parties thereto to change certain provisions therein, including extinguishing loans in an aggregate principal amount equal to the Exchanging Loans outstanding thereunder together with all accrued and unpaid interest thereon, paying a portion of the prepayment fee payable thereunder in respect of the Exchanging Loans with proceeds of additional loans under the Second A&R Credit Agreement, with the remaining portion of the prepayment fee exchanged for an additional 0.9 million shares of our common stock, reducing the amount of credit availability thereunder, decreasing the interest rate and eliminating certain financial covenants, which occurred on October 1, 2020, as described in more detail under *Note 7, “Debt”*; and
- the launch by the Company of a rights offering to allow our stockholders to purchase up to an aggregate of \$15 million of our common stock at the same price per share as the \$1.07 per share exchange price used to exchange the Exchanging Loans into our common stock as part of the Share Issuance (the “Rights Offering”), which commenced on November 5, 2020 and expired on December 4, 2020 and resulted in the issuance of 712,646 shares of our common stock and gross proceeds of \$0.8 million, as described in more detail under *Note 8, “Equity”*.

As a result of the completion of these Restructuring Transactions, Royalty Opportunities and ROS own, in the aggregate, approximately 93.9% of the outstanding common stock and all other existing stockholders of the Company own approximately 6.1% of the outstanding common stock as of December 31, 2020. Following completion of these Restructuring Transactions, the remaining principal balance of our outstanding debt totals \$15.6 million.

Investor Rights Agreement

We are party to an Investor Rights Agreement with ROS and 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 2020 or 2019. Management believes that all significant credit risks have been identified at December 31, 2020.

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. Significant estimates include the carrying amount of property and equipment, goodwill, and intangible assets and liabilities; valuation allowances for trade receivables, inventory and deferred income tax assets and liabilities; current and long-term lease obligations and corresponding right-of-use asset; and estimates for the fair value of long-term debt, stock option grants and other equity awards upon which the Company determines stock-based compensation expense. Actual results could differ from those estimates.

Cash and Cash Equivalents

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.

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.

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments* to change the impairment model for most financial assets and certain other instruments. For trade and other receivables, held to maturity debt securities, loans, and other instruments, entities are required to use a new forward-looking “expected loss” model that generally will result in the earlier recognition of allowances for losses. The Company adopted the guidance on January 1, 2020 and recognized a cumulative effect adjustment of \$47,000 to retained earnings and accounts receivable, net as a result of adoption. The Company has included the additional disclosures required by ASU 2016-13 in Note 2, “*Receivables*.”

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 purchase 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 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.

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. Upon receipt of the hospital purchase order, the Company invoices the hospital, and revenue is recognized in the proper period.

Additionally, the Company sells product directly to domestic and international stocking 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 products are shipped, 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, Asia Pacific and Latin 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, 2020 and 2019 (dollars in thousands):

	Year Ended December 31, 2020	Percentage of Total Revenue	Year Ended December 31, 2019	Percentage of Total Revenue
Orthobiologics	\$ 39,308	74%	\$ 46,663	72%
Spinal implant	13,880	26%	17,872	28%
Other revenue	149	0%	147	0%
Total revenue	<u>\$ 53,337</u>	<u>100%</u>	<u>\$ 64,682</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. Diluted net loss per share was the same as basic net loss per share for the years ended December 31, 2020 and 2019, as shares issuable upon the exercise of stock options and warrants and settlement of restricted stock units were anti-dilutive as a result of the net losses incurred for those periods. Diluted net loss per share is not reported as the effects of including 5,115,868 and 4,011,754 outstanding stock options, warrants and restricted stock units for the years ended December 31, 2020 and 2019, 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, 2020 and 2019, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

Reclassification

Certain prior year amounts have been reclassified to conform with current year presentation.

(2) Receivables

Concurrent with the adoption of ASU 2016-13, the Company's allowance for doubtful accounts was expanded to include provision for current expected credit loss ("CECL"). The Company's provision for CECL 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 year ended December 31, 2020 (in thousands):

Balance at January 1, 2020	\$ 547
Provision for expected credit losses	307
Write-offs charged against allowance	(201)
Balance at December 31, 2020	\$ 653

(3) Inventories

Inventories consist of the following (in thousands):

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Raw materials	\$ 3,757	\$ 3,386
Work in process	1,733	1,256
Finished goods	15,918	11,459
	<u>\$ 21,408</u>	<u>\$ 16,101</u>

(4) Property and Equipment, Net

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

	December 31, 2020	December 31, 2019
Equipment	\$ 4,807	\$ 4,250
Computer equipment	649	455
Computer software	570	570
Furniture and fixtures	133	124
Leasehold improvements	3,987	3,980
Other	10	10
Surgical instruments	11,291	10,897
Total cost	21,447	20,286
Less: accumulated depreciation	(17,100)	(15,591)
	<u><u>\$ 4,347</u></u>	<u><u>\$ 4,695</u></u>

Depreciation expense related to property and equipment, including property under capital lease, for the years ended December 31, 2020 and 2019 was \$2.0 million and \$3.1 million, respectively.

The Company leases certain equipment under finance leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of December 31, 2020 and 2019, the Company has recorded \$0.5 million and \$1.4 million, respectively, within Equipment, and \$0.4 million and \$1.0 million, respectively, of accumulated depreciation.

(5) Goodwill and Intangible Assets

The results of the Company's annual goodwill impairment tests for the years ended December 31, 2020 and 2019 indicated that no goodwill impairment existed as of the test date.

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

	December 31, 2020	December 31, 2019
Patents	\$ 847	\$ 847
Accumulated amortization	(390)	(332)
Net carrying value	<u><u>\$ 457</u></u>	<u><u>\$ 515</u></u>

Amortization expense was \$0.1 million for both of the years ended December 31, 2020 and 2019. The following is a summary of estimated future amortization expense for intangible assets as of December 31, 2020 (in thousands):

2021	\$ 56
2022	54
2023	53
2024	52
2025	52
Thereafter	190
Total	<u><u>\$ 457</u></u>

(6) Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Wages/commissions payable	\$ 4,057	\$ 3,902
Other accrued liabilities	2,063	2,730
Accrued liabilities	<u>6,120</u>	<u>6,632</u>

(7) Debt

Second A&R Credit Agreement

On March 29, 2019, the Company and ROS and Royalty Opportunities entered into a Second A&R Credit Agreement, which amended and restated the Amended and Restated Credit Agreement by and between Bacterin and ROS (collectively, the “Prior Credit Agreement” and the facility created under such agreement, the “Credit Facility”). Under the Second A&R Credit Agreement, some of which terms have been further amended:

- We may continue to make requests for term loans in amounts equal to the remaining commitment for additional delayed draw loans, which was approximately \$2.2 million as of the date of the Second A&R Credit Agreement, and could request additional term loans with ROS and Royalty Opportunities in an aggregate amount of up to \$10.0 million, with the amount of each loan draw to be subject to our production of a thirteen-week cash flow forecast that is approved by ROS and Royalty Opportunities and which shows a projected cash balance for the following two-week period of less than \$1.5 million, as well as the satisfaction (or waiver in writing by ROS and Royalty Opportunities) of conditions precedent, including closing certificate, delivery of budget, and other satisfactory documents;
- no interest would accrue on the loans outstanding under the Second A&R Credit Agreement (the “Loans”) from and after January 1, 2019 until March 31, 2020;
- beginning April 1, 2020 through the maturity date of the Second A&R Credit Agreement, interest payable in cash would accrue on the Loans under the Credit Agreement at a rate per annum equal to the sum of (a) 10.00% plus (b) the higher of (x) the LIBO Rate (as such term is defined in the Second A&R Credit Agreement) and (y) 2.3125%;
- the maturity date of the Loans was March 31, 2021;
- the Consolidated Senior Leverage Ratio and Consolidated EBITDA (as such terms were defined in the Prior Credit Agreement) financial covenants were deleted, and a new Revenue Base (as such term is defined in the Second A&R Credit Agreement) financial covenant was added; and
- the key person event default provision was revised to refer specifically to certain then recently-hired executive officers of the Company.

Long-term debt, less issuance costs consists of long-term debt due to the lenders under the Second A&R Credit Agreement as of December 31, 2019. The execution of the Second A&R Credit Agreement during the first quarter of 2019 and the changes to our credit facility reflected therein, including the interest rate relief and extended maturity, along with the additional availability, were determined to be and accounted for as a debt extinguishment under U.S. generally accepted accounting principles (“GAAP”), resulting in the write-off of the original loan and associated issuance costs. The present value of the new loan was determined to be \$72.7 million as of March 31, 2019 with the Company recording an increase to additional paid-in capital of \$7.3 million. Because of the related party affiliation between the Company and ROS and Royalty Opportunities, this debt extinguishment resulted in an increase in additional paid-in capital rather than flowing through our consolidated statements of operations as a gain on extinguishment.

On April 1, 2019, we issued warrants to purchase an aggregate of 1.2 million shares of our common stock to ROS and Royalty Opportunities, with an exercise price of \$0.01 per share and an expiration date of April 1, 2029 (collectively, the “2019 Warrants”). The issuance of the 2019 Warrants (see Note 9, “Stock-Based Compensation”) occurred on April 1, 2019 and was a condition to the effectiveness of the Second A&R Credit Agreement. These 2019 Warrants were exercised in full in November 2020.

On May 6, 2020, we entered into a First Amendment to the Second A&R Credit Agreement (the “First Amendment”) with ROS and Royalty Opportunities among other things, provided that:

- No interest would accrue on the Loans from and after March 31, 2020 until September 30, 2020;
- Beginning October 1, 2020 through the maturity date of the Second A&R Credit Agreement, interest payable in cash would accrue on the Loans under the Second A&R Credit Agreement at a rate per annum equal to the sum of (i) 10.00% plus (ii) the higher of (x) the LIBO Rate (as such term is defined in the Second A&R Credit Agreement) and (y) 2.3125%;
- The maturity date of the Loans is December 31, 2021;
- The Revenue Base (as such term is defined in the Second A&R Credit Agreement) financial covenant was revised through December 31, 2021; and
- The key person event default provision was revised to refer specifically to Sean Browne in lieu of a former executive.

On May 6, 2020, we issued warrants to purchase an aggregate of 2.4 million shares of our common stock to ROS and Royalty Opportunities, with an exercise price of \$0.01 per share and an expiration date of May 6, 2030 (collectively, the “2020 Warrants”). The issuance of the 2020 Warrants was a condition to the effectiveness of the First Amendment. The First Amendment was accounted for as a debt modification whereby the recorded debt balance was discounted for the fair value of the 2020 Warrants issued and interest expense is accrued through the maturity date of the Loans at the post-amendment effective interest rate of 10.02%. These 2020 Warrants were exercised in full in November 2020.

On October 1, 2020, in connection with our recent debt restructuring transaction, we entered into a Second Amendment to the Second A&R Credit Agreement (the “Second Amendment”) with ROS and Royalty Opportunities, which among other things, provided for:

- Extinguishment by ROS and Royalty Opportunities of approximately \$61.9 million of principal and paid-in-kind interest outstanding on the Loans in exchange for approximately 57.8 million shares of our common stock and the addition of a principal amount equal to prepayment fees associated with the Loans not paid in cash or exchanged for shares of our common stock;
- Exchange of approximately \$0.9 million of prepayment fees associated with the Loans for approximately 0.9 million shares of our common stock (the “Prepayment Fee Shares”);
- Elimination of the availability of additional draw loan advances and reduction of available additional term loans to \$5.0 million, the availability of which is in the sole and absolute discretion of the lender;
- Accrual of interest payable in cash for the remaining term of the Second A&R Credit Agreement at a rate per annum equal to the sum of (i) 7.00% plus (ii) the higher of (x) the LIBO Rate (as such term is defined in the Second A&R Credit Agreement) and (y) 1.00%; and
- Elimination of certain financial covenants.

As a result of our recent debt restructuring, as previously described, we recorded a gain on restructuring totaling \$15.1 million. The gain represents the excess of the carrying value of our outstanding loans under the Second A&R Credit Agreement prior to the extinguishment of such debt in the debt restructuring transaction, \$80.3 million, over the sum of the fair value of the 57.8 million shares issued therewith, \$48.2 million based on the closing price of our common stock on October 1, 2020, and \$17.1 million of undiscounted future cash payments associated with the Second Amendment. Because of the related party affiliation between the Company and ROS and Royalty Opportunities, this debt extinguishment resulted in an increase in additional paid-in capital rather than flowing through our consolidated statements of operations as a gain on extinguishment.

The carrying value of loans outstanding under the Second A&R Credit Agreement is equal to the undiscounted future cash payments associated with the Second Amendment and principal associated with loans thereunder. Cash interest payments in connection with the Second A&R Credit Agreement will reduce the carrying value of associated loans; and accordingly, no interest expense related to cash interest payments will be recorded for the duration of the Second A&R Credit Agreement. As a result of the Second Amendment, Royalty Opportunities became the sole holder of our outstanding long-term debt and the sole lender under the credit agreement.

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

	December 31, 2020	December 31, 2019
Amounts due under the Credit Facility	\$ 15,556	\$ 72,657
PIK interest payable related to the Credit Facility	—	3,280
Plus: 2% exit fee on Credit Facility	—	399
Gross long-term debt	<u>15,556</u>	<u>76,336</u>
Premium related to Second Amendment	1,241	—
Less: current maturities	(16,797)	
Less: total debt issuance costs	—	(92)
Long-term debt, less issuance costs	<u>\$ —</u>	<u>\$ 76,244</u>

All gross long-term debt will mature December 31, 2021 and become payable at that time. Since the maturity date of the indebtedness outstanding under our credit facility is December 31, 2021, all outstanding indebtedness is classified as current as of December 31, 2020 on the accompanying consolidated balance sheet.

(8) Equity

Charter Amendments

On October 30, 2019, the Company's stockholders, upon recommendation of the Board, approved an amendment to the Company's Charter to increase the number of authorized shares of common stock from 50 million to 75 million. This Charter amendment was effective upon the filing of a Certificate of Amendment with the Office of the Secretary of State of the State of Delaware on October 30, 2019. On August 7, 2020, the Company's stockholders, upon recommendation of the Board, approved an amendment to the Company's Charter to increase the number of authorized shares of common stock from 75 million to 300 million. This Charter amendment was effective upon the filing of a Certificate of Amendment with the Office of the Secretary of State of the State of Delaware on October 1, 2020.

Debt Restructuring

On October 1, 2020, we issued 58.7 million shares of our common stock in connection with our recent debt restructuring. See Note (1) Business Description and Summary of Significant Accounting Policies – Debt Restructuring.

Rights Offering

On November 6, 2020, we distributed to holders of our common stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 14,018,690 shares of our common stock (the “Rights Offering”). In the Rights Offering, holders received 0.194539 subscription rights for each share of common stock held on the record date, November 5, 2020. Each whole subscription right entitled the holder to purchase one share of our common stock for \$1.07 in cash. The Rights Offering was commenced on November 6, 2020 and expired on December 4, 2020, at which time the rights were no longer exercisable. We issued 712,646 shares of our common stock in the Rights Offering, resulting in \$0.8 million in gross proceeds to us.

Warrant Exercises

On November 17, 2020, ROS and Royalty Opportunities exercised warrants representing an aggregate of 4.8 million shares of our common stock and in connection therewith we received aggregate proceeds of \$48,000. See Note (10) Warrants.

(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 further increase the number of shares of our common stock available for issuance under the 2018 Plan by an additional 5,550,308 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 8,358,055 shares, of which 3,507,165 shares remained available for grant as of December 31, 2020. 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:

	2020			2019		
	Shares	Weighted Average Price	Weighted Average Date	Shares	Weighted Average Price	Weighted Average Date
		Exercise	Fair Value at Grant		Exercise	Fair Value at Grant
Outstanding at January 1	602,966	\$ 6.07	\$ 3.99	496,958	\$ 9.90	\$ 6.62
Granted	1,708,743	1.24	1.01	554,825	2.55	2.01
Cancelled or expired	(120,817)	6.95	4.31	(448,817)	5.96	4.45
Outstanding at December 31	2,190,892	\$ 2.25	\$ 1.65	602,966	\$ 6.07	\$ 3.99
Exercisable at December 31	122,739	\$ 14.74	\$ 8.95	25,063	\$ 83.78	\$ 46.66

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,	
	2020	2019
Risk free interest rate	0.54%	1.82%
Dividend yield	0%	0%
Expected term	6.2 years	7.1 years
Expected volatility	105%	92%

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

	2020			2019		
	Shares	Weighted Average Fair Value at Grant	Date Per Share	Shares	Weighted Average Fair Value at Grant	Date Per Share
Outstanding at January 1	499,914	\$ 2.87		40,000	\$ 6.20	
Granted	2,148,662	\$ 1.29		459,914	\$ 2.65	
Vested	(144,878)	\$ 2.52		-	\$ -	
Outstanding at December 31	2,503,698	\$ 1.54		499,914	\$ 2.87	

Total stock-based compensation expense recognized for employees and directors was \$1.1 million and \$0.5 million for the years ended December 31, 2020 and 2019, respectively, and was recognized as general and administrative expense. The aggregate intrinsic value of options outstanding as of December 31, 2019 was \$16,000. As of December 31, 2020, total compensation expense related to unvested employee stock options not yet recognized was \$2.3 million, which is expected to be allocated to expenses over a weighted-average period of 3.7 years. Total compensation expense related to unvested restricted stock units not yet recognized was \$3.2 million as of December 31, 2020, which is expected to be allocated to expenses over a weighted-average period of 3.4 years.

(10) Warrants

2020 Warrants

As noted in Note 7, “*Debt*,” on May 6, 2020, we issued warrants to purchase an aggregate 2.4 million shares of our common stock to ROS and Royalty Opportunities with an exercise price of \$0.01 per share and an expiration date of May 6, 2030. The issuance of the 2020 Warrants was a condition to the effectiveness of the First Amendment. The fair value of the 2020 Warrants upon issuance was determined to be \$1.9 million. The 2020 Warrants met all the requirements to be classified as equity awards in accordance with Accounting Standards Codification (“ASC”) No. 815-40. The number of shares of our common stock issuable upon exercise of the 2020 Warrants was subject to standard and customary anti-dilution provisions for stock splits, stock dividends, or similar transactions. The 2020 Warrants were exercised in full on November 17, 2020.

2019 Warrants

On April 1, 2019, we issued warrants to purchase an aggregate of 1.2 million shares of our common stock to ROS and Royalty Opportunities with an exercise price of \$0.01 per share and an expiration date of April 1, 2029. The issuance of the 2019 Warrants was a condition to the effectiveness of the Second A&R Credit Agreement. The fair value of the 2019 Warrants upon issuance was determined to be \$9,000. The 2019 Warrants met all the requirements to be classified as equity awards in accordance with ASC No. 815-40. The number of shares of our common stock issuable upon exercise of the 2019 Warrants was subject to standard and customary anti-dilution provisions for stock splits, stock dividends, or similar transactions. The 2019 Warrants were exercised in full on November 17, 2020.

The following table summarizes our warrant activities for the years ended December 31, 2020 and 2019:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding as of January 1, 2019	1,710,609	\$ 7.33
Issued	1,200,000	0.01
Expired	(1,735)	259.60
Outstanding as of December 31, 2019	2,908,874	\$ 4.16
Issued	2,400,000	0.01
Exercised	(4,800,000)	0.01
Expired	(87,596)	85.92
Outstanding at December 31, 2020	<u><u>421,278</u></u>	<u><u>\$ 10.80</u></u>

The following table summarizes our activities related to warrants accounted for as a derivative liability for the years ended December 31, 2020 and 2019:

	2020	2019
Balance at January 1	87,509	87,509
Derivative warrants expired	<u>(87,509)</u>	—
Balance at December 31	<u>—</u>	<u>87,509</u>

(11) Commitments and Contingencies

In 2019, we adopted ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize a right-of-use (“ROU”) asset and lease liability on their balance sheet for all leases with terms beyond 12 months. The new standard also requires enhanced disclosures intended to provide more transparency and information to financial statement users about lease portfolios. The distinction between operating and finance leases will continue to exist under the new standard. Additionally, the recognition and measurement of operating and finance lease expenses and cash flows will not change significantly from current treatment. For finance leases, lessees will continue to recognize interest expense on the lease liability using the effective yield method, while the right-of-use asset will be amortized on a straight-line basis. For operating leases, expense will be recognized on a straight-line basis, consistent with the previous standard.

Operating Leases

We currently lease four office facilities. These leases are under non-cancelable operating lease agreements with expiration dates between 2023 and 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, 2020, the weighted-average remaining lease term was 4 years. Lease expense related to operating leases was \$0.6 million for both of the years ended December 31, 2020 and 2019, respectively. The Company’s lease agreements do not provide a readily determinable implicit rate nor is it available to the Company from its lessors. Instead, as of December 31, 2020, the Company estimates the weighted-average discount rate for its operating leases to be 5.2% to present value based on the incremental borrowing rate.

Future minimum payments for the next five years and thereafter as of December 31, 2020 under these long-term operating leases are as follows (in thousands):

2021	\$	507
2022		521
2023		489
2024		224
Thereafter		180
Total future minimum lease payments		1,921
Less amount representing interest		(195)
Present value of obligations under operating leases		1,726
Less current portion		(423)
Long-term operating lease obligations	\$	1,303

Finance Leases

During the years ended December 31, 2020 and 2019, we incurred lease interest cost of \$13,000 and \$0.1 million, respectively, and amortization expense of \$0.1 million and \$0.2 million, respectively

Litigation

On December 13, 2018, a complaint was filed by RSB Spine, LLC, against Xtant Medical Holdings, Inc., which claimed that some of our products, including the Irix-A Lumbar Integrated Fusion System and the Irix-C Cervical Integrated Fusion System, infringe certain of RSB Spine's patents. On February 28, 2020, we entered into a confidential settlement and patent license agreement with RSB Spine pursuant to which we agreed to make an undisclosed settlement payment to RSB Spine and pay royalties on future sales of the two products through the expiration of the asserted patents. The settlement payment was included in accrued expenses as of December 31, 2019.

In November 2020, we received a letter from a third party's legal counsel claiming that some of our products, including the Butrex Plating System, Spider Plating System, Aranax Plating System and Irix Fusion System, infringe a patent held by the third party and offering to discuss settlement terms. Because this matter is in early stages and because of the complexity of the claims, we cannot estimate the possible loss or range of loss, if any, associated with its resolution. However, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition or results of operations.

In addition, 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 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,	
	2020	2019
United States	\$ (6,727)	\$ (8,123)
Total	\$ (6,727)	\$ (8,123)

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

	Year Ended December 31,	
	2019	2019
Current:		
Federal	\$ 51	\$ —
State	245	98
Total current	296	98
Deferred:		
Federal	—	—
State	—	—
Total deferred	—	—
Total Provision for Income Taxes	\$ 296	\$ 98

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,	
	2020	2019
Statutory Federal tax rate	\$ (1,413)	\$ (1,706)
Valuation allowance	(10,968)	73
State income taxes, net of Federal benefit	619	34
Attribute reduction related to Sec. 382	8,607	—
Change in state income tax rate	(61)	(136)
Gain on extinguishment of debt	3,488	1,534
Stock compensation adjustment and other reconciling items	14	282
Nondeductible meals and entertainment expense	10	17
Total Provision for Income Taxes	\$ 296	\$ 98

Deferred tax components are as follows (in thousands):

	At December 31,	
	<u>2020</u>	<u>2019</u>
Deferred tax assets:		
Accrued liability for vacation	\$ 123	\$ 111
Accrued commissions and bonuses / compensation	565	298
Accrued contingencies	42	132
Amortization	32	36
Depreciation	—	157
Bad debt reserve	174	133
Charitable contributions carryforward	—	8
Lease liability	459	564
Interest expense	2,342	3,407
Inventory reserve	2,975	3,058
Net operating loss carryovers	12,114	22,009
Stock option compensation	653	476
Other	109	102
Total deferred tax assets	19,588	30,491
Deferred tax liabilities:		
Right of use asset	(450)	(558)
Prepays	(73)	—
Depreciation	(100)	—
Total deferred tax liabilities	(623)	(558)
Valuation allowance	(18,965)	(29,933)
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 decreased by \$11.0 million in 2020 and increased by \$0.1 million in 2019.

At December 31, 2020 and 2019, the Company had total domestic Federal and state net operating loss carryovers of approximately \$97.0 million and \$149.8 million, respectively. Federal net operating losses generated prior to 2018 and State net operating loss carryovers expire at various dates between 2024 and 2040. Federal net operating losses generated after 2017 have an indefinite carryforward and are only available to offset 80% taxable income beginning in 2021.

On March 27, 2020 the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) was signed into law. The CARES Act provided for an increased interest deduction for tax years 2019 and 2020, as well as the deferral of the employer portion of social security taxes.

The Company has completed a study to assess whether an ownership change, as defined by Section 382 of the Internal Revenue Code, had occurred from the Company’s formation through December 31, 2020. 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 net operating loss 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 2017 through 2019 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, 2020 and 2019.

(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 401(k) plan matching contributions by the Company were temporarily suspended at the onset of the COVID-19 pandemic, but future plan matching contributions were subsequently restored effective July 1, 2020. The Company contributed \$0.2 million as part of the employer match program for each of the years ended December 31, 2020 and 2019.

(14) Supplemental Disclosure of Cash Flow Information

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

	Year Ended December 31,	
	2020	2019
<i>Cash paid during the period for:</i>		
Interest	\$ 13	\$ 51
<i>Non-cash activities:</i>		
ASU 2016-13 cumulative effect adjustment	\$ 47	\$ —
Recognition of 2020 Warrants	\$ 1,862	\$ —
Partial extinguishment of Second Amended and Restated Credit Agreement (including debt issuance costs)	\$ 63,233	\$ —
Lease liability from right-of-use assets	\$ —	\$ 2,296
Extinguishment of the Company's Prior Credit Agreement (including debt issuance costs)	\$ —	\$ 79,624
Recognition of Second Amended and Restated Credit Agreement	\$ —	\$ 72,657
Write-off of Prior Credit Agreement debt issuance costs and existing ROS fees	\$ —	\$ 307
Recognition of 2019 Warrants	\$ —	\$ 9

(15) Related Party Transactions

Royalty Opportunities, owning approximately 22% of the Company's outstanding common stock, is the sole holder of our outstanding long-term 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 the Investors. Transactions between the Company and the Investors are conducted under the provisions of the Second Amended and Restated Credit Agreement, the Prior Credit Agreement, the Investor Rights Agreement, and the Registration Rights Agreement, as noted above.

On April 5, 2019, the Company entered into a Sublease Agreement wherein the Company leases from Cardialen, Inc., a portion of Cardialen's office space commencing April 2019 on a month-to-month basis until January 2024, unless terminated earlier upon notice of 60 days. The rent is approximately \$1,000 per month. Because Jeffrey Peters is both a member of our Board of Directors and the Chief Executive Officer, President, and a director of Cardialen, this transaction qualifies 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 98% and 96% of revenue was in the United States for the years ended December 31, 2020 and 2019, respectively. Total revenue by major geographic area is as follows (in thousands):

	Year Ended December 31,	
	2020	2019
United States	\$ 52,147	\$ 62,377
Rest of World	1,190	2,305
Total	\$ 53,337	\$ 64,682

(17) Subsequent Event

On February 22, 2021, the Company entered into a securities purchase agreement with a single healthcare-focused institutional investor (the "Investor") pursuant to which we agreed to issue 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") in a private placement (the "Private Placement"). The closing of the Private Placement is expected to occur on February 24, 2021, subject to the satisfaction of customary closing conditions. We expect to receive gross proceeds of approximately \$20 million before deducting fees and other estimated offering expenses from the Private Placement. We expect to use the net proceeds from the Private Placement for working capital and other general corporate purposes.

The Investor Warrant will have an exercise price of \$2.25 per share, subject to customary anti-dilution, but not price protection, adjustments, and will be immediately exercisable and expire on the five-year anniversary of the date of issuance.

Under the terms of the Securities Purchase Agreement, we agreed that in the event we propose to offer and sell shares of our common stock or certain common stock equivalents to non-strategic investors primarily for capital raising purposes, we would provide the Investor the right, but not the obligation, to participate in such offering in an amount of up to 25% of the securities offered in such offering. This participation right will expire upon the earlier of 12 months after the closing of the Private Placement or upon the occurrence of certain change in control events.

We also agreed, under the terms of the Securities Purchase Agreement, to enter into a registration rights agreement (the "Registration Rights Agreement") with the Investor pursuant to which we will agree to prepare and file a registration statement (the "Resale Registration Statement") with the SEC within 45 days of the closing date for purposes of registering the resale of the shares of common stock issued to the Investor and the shares of common stock issuable upon exercise of the Investor Warrant. We will also agree to use our reasonable best efforts to cause the Resale Registration Statement to be declared effective by the SEC within 60 calendar days of the closing of the Private Placement (75 calendar days in the event the registration statement is reviewed by the SEC). If we fail to meet the specified filing deadlines or keep the Resale Registration Statement effective, subject to certain permitted exceptions, we will be required to pay liquidated damages to the Investor.

In connection with the Private Placement, we entered into a placement agent agreement with A.G.P./Alliance Global Partners (the "Placement Agent") pursuant to which the Placement Agent is serving 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 certain percentage of the aggregate gross proceeds from the 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 Private Placement, or 444,444 shares of our common stock (the "Placement Agent Warrant"). The Placement Agent Warrant will have an exercise price of \$2.8125 per share, subject to customary anti-dilution, but not price protection, adjustments and will be immediately exercisable and expire on the five-year anniversary of the date of issuance.

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, 2020. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2020, 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, 2020.

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, 2020 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 22, 2021. 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
Jeffrey Peters	52	Chairman of the Board and Director	2018
Sean E. Browne	55	President and Chief Executive Officer and Director	2019
John Bakewell ⁽¹⁾	59	Director	2018
Michael Eggenberg ⁽²⁾	51	Director	2018
Robert McNamara ⁽¹⁾⁽²⁾	64	Director	2018
Matthew Rizzo ⁽²⁾	48	Director	2018
Kevin D. Brandt	55	Chief Commercial Officer	2018
Greg Jensen	60	Vice President, Finance and Chief Financial Officer	2019

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

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

Jeffrey Peters has served as Chairman of the Board and a member of our Board since February 2018. Mr. Peters was initially elected to the Board in connection with our restructuring in February 2018. Mr. Peters has over 25 years of medical device experience. Mr. Peters is a designee of Royalty Opportunities and ROS under the Investor Rights Agreement. Since December 2017, Mr. Peters has served as the President and Chief Executive Officer of Cardialen, Inc., a private medical device company developing low-energy therapy for cardiac arrhythmias. Mr. Peters is also a Venture Partner for OrbiMed Advisors LLC, a private equity and venture capital firm, a position he has held since January 2018. Mr. Peters served as Executive Chairman of Neurovasc Technologies, Inc. an interventional neuroradiology ischemic stroke technology company, from December 2015 to May 2017, and served as Chief Executive Officer of Anulex Technologies Inc., a former privately held medical device manufacturer, from April 2011 until May 2016. From 2013 to December 2017, Mr. Peters also served as an independent medical device consultant. From 2001 to 2007, Mr. Peters served in various positions at ev3 Inc., an endovascular company now owned by Medtronic plc, and its predecessor companies, including Chief Technology Officer, Vice President, Research and Development, Cardio Peripheral Division and Vice President, Business Development. Mr. Peters’ financial roles include portfolio manager at Black River Asset Management LLC from 2007 to 2008, an entrepreneur-in-residence at Foundation Medical Partners from 2009 to 2011, and an equity research analyst at Dain Rauscher Wessels from 1997 to 2001. Mr. Peters currently serves as a member of the board of directors of Children’s Minnesota. Mr. Peters received his BS in Mechanical Engineering. and MBA from the University of Minnesota. Mr. Peters brings substantial medical device experience, including having served in several executive roles with start-up and emerging medical device companies, and significant financial and operating experience to the Board.

Sean E. Browne was appointed our President and Chief Executive Officer effective October 7, 2019 and has served as a member of our Board since October 30, 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 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, as a result of his role as President and Chief Executive Officer, Mr. Browne provides unique insight into our future 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. Mr. Bakewell was initially elected to the Board in connection with our restructuring in February 2018. Mr. Bakewell is an independent board member and consultant to the medical technology industry. He also serves on the board of directors of Neuronetics, Inc. (STIM) and of Treace Medical Concepts, Inc., a private company. Mr. Bakewell served as the Chief Financial Officer of Exact Sciences Corporation, a molecular diagnostics company, from January 2016 to November 2016. Mr. Bakewell previously served as the Chief Financial Officer of Lantheus Holdings, Inc., a diagnostic medical imaging company, from June 2014 to December 2015, as the Chief Financial Officer of Interline Brands, Inc., a distributor and direct marketer of broad-line maintenance, repair and operations products, from June 2013 to May 2014, and as the Executive Vice President and Chief Financial Officer of RegionalCare Hospital Partners, an owner and operator of non-urban hospitals, from January 2010 to December 2011. In addition, Mr. Bakewell held the position of Chief Financial Officer with Wright Medical Group, Inc., an orthopaedic company, from 2000 to 2009, with Altra Energy Technologies, Inc. from 1998 to 2000, with Cyberonics, Inc. from 1993 to 1998 and with Zeos International, Ltd. from 1990 to 1993. Mr. Bakewell 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. 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 extensive financial and 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. 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 Modulation Technologies (AXNX). 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 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., Somnus Medical Technologies Inc. and Target Therapeutics, Inc., was a member of the board of directors of Northstar Neurosciences Inc. and is the former Mayor of Menlo Park, California. Mr. McNamara holds a Masters of Business Administration in Finance from The Wharton School at the University of Pennsylvania and a Bachelor of Science in Accounting from the University of San Francisco. 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 April 2010, Mr. Rizzo has been a Partner with OrbiMed Advisors LLC, a private equity and venture capital firm, and is focused on healthcare royalty and structured finance investments. 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 was appointed our Chief Commercial Officer in 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 28 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.

Greg Jensen was appointed our Vice President, Finance and Chief Financial Officer in August 2019. From February 2019 to August 2019, Mr. Jensen served as our Vice President, Finance and Interim Chief Financial Officer. Prior to joining Xtant, Mr. Jensen served as a Financial Executive Advisor from May 2005 to February 2019 at GPJ Consulting LLC, a financial consulting firm he founded to drive financial and operational performance for small- and medium-sized businesses. From November 2014 to October 2015, Mr. Jensen also served as Chief Financial Officer at Windings Inc., an international manufacturer of highly specialized components for electrical motors. Additionally, from 2010 to April 2013, Mr. Jensen served as Vice President of Finance at American Solutions for Business Inc., a national distributor of business products and services. Prior to holding these positions, Mr. Jensen served as Chief Financial Officer of WTC Industries Inc., a manufacturing company, from 1996 to 2005. He has over 30 years of finance leadership experience in both public accounting and corporate finance and accounting. He is a Certified Public Accountant (inactive). Mr. Jensen holds a Bachelor of Science in Business Administration, Accounting from the University of North Dakota, Grand Forks.

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 (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 \$1,500,000 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, 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 have so designated Jeffrey Peters. Accordingly, Mr. Peters serves as Chairman of the Board. In October 2019, Sean E. Browne was appointed 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.

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 board committees as of February 22, 2021.

Director	Audit Committee	Compensation Committee
John Bakewell	Chair	
Sean Browne		●
Michael Eggenberg		●
Robert McNamara	●	Chair
Jeffrey Peters		●
Matthew Rizzo		●

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 2020. 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

In November 2018, the Board created a Compensation Committee to assist the Board with various compensation related matters. 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 four times during fiscal 2020.

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 2020, 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 individuals that served as a principal executive officer of the Company during the year ended December 31, 2020, and the two most highly compensated executives for the year ended December 31, 2020.

Name and Principal Position	Year	Salary ⁽¹⁾	Bonus ⁽²⁾	Stock Awards ⁽³⁾	Option Awards ⁽⁴⁾	Non-Equity Incentive Plan Compensation ⁽⁵⁾	All Other Compensation ⁽⁶⁾	Total
Sean E. Browne ⁽⁷⁾ <i>President and Chief Executive Officer</i>	2020	\$ 603,692	\$ —	\$ 1,850,762	\$ 1,508,484	\$ 510,000	\$ 76,116	\$ 4,549,054
Greg Jensen ⁽⁸⁾ <i>Vice President, Finance and Chief Financial Officer</i>	2019	115,745	—	888,419	688,130	150,000	9,970	1,852,264
Kevin D. Brandt <i>Chief Commercial Officer</i>	2020	402,462	—	107,557	108,469	170,000	72,616	861,104
	2019	336,032	—	93,558	82,056	114,375	63,173	689,194
	2020	417,554	—	107,557	108,469	176,375	11,400	821,355
	2019	398,113	90,000	97,066	85,546	124,125	17,416	812,266

(1) All salaries for 2020 reflect a 20% temporary reduction during second quarter of 2020 as part of our cost-savings measures in response to the COVID-19 pandemic. Additional detail on these measures and their impact on executive compensation is below under "Impact of COVID-19 Pandemic."

- (2) 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 2020. Annual cash incentive bonus payouts based on performance against pre-established performance goals are reported in the “Non-equity incentive plan compensation” column.
- (3) 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 2020 and on the date immediately prior to the grant date for 2019.
- (4) 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
11/15/2020		\$ 1.03	0.56%	6.25 years	105.28%	—
08/15/2020		0.90	0.43%	6.25 years	101.99%	—
10/15/2019		2.09	1.65%	6.50 years	92.55%	—
08/15/2019		2.11	1.45%	6.25 years	92.76%	—

- (5) 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.
- (6) The table below provides information concerning amounts reported in the “All Other Compensation” column of the Summary Compensation Table for 2020 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	\$ 8,327	\$ 67,789	\$ 76,116
Greg Jensen	11,400	61,216	72,616
Kevin D. Brandt	11,400	—	11,400

- (7) Mr. Browne was appointed our President and Chief Executive Officer effective October 7, 2019.
- (8) Mr. Jensen was appointed our Vice President, Finance and Chief Financial Officer effective August 8, 2019. From February 2019 to August 2019, Mr. Jensen served as our Vice President, Finance and Interim Chief Financial Officer, and from March 18, 2019 until the appointment of Mr. Browne as President and Chief Executive Officer on October 7, 2019, Mr. Jensen served in the capacity as our principal executive officer.

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.”

We are party to an employment agreement with Mr. Jensen pursuant to which he serves as Vice President, Finance and Chief Financial Officer and which provides for an annual base salary \$400,000 and a target annual bonus opportunity equal to 50% of his annual base salary. This agreement also contains standard confidentiality, non-competition, non-solicitation and assignment of intellectual property provisions, as well as standard severance and change in control benefits, 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*.”

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.

Impact of the COVID-19 Pandemic

In response to the COVID-19 pandemic, during the second quarter of 2020, we implemented a series of cost-savings actions intended to preserve capital to support our operations, many of which impacted our executive compensation. These temporary cost-saving actions included:

- termination or furlough of 42% of our workforce;
- suspension in hiring most open positions;
- elimination of planned merit increases;
- institution of a temporary 20% base salary or wage reduction for all executive officers and employees;
- 20% reduction in non-employee director retainers for second quarter of 2020;
- suspension of future 401(k) plan matching contributions by the Company; and
- reduction in sales and marketing expenses and other discretionary spending

Effective July 1, 2020, we reinstated the full base salaries and wages of all our employees and restored future 401(k) plan matching contributions.

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. As mentioned above, we suspended matching contributions during the second quarter of 2020 as part of our cost-savings measures in response to the COVID-19 pandemic.

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, 2020. 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⁾	Market Value of Shares or Units of Stock that Have Not Vested	Value of Shares or Units of Stock that Have Not Vested ⁽²⁾
Sean E. Browne	65,809	263,235(3)	\$ 2.70	10/15/2029	263,235(4)	\$ 315,882
	—	1,468,859(5)	1.26	11/15/2030	1,468,859(6)	1,762,631
Greg Jensen	9,765	29,298(7)	2.76	08/15/2029	25,424(8)	30,509
	—	119,942(9)	1.13	08/15/2030	95,183(10)	114,220
Kevin D. Brandt	15,384	15,386(11)	6.20	08/15/2028	40,000(12)	48,000
	10,131	30,396(7)	2.76	08/15/2029	26,377(8)	31,652
	—	119,942(9)	1.13	08/15/2030	95,183(10)	114,220

- (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, 2020 (\$1.20), 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 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.
- (8) 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.
- (9) 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.
- (10) 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.
- (11) This stock option vests in equal installments annually over a four-year period beginning on August 15, 2019. 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. Brandt dies.
- (12) This RSU award will vest in full on July 9, 2021 but may terminate earlier if the recipient's employment or service relationship with the Company terminates. 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 Mr. Brandt dies.

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

In 2020, the Board approved and the Company's stockholders approved and adopted the Xtant Medical Holdings, Inc. 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 8,358,055 shares. To date, the Company has granted stock options, restricted stock and RSUs under the 2018 Plan. As of December 31, 2020, 3,507,165 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 equity grants in the form of RSU awards every two years.

The table below sets forth the annual cash retainers for 2020:

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

The equity compensation component is intended to match the dollar value of the annual cash retainers over a two-year period. On February 5, 2020, Messrs. McNamara, Bakewell and Peters each received an RSU award valued at \$165,000 for 116,197 shares of our common stock and Messrs. Eggenberg and Rizzo, the Investor Designees who are employees of OrbiMed, each received an RSU award valued at \$100,001 for 70,423 shares of our common stock. All of these RSU awards vest in nearly equal installments on each of February 15, 2021 and February 15, 2022.

Director Compensation Table for Fiscal 2020

The table below describes the compensation earned by our directors during fiscal 2020, 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	\$ 168,486	\$ —	\$ —	\$ 250,986
Michael Eggenberg	50,000	102,113	—	—	152,113
Robert McNamara	82,500	168,486	—	—	250,986
Jeffrey Peters	82,500	168,486	—	—	250,986
Matthew Rizzo	50,000	102,113	—	—	152,113

- (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 2020. 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, 2020, each non-employee director held the following number of unvested stock awards (all of which are in the form of RSU awards): Mr. Bakewell (116,197); Mr. Eggenberg (70,423); Mr. McNamara (116,197); Mr. Peters (116,197); and Mr. Rizzo (70,423).

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	72,873,494	93.6%

- (1) Percent of class is based on 77,818,396 shares of our common stock outstanding as of February 22, 2021.
- (2) Based in-part on information contained in a Schedule 13D/A filed with the SEC on October 5, 2020. Includes 55,820,296 shares of common stock held of record by ROS Acquisition Offshore LP. OrbiMed Advisors LLC, a registered adviser under the Investment Advisors Act of 1940, as amended, is the investment manager of ROS. OrbiMed is also the investment manager of Royalty Opportunities S.àrl., of which ROS is a wholly-owned subsidiary. By virtue of such relationships, OrbiMed may be deemed to have voting and investment power with respect to the securities held by ROS noted above and as a result may be deemed to have beneficial ownership over such securities. OrbiMed exercised this investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the securities held by ROS.

Also includes 17,053,198 shares of common stock held of record by OrbiMed Royalty Opportunities II, LP. OrbiMed ROF II LLC ("ROF II") is the sole general partner of Royalty Opportunities, and OrbiMed is the sole managing member of ROF II. By virtue of such relationships, OrbiMed may be deemed to have voting and investment power with respect to the securities held by Royalty Opportunities noted above and as a result may be deemed to have beneficial ownership over such securities. OrbiMed exercised this investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the securities held by Royalty Opportunities.

Security Ownership of Management

The table below sets forth information relating to the beneficial ownership of our common stock as of February 22, 2021, 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 22, 2021, 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 77,818,396 shares of our common stock outstanding as of February 22, 2021. Shares of our common stock that a person has the right to acquire within 60 days of February 22, 2021, 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	89,695	*
Common Stock	Michael Eggenberg	—	—
Common Stock	Robert McNamara	87,958	*
Common Stock	Jeffrey Peters	89,695	*
Common Stock	Matthew Rizzo	—	—
Common Stock	Sean E. Browne	131,618	*
Common Stock	Greg Jensen	18,239	*
Common Stock	Kevin D. Brandt	34,307	*
Common Stock	All executive officers and directors as a group (8 persons)	451,512	*

* 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 22, 2021:

Name	Options	RSUs
John Bakewell	—	—
Michael Eggenberg	—	—
Robert McNamara	—	—
Jeffrey Peters	—	—
Matthew Rizzo	—	—
Sean E. Browne	65,809	—
Greg Jensen	9,765	—
Kevin D. Brandt	25,515	—
All directors and executive officers as a group (8 persons)	101,089	—

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, 2020.

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	4,694,590	\$ 2.95	3,507,165
Equity compensation plans not approved by security holders	—	—	—
Total	4,694,590	\$ 2.95	3,507,165

- (1) Amount includes 2,176,272 shares of our common stock issuable upon the exercise of stock options granted under the 2018 Plan, 14,620 shares of our common stock issuable upon the exercise of stock options granted under the Prior Plan and 2,503,698 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 2,503,698 RSU awards.
- (3) Amount includes 3,507,165 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.

In addition, because of its significance, the debt restructuring described below was also approved by a Special Restructuring Committee composed solely of the two Audit Committee members and prior to approving the transaction the Special Restructuring Committee received a written opinion dated August 7, 2020 from its advisor, Duff & Phelps, LLC, that, as of the date of such opinion, the exchange price of the debt restructuring was fair, from a financial point of view, to the stockholders of the Company unaffiliated with Royalty Opportunities and ROS, without giving effect to any impact of the proposed transaction on any particular stockholder other than in its capacity as a stockholder.

Related Party Transactions

Debt Restructuring

On August 7, 2020, we entered into the Restructuring Agreement with Royalty Opportunities and ROS, pursuant to which the parties thereto agreed, subject to the terms and conditions set forth therein, to complete the Restructuring Transactions in furtherance of a restructuring of our outstanding indebtedness under that certain Second A&R Credit Agreement. The primary purpose of the Restructuring Transactions was to improve our capital structure by reducing the amount of our indebtedness and cost to service our debt, which should make it easier for us to refinance or replace this debt in the future, as well as facilitate easier access to capital markets for investment in our growth initiatives. The Restructuring Transactions also allowed us to regain compliance with the NYSE American continued listing standards, which we achieved on October 5, 2020. The Restructuring Transactions included, among others:

- an amendment to our Charter to increase the number of authorized shares of our common stock from 75 million to 300 million (the “Charter Amendment”);
- the exchange by the Company of shares of our common stock for approximately \$40.8 million of the aggregate outstanding principal amount of loans outstanding held by the Royalty Opportunities and ROS under the Second A&R Credit Agreement, as well as, without duplication, approximately \$21.1 million of the outstanding amount of PIK Interest (as defined in the Second A&R Credit Agreement) (such loans and PIK Interest, the “Exchanging Loans”), plus all other accrued and unpaid interest on the Exchanging Loans outstanding as of the closing date, at an exchange price of \$1.07 per share, representing the average closing price of our common stock over the 10 trading days immediately prior to the parties entering into the Restructuring Agreement;
- the execution of an amendment to the Second A&R Credit Agreement by the parties thereto to change certain provisions therein, including extinguishing loans in an aggregate principal amount equal to the Exchanging Loans outstanding thereunder together with all accrued and unpaid interest thereon, paying a portion of the prepayment fee payable thereunder in respect of the Exchanging Loans with proceeds of additional loans under the Second A&R Credit Agreement, with the remaining portion of the prepayment fee exchanged for an additional 0.9 million shares of our common stock, reducing the amount of credit availability thereunder, decreasing the interest rate and eliminating certain financial covenants; and
- the launch by the Company of a rights offering to allow stockholders of the Company to purchase up to an aggregate of \$15 million of our common stock at the same price per share as the \$1.07 per share exchange price used to exchange the Exchanging Loans into our common stock as part of the Share Issuance.

Immediately after the execution of the Restructuring Agreement by the parties thereto, we solicited and obtained the written consent of Royalty Opportunities and ROS, the holders of an aggregate of 9,248,678 shares of our common stock as of August 7, 2020 (the “Consenting Majority Stockholders”), representing a majority of the outstanding shares of our common stock as of such date, for the approval of the Charter Amendment and the Share Issuance, in accordance with applicable provisions of the DGCL and the Company’s Bylaws. The written consent of the Consenting Majority Stockholders was sufficient to approve the Charter Amendment and the Share Issuance. Therefore, no proxies or additional consents were solicited by us in connection with the Charter Amendment and the Share Issuance. Pursuant to Section 14(c) of the Exchange Act, and the rules and regulations promulgated thereunder, on September 10, 2020, we sent a definitive information statement to all holders of our common stock as of August 7, 2020 for the purpose of informing such stockholders of the written actions taken by the Consenting Majority Stockholders. In accordance with Exchange Act Rule 14c-2, the stockholder consent of the Consenting Majority Stockholders could not become effective until at least 20 calendar days following the mailing of the Information Statement.

On October 1, 2020, the closing of the Restructuring Transactions, other than the Rights Offering, occurred, and in connection therewith, the following actions took place:

- the Charter Amendment was filed with the Office of the Secretary of State of the State of Delaware;
- the Share Issuance occurred;
- an amendment to the Second A&R Credit Agreement was executed by the parties thereto, and in connection therewith, the Company issued an additional 0.9 million shares of Common Stock in exchange for a portion of the prepayment fee payable under the Second A&R Credit Agreement in respect of the Exchanging Loans; and
- the Registration Rights Agreement, as described in more detail below, was executed by the parties thereto.

As a result of the completion of these Restructuring Transactions, Royalty Opportunities and ROS owned immediately thereafter, in the aggregate, approximately 93.9% of our outstanding common stock, and all other existing stockholders of the Company own approximately 56.1% of our outstanding common stock as of December 31, 2020.

Pursuant to the terms of the Restructuring Agreement, we commenced the Rights Offering to allow our stockholders as of the November 5, 2020 record date to purchase up to an aggregate of 14,018,690 shares of our common stock at a subscription price of \$1.07 per share, the same price per share as the \$1.07 per share exchange price used in the Share Issuance. The rights offering expired on December 4, 2020. We issued 712,646 shares of common stock in the Rights Offering and received \$762,531 in gross proceeds.

2020 Registration Rights Agreement

Effective October 1, 2020, we entered into a Registration Rights Agreement with Royalty Opportunities and ROS, which requires us, among other things, to file with the SEC a shelf registration statement covering the resale, from time to time, of our common stock that was issued pursuant to the Share Issuance no later than December 30, 2020 and use our best efforts to cause the shelf registration statement to become effective under the Securities Act no later than March 30, 2021. This registration statement was filed on December 18, 2020 and was declared effective by the SEC on December 23, 2020.

Investor Rights Agreement

We are party to an Investor Rights Agreement with Royalty Opportunities and 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, 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 may be terminated (a) upon the mutual written agreement of all the parties, (b) upon our written notice, Royalty Opportunities or ROS if their ownership percentage of our then outstanding common stock is less than 10%, or (c) upon written notice of Royalty Opportunities and ROS.

Second Amended and Restated Credit Agreement and Warrant Issuance

On March 29, 2019, the Company and our subsidiaries, Bacterin International, Inc., Xtant Medical Systems, Inc. and X-spine Systems, Inc., entered into a Second Amended and Restated Credit Agreement with OrbiMed Royalty Opportunities II, LP, and ROS Acquisition Offshore LP, as amended, which amended and restated the prior Amended and Restated Credit Agreement dated as of July 27, 2015 among the parties thereto, and as subsequently amended through the Twenty-Fifth Amendment to the Amended and Restated Credit Agreement (the “Prior Credit Agreement”). Under the terms of the Second A&R Credit Agreement, the Prior Credit Agreement was amended to provide that:

- we may request additional term loans from Royalty Opportunities and ROS in the remaining amount available to be requested as additional delayed draw loans, which was approximately \$2,200,000 as of the date of the Second A&R Credit Agreement, and may request new additional term loans in an aggregate amount of up to \$10 million, the

making of each such loan to be subject to the discretion of Royalty Opportunities and ROS and the Company's production of a thirteen-week cash flow forecast that is approved by Royalty Opportunities and ROS and shows a projected cash balance for the following two-week period of less than \$1,500,000, as well as the satisfaction (or waiver in writing by each Investor) of conditions precedent, including closing certificate, delivery of budget, and other satisfactory documents;

- no interest would accrue on the loans thereunder from and after January 1, 2019 until March 31, 2020;
- beginning April 1, 2020 through the maturity date of the Second A&R Credit Agreement, interest payable in cash would accrue on the loans thereunder at a rate per annum equal to the sum of (i) 10.00% plus (ii) the higher of (x) the LIBO Rate (as such term is defined in the Second Amended and Restated Credit Agreement) and (y) 2.3125%;
- the maturity date of the loans would be March 31, 2021;
- The Consolidated Senior Leverage Ratio and Consolidated EBITDA (as such terms were defined in the Prior Credit Agreement) financial covenants were deleted and a new Revenue Base (as such term is defined in the Second Amended and Restated Credit Agreement) financial covenant was added; and
- The key person event default provision was revised to refer specifically to certain then recently hired executives.

On April 1, 2019, we issued warrants to purchase an aggregate of 1.2 million shares of our common stock to the Investors, with an exercise price of \$0.01 per share and an expiration date of April 1, 2029. The issuance of these warrants occurred on April 1, 2019 and was a condition to the effectiveness of the Second A&R Credit Agreement. These warrants were exercised in full in November 2020.

First Amendment to Second Amended and Restated Credit Agreement and Warrant Issuance

On May 6, 2020, the Company and our subsidiaries, Bacterin International, Inc., Xtant Medical, Inc. and X-spine Systems, Inc., entered into a First Amendment to the Second Amended and Restated Credit Agreement with Royalty Opportunities and ROS, which among other things, provided that:

- no interest would accrue on outstanding loans thereunder from and after March 31, 2020 until September 30, 2020;
- beginning October 1, 2020 through the maturity date, interest payable in cash will accrue on the loans thereunder at a rate per annum equal to the sum of (i) 10.00% plus (ii) the higher of (x) the LIBO Rate (as such term is defined in the Second A&R Credit Agreement) and (y) 2.3125%;
- the maturity date of the loans thereunder was extended to December 31, 2021;
- the Revenue Base financial covenant was revised through December 31, 2021; and
- the key person event default provision was revised to refer specifically to Sean Browne in lieu of Ron Berlin.

In conjunction therewith, we issued warrants to purchase an aggregate of 2.4 million shares of our common stock to Royalty Opportunities and ROS, with an exercise price of \$0.01 per share and an expiration date of May 6, 2030. The issuance of these warrants was a condition to the effectiveness of this amendment. These warrants were exercised in full in November 2020.

Second Amendment to Second Amended and Restated Credit Agreement

On October 1, 2020, pursuant to the Restructuring Transactions discussed above, the Company and our subsidiaries, Bacterin International, Inc., Xtant Medical, Inc. and X-spine Systems, Inc., entered into a Second Amendment to the Second Amended and Restated Credit Agreement with Royalty Opportunities and ROS, which among other things, provided for:

- extinguishment by Royalty Opportunities and ROS of approximately \$61.9 million of principal and paid-in-kind interest outstanding on the loans under the Second A&R Credit Agreement in exchange for approximately 57.8 million shares of our common stock and the addition of a principal amount equal to prepayment fees associated with the loans thereunder not paid in cash or exchanged for shares of our common stock;
- exchange of approximately \$0.9 million of prepayment fees associated with the loans thereunder for approximately 0.9 million shares of our common stock;
- elimination of the availability of additional draw loan advances and reduction of available additional term loans to \$5.0 million, the availability of which is in the sole and absolute discretion of the lender;
- accrual of interest payable in cash for the remaining term of the Second A&R Credit Agreement at a rate per annum equal to the sum of (i) 7.00% plus (ii) the higher of (x) the LIBO Rate (as such term is defined in the Second A&R Credit Agreement) and (y) 1.00%; and
- elimination of the Base Revenue financial covenant.

Royalty Opportunities is the sole holder of the Company's outstanding long-term debt and the sole lender under the Second A&R Credit Agreement, as amended.

During the year ended December 31, 2020, the largest amount of principal outstanding under this credit facility was \$55.8 million, and as of February 22, 2021, the amount of principal outstanding was \$15.6 million. Other than principal and interest paid in Xtant common stock as part of the debt restructuring transaction described above under "Debt Restructuring," the Company paid \$0.3 million in interest under the credit facility and no principal amount during the year ended December 31, 2020.

Warrant Exercises

On November 17, 2020, ROS and Royalty Opportunities exercised warrants representing an aggregate of 4.8 million shares of Xtant common stock and in connection therewith the Company received aggregate proceeds of \$48,000.

Sublease Agreement

We are party to a Sublease Agreement with Cardialen, Inc., under which we lease a portion of Cardialen's office space in Plymouth, Minnesota. The Sublease Agreement has been amended several times to change the amount of office space and monthly rent. Under the amended Sublease Agreement, we agreed to pay rent of \$1,350 per month for 2020, \$1,400 per month for 2021, \$1,450 per month for 2022 and \$1,500 per month thereafter through the expiration date of January 31, 2024. Because Jeffrey Peters is both a member of our Board and the Chief Executive Officer, President, and a director of Cardialen, this transaction qualifies as a related party transaction.

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 ending December 31, 2020 and 2019.

The table below presents the aggregate fees billed for professional services rendered by Plante Moran for the years ended December 31, 2020 and December 31, 2019.

	2020	2019
Audit fees	\$ 262,116	\$ 297,300
Audit-related fees	—	20,000
Tax fees	—	—
All other fees	18,500	9,357
Total fees	\$ 280,616	\$ 326,657

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 2020 and 2019.

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 shareholder upon receipt from any such person of a written request for any such exhibit. Such request should be sent to: Greg Jensen, Vice President, Finance and Chief Financial Officer, Xtant Medical Holdings, Inc., 664 Cruiser Lane, Belgrade, MT 59714, Attn: Stockholder Information.

Exhibit No.	Description
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</u>
4.2	<u>Form of Common Stock Certificate (filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 filed with the SEC on December 21, 2015 (SEC File No. 333-208677) and incorporated by reference herein)</u>
4.3	<u>Form of Warrant Certificate for Warrants underlying Units (filed as Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016 (SEC File No. 001-34951) and incorporated by reference herein)</u>
4.4	<u>Form of Warrant Agreement (filed as Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016 (SEC File No. 001-34951) and incorporated by referenced herein)</u>

Exhibit**No.**

4.5

Description

[Registration Rights Agreement \(for Common Stock underlying the Indenture Notes\) dated January 17, 2017 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\)](#)

4.6

[Registration Rights Agreement \(for Common Stock underlying the PIK Notes\) dated January 17, 2017 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\)](#)

4.7

[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 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\)](#)

4.8

[Registration Rights Agreement dated October 1, 2020 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\)](#)

4.9

[Investor Rights Agreement dated February 14, 2018 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\)](#)

10.1•

[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\)](#)

10.2•

[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\)](#)

10.3•

[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\)](#)

10.4•

[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\)](#)

10.5•

[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\)](#)

10.6•

[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\)](#)

Exhibit**No.**

10.7•

Description

[Employment Agreement dated as of October 7, 2019 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\)](#)

10.8•

[Employment Agreement effective as of July 9, 2018 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\)](#)

10.9•

[Amended and Restated Employment Agreement effective as of August 8, 2019 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\)](#)

10.10

[Restructuring and Exchange Agreement dated as of January 11, 2018 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\)](#)

10.11

[Securities Purchase Agreement dated as of February 14, 2018 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\)](#)

10.12

[Second Amended and Restated Credit Agreement dated March 29, 2019 among Xtant Medical Holdings, Inc., Bacterin International, Inc., Xtant Medical Systems, Inc., X-spine Systems, Inc., OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP \(filed as Exhibit 10.47 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\)](#)

10.13

[First Amendment to Second Amended and Restated Credit Agreement effective as of April 1, 2020 among Xtant Medical Holdings, Inc., Bacterin International, Inc., Xtant Medical Systems, Inc., X-spine Systems, Inc., OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP \(filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 \(SEC File No. 001-34951\) and incorporated by reference herein\)](#)

10.14

[Second Amendment to Second Amended and Restated Credit Agreement effective as of October 1, 2020 among Xtant Medical Holdings, Inc., Bacterin International, Inc., Xtant Medical, Inc., X-spine Systems, 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 October 1, 2020 \(SEC File No. 001-34951\) and incorporated by reference herein\)](#)

10.15

[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\)](#)

10.16

[Distribution Agreement dated January 23, 2014 between X-spine Systems, Inc. and Zimmer Spine, Inc., as amended \(filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 3, 2015 \(SEC File No. 001-34951\) and incorporated by reference herein\)](#)

16.1

[Letter from EKS&H LLLP to the SEC dated October 8, 2018 \(filed as Exhibit 16.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 9, 2018 \(SEC File No. 001-34941\) and incorporated by reference herein\)](#)

Exhibit**No.****Description**

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*	XBRL INSTANCE DOCUMENT
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF*	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

● Indicates a management contract or compensatory plan

* Filed herewith

** Furnished herewith

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.

February 24, 2021

By: /s/ Sean E. Browne

Name: Sean E. Browne

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

By: /s/ Greg Jensen

Name: Greg Jensen

Title: Vice President, Finance and 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 February 24, 2021.

Signature	Title
<u>/s/ Sean E. Browne</u> Sean E. Browne	President and Chief Executive Officer (principal executive officer)
<u>/s/ Greg Jensen</u> Greg Jensen	Vice President, Finance and 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/ Jeffrey Peters</u> Jeffrey Peters	Director
<u>/s/ Matthew Rizzo</u> Matthew Rizzo	Director