XTANT MEDICAL HOLDINGS, INC.

2019 ANNUAL REPORT

FORM 10-K

664 Cruiser Lane
Belgrade, Montana 59714
(406) 388-0480

Dear Stockholders,

As I write this letter in September of 2020, for a 2019 annual report to stockholders, I would be remiss if I did not speak to both the significant progress Xtant Medical made in 2019 and the transformational changes that have taken place since the COVID-19 pandemic hit our shores. Sometimes to move a business forward, you must first address legacy issues. To that end, 2019 was the year of "remediation," where much of our time and energy was focused on fixing numerous legacy issues to position the business for future revenue growth. The time and energy we spent resulted in the following successes:

- Remediation of 21 individual identified projects or issues across our commercial, operational and administrative functions. These projects and issues were resolved for significantly less cost than their original estimates, owing to the resourcefulness and dedication of our team.
- Implementation of a new and more dynamic financial forecasting process that more accurately predicts how the business will perform. Through this new process, our ability to predict and manage the company has dramatically improved.
- Reorganization of the teams in a manner that should allow Xtant to grow now and provide a foundation for additional growth in the future.
- Identification of the operational areas that needed to be re-engineered and began the planning required to embark on those projects.

The management team had planned to build upon these 2019 successes, and 2020 was off to a good start as we were meeting the goals and objectives of our 2020 Annual Operating Plan. Then, in March 2020, the COVID-19 pandemic unexpectedly led to the shutdown of over 90% of the elective spine surgeries that utilize our products. At that point, we had to act quickly and with purpose to revise the plan for the remainder of 2020 and identify what mattered most for the business and our long-term success. Through this very trying time, the following three major themes emerged, which I will discuss in more detail below: (i) Realignment with our Mission; (ii) Re-engineering our Business Process; and (iii) Re-birth.

First and foremost, we had to ***Realign with our Mission*** of "Honoring the gift of donation by allowing our patients to live as full a life as possible." This realignment meant that we had to reexamine each aspect of our business to identify what was most important for our business, first to survive and then secondly to thrive. One element of our business where we have always been outstanding is the extraordinarily high quality of our biologic products. However, over time, our production yields had become suboptimal, threatening our ability to ensure timely delivery of products to our customers. By refocusing on our Mission and the incredible gift of donation, we were able to identify and implement specific operational procedural changes, and our yields are now beginning to return to optimal levels.

In the early days of the pandemic, we worked on predicting what would become the new reality of our business. The most obvious change we envisioned was a world where we served considerably fewer

spine procedures than in 2019. From there, we proceeded to build a new cost structure sized to meet anticipated lower revenue levels so that we could approach both profitability at an operating level and neutral to positive cash-flow. Through this process, we had to make the tough decision to reduce Xtant's personnel by 42% and our planned discretionary and capital expenditures by over 50%. The upside to this unfortunate necessity is the Xtant team that remains is dedicated, motivated, and eager to take on the challenges that lie ahead.

Second, we needed to ***Re-engineer our Business Processes***. In order to truly Realign with our Mission, we knew certain outdated and inefficient processes that drove our business previously would no longer work. Xtant's bioproduction capabilities and capacity had started to encounter challenges keeping up with our base demand, and our hardware supply chain was becoming outdated and cumbersome, resulting in longer and unacceptable lead times and inefficiencies. As business slowed, due to the COVID-19 driven decline in elective procedures, our team took advantage of the downtime to review and enhance our processes, people, structure, technology, and facilities. Although we continue to seek areas for improvement, we have successfully rebuilt vital processes in our bioprocessing and inventory management systems. These changes have improved our yields significantly while enhancing our ability to support our current and future commercial activities.

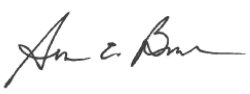
Finally, the one overriding feeling within Xtant Medical today is ***Re-Birth***. Now that we have streamlined our team and cost structure, there is an overwhelming feeling of new life within the company. There is also a sense of excitement regarding the company's prospects. This is especially true in light of:

- The proposed debt conversion, which will relieve Xtant of the burden of servicing a significant debt level and provide for interest rates that are approximately 400 basis points lower than our current rate.
- Xtant Medical's new product pipeline, which is growing, as evidenced by our most recent announcement of our new Synthetic Biologic offering of Matriform Si. This new offering is our third new release for the year and is expected to be one of many new products Xtant anticipates to deliver to the market in the years ahead.
- A recently signed agreement with one of the largest group purchasing organizations (GPOs) in the country. This agreement diversifies our contract portfolio and opens the door for new distributors in geographies where we see significant growth opportunities.

Throughout the remainder of 2020, we intend to continue our efforts to ensure that Xtant Medical is poised to be a market leader. To this end, we know there is still much to be done at Xtant Medical, however through ***Realigning with our Mission*** and the on-going ***Re-engineering of our Business Processes***, we are looking forward to the future of our business and the ***Re-Birthed*** Xtant Medical.

In the months ahead, I look forward to keeping you updated on our future success.

Thank you for your continued support!



Sean Browne
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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 $.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, or 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	[X]
		Emerging growth company	[ ]

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

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

The aggregate market value of the common stock held by non-affiliates as of June 30, 2019 was $11.6 million (based on the closing price of the Company's common stock on the last business day of the Company's most recently completed second fiscal quarter, as reported on the NYSE American).

The number of shares of the Company's common stock, $0.000001 par value, outstanding as of March 2, 2020 was 13,223,565.

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 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 asset, 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.

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 largely through independent distributors and stocking agents, augmented 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, Europe, Australia, and certain Pacific region countries.

While we focused on improving our balance sheet and operational efficiencies in 2019, 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 2019, we took several actions in furtherance of these objectives, including:

- Rebuilt our senior management team by hiring a new Chief Executive Officer, Chief Operations Officer and Chief Financial Officer and enhanced our commercial organization under the leadership of our Chief Commercial Officer by hiring five senior sales executives;

- Reengaged with our distribution network;

- Introduced new products, including the Intice-C Titanium Cervical Interbody Spacer, Atrix-C Union Cervical Interbody Spacer, and the Calix-C PC Plasma Coated PEEK Implant, and committed resources to develop and introduce additional new products, especially in our orthobiologics business; and

- Enhanced our operational efficiencies, including upgrades to our existing Enterprise Resource Planning ("ERP") platform, which will continue throughout 2020 and which we believe should enable our employees to better serve our customers, which we believe is necessary for improving our sales performance and the deployment of our resources.

Our common stock trades on the NYSE American under the symbol "XTNT" and we remain firmly committed to maintaining our stock exchange listing. During 2019, we outlined to the NYSE American certain milestones that we intend to achieve to regain compliance with the NYSE American's continued listing requirements by no later than October 4, 2020. These milestones include steps intended to improve our revenue performance, operational efficiency and balance sheet, with the goal to increase our stockholders' equity to meet the minimum $6.0 million requirement.

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 facilitate healing, encourage bone tissue augmentation, compensate in areas where bone tissue is depleted and restore structure to allow for repair. Orthopedic biomaterials are capable of producing specific biological action or regenerative responses that are beyond what is observed in normal healing. 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 is 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 GPO, 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, OsteoSTX, and our line of 3Demin products, as described below, as well as other allografts:

- OsteoSponge is a form of demineralized bone matrix 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. Its unique mechanical and biological properties 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. We have received permission from the U.S. Food and Drug Administration ("FDA"), which is a Federal agency of the United States Department of Health and Human Services, to market this product as a subchondral bone void filler and are currently marketing it as such.

- 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 DMB 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, act as a biologic plate 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.

- OsteoSTX are demineralized cortical sticks processed from human allograft bone. Utilizing our patented demineralization technology, the grafts are flexible and feature osteoinductive properties. The nature of demineralized cortical bone provides all the necessary elements for bone regeneration. OsteoSTX are designed for posterolateral spine surgery applications ranging from one-level to multi-level fusions, including scoliosis procedures.

- 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.

Our biologics are generally terminally sterilized and packaged to enhance the safety of our grafts for our physician customers and their patients.

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 independent health delivery network hospitals and through group purchasing organizations. We have biologics contracts with major GPO, 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, Europe, 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. 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., Nuvasive, Inc., and Globus Medical, Inc. Together, we believe these large competitors have almost 80% market share. We compete with these larger competitors and several others, including RTI Surgical, 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 were recently subject to patent infringement litigation and 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 or license fees 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, 2019, our fixation patent portfolio includes over 53 issued patents globally and 1 patent application pending, and our biologics patent portfolio includes over 14 issued patents globally and over 12 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®, OsteoVine®, 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 Oher 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 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. 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 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. Although not legally binding, these products have also been viewed by the Tissue Reference Group as HCT/Ps.

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.

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.

To market our product devices in the member countries of the European Union ("EU"), we are required to comply with the European Medical Device Directives and to obtain CE mark certification. CE mark certification is the European symbol of adherence to quality assurance standards and compliance with applicable European Medical Device Directives. Under the European Medical Device Directives, all medical devices must qualify for CE marking. To obtain authorization to affix the CE mark to one of our products, a recognized European Notified Body must assess our quality systems and the product's conformity to the requirements of the European Medical Device Directives. We are subject to inspection by the Notified Bodies for compliance with these requirements. In March 2019, our Notified Body informed us that we are at risk of losing our CE mark on several products for failing to comply with post market clinical follow up requirements. We are working with our Notified Body to remediate this nonconformance and in January 2020 began the post market clinical follow up requirements with respect to some of the affected products. There can be no assurance that we will be able to remediate this matter. If this risk were to materialize, we may be required to remove the affected products from the EU market countries until we comply with these requirements.

The new European Medical Device Regulation ("MDR") intended to replace the current Medical Device Directives came into force May 2017. Manufacturers of approved medical devices will have until May 2020 to transition their devices to meet the requirements of the MDR. After May 2020, manufacturers are offered a grace period which further extends the transition time for some medical devices. We are currently reviewing our product portfolios, quality system and processes in an effort to meet the new regulations within the timeframes we are afforded, although no assurance can be provided that we will be able to do so. Our failure to meet these new regulations would cause us to lose our CE mark certification.

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 provides for treble damages and mandatory minimum penalties of $5,500 to $11,000 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 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. 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 Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

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 proud to be an International Organization for Standardization ("ISO") certified organization, which declares our company-wide commitment to quality. 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, 2019, Xtant had 141 employees, of whom 70 were in operations, 24 were in sales and marketing, 6 in research and development and engineering, 16 in regulatory and quality affairs, and 25 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." Xtant, Bacterin and X-spine are jointly referred to herein as the "Company".

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

During the first quarter of 2018, we completed a significant debt restructuring pursuant to which then outstanding indebtedness amounting to an aggregate of $76.6 million in principal, together with accrued and unpaid interest, was converted into shares of our common stock and we issued an additional 946 thousand shares of common stock to certain of our lenders in a private placement. As a result of this debt restructuring, ROS Acquisition Offshore LP ("ROS") and OrbiMed Royalty Opportunities II, LP ("Royalty Opportunities" and together with ROS, our "lenders"), which are funds affiliated with OrbiMed Advisors LLC ("OrbiMed"), collectively own approximately 70% of our outstanding common stock. Because of this significant stock ownership, 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.

Available Information

We make available, free of charge and through our Internet web site, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). Reports filed with the SEC may be viewed at www.sec.gov.

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 most significant events, facts or circumstances that could have a material adverse effect upon our business, financial condition, results of operations, ability to implement our business plan 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.

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 never be profitable.

We have a history of incurring net losses and at December 31, 2019, we had an accumulated deficit of $223.3 million. During the year ended December 31, 2019, we incurred a net loss of $8.2 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 ability to attract and retain key personnel. As a result, we may continue to incur operating losses for the foreseeable future. These losses will continue to have an adverse impact on our stockholders' equity, and we may never achieve or sustain profitability.

We may need additional financing to satisfy our anticipated future liquidity requirements, which financing may not be available on favorable terms 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 $5.2 million as of December 31, 2019, together with our existing credit availability under our Second Amended and Restated Credit Agreement, will be sufficient to meet our anticipated cash requirements through at least the end of March 2021. Although we have availability under our Second Amended and Restated Credit Agreement, this credit facility expires March 31, 2021 and all of our indebtedness thereunder matures on such date. While we intend to extend the maturity date of this facility and our outstanding indebtedness, no assurance can be provided that we will do so or on terms that are favorable to us. In addition, we may require additional funds to fund our future operations and business strategy prior to March 2021. Accordingly, there is no assurance that we will not need or seek additional funding. 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 liquidation or other preferences that adversely affect the rights of 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 ROS and Royalty Opportunities, the lenders under our Second Amended and Restated Credit Agreement and parties to an Investor Rights Agreement with the Company, and no assurance can be provided that ROS and Royalty Opportunities would provide such consent, which could limit our ability to raise additional financing.

We have a significant amount of indebtedness. We may not be able to 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.

We have a significant amount of indebtedness. As of December 31, 2019, we had $75.9 million in aggregate principal and accrued interest outstanding under our credit facility. 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 lenders, 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 Amended and Restated 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 Amended and Restated Credit Agreement could limit our ability to conduct our business, take advantage of business opportunities and respond to changing business, market, and economic conditions.

Our Second Amended and Restated 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 and a minimum revenue base, each 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 our business, take advantage of business opportunities, and respond to changing business, market, and economic conditions. In addition, they may place us at a competitive disadvantage relative to other companies that may be subject to fewer, if any, restrictions or may otherwise adversely affect our business. Transactions that we may view as important opportunities, such as significant acquisitions or business combinations, may be subject to the consent of the lenders, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

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

Availability under the Second Amended and Restated Credit Agreement is based on the amount of our liquidity and revenue. As a result, our access to credit under the Second Amended and Restated Credit Facility is subject to fluctuations depending on our financial results and projected cash balances as of any valuation date. Our inability to borrow additional amounts under the credit facility may adversely affect our liquidity, results of operations, and financial condition.

Our outstanding indebtedness under the credit facility will, after March 31, 2020, bear 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 our indebtedness, thereby affecting our profitability. In the event of a default under our Second Amended and Restated Credit Agreement, the lenders may terminate their 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 Amended and Restated Credit Agreement, the lenders 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 lenders 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 Amended and Restated Credit Agreement or the exercise by the lenders thereto of their 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 Amended and Restated Credit Agreement, and we may be unable to successfully negotiate waivers to cure any covenant violations.

Our Second Amended and Restated Credit Agreement contains representations, warranties, fees, affirmative and negative covenants, including a minimum liquidity covenant and a minimum revenue base covenant, and default provisions. A breach of any of these covenants could result in a default under this agreement. Upon the occurrence of an event of default under the Second Amended and Restated Credit Agreement, the lenders 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 lenders accelerate 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 Amended and Restated Credit Agreement, we pledged substantially all of our assets, including our intellectual property, to the lenders. Our failure to comply with the covenants under the Second Amended and Restated Credit Agreement could result in an event of default, the acceleration of our debt and the loss of our assets.

Risks Related to Our Business

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 until recently we have not focused on 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.

Until recently, we have not focused significantly on the development of new products. Due to lack of funding, our research and development efforts have suffered during the past few 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. 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.

We are 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.

We are 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. For example, the media has reported examples of alleged illegal harvesting of body parts from cadavers and resulting recalls conducted by certain companies selling human tissue based products affected by the alleged illegal harvesting. These reports and others could have a negative effect on our biologics business.

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. We are currently experiencing a supply issue with certain of our biologics and hardware products, which if it continues could seriously harm our reputation, business, financial condition and results of operations. It is possible that these issues will continue especially since many of our suppliers have long lead times for the ordering of products, raw materials and components and our forecasting and planning capabilities and visibility into our future needs are poor. In 2013, we experienced supply shortages in collagen ceramic matrix bone void fillers, which adversely affected sales of our orthobiologics products, even after the supply shortage was resolved.

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.

We have limited staffing and are dependent upon key employees, the loss of whom could adversely affect our operations. 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, will 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 during the past year, including members of our management team, most of whom have joined the Company in the past year. 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 have 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. This is particularly true recently with respect to our biologics business where we are currently in the process of recruiting a substantial number of additional employees and to date have experienced tight labor conditions in the Belgrade, Montana area. 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 recently enhance our wages and benefit packages to attract a sufficient number of workers and it is possible that these increased labor costs may not be effective in recruiting and retaining a sufficient number of qualified personnel. There can be no assurance that we will be successful in retaining our current personnel or in hiring or retaining a sufficient number of qualified personnel in the future. If we cannot attract and retain qualified personnel or if we must increase substantially our labor costs to attract and retain qualified personnel, the growth and success of our business, as well as our operating results and financial condition, will be adversely affected.

We 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. This risk is particularly relevant with respect to the Class 2 recall of our Calix Lumbar Spine Implant System initiated in December 2018; 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.

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

The manufacture and sale of medical devices and biologics expose us to significant risk of product liability claims. We may incur material liabilities relating to product liability claims, including product liability claims arising out of the use of our products. 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. This risk is particularly relevant with respect to our Calix Lumbar Spine Implant System recall initiated in December 2018; 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. 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, financial condition, and operating results.

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, financial condition, reputation, and operating results. 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, financial condition, and operating results, 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;
- 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;
- 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;
- 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.

During the year ended December 31, 2018, we incurred a goodwill impairment of $38.3 million as well as an impairment charge of $9.8 million to tradenames, technology, and customer relationships related to the fixation business that we acquired in connection with our 2015 acquisition of X-spine Systems, Inc. As of December 31, 2019, our goodwill was $3.2 million and our intangible assets were $0.5 million.

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. 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 lenders under our credit facility. We cannot predict whether such approvals would be forthcoming or the terms on which the lenders 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.

We believe our quarterly revenue and operating results may vary significantly in the future 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 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 our 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 factors; and
- increases of interest rates, which can increase the cost of borrowings under our credit facility, and generally affect the level of economic activity.

A significant portion of our product revenue is conducted through independent distributors and sales agents who we do not control.

A significant portion of our product 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. During 2018, we experienced changes to and turnover within our distributor and independent sales organization which had an adverse effect on our business. 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 orthopedic 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.

The termination of a consulting agreement in March 2019 adversely affected our operating results during the year ended December 31, 2019 and may continue to adversely affect our future operating results.

In March 2019, a consulting agreement with an entity that has close relationships with several of our customers representing approximately 23% of our revenue during the year ended December 31, 2018 terminated thereby adversely affecting our revenue and other operating results for the year ended December 31, 2019. We anticipate that the termination of this agreement may continue to negatively impact our future revenues during 2020 and future years.

Worldwide economic 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, affects our business and operating results. 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 could also adversely impact our suppliers' ability to provide us with materials and components, either of 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. Further, there are concerns for the overall stability and suitability of the Euro as a single currency, given the economic and political challenges facing individual Eurozone countries and Brexit. Continuing deterioration in the creditworthiness of the Eurozone countries, the

withdrawal of one or more member countries from the European Union, or the failure of the Euro as a common European currency could adversely affect our revenue, financial condition, or operating results.

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 4% of our total revenue for our year ended December 31, 2019. Our operations outside of the United States 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 currency risk between the U.S. dollar and foreign currencies, in our target markets;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- the imposition of restrictions on the activities of foreign agents, representatives, and distributors;
- 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, acts of war or terrorist acts;
- complex data privacy requirements and labor relations laws; and
- exposure to different legal and political standards.

In addition, in June 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, commonly referred to as "Brexit." In March 2017, the United Kingdom formally gave notice of its intent to withdraw from the European Union. Serving this notice began a more than two-year period during which the United Kingdom and the European Union negotiated the terms of the United Kingdom's withdrawal from the European Union and future terms of the United Kingdom's relationship with the European Union, including the terms of trade between the United Kingdom and the European Union. Unable to reach an agreement or further extend the deadline for withdrawal, on January 31, 2020, the United Kingdom withdrew from the European Union without an agreement in place. It is possible that, following this withdrawal, there will be greater restrictions on the movement of goods and people between the United Kingdom and European Union countries and increased regulatory complexities, which could affect our ability to sell our products in certain European Union countries. The withdrawal could also adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the British pound and Euro. We do not know to what extent these changes will impact our business. Any of these effects of Brexit, and others that we cannot anticipate, could adversely affect our business, operations and financial results. In addition, other European countries may seek to conduct referenda with respect to continuing membership with the European Union. At this time, it is not certain what steps may be taken to facilitate the United Kingdom's exit from the European Union, which has created significant uncertainty about the future relationship between the United Kingdom and the European Union. This development has had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets. Given the lack of comparable precedent, it is unclear how the withdrawal of the United Kingdom from the European Union will impact our business, financial condition and operating results.

In addition, public health crises, epidemics and pandemics, such as the novel strain of coronavirus that recently originated in China, could adversely impact our distribution systems and reduce demand for our products. Any disruption of the operations of our suppliers or customers would likely impact our sales and operating results. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products and likely impact our operating results.

The costs of complying with the requirements of the EU-wide General Data Protection Regulation and the potential liability associated with failure to do so could materially adversely affect our business and results of operations.

In May 2018, the EU-wide General Data Protection Regulation ("GDPR") became effective, replacing the current data protection laws of each EU member state. The GDPR implemented more stringent operational requirements for personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements and higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Any failure or perceived failure by us to comply with privacy or security laws, policies, legal obligations or industry standards or any security incident that results in the unauthorized release or transfer of personally identifiable information may result in governmental enforcement actions and investigations including by European Data Protection Authorities, fines and penalties, litigation and/or adverse publicity, and could cause our customers to lose trust in us, which could have an adverse effect on our reputation and business. Such failures could have a material adverse effect on our operating results and financial condition. If the third parties we work with violate applicable laws, contractual obligations or suffer a security breach, such violations may also put us in breach of our obligations under privacy laws and regulations and/or could in turn have a material adverse effect on our business. In addition, we have spent and expect to continue to expend significant time, costs and resources to comply with the GDPR.

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

We rely extensively on information technology ("IT") systems to conduct business. These systems include, but are not limited to, ordering and managing materials from suppliers, converting materials to finished products, invoicing and shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, and providing data security and other processes necessary to manage our business. 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. 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.

We are in the process of implementing a substantial upgrade to our enterprise resource planning ("ERP") system, and difficulties in implementing this upgrade or an inability to successfully manage our ERP system could disrupt or reduce the efficiency of our entire operations and have a material adverse effect on our operating results and cash flows.

During the second quarter of fiscal 2019, we began the implementation of a significant upgrade to our ERP system. The ERP system is designed to efficiently maintain our financial records and provide information important to the operation of our business to our management team. We plan to complete the implementation during the first half of fiscal 2020. As part of these efforts, we have consolidated and integrated the number of systems we operate. These changes have affected many of our existing operating and financial systems. The implementation of the ERP system upgrade is a major undertaking both financially and from a management and personnel perspective. It will continue to require significant investment of human and financial resources.

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.

Our inability to maintain effective internal controls could cause investors to lose confidence in our reported financial information.

Effective internal controls are necessary for us to provide reliable and accurate financial reports and to effectively prevent fraud. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish a report by our management on our internal control over financial reporting and if we become an accelerated filer under the federal securities laws we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We devote significant resources and time to comply with the internal control over financial reporting requirements of the Sarbanes-Oxley Act of 2002. 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 light of changes in accounting standards and in the context of acquisitions of other businesses. The integration of combined or acquired businesses is likely to result in our systems and controls becoming increasingly complex and more difficult to manage.

If we fail to maintain the adequacy of our internal control over financial reporting or our disclosure controls and procedures, we could be subjected to regulatory scrutiny, civil or criminal penalties or stockholder litigation, the defense of any of which could cause the diversion of management's attention and resources, we could incur significant legal and other expenses, and we could be required to pay damages to settle such actions if any such actions were not resolved in our favor. Continued or future failure to maintain adequate internal control over financial reporting could also result in financial statements that do not accurately reflect our financial condition or results of operations. There can be no assurance that we will not identify any significant deficiencies or material weaknesses that will impair our ability to report our financial condition and results of operations accurately or on a timely basis. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock and our access to capital.

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, 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.

Our ability to use our net operating loss carry-forwards and other tax attributes to offset future taxable income is limited.

Section 382 of the Internal Revenue Code of 1986, as amended ("Code"), imposes restrictions on the use of a corporation's net operating losses, as well as other tax attributes including capital loss carryforwards and other losses and credits, after an "ownership change" occurs. A Section 382 "ownership change" occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock (including certain "public groups" deemed created for Section 382 purposes) increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. We believe that we experienced an ownership change within the meaning of Section 382 upon the conversion of our prior convertible notes in early 2018 that could result in significant limitations under Sections 382 on the use of our net operating

losses and other tax attributes. Additional debt conversions, if any, could further limit the use of those net operating losses and other tax attributes. However, Section 382 of the Code is an extremely complex provision with respect to which there are many uncertainties, and we have not requested an opinion of a law firm or accounting firm to confirm our analysis of the ownership change limitations related to the net operating losses generated by the Company. Therefore, we have not established whether the U.S. Internal Revenue Service would agree with our analysis regarding the application of Section 382 of the Code.

When an "ownership change" occurs, Section 382 imposes an annual limit on the amount of pre-change net operating losses and other tax attributes we can use to reduce our taxable income generally equal to the product of the total value of our outstanding equity immediately prior to the "ownership change" (subject to certain adjustments) multiplied by the applicable federal long-term tax-exempt interest rate for the month of the "ownership change."

Losses arising in taxable years beginning after December 31, 2017 are limited in the amount of taxable income they can offset but carry forward indefinitely. Net operating losses incurred in taxable years ending on or before December 31, 2017 generally may be carried forward for up to 20 years to offset future taxable income but are subject to the Section 382 limitations for losses incurred prior to an ownership change date. Any Section 382 annual limitation may effectively provide a cap on the cumulative amount of pre-ownership change losses that may be utilized during a carryforward period. Such pre-ownership change losses in excess of the cap may be lost and could cause a net increase in our United States federal income tax liability in the future, with United States federal income taxes to be paid earlier than they otherwise would be paid if such limitations were not in effect. Further, for financial reporting purposes the amount or value of these deferred tax assets may be reduced as a result of the Section 382 limitation. Such reduction could negatively impact the book value of our common stock and could result in an incremental U.S. income tax expense for the Company.

In addition, the Tax Cuts and Jobs Act limits the deduction for net operating loss carryforwards to 80 percent of taxable income for losses arising in taxable years beginning after December 31, 2017. Net operating losses subject to these limitations may be carried forward indefinitely.

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) will be 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. Disallowed interest deductions will be 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 definition 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, such as Massachusetts, Connecticut, Nevada and Vermont, require different types of compliance 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 the Centers for Medicare & Medicaid Services ("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 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives;

- 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 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. 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. Obtaining and maintaining foreign regulatory approvals, certifications or registrations are expensive, and we cannot be certain that we will receive regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products. 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.

In order to market our products in the Member States of the European Economic Area ("EEA"), our devices are required to comply with the essential requirements of the EU Medical Devices Directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, and Council Directive 90/385/EEC of 20 June 2009 relating to active implantable medical devices, as amended). On April 5, 2017, the EU adopted MDR 2017/745, the new Medical Devices Regulation, replacing the two existing directives, the Medical Devices Directive and the Active Implantable Medical Devices Directive. The new regulation will enter into force after a three-year transition period ending in spring 2020. This means that the market access framework for all member countries of the European single market (28 EU member states including the UK, the members of the EEA – Iceland, Lichtenstein and Norway, and through bilateral treaties Switzerland) will change significantly. The key changes that are expected include stricter control, transparency, and enforcement, the strengthening of post market surveillance requirements, and the possibility that the classification of some of our products will change, requiring more rigorous clinical testing and data.

Compliance with these requirements entitles us to affix the CE conformity mark to our medical devices, without which they cannot be commercialized in the EEA. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directives, a conformity assessment procedure requires the intervention of a "Notified Body", which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up an EC Declaration of Conformity, which allows us to affix the CE mark to our products.

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 or Notified Bodies in other countries, and approval or certification by one foreign regulatory authority or Notified Body does not ensure approval by regulatory authorities in other countries or by the FDA. We may be required to perform additional pre-clinical or clinical studies even if FDA clearance or approval, or the right to bear the CE mark, has been obtained. If we fail to obtain or maintain regulatory approvals, certifications or registrations in any foreign country in which we plan to market our products, our business, financial condition and operating results could be adversely affected.

In the EEA we must comply with the EU Medical Device Vigilance System, the purpose of which is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents must be reported to the competent authorities of the Member States

of the EEA. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. Incidents are evaluated by the EEA competent authorities to whom they have been reported, and where appropriate, information is disseminated between them in the form of National Competent Authority Reports ("NCARs"). The Medical Device Vigilance System is further intended to facilitate a direct, early and harmonized implementation of Field Safety Corrective Actions ("FSCAs") across the Member States of the EEA where the device is in use. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Further, the advertising and promotion of our products is subject to EEA Member States Medical Device related laws including 2017/745, the new Medical Device Regulation, or the 2006/114/EC concerning misleading and comparative advertising, as amended, or Directive 2005/29/EC on unfair commercial practices, as amended, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Our failure to comply with all these laws and requirements may harm our business and operating results.

We may also be required to perform post market clinical follow up studies to periodically evaluate the safety and performance of previously approved products. The results of these studies may cause us to lose our approvals, to market the product or require us to modify our products to address deficiencies in order to preserve our approvals to market the product. In March 2019, our Notified Body informed us that we are at risk of losing our CE mark on several products for failing to comply with post market clinical follow up requirements. We are working with our Notified Body to remediate this nonconformance and in January 2020 began the post market clinical follow up requirements with respect to some of the affected product. There can be no assurance that we will be able to remediate this matter. If this risk were to materialize, we may be required to remove the affected products from the EU market countries until we comply with these requirements.

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. The new 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.

Clinical trials can be long, expensive and ultimately uncertain, which could jeopardize our ability to obtain regulatory approval and market our products or affect our ability to make claims for our products that are necessary or desirable for commercialization.

Clinical trials are generally required to support a de novo request or PMA application and are sometimes required for 510(k) clearance. Such trials generally require an investigational device exemption application ("IDE") approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a nonsignificant risk device, or another exemption applies. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. All clinical trials, including IDE studies and nonsignificant risk device studies, must be conducted under the oversight of an institutional review board ("IRB") for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients' informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection laws and regulations, unless an exemption applies. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. In addition, the commencement or completion of any clinical trial may be delayed or halted for numerous reasons, including, but not limited to patients not enrolling in clinical trials at the rate we expect, patients experiencing adverse side effects, third-party contractors failing to perform in accordance with our anticipated schedule or consistent with good clinical practices, negative interim trial results, or our inability to obtain sufficient quantities of raw materials to produce our products. Clinical trials often take several years to execute. The outcome of any trial is uncertain and may have a significant impact on the success of our current and future products. Our development costs may increase if we have material delays in clinical trials or if we need to perform more or larger clinical trials than planned. If this occurs, our financial results and the commercial prospects for our products may be harmed. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA approval or clearance to market the product in the United States. Moreover, success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of the later trials will replicate those of earlier or prior trials. It is also possible that subjects enrolled in our clinical trials will experience adverse side effects that are not an anticipated part of the product's safety profile and, if so, these findings may result in lower market acceptance, which could have a material and adverse effect on our business, results of operations and financial condition.

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 clearance (510(k)), de novo classification, or approval (PMA) 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, the company's quality system and compliance with reporting requirements, the company's compliance with post-approval clinical data requirements, and the company's promotional activities related to its 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 ("HCT/Ps"), we are required to report all adverse reactions involving a communicable disease if it is fatal, life threatening, results in permanent impairment of a body function or permanent damage to body structure, or necessitates medical or surgical intervention, including hospitalization. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as mandatory recalls, destruction, cessation of manufacturing, inspection or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We may implement a product recall or voluntary market withdrawal due to product defects, product enhancements and modifications or other reasons, which 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. 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. This recall negatively affected our sales during 2019 and likely also harmed our reputation. 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, EU and Health Canada 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. Human tissues intended for transplantation have been regulated by the FDA since 1993.

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 to the recipient/patient, 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 premarket clearance (510(k)), de novo classification or approval (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 determined by labeling, advertising or other indications of the manufacturer's objective intent; (iii) the manufacture does not involve combination 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 PHSA. 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 PHSA, or devices or drugs under the FDCA, including premarket 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 PHSA 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 PHSA. 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 in the future. 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 PHSA, and therefore that one or more of the HCT/Ps require approval or clearance of a marketing application. For our HCT/Ps that are not combined with another article, the FDA could conclude that the tissue is more than minimally manipulated, that the product is intended for a non-homologous use, or that the product has a systemic effect or is dependent on the metabolic activity of living cells for its primary function. If the FDA were to draw these conclusions, it would likely require the submission and 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 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.

Our biologics products may be subject to regulation in the European Union as well, should we enter that market. In the European Union regulations, if applicable, differ from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the European Union, as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. Some of our products may be subject to EU member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. Some EU member states have their own tissue banking regulations.

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

We are accredited with the American Association of Tissue Banks ("AATB"), 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.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failure to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing and reporting standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a substantial impact on our business and results of operations, including the imposition of substantial fines or other sanctions.

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 were recently subject to patent infringement litigation and there can be no assurances that we do not infringe any patents or other proprietary rights. In addition to being costly, protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

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

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

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

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

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

We may not be able to obtain, maintain and protect certain proprietary rights necessary for the development and commercialization of our products or product candidates. Our commercial success will depend in part on obtaining and maintaining patent protection on our products, successfully asserting these patents against competitors employing infringing technology, and successfully defending these patents against third-party challenges. Even if our patents cover a competing technology, a competitor may not accede to our demands to cease and desist or license our patent rights, which will then require us to pursue costly and time-consuming litigation. Even if we were successful in any such litigation, a court may not issue an injunction, or the infringing competitor may alter its technology to no longer infringe. Our ability to commercialize our products will also depend in part on the patent positions of third parties, including those of our competitors. The patent positions

of medical device and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict with certainty the scope and breadth of patent claims that may be afforded to other companies' patents. We could incur substantial costs in litigation if we are required to defend against patent suits brought by third parties, or if we initiate suits to protect our patent rights. Such suits that we may need to defend extend beyond suits by our competitors and may include patent assertion entities, which acquire and assert patents as a means to generate income, due to the expensive nature of patent litigation. In the ordinary course of litigation, attorney fees are not recoverable.

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

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

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

Risks Related to Our Common Stock

Shares of our common stock are equity securities and are subordinate to our outstanding indebtedness, which is significant.

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 Amended and Restated 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 Amended and Restated 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.

Funds affiliated with OrbiMed have beneficial ownership of 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.

Funds affiliated with OrbiMed Advisors LLC, OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP, own approximately 70% of our outstanding common stock and beneficially own, including their warrants to purchase an additional 2,407,309 shares of our common stock, approximately 75% of our outstanding common stock. Royalty Opportunities and ROS are also the lenders under our Second Amended and Restated Credit Agreement and hold all of our outstanding indebtedness thereunder.

In addition, we are party to an Investor Rights Agreement, dated as of February 14, 2018 ("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 the 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, ROS and two other funds party to the Investor Rights Agreement 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, including amendments to our Amended and Restated Certificate of Incorporation, Amended and Restated 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. The interests of OrbiMed may not in all cases be aligned with the interests of our other stockholders. In addition, OrbiMed and their affiliates may have an interest in pursuing acquisitions, divestitures and other transactions that, in their judgment, could enhance their investment, even though such transactions might involve risks to our other stockholders. For example, OrbiMed could cause us to make acquisitions that increase our indebtedness or cause us to sell revenue-generating assets. In addition, OrbiMed and their affiliates are able to determine the outcome of all matters requiring stockholder approval and are able to cause or prevent a change of control of our company or a change in the composition of our Board of Directors and could preclude any acquisition of our company. This concentration of voting control could deprive our other stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of our company and ultimately might affect the market price of our common stock.

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

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

We are currently out of compliance with the continued listing standards of the NYSE American. Our failure to resume compliance with the continued listing standards prior to October 4, 2020 or make continued progress toward compliance consistent with the plan of compliance we submitted to NYSE Regulation may result in the delisting of our common stock.

Our common stock is listed on the NYSE American. In order to maintain this listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders. In addition to these objective standards, NYSE Regulation may delist the securities of any issuer (i) if, in its opinion, the issuer's financial condition and/or operating results appear unsatisfactory; (ii) if it appears that the extent of public distribution or the aggregate market value of the security has become so reduced as to make continued listing on the NYSE American inadvisable; (iii) if the issuer sells or disposes of principal operating assets or ceases to be an operating company; (iv) if an issuer fails to comply with the NYSE American's listing requirements; (v) if an issuer's common stock sells at what NYSE Regulation considers a "low selling price" and the issuer fails to correct this via a reverse split of shares after notification by NYSE Regulation; or (vi) if any other event occurs or any condition exists which makes continued listing on the NYSE American in its opinion, inadvisable.

As part of these continued listing requirements, we must maintain stockholders' equity of $6.0 million or more since we have reported losses from continuing operations and/or net losses in our five most recent fiscal years under Section 1003(a)(iii) of the NYSE American Company Guide. Our audited consolidated financial statements for the year ended December 31, 2019 reflect stockholders' deficit of $44.2 million. On April 4, 2019, we received a letter from NYSE Regulation notifying us that we are not in compliance with the NYSE American's continued listing standards relating to stockholders' equity. As a result, we became subject to the procedures and requirements of Section 1009 of the NYSE American Company Guide. On May 3, 2019, we submitted a plan of compliance to NYSE Regulation addressing how we intend to regain compliance with the continued listing requirements by October 4, 2020. On May 23, 2019, we received a letter from NYSE Regulation stating that our plan of compliance has been accepted and we have been granted a plan period through October 4, 2020. We have been advised that we will be subject to delisting proceedings if we do not regain compliance prior to October 4, 2020 or if NYSE Regulation determines that we are not making progress consistent with our plan of compliance. Although we intend to regain compliance with the continued listing requirements prior to October 4, 2020, no assurance can be provided that we will do so. If delisting proceedings are commenced, the NYSE American rules permit us to appeal a staff delisting determination. Our common stock will continue to be listed and traded on the NYSE American during the plan period, subject to our compliance with the NYSE American's other applicable continued listing standards. If NYSE Regulation delists our common stock, investors may face material adverse consequences, including, but not limited to, a lack of trading market for our securities, reduced liquidity, decreased analyst coverage of our securities, and an inability for us to obtain additional financing to fund our operations.

We may conduct a transaction or transactions prior to October 4, 2020 that would likely result in significant dilution to our existing stockholders. The transaction(s) could include the private investment in public equity, a public rights offering, a debt restructuring or any combination of these or similar transactions with the intent of maintaining our NYSE American listing. Such transaction(s), if completed, would be dilutive to certain stockholders, could adversely affect the market price of our common stock, would involve some expense and management distraction from our business and ultimately may not be successful in maintaining our NYSE American listing.

To maintain our NYSE American listing, we may conduct a private investment in public equity, a public rights offering, a debt restructuring or any combination of these or similar transactions prior to October 4, 2020. Although no assurance can be provided that we complete any of these transactions, if a transaction occurs, it would be dilutive to certain stockholders and could adversely or favorably affect the market price of our common stock. Furthermore, any transaction would involve some expense and management distraction from our business, and it is possible that despite the transaction, we may still be unsuccessful in maintaining our NYSE American listing. If NYSE Regulation delists our common stock, investors may face material adverse consequences, including, but not limited to, a lack of trading market for our securities, reduced liquidity, decreased analyst coverage of our securities, and an inability for us to obtain additional financing to fund our operations.

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 beyond our control. During 2019, the sale price of our common

stock ranged from $1.42 to $4.75 per share. 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 Amended and Restated Credit Agreement;
- our observance of covenants under our Second Amended and Restated 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 and other external factors; 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, 2019, we had warrants to purchase an aggregate of 2,908,874 shares of our common stock, options to purchase an aggregate of 602,966 shares of our common stock and restricted stock units covering an aggregate of 499,914 shares of our common stock outstanding. 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.

If securities analysts stop publishing research or reports about us or our business, or if they downgrade our common stock, the trading volume and market price of our common stock could decline.

The market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. If any analyst who covers us downgrades our stock or lowers its future stock price targets or estimates of our operating results, the market price of our common stock could decline rapidly. Furthermore, if any analyst ceases to cover our Company, we could lose visibility in the market. Each of these events could, in turn, cause the trading volume and market price of our common stock to decline.

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 Amended and Restated Certificate of Incorporation and Second Amended and Restated 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 Amended and Restated Certificate of Incorporation and Second Amended and Restated 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 Amended and Restated Certificate of Incorporation related to the amendment of our Second Amended and Restated Bylaws, the Board of Directors and our stockholders as well as the general provisions of our Amended and Restated Certificate of Incorporation.

- 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 Amended and Restated Certificate of Incorporation or our Second Amended and Restated 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, OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP 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 Amended and Restated Certificate of Incorporation authorizes our Board of Directors, without the approval of our stockholders, to issue up to 10,000,000 shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our Amended and Restated Certificate of Incorporation, 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 Amended and Restated Certificate of Incorporation 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 Amended and Restated Certificate of Incorporation 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 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 Amended and Restated Certificate of Incorporation related to choice of forum. The choice of forum provision in our Amended and Restated Certificate of Incorporation may limit the ability of our stockholders to obtain a favorable judicial forum for disputes with us.

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 Securities Exchange Act of 1934 (the "Exchange Act"), and the corporate governance standards of the Sarbanes-Oxley Act of 2002 (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.

We may be subject to securities litigation, which is expensive and could divert management attention.

Our stock price has been volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition, or prospects. Any adverse determination in litigation could also subject us to significant liabilities.

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 Amended and Restated 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.

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. 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 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.

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

On December 13, 2018, a complaint was filed by RSB Spine, LLC, against Xtant Medical Holdings, Inc., which claims 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. The complaint seeks an adjudication of infringement, an injunction against future infringement, unspecified damages for infringement, a finding that such infringement is willful, and treble damages for such willful infringement. This action was brought in the United States District Court for the District of Delaware. We filed an answer and affirmative defenses to the complaint on March 29, 2019, denying the allegations of infringement and seeking dismissal of RSB Spine's claims and requested relief. The Court entered a scheduling order on May 9, 2019, scheduling trial for no sooner than June 21, 2021. On February 28, 2020, we entered into a confidential settlement and patent license agreement with RSB Spine that includes a dismissal with prejudice and a release of claims in exchange for certain payments by us. Based on information presently known to management, we believe the settlement will not have a material adverse effect on our business, financial condition, cash flows or results of operations.

In addition, we are subject to potential liabilities under government regulations and various claims and legal actions that are pending or may be asserted 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

Holders of Record

As of March 2, 2020, we had 172 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 Amended and Restated 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, 2019.

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, 2019.

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."

Executive Summary

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 and sell our products in the United States largely through independent commissioned agents and stocking distributors, augmented 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 independent health delivery network 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. We promote and sell our products internationally through stocking distribution partners in Canada, Mexico, South America, Europe, Australia, and certain Pacific region countries.

While we focused on improving our balance sheet and operational efficiencies in 2019, 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 2019, we took several actions in furtherance of these objectives, including:

- Rebuilt our senior management team by hiring a new Chief Executive Officer, Chief Operations Officer and Chief Financial Officer and enhanced our commercial organization under the leadership of our Chief Commercial Officer by hiring five senior sales executives;

- Reengaged with our distribution network;

- Introduced new products, including the Intice-C Titanium Cervical Interbody Spacer, Atrix-C Union Cervical Interbody Spacer, and the Calix-C PC Plasma Coated PEEK Implant, and committed resources to develop and introduce additional new products, especially in our orthobiologics business; and

- Enhanced our operational efficiencies, including upgrades to our existing ERP) platform, which will continue throughout 2020 and which we believe should enable our employees to better serve our customers, which we believe is necessary for improving our sales performance and the deployment of our resources.

Our common stock trades on the NYSE American under the symbol "XTNT" and we remain firmly committed to maintaining our stock exchange listing. During 2019, we outlined to the NYSE American certain milestones that we intend to achieve to regain compliance with the NYSE American's continued listing requirements by no later than October 4, 2020. These milestones include steps intended to improve our revenue performance, operational efficiency and balance sheet, with the goal to increase our stockholders' equity to meet the minimum $6.0 million requirement.

While our revenue decreased during 2019 compared to 2018, we improved our gross margins and decreased significantly our operating expenses, resulting in a net loss of $8.2 million for the year ended December 31, 2019, compared to $70.1 million for the year ended December 31, 2018. The net loss for 2018 included a $48.1 million impairment of goodwill and intangible assets.

Results of Operations

Comparison of Years Ended December 31, 2019 and December 31, 2018

The following table sets forth our results of operations for 2019 and 2018 (in thousands):

	Year Ended December 31,			
	2019		2018	
	Amount	% of Revenue	Amount	% of Revenue
Revenue				
Orthopedic product sales	$ 64,516	99.7%	$ 71,814	99.5%
Other revenue	166	0.3%	389	0.5%
Total Revenue	64,682	100.0%	72,203	100.0%
Cost of Sales	22,166	34.3%	28,717	39.8%
Gross Profit	42,516	65.7%	43,486	60.2%
Operating Expenses				
General and administrative	17,936	27.7%	14,277	19.8%
Sales and marketing	25,843	40.0%	31,464	43.6%
Research and development	932	1.4%	1,702	2.4%
Amortization	58	0.1%	3,437	4.7%
Impairment of goodwill and intangible assets	—	0.0%	48,146	66.7%
Restructuring expenses	—	0.0%	2,970	4.1%
Separation related expenses	—	0.0%	1,568	2.2%
Total Operating Expenses	44,769	69.2%	103,564	143.4%
Loss from Operations	(2,253)	(3.5)%	(60,078)	(83.2)%
Other Income (Expense)				
Interest expense	(5,772)	(8.9)%	(10,145)	(14.1)%
Change in warrant derivative liability	3	0.0%	121	0.2%
Other income (expense)	(101)	(0.2)%	3	0.0%
Total Other Expense	(5,870)	(9.1)%	(10,021)	(13.9)%
Net Loss from Operations Before Provision for Income Taxes	(8,123)	(12.6)%	(70,099)	(97.1)%
Provision for Income Taxes				
Current and Deferred	(98)	(0.1)%	—	0.0%
Net Loss	$ (8,221)	(12.7)%	$ (70,099)	(97.1)%

Revenue

Total revenue for the year ended December 31, 2019 decreased 10.4% to $64.7 million compared to $72.2 million for the prior year. The decrease of $7.5 million is primarily due to $7.1 million in reductions due to company and distributor initiated discontinued distributor arrangements related to our hardware business and lower demand for certain hardware products, as well as pricing pressures experienced with the execution of new GPO and IDN contracts and continued competition due to our lack of new product introductions over the last several years. This decrease was partially offset by sales growth from our key biologics customers.

Cost of Sales

Costs of sales consist primarily of manufacturing and 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 22.8%, or $6.6 million, to $22.2 million for the year ended December 31, 2019 from $28.7 million for the year ended December 31,

2018. Cost of sales as a percent of total revenue was 34.3% of revenue for the year ended December 31, 2019, compared to 39.8% for the prior year.

The primary reason for the reduction in cost of goods sold in 2019 was the significant reduction in the expense for estimated excess inventory which decreased to $0.5 million in 2019 from $4.9 million in 2018. The $4.9 million expense for 2018 was due primarily to the significant decrease in fixation sales and our change in estimate for determining excess and obsolete inventory.

General and Administrative

General and administrative expenses consist primarily of personnel costs for corporate employees, cash based and stock-based compensation related costs and corporate expenses for legal, accounting and other professional fees, as well as occupancy costs. General and administrative expenses increased 25.6%, or $3.7 million, to $17.9 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was due primarily to legal settlements and remediation expenses totaling $1.6 million, retention of finance and accounting consultants previously utilized in connection with our restructuring for assistance in general and administrative functions totaling $1.3 million, increased bad debt expense of $0.5 million, executive recruiting fees of $0.5 million and fees associated with our ERP project of $0.4 million.

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 17.9%, or $5.6 million, to $25.8 million for the year ended December 31, 2019, compared to $31.5 million for the year ended December 31, 2018. As a percentage of revenue, sales and marketing expenses were 40.0% in 2019, compared to 43.6% in the prior year. This decrease was due primarily to the favorable impact from changes made to the commission rate structure under certain distribution agreements, lower travel expenses, a reduction in headcount, and decreased commissions attributable to decreased revenue in 2019 compared to 2018.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new product technologies and processes. Research and development expenses decreased $0.8 million, or 45.2%, to $0.9 million for the year ended December 31, 2019 from $1.7 million for the year ended December 31, 2018. This decrease was due primarily to a reduction in research and development headcount in 2019 compared to 2018.

Amortization

Amortization expense decreased $3.3 million to $0.1 million for the year ended December 31, 2019, from $3.4 million for the year ended December 31, 2018, primarily due to the impairment of amortizable intangible assets during the year ended December 31, 2018.

Impairment of Goodwill and Intangible Assets

We recorded no impairment charges during 2019. During 2018, we recorded an impairment charge of $48.1 million relating to our X-spine fixation business which we acquired in 2015, consisting of a $38.3 million impairment charge to goodwill and a $9.8 million impairment charge to other intangible assets. The goodwill impairment charge was based on the analysis performed in comparing the carrying value of our fixation assets, including cash, and non-interesting bearing liabilities to the derived enterprise value of our fixation business. The remaining intangible asset impairment charge related to tradenames, technology and customer relationships, the result of their carrying amounts exceeding the future net cash flow expected to be generated by these intangible assets.

Restructuring Expenses

We incurred no restructuring expenses during 2019. During 2018, we incurred restructuring expenses of $3.0 million related to our debt restructuring and certain performance improvement measures performed in 2018.

Separation Related Expenses

We incurred no separation related expenses during 2019. During 2018, we incurred separation related expenses of $1.6 million related to severance and related benefit expenses for personnel reductions as part of our restructuring and closure of our Dayton, Ohio facility, as well as severance paid to our former Chief Executive Officer.

Interest Expense

Interest expense for the year ended December 31, 2019 decreased $4.3 million to $5.8 million as compared to $10.1 million for the year ended December 31, 2018. This decrease was due to an amendment to our credit agreement resulting in a lower effective interest rate on our outstanding debt.

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 offering and other debt transactions.

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

	December 31,	
	2019	**2018**
Cash and cash equivalents	$ 5,237	$ 6,797
Accounts receivable, net	10,124	9,990
Inventories	16,101	17,301
Total current assets	32,246	34,677
Accounts payable	2,188	6,465
Accrued liabilities	6,625	5,150
Total current liabilities	9,390	12,051
Net working capital	22,856	22,626
Long-term debt, less issuance costs	76,244	77,939

Cash Flows

Net cash used in operating activities for the year ended December 31, 2019 was $0.4 million compared to net cash provided by operating activities of $1.2 million for the year ended December 31, 2018. This decrease was due primarily to higher usage of cash from working capital to significantly reduce accounts payable to restore vendor relationships and an increase in trade accounts receivable, which was partially offset by higher accrued liabilities. The higher accrued liabilities relate primarily to the settlement of our patent infringement litigation.

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 $0.4 million. Net cash used in investing activities for the year ended December 31, 2018 was $0.4 million, primarily representing purchases of property and equipment of $0.6 million, partially offset by proceeds from sale of fixed assets of $0.2 million.

Net cash used in financing activities was $0.6 million during the year ended December 31, 2019 consisting of payment on capital leases of $0.5 million and costs associated with our Second Amended and Restated Credit Agreement of $0.1 million. Net cash provided by financing activities was $3.1 million for the year ended December 31, 2018 consisting of $6.8 million in proceeds from a private placement, partially offset by $3.4 million in costs associated with the debt conversion.

Cash Requirements

We believe that our cash and cash equivalents of $5.2 million as of December 31, 2019, together with the availability of $10.0 million under our Second Amended and Restated Credit Agreement, will be sufficient to meet our anticipated cash requirements through at least March 2021. Although we have availability under our Second Amended and Restated Credit

Agreement, this credit facility expires March 31, 2021 and all of our indebtedness thereunder matures on such date. While we intend to extend the maturity date of this facility and our outstanding indebtedness, no assurance can be provided that we will do so or on terms that are favorable to us. In addition, we may require additional funds to fund our future operations and business strategy prior to March 2021. Accordingly, there is no assurance that we will not need or seek additional funding prior to such 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.

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 liquidation or other preferences that would adversely affect the rights of 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 ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP, and no assurance can be provided that they would provide such consent, which could limit our ability to raise additional financing.

Second Amended and Restated Credit Agreement

On March 29, 2019, we entered into a Second Amended and Restated Credit Agreement, which amended and restated our prior credit agreement with our lenders. Under the Second Amended and Restated Credit Agreement:

- 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 Amended and Restated Credit Agreement, and may request additional term loans with the lenders 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 the lenders 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 each Investor) of conditions precedent, including closing certificate, delivery of budget, and other satisfactory documents;

- No interest will accrue on the loans under the Second Amended and Restated Credit Agreement from and after January 1, 2019 until March 31, 2020;

- Beginning April 1, 2020 through the maturity date of the Second Amended and Restated Credit Agreement, interest payable in cash will accrue on the loans under the 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 Amended and Restated Credit Agreement) and (y) 2.3125%;

- The maturity date of the loans is 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 executive officers of the Company.

Long-term debt, less issuance costs consists of long-term debt due to the lenders under the Second Amended and Restated Credit Agreement as of December 31, 2019 and under the Prior Credit Agreement as of December 31, 2018. The execution of the Second Amended and Restated 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 the credit facility lenders, 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. As of December 31, 2019, our long-term debt, less issuance costs was $76.2 million. Assuming no debt payments are made, our long-term debt, less issuance costs line item will continue to increase until the loan's March 31, 2021 maturity date. While our long-term debt, less issuance costs balance was $76.2 million as reported under GAAP as of December 31, 2019, we owe a principal balance of $55.8 million plus accrued PIK interest of $21.1 million as of December 31, 2019.

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. Different, reasonable estimates could have been used in the current period. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition, or results of operations.

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. Based upon our annual goodwill impairment test last year we concluded that goodwill was impaired due to a significant reduction of results from operations during the year ended December 31, 2018 compared to the

prior year. Our annual impairment test as of December 31, 2018 resulted in an impairment charge related to our goodwill of $38.3 million. There was no impairment of goodwill recorded in 2019.

In connection with our testing for goodwill impairment as of December 31, 2018, an Accounting Standards Codification 360, *Property, Plant and Equipment*, test was performed on our identified intangible assets. As a result of the analysis, we recorded an impairment charge in 2018 of $9.8 million related to tradenames, technology and customer relationships based on the carrying amount exceeding the estimated fair value of these intangible assets. The was no impairment of our identified intangible assets recorded in 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 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 our total inventory reserve at December 31, 2019 of $11.4 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. 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 to bad debt expense in the period that we made such a determination. We believe our allowance for doubtful accounts at December 31, 2019 of $0.5 million is adequate.

Going Concern

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

Management's evaluation of going concern was conducted as part of its discussions with and the review by the Board of Directors of our 2020 Annual Operating Plan. Management believes that our cash and cash equivalents of $5.2 million as of December 31, 2019, together with the availability of $10.0 million under our Second Amended and Restated Credit

Agreement, will be sufficient to meet our anticipated cash requirements and continue as a going concern through at least March 2021.

Although we have availability under our Second Amended and Restated Credit Agreement, this agreement is scheduled to terminate on March 31, 2021. Accordingly, we anticipate that we will need to refinance our outstanding indebtedness and obtain additional credit availability in the near future. 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 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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years ended December 31, 2019 and 2018, 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, 2019 and 2018, and the results of its operations and its cash flows for the years ended December 31, 2019 and 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Plante & Moran, PLLC

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

Denver, Colorado

March 5, 2020

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

	Year Ended December 31, 2019	2018
Revenue		
Orthopedic product sales	$ 64,516	$ 71,814
Other revenue	166	389
Total Revenue	64,682	72,203
Cost of Sales	22,166	28,717
Gross Profit	42,516	43,486
Operating Expenses		
General and administrative	17,936	14,277
Sales and marketing	25,843	31,464
Research and development	932	1,702
Amortization	58	3,437
Impairment of goodwill and intangible assets	—	48,146
Restructuring expenses	—	2,970
Separation related expenses	—	1,568
Total Operating Expenses	44,769	103,564
Loss from Operations	(2,253)	(60,078)
Other Income (Expense)		
Interest expense	(5,772)	(10,145)
Change in warrant derivative liability	3	121
Other income (expense)	(101)	3
Total Other Expense	(5,870)	(10,021)
Net Loss from Operations Before Provision for Income Taxes	(8,123)	(70,099)
Provision for Income Taxes		
Current and Deferred	(98)	—
Net Loss	$ (8,221)	$ (70,099)
Net loss per share:		
Basic	$ (0.63)	$ (5.97)
Dilutive	$ (0.63)	$ (5.97)
Shares used in the computation:		
Basic	13,163,931	11,740,550
Dilutive	13,163,931	11,740,550

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except number of shares and par value)

	As of December 31, 2019	As of December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,237	$ 6,797
Trade accounts receivable, net of allowance for doubtful accounts of $500 and $2,140, respectively	10,124	9,990
Inventories	16,101	17,301
Prepaid and other current assets	784	589
Total current assets	32,246	34,677
Property and equipment, net	4,695	7,174
Right of use asset, net	2,100	—
Goodwill	3,205	3,205
Intangible assets, net	515	573
Other assets	394	793
Total Assets	$ 43,155	$ 46,422
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 2,188	$ 6,465
Accrued liabilities	6,625	5,150
Warrant derivative liability	7	10
Current portion of lease liability	394	—
Current portion of finance lease obligations	176	426
Total current liabilities	9,390	12,051
Long-term Liabilities:		
Lease obligation, less current portion	1,726	—
Finance lease obligation, less current portion	—	204
Long-term debt, less issuance costs	76,244	77,939
Total Liabilities	87,360	90,194
Commitments and Contingencies (note 10)		
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; 75,000,000 shares authorized; 13,161,762 shares issued and outstanding as of December 31, 2019 and 50,000,000 shares authorized; 13,172,179 shares issued and outstanding as of December 31, 2018	—	—
Additional paid-in capital	179,061	171,273
Accumulated deficit	(223,266)	(215,045)
Total Stockholders' Equity (Deficit)	(44,205)	(43,772)
Total Liabilities & Stockholders' Equity (Deficit)	$ 43,155	$ 46,422

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	Retained	Total Stockholders'
	Shares	Amount	Paid-In-Capital	Deficit	Equity (Deficit)
Balance at December 31, 2017	1,514,899	$ —	$ 86,247	$ (144,946)	$ (58,699)
Stock-based compensation	—	—	814	—	814
Issuance of common stock	11,657,280	—	79,098	—	79,098
Issuance of warrants	—	—	5,114	—	5,114
Net loss	—	—	—	(70,099)	(70,099)
Balance at December 31, 2018	13,172,179	$ —	$ 171,273	$ (215,045)	$ (43,772)
Stock-based compensation	—	—	515	—	515
Forfeiture or restricted stock	(10,417)	—	—	—	—
Debt extinguishment	—	—	7,264	—	7,264
Issuance of warrants	—	—	9	—	9
Net loss	—	—	—	(8,221)	(8,221)
Balance at December 31, 2019	13,161,762	$ —	$ 179,061	$ (223,266)	$ (44,205)

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (8,221)	$ (70,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,143	6,590
Goodwill and intangible asset impairment	—	48,146
Non-cash interest	5,726	9,848
Non-cash rent	20	—
(Gain) loss on sale of fixed assets	(61)	103
Stock-based compensation	515	694
Provision for reserve on accounts receivable	513	188
Provision for excess and obsolete inventory	509	4,932
Change in warrant derivative liability	(3)	(121)
Changes in operating assets and liabilities:		
Trade accounts receivable	(647)	2,536
Inventories	692	40
Prepaid and other assets	204	1,055
Accounts payable	(4,278)	(3,011)
Accrued liabilities	1,475	311
Net cash provided by (used in) operating activities	(413)	1,212
Investing activities:		
Purchases of property and equipment	(879)	(624)
Proceeds from sale of fixed assets	335	257
Net cash used in investing activities	(544)	(367)
Financing activities:		
Payments on capital leases	(455)	(359)
Costs associated with Second Amended and Restated Credit Agreement	(148)	—
Costs associated with conversion of debt and private placement	—	(3,356)
Proceeds from equity private placement	—	6,810
Net proceeds from issuance of stock and warrants	—	1
Net cash provided by (used in) financing activities	(603)	3,096
Net change in cash and cash equivalents	(1,560)	3,941
Cash and cash equivalents at beginning of year	6,797	2,856
Cash and cash equivalents at end of year	$ 5,237	$ 6,797

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.

As described in more detail below, effective as of February 13, 2018, the Company effected a 1-for-12 reverse split of its common stock (the "Reverse Stock Split"). The Reverse Stock Split is reflected in the share amounts in all periods presented in this report.

At December 31, 2019, the Company had cash and cash equivalents of $5.2 million, and an accumulated deficit of $223.3 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 2020 Annual Operating Plan. Management believes that the Company's cash and cash equivalents of $5.2 million as of December 31, 2019, together with the availability of $10.0 million under its Second Amended and Restated Credit Agreement, will be sufficient to meet its anticipated cash requirements and continue as a going concern through at least March 2021.

Corporate Restructuring

Restructuring Agreement

On January 11, 2018, we entered into a Restructuring and Exchange Agreement (the "Restructuring Agreement") with ROS Acquisition Offshore LP, OrbiMed Royalty Opportunities II, LP (collectively referred to herein as the "Investors"), Bruce Fund, Inc., Park West Partners International, Limited ("PWPI"), Park West Investors Master Fund, Limited ("PWIMF"), and Telemetry Securities, L.L.C., and with the Investors, are collectively referred to herein as the "Holders".

Pursuant to the Restructuring Agreement, and following the execution of an amendment to the indenture governing our then outstanding 6% convertible senior unsecured notes due 2021 (the "2017 Notes"), described in the "Debt" and "Equity" sections below, on January 17, 2018, the Investors converted the 2017 Notes, plus accrued and unpaid interest, at the $9.11 per share conversion rate originally provided thereunder, into 189,645 shares of our common stock.

On February 14, 2018, after giving effect to the Reverse Stock Split (described below), $70.3 million aggregate principal amount of our then outstanding 2017 Notes held by the Holders (the "Remaining Notes"), plus accrued and unpaid interest, were exchanged for newly-issued shares of our common stock at an exchange rate of 138.8889 shares per $1,000 principal amount of the Remaining Notes, for an exchange price of $7.20 per share (the "Notes Exchange"). This resulted in the issuance of 10,401,309 shares of our common stock to the Holders and the Investors acquiring an approximately 70% controlling interest in our outstanding shares of common stock. Upon the completion of the Notes Exchange, all outstanding obligations under our convertible senior secured notes were satisfied in full and the Indentures governing such notes were discharged.

Pursuant to the terms of the Restructuring Agreement, we commenced a rights offering to allow our stockholders as of the April 27, 2018 record date to purchase up to an aggregate of 1,137,515 shares of our common stock at a subscription

price of $7.20 per share. The rights offering expired on June 18, 2018. We issued 129 shares of common stock in the rights offering and received $0.9 thousand in gross proceeds.

Amended and Restated Certificate of Incorporation

On February 13, 2018, following a special meeting of our stockholders, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation (the "Certificate Amendment"). The Certificate Amendment amended and restated our Certificate of Incorporation (the "Charter") to, among other things:

- effect the Reverse Stock Split;
- after giving effect to the Reverse Stock Split, decrease the number of authorized shares of common stock available for issuance from 95,000,000 to 50,000,000 and increase the number of authorized shares of preferred stock available for issuance from 5,000,000 to 10,000,000; and
- authorize the Company's Board of Directors ("Board") to increase or decrease the number of shares of any series of our capital stock, provided that such increase or decrease does not exceed the number of authorized shares or be less than the number of shares then outstanding.

The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on February 13, 2018, and our common stock began trading on a split-adjusted basis when the market opened on February 14, 2018. Upon the effectiveness of the Reverse Stock Split, every 12 shares of our issued and outstanding common stock automatically converted into one share of common stock, without any change in the par value per share. In addition, a proportionate adjustment was made to the per share exercise or conversion price and the number of shares issuable upon the exercise of all of our outstanding stock options and convertible securities to purchase shares of common stock and the number of shares underlying restricted stock awards and reserved for issuance pursuant to our equity incentive compensation plan. Any fraction of a share of common stock that would otherwise have resulted from the Reverse Stock Split was rounded down to the nearest whole share. All share and per share amounts have been retroactively restated to reflect the Reverse Stock Split.

Private Placement SPA

On February 14, 2018, we entered into a Securities Purchase Agreement (the "Private Placement SPA") with the Investors pursuant to which the Investors purchased from us an aggregate of 945,819 shares of our common stock, at a price of $7.20 per share, for aggregate proceeds of $6.8 million.

Investor Rights Agreement

Effective February 14, 2018, we entered into an Investor Rights Agreement (the "Investor Rights Agreement") with the Holders. Under the Investor Rights Agreement, the Investors are permitted to nominate a majority of our directors and designate the chairperson of the Board at subsequent annual meetings, as long as the Investors maintain an ownership threshold in the Company of at least 40% of our then outstanding common stock (the "Ownership Threshold"). If the Investors are unable to maintain the Ownership Threshold, the Investor Rights Agreement contemplates a reduction of nomination rights commensurate with their ownership interests.

For so long as the Ownership Threshold is met, we must obtain the approval of the Investors to proceed with the following actions: (i) issue new securities; (ii) incur over $0.25 million of debt in a fiscal year; (iii) sell or transfer over $0.25 million of our assets or businesses or our subsidiaries in a fiscal year; (iv) acquire over $0.25 million of assets or properties in a fiscal year; (v) make capital expenditures over $0.125 million 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 the Board; 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 $0.25 million in a fiscal year. As long as the Ownership Threshold is met, we may not increase the size of the Board beyond seven directors without the approval of a majority of the directors nominated by the Investors.

The Investor Rights Agreement grants the Holders 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 written notice of the Company or an Investor, if such Investor's ownership percentage of our then outstanding common stock is less than 10%, or (c) upon written notice by the Investors. PWPI and PWIMF's right to purchase

from us a pro rata amount of any new securities will also terminate at such time as their aggregate ownership percentage of our then outstanding common stock is less than 8.5%.

Registration Rights Agreement

Effective February 14, 2018, we entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Holders. The Registration Rights Agreement requires us to, among other things, file with the U. S. Securities and Exchange Commission ("SEC") a shelf registration statement within 90 days of the date of the Registration Rights Agreement covering the resale, from time to time, of our common stock issued. This registration statement became effective on June 4, 2018.

Second Amended and Restated Bylaws

On February 14, 2018, we amended and restated our current bylaws by adopting the Second Amended and Restated Bylaws of the Company (the "Amended Bylaws"). The Amended Bylaws amended our existing bylaws to, among other things:

- provide for annual and special meetings of stockholders to be held through remote communications;
- provide for the election of any directors not elected at an annual meeting of stockholders to be elected at a special meeting of stockholders;
- declassify the Board into one group of directors that will hold office until the subsequent annual meeting of stockholders and until the election and qualification of such directors' respective successors;
- provide for the filling of a new directorship or director vacancy by the affirmative vote of the holders of a majority of the voting power of our shares of stock;
- allow for a majority of the Board present to adjourn a Board meeting if a quorum is not met;
- unless otherwise restricted in the Amended Bylaws or our Charter, provide the Board with the authority to fix the compensation of directors, including without limitation, compensation for services as members of Board committees;
- allow us to enter into an agreement with a stockholder to restrict the transfer of shares held by such stockholder in any manner not prohibited by the DGCL; and
- allow the Board to declare dividends on our capital stock, subject to any provisions of our Charter and applicable law.

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 revenue or accounts receivable in the fiscal years 2019 or 2018. The Company provides for uncollectible amounts when specific credit issues arise. Management believes that all significant credit risks have been identified at December 31, 2019.

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.

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. 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 will 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.

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, Europe, 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, 2019 and 2018:

	Year Ended December 31, 2019	Percentage of Total Revenue	Year Ended December 31, 2018	Percentage of Total Revenue
Orthobiologics	$ 46,663	72%	$ 48,984	68%
Spinal implant	17,872	28%	22,830	31%
Other revenue	147	0%	389	1%
Total revenue	$ 64,682	100%	$ 72,203	100%

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, 2019 and 2018, as shares issuable upon the exercise of stock options and warrants 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 4,011,754 and 2,247,567 outstanding stock options, warrants and restricted stock units for the years ended December 31, 2019 and 2018, 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, 2019 and 2018, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

The following table sets forth by level, within the fair value hierarchy, our liabilities as of December 31, 2019 and 2018 that are measured at fair value on a recurring basis (in thousands):

Warrant derivative liability

	As of December 31, 2019	As of December 31, 2018
Level 1	—	—
Level 2	—	—
Level 3	$ 7	$ 10

The valuation technique used to measure fair value of the warrant liability is based on a lattice valuation model and significant assumptions and inputs determined by us (See Note 9, "Warrants" below).

Recent Accounting Pronouncements

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*, which amends certain provisions of Accounting Standards Codification ("ASC") 326, *Financial Instruments-Credit Loss*. The new standard is effective for reporting periods beginning after December 15, 2019. The standard replaces the impairment methodology with a methodology that reflects expected credit losses for accounts receivables, loans and other financial instruments. The standard is not expected to have a material impact on our consolidated financial statements.

Reclassification

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

(2) Inventories

Inventories consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Raw materials	$ 3,805	$ 4,136
Work in process	1,603	949
Finished goods	22,135	24,618
Gross inventories	27,543	29,703
Reserve for obsolescence	(11,442)	(12,402)
	$ 16,101	$ 22,423

(3) Property and Equipment, Net

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

	December 31, 2019	December 31, 2018
Equipment	$ 4,250	$ 4,145
Computer equipment	455	481
Computer software	570	570
Furniture and fixtures	124	164
Leasehold improvements	3,980	3,941
Vehicles	10	10
Surgical instruments	10,897	10,772
Total cost	20,286	20,083
Less: accumulated depreciation	(15,591)	(12,909)
	$ 4,695	$ 7,174

Depreciation expense related to property and equipment, including property under capital lease, for the years ended December 31, 2019 and 2018 was $3.1 million and $3.2 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, 2019 and 2018, the Company has recorded $1.4 million and $1.6 million, respectively, within Equipment, and $1.0 million and $0.9 million, respectively, of accumulated depreciation.

(4) Goodwill and Intangible Assets

Goodwill represents the excess of costs over fair value of assets on businesses acquired associated with the acquisition of X-spine.

During the fourth quarter of 2018, changes in our business led us to conclude that a goodwill impairment charge was appropriate. First, in connection with our annual planning process for 2019, we determined that the revenue growth rates for our fixation business likely would not be consistent with the expectations on which our initial 2018 annual plan was built. Second, in connection with our annual planning process for 2019, we curtailed a new sales channel strategy that we had implemented in 2018 to build a direct sales force since we determined that the sales channel strategy was not generating the benefits that we had originally thought it would. We also determined by the end of 2018 that our assumptions regarding the expansion of our international business likely would not prove to be true in the near future in light of our business priorities, international regulatory issues and anticipated funding requirements.

We engaged a third-party specialist to assist in performing a single-step impairment analysis which compared the carrying value of the assets, including cash, and non-interest-bearing liabilities, to the derived enterprise value of the business. As a result, we recorded a non-cash goodwill impairment charge of $38.3 million during the year ended December 31, 2018. There was no impairment of goodwill recorded in 2019.

Intangible assets consist of various patents with regards to processes for our products and intangible assets associated with the acquisition of X-spine.

In connection with the goodwill impairment analysis performed during 2018, management analyzed the Company's finite-lived intangible assets for impairment in accordance with ASC 360, *Property, Plant and Equipment*. As a result of the analysis, the Company recorded an impairment charge of $9.8 million to its intangible assets during the year ended December 31, 2018. We did not have a triggering event in 2019.

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

	December 31, 2019	December 31, 2018
Patents	$ 847	$ 847
Accumulated amortization	(332)	(274)
Net carrying value	$ 515	$ 573

Amortization expense for the years ended December 31, 2019 and 2018 was $58 thousand and $3.4 million, respectively. The following is a summary of estimated future amortization expense for intangible assets as of December 31, 2019 (in thousands):

2020	$ 56
2021	56
2022	55
2023	53
2024	52
Thereafter	243
Total	$ 515

(5) Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Wages/commissions payable	$ 3,902	$ 3,332
Other accrued liabilities	2,723	1,818
Accrued liabilities	$ 6,625	$ 5,150

(6) Debt

Second Amended and Restated Credit Agreement

On March 29, 2019, the Company and the Investors entered into a Second Amended and Restated Credit Agreement (the "Second Amended and Restated 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 Amended and Restated Credit Agreement:

- 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 Amended and Restated Credit Agreement, and may request additional term loans with the Investors 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 the Investors 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 each Investor) of conditions precedent, including closing certificate, delivery of budget, and other satisfactory documents;

- no interest will accrue on the Loans under the Second Amended and Restated Credit Agreement from and after January 1, 2019 until March 31, 2020;

- beginning April 1, 2020 through the maturity date of the Second Amended and Restated Credit Agreement, interest payable in cash will 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 Amended and Restated Credit Agreement) and (y) 2.3125%;

- the maturity date of the Loans is 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 executive officers of the Company.

Long-term debt, less issuance costs consists of long-term debt due to the lenders under the Second Amended and Restated Credit Agreement as of December 31, 2019 and under the Prior Credit Agreement as of December 31, 2018. The execution of the Second Amended and Restated 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 the credit facility lenders, 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. As of December 31, 2019, our long-term debt, less issuance costs was $76.2 million. Assuming no debt payments are made, our long-term debt, less issuance costs line item will continue to increase until the loan's March 31, 2021 maturity date.

While our long-term debt, less issuance costs balance was $76.2 million as reported under GAAP as of December 31, 2019, the Company owes a principal balance of $55.8 million plus accrued PIK interest of $21.1 million as of December 31, 2019.

Due to the terms within the Second Amended and Restated Credit Agreement, the Company performed an assessment of the changes to the terms of the Prior Credit Agreement in accordance with ASC 470. Given there were cumulative changes to the Prior Credit Agreement within one year of March 29, 2019, the debt terms that existed as of March 29, 2018 were used in the evaluation of the present value of cash flows for the old and new debt instruments which resulted in the extinguishment of the Prior Credit Agreement and recognition of the Second Amended and Restated Credit Agreement. A new effective interest rate of 13.19% for the Second Amended and Restated Credit Agreement was calculated based on the carrying amount of the debt and the present value of the revised future cash flows. This rate is effective through the remaining life of the loan.

On April 1, 2019, the Company issued warrants to purchase an aggregate of 1.2 million shares of Company common stock to the Investors, 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) occurred on April 1, 2019 and was a condition to the effectiveness of the Second Amended and Restated Credit Agreement.

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

	December 31, 2019	December 31, 2018
Amounts due under the Credit Facility	$ 72,657	$ 55,787
PIK interest payable related to the Credit Facility	3,280	27,178
Plus: 2% exit fee on Credit Facility	399	254
Gross long-term debt	76,336	83,219
Less: discount on Credit Facility	—	(5,114)
Less: total debt issuance costs	(92)	(166)
Long-term debt, less issuance costs	$ 76,244	$ 77,939

All gross long-term debt will mature March 31, 2021 and become payable at that time.

Convertible Note Indenture

During the first quarter of 2018 in connection with our Restructuring, all of the outstanding 6.00% convertible senior unsecured notes due 2021 were converted into shares of our common stock and the Indenture governing such notes was discharged.

Amendments to Prior Credit Agreement

Twenty-Second Amendment to the Prior Credit Agreement

Effective January 30, 2018, the Company and Investors entered into the Twenty-Second Amendment to the Amended and Restated Credit Agreement dated July 27, 2015, which amended the Prior Credit Agreement. This amendment further deferred the Company's accrued interest payment date until February 28, 2018.

Twenty-Third Amendment to the Prior Credit Agreement

Effective February 14, 2018, the Company and Investors entered into the Twenty-Third Amendment to the Prior Credit Agreement, which further amended the Prior Credit Agreement and terms of the Credit Facility. As of result of this amendment, the interest payable was carried forward and as modified, the interest rate options within the Credit Facility were as follows: (a) through December 31, 2018, we would have the option at our sole discretion (i) to pay PIK Interest at LIBOR (as defined in the Credit Facility) plus 12% or (ii) pay cash interest at LIBOR plus 10%; (b) beginning January 1, 2019 through June 30, 2019, we would have the option at our sole discretion to either (i) pay PIK Interest at LIBOR plus 15% or (ii) pay cash interest at LIBOR plus 10%; and (c) beginning July 1, 2019 through the maturity date of the Credit Facility, we would pay cash interest at LIBOR plus 10%. The amendment also reduced the prepayment or repayment fee under the Credit Facility to 1%.

This amendment also modified the financial covenants in the Prior Credit Agreement, including removing the minimum revenue covenant, providing a minimum liquidity covenant, a consolidated leverage ratio covenant, and a minimum consolidated EBITDA covenant, all as defined in the Prior Credit Agreement.

Twenty-Fourth Amendment to the Prior Credit Agreement

On September 17, 2018, the Company and Investors entered into the Twenty-Fourth Amendment to the Prior Credit Agreement (the "24th Amendment"), which further amended the Prior Credit Agreement and terms of the Credit Facility, effective as of April 1, 2018. Under the terms of the 24th Amendment, no interest would be charged on the loans under the Credit Facility (the "Loans") from April 1, 2018 until June 30, 2018.

Due to the interest rate relief provided by the 24th Amendment, the Company performed an assessment of the changes to the terms of the Credit Facility in accordance ASC 470*, Debt.* The Credit Facility was modified based on an evaluation of the present value of cash flows for the old and new debt instruments. Given the modification, a new effective interest rate of 13.45% for the modified loan was calculated based on the carrying amount of the debt and the present value of the revised future cash flows. The modified interest rate is effective through the remaining life of the loan.

Twenty-Fifth Amendment to the Prior Credit Agreement

Also, on September 17, 2018, the Company and the Investors entered into the Twenty-Fifth Amendment to the Prior Credit Agreement (the "25th Amendment"), which further amended the Prior Credit Agreement and terms of the Credit Facility, effective as of August 1, 2018. Under the terms of the 25th Amendment:

- no interest would be charged on the Loans under the Credit Facility from July 1, 2018 until December 31, 2018;
- the Optional PIK Interest (as such term is defined in the Prior Credit Agreement) was decreased from 15% plus the LIBO Rate (as such term is defined in the Prior Credit Agreement) to 10% plus the LIBO Rate, with a 2.3125% floor;
- a LIBO Rate floor of 2.3125% was added; and
- the fee due upon payment, prepayment or repayment of the principal amount of the Loans under the Credit Facility, whether on the maturity date or otherwise, was increased to 2% from 1% of the aggregate principal amount of such payment, prepayment or repayment.

The Company issued warrants to purchase an aggregate of 1.2 million shares of Company common stock to the Investors, with an exercise price of $0.01 per share and an expiration date of August 1, 2028 (collectively, the "2018 Warrants"). The issuance of the 2018 Warrants occurred on September 17, 2018 and was a condition to the effectiveness of the 25th Amendment. (See Note 9, "Warrants" below).

(7) Equity

Charter Amendment

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 50,000,000 to 75,000,000. 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.

Convertible Note Indenture

During the first quarter of 2018, in connection with the Restructuring (defined above), all of the outstanding 6.00% convertible senior unsecured notes due 2021 were converted or exchanged into shares of our common stock and the Indenture governing such notes was discharged. On January 17, 2018, the Investors converted $1.6 million aggregate principal amount of 6.00% convertible senior unsecured promissory notes due in 2021, which were issued effective January 17, 2017, plus accrued and unpaid interest, into 189,645 shares of our common stock. On February 14, 2018, an additional $70.3 million aggregate principal amount of notes, plus accrued and unpaid interest, were exchanged for 10,401,309 newly-issued shares of our common stock.

Private Placement SPA

On February 14, 2018, we sold to the Investors pursuant to the Private Placement SPA 945,819 shares of our common stock, at a price of $7.20 per share, for aggregate proceeds of $6.8 million.

Registration Rights Agreement

On May 15, 2018, we filed a shelf resale registration statement with the Securities and Exchange Commission ("SEC") pursuant to our obligations under the Registration Rights Agreement. This registration statement was declared effective by the SEC on June 4, 2018.

Rights Offering

On May 18, 2018, we distributed to holders of our common stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 1,137,515 shares of our common stock (the "Rights Offering"). In the Rights Offering, holders received 0.0869816 subscription rights for each share of common stock held on the record date, April 27, 2018. The units were priced at $7.20 per unit. The Rights Offering expired on June 18, 2018, at which time the rights were no longer exercisable. We issued 129 shares of our common stock in the Rights Offering, resulting in $0.9 thousand in gross proceeds to us.

(8) 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 (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 2,807,747 shares, of which 1,650,005 shares remained available for grant as of December 31, 2019. 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.

The Board has granted various awards under the 2018 Plan to certain directors, officers and employees. As of December 31, 2019, stock options to purchase an aggregate of 585,595 shares of our common stock, a restricted stock award for 13,021 shares of common stock, and restricted stock units covering 499,914 shares were outstanding under the 2018 Plan. During the year ended December 31, 2019, options to purchase 420,000 shares of common stock granted under the 2018 Plan were forfeited and cancelled as a result of the termination of employment of optionees. During the year ended December 31, 2019, 459,914 restricted stock units were granted, which vest over a weighted average period of 4.3 years.

Various awards also remain outstanding under the Prior Plan. As of December 31, 2019, stock options to purchase an aggregate of 17,371 shares of our common stock and restricted stock awards for 23,438 shares of our common stock were outstanding under the Prior Plan. During the year ended December 31, 2019, options to purchase 3,781 shares of our common stock granted under the Prior Plan were forfeited and cancelled as a result of the termination of employment of optionees and a restricted stock award for 10,417 shares of our common stock was forfeited and cancelled as a result of the termination of service of a director.

From time to time, we have granted options to purchase shares of our common stock outside of any stockholder-approved plan to new hires (collectively the "Non-Plan Grants"). As of December 31, 2019, no Non-Plan Grants were outstanding. During the year ended December 31, 2019, Non-Plan Grants to purchase 25,000 shares of common stock were forfeited and cancelled as a result of the termination of employment of the optionee.

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 options to purchase an aggregate of 554,825 shares of common stock were issued during the year ended December 31, 2019; options to purchase an aggregate of 650,770 shares of common stock were issued during the same period in 2018.

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

	2019			2018		
	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date
Outstanding at January 1	496,958	$ 9.90	$ 6.62	67,465	$ 71.03	$ 36.85
Granted	554,825	2.55	2.01	650,770	4.79	4.15
Cancelled or expired	(448,817)	5.96	4.45	(221,277)	13.45	7.77
Outstanding at December 31	602,966	$ 6.07	$ 3.99	496,958	$ 9.90	$ 6.62
Exercisable at December 31	25,063	$ 83.78	$ 46.66	66,188	$ 46.88	$ 25.92

The estimated fair value of stock options granted is done 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,	
	2019	2018
Risk free interest rate	1.82%	2.97%
Dividend yield	0%	0%
Expected term	7.1 years	10.0 years
Expected volatility	92%	89%

Total stock-based compensation expense recognized for employees and directors was $0.5 million and $0.7 million for the years ended December 31, 2019 and 2018, respectively, and was recognized as general and administrative expense. The aggregate intrinsic value of options outstanding as of December 31, 2019 was $2 thousand. As of December 31, 2019, total compensation expense related to unvested employee stock options not yet recognized was $1.0 million, which is expected to be allocated to expenses over a weighted-average period of 4.3 years.

(9) Warrants

2018 Warrants

The Company issued warrants to purchase an aggregate of 1.2 million shares of Company common stock to the Investors, with an exercise price of $0.01 per share and an expiration date of August 1, 2028. The issuance of the 2018 Warrants occurred on September 17, 2018 and was a condition to the effectiveness of the 25th Amendment. The fair value of these warrants upon issue was determined to be $5.1 million (see Note 6). In accordance with ASC 815-40, the 2018 Warrants meet all requirements to be classified as equity awards. The number of shares of Company common stock issuable upon exercise of the 2018 Warrants are subject to standard and customary anti-dilution provisions for stock splits, stock dividends or similar transactions.

2019 Warrants

On April 1, 2019, the Company issued warrants to purchase an aggregate of 1.2 million shares of Company common stock to the Investors with an exercise price of $0.01 per share and an expiration date of April 1, 2029. As a result of the issuance of the warrants to purchase 1.2 million shares of common stock on April 1, 2019, the total outstanding common stock warrants as of April 1, 2019 was 2,910,609. The issuance of the 2019 Warrants was a condition to the effectiveness of the Second Amended and Restated Credit Agreement. The fair value of the 2019 Warrants upon issuance was determined to be $9 thousand. The significant decrease in value of the 2019 Warrants compared to the 2018 Warrants was attributable to the updated forecasts and assumptions used by the Company during the annual planning process for 2019 that resulted in our decision to conclude that a goodwill and intangible asset impairment charge was appropriate during the fourth quarter of 2018. The 2019 Warrants meet all the requirements to be classified as equity awards in accordance with ASC No. 815-40. The number of shares of Company common stock issuable upon exercise of the 2019 Warrants is subject to standard and customary anti-dilution provisions for stock splits, stock dividends, or similar transactions.

The following table summarizes our warrant activities for the years ended December 31, 2019 and 2018:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding as of January 1, 2018	519,917	$ 25.68
Issued	1,200,000	.01
Expired	(9,308)	88.84
Outstanding as of December 31, 2018	1,710,609	$ 7.33
Issued	1,200,000	.01
Expired	(1,735)	259.60
Outstanding at December 31, 2019	2,908,874	$ 4.16

The following table summarizes our activities related to warrants accounted for as a derivative liability for the years ended December 31, 2019 and 2018:

	2019	2018
Balance at January 1	87,506	93,759
Derivative warrants expired	—	(6,250)
Balance at December 31	87,509	87,509

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The valuation model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. Under the terms of some of our warrant agreements, at any time while the warrant is outstanding, the exercise price per share can be reduced to the price per share of future subsequent equity sales of our common stock or a common stock equivalent that is lower than the exercise price per share as stated in the warrant agreement.

The estimated fair value was derived using the lattice model with the following weighted-average assumptions:

	Year Ended December 31,	
	2019	2018
Value of underlying common stock (per share)	$ 1.96	$ 1.61
Risk free interest rate	1.67%	2.48%
Expected term	2.7 years	3.6 years
Volatility	82%	92%
Dividend yield	0%	0%

(10) 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, 2019, the weighted-average remaining lease term was 5 years. Lease expense related to operating leases was $588 thousand during the year ended December 31, 2019. 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, 2019, 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, 2019 under these long-term operating leases are as follows (in thousands):

2020	$ 501
2021	507
2022	521
2023	489
2024	224
Thereafter	180
Total future minimum lease payments	2,422
Less amount representing interest	(302)
Present value of obligations under operating leases	2,120
Less current portion	(394)
Long-term operating lease obligations	$ 1,726

Finance Leases

During the year ended December 31, 2019, we incurred lease interest cost of $51 thousand and amortization expense of $175 thousand. Future minimum payments under finance leases are as follows as of December 31, 2019 (in thousands):

2020	$ 192
Less amount representing interest	(16)
Present value of obligations under finance leases	$ 176

Litigation

On December 13, 2018, a complaint was filed by RSB Spine, LLC, against Xtant Medical Holdings, Inc., which claims 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.

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.

(11) 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,	
	2019	2018
United States	$ (8,123)	$ (70,059)
Total	$ (8,123)	$ (70,059)

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

	Year Ended December 31,	
	2018	2017
Current:		
Federal	$ —	$ —
State	98	—
Total current	98	—
Deferred:		
Federal	—	—
State	—	—
Total deferred	—	—
Total Provision for Income Taxes	$ 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,	
	2019	2018
Statutory Federal tax rate	$ (1,706)	$ (14,712)
Valuation allowance	73	7,270
State income taxes, net of Federal benefit	34	(1,740)
Goodwill impairment	—	8,049
Change in state income tax rate	(136)	396
Gain on extinguishment of debt	1,534	—
Change in warrant derivative liability	—	(25)
Stock compensation adjustment and other reconciling items	282	349
Nondeductible interest	—	247
Restructuring expenses	—	117
Nondeductible meals and entertainment expense	17	49
Total Provision for Income Taxes	$ 98	$ —

Deferred tax components are as follows (in thousands):

	At December 31,	
	2019	2018
Deferred tax assets:		
Accrued liability for vacation	$ 111	$ 77
Accrued commissions and bonuses / compensation	298	332
Accrued contingencies	132	121
Amortization	36	40
Depreciation	157	—
Bad debt reserve	133	552
Charitable contributions carryforward	8	7
Lease liability	564	—
Interest expense	3,407	2,173
Inventory reserve	3,058	3,200
Net operating loss carryovers	22,009	22,996
Stock option compensation	476	475
Other	102	24
Total deferred tax assets	30,491	29,997
Deferred tax liabilities:		
Right of use asset	(558)	—
Depreciation	—	(137)
Total deferred tax liabilities	(558)	(137)
Valuation allowance	(29,933)	(29,860)
Net deferred tax assets	$ —	$ —

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management does not believe it is more likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a valuation allowance equal to the net realizable deferred tax assets. The valuation allowance increased by $0.1 million in 2019 and increased by $7.3 million in 2018.

At December 31, 2018 and 2017, the Company had total domestic Federal and state net operating loss carryovers of approximately $149.8 million and $158.7 million, respectively. Federal and state net operating loss carryovers both expire at various dates between 2024 and 2038. Federal net operating losses generated after 2017 have an indefinite carryforward and are only available to offset 80% taxable income.

Under the Tax Reform Act of 1986, as amended, the amounts of and benefits from net operating loss carryovers and research and development credits may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three-year period. The Company has not performed an analysis to determine if an ownership change has occurred for 2019 or 2018.

The 2016 through 2018 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, 2019 and 2018.

(12) Employee Benefit Plans

We have a 401(k) plan for our employees. The 401(k) plan is a defined contribution plan covering substantially all of our employees. Employees are eligible to participate in the plan on the first day of any month after starting employment. Employees are allowed to contribute a percentage of their wages to the 401(k) plan, subject to statutorily prescribed limits and are subject to a discretionary employer match of 100% of their wage deferrals not in excess of 4% of their wages. The Company contributed $0.2 and $0.3 million as part of the employer match program for the year ended December 31, 2019 and 2018, respectively.

(13) Supplemental Disclosure of Cash Flow Information

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

	Year Ended December 31,	
	2019	**2018**
Cash paid during the period for:		
Interest	$ 51	$ 186
Non-cash activities:		
Lease liability from right of use asset	$ 2,296	$ —
Issuance of capital leases	$ —	$ 84
Interest converted into common stock	$ —	$ 556
Conversion of convertible debt to equity	$ —	$ 71,856
Convertible PIK interest	$ —	$ 4,764
Conversion of interest related to the Credit Facility to long-term debt	$ —	$ 7,977
Write-off of convertible debt issuance cost	$ —	$ 1,012
Debt discount on long-term credit facility	$ —	$ 5,114
Extinguishment of Prior Credit Agreement (including debt issuance costs)	$ 79,624	$ —
Write-off of Prior Credit Agreement debt issuance costs and existing ROS fees	$ 307	$ —
Recognition of Second Amended and Restated Credit Agreement	$ 72,657	$ —
Recognition of 2019 Warrants	$ 9	$ —
Net Transfer of inventory to property and equipment	$ —	$ 149
Restricted stock unit vesting	$ —	$ 120

(14) Related Party Transactions

The Investors, owning approximately 70% of the Company's outstanding common stock, are the sole holders 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 was $2,100 per month for the months of April through July 2019 and is currently $1,260 per month. 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.

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

(15) 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 96% and 95% of revenue were in the United States for the years ended December 31, 2019 and 2018, respectively. Total revenue by major geographic area is as follows (in thousands):

	Year Ended December 31,	
	2019	**2018**
United States	$ 62,377	$ 68,880
Rest of World	2,305	3,323
Total	$ 64,682	$ 72,203

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, 2019. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2019, 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, 2019.

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, 2019 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 March 2, 2020. No family relationships exist among our directors or executive officers.

Name	Age	Position	Director/ Officer Since
Jeffrey Peters	51	Chairman of the Board and Director	2018
John Bakewell[(1)]	58	Director	2018
Michael Eggenberg[(2)]	50	Director	2018
Robert McNamara[(1)(2)]	63	Director	2018
Matthew Rizzo[(2)]	47	Director	2018
Sean E. Browne	54	President and Chief Executive Officer	2019
Ronald G. Berlin	66	Vice President, Chief Operations Officer and General Manager	2019
Kevin D. Brandt	54	Chief Commercial Officer	2018
Greg Jensen	59	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 the Investors 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.

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. 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 chief financial officer of several publicly traded medical technology companies and his background and sophistication in finance and accounting 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 the Investors 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 Bachelor of Science in Accounting from the University of San Francisco and a Masters of Business Administration in Finance from The Wharton School at the University of Pennsylvania. Mr. McNamara brings valuable finance and accounting experience in the medical device industry to the Board.

Matthew Rizzo has served as a member of our Board since February 2018. Mr. Rizzo was initially elected to the Board in connection with our restructuring in February 2018. Mr. Rizzo is a designee of the Investors 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.

Sean E. Browne was appointed our President and Chief Executive Officer effective October 7, 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.

Ronald G. Berlin has served as our Vice President and Chief Operations Officer since January 2019 and our General Manager since March 2019. Prior to this, Mr. Berlin served as Vice President, Global Operations of Coorstek Medical, a medical device company, from July 2015 to May 2017. Prior to that position, Mr. Berlin served as Vice President, Global Strategic Sourcing and Procurement Operations of Integra LifeSciences Holdings Corporation, a medical device company, from September 2013 to October 2014. Mr. Berlin holds a Bachelor of Science in Business and Economics from SUNY Oswego and an MBA from Canisius College.

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

During the first quarter of 2018, we completed a significant debt restructuring pursuant to which $76.6 million in principal, together with accrued and unpaid interest, of our then outstanding indebtedness was converted into shares of our common stock and we issued an additional 946 thousand shares of common stock to certain of our lenders in a private placement. As a result of this debt restructuring, ROS Acquisition Offshore LP ("ROS") and OrbiMed Royalty Opportunities II, LP ("Royalty Opportunities" and together with ROS, our "lenders"), which are funds affiliated with OrbiMed Advisors LLC ("OrbiMed"), collectively own approximately 70% of our outstanding common stock. Because of this significant stock ownership, 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

In connection with our 2018 debt restructuring, we entered into an Investor Rights Agreement with Royalty Opportunities, ROS, Park West Investors Master Fund, Limited ("PWIMF") and Park West Partners International, Limited ("PWPI"). Under the Investor Rights Agreement, ROS and Royalty Opportunities 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 ROS and Royalty Opportunities 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 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 or Directors beyond seven directors without the approval of a majority of the directors nominated by ROS and Royalty Opportunities.

The Investor Rights Agreement grants Royalty Opportunities, ROS, PWPI and PWIMF 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. The right of PWPI and PWIMF to purchase from us a pro rata amount of any new securities will terminate at such time as their aggregate ownership percentage of our then outstanding common stock is less than 8.5%.

Director Independence

The Board has affirmatively determined that the following two Board members are currently "independent directors," as defined under the independence standards of the NYSE American: John Bakewell and Robert McNamara.

Board Leadership Structure

Under the terms of the Investor Rights Agreement, the Investors 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 March 2, 2020.

Director	Audit Committee	Compensation Committee
John Bakewell	Chair	
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 six times during fiscal 2019.

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 five times during fiscal 2019.

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 2019, 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, 2019, and the two most highly compensated executives for the year ended December 31, 2019.

Name and Principal Position	Year	Salary	Bonus[1]	Stock Awards[2]	Option Awards[3]	Non-Equity Incentive Plan Compensation[4]	All Other Compen-sation[5]	Total
Sean E. Browne[6] *President and Chief Executive Officer*	2019	$ 115,745	$ —	$ 888,419	$ 688,130	$ 150,000	$ 9,970	$ 1,852,264
Michael Mainelli[7] *Former Interim Chief Executive Officer*	2019 2018	184,050 92,885	— —	— 153,331	— 670,560	— 90,865	10,859 89,889	194,909 1,097,530
Greg Jensen[8] *Vice President, Finance and Chief Financial Officer*	2019	336,032	—	93,558	82,056	114,375	63,173	689,194
Kevin D. Brandt[9] *Chief Commercial Officer*	2019 2018	398,113 176,923	90,000 —	97,066 248,000	85,546 165,186	124,125 76,154	17,416 —	812,266 666,263
Ronald G. Berlin[10] *Vice President, Chief Operations Officer and General Manager*	2019	362,709	50,000	—	121,517	109,875	11,873	655,974

(1) We generally do not pay any discretionary bonuses or bonuses that are subjectively determined and did not pay any such bonuses to any named executive officers in 2019, other than signing bonuses paid to Messrs. Brandt and Berlin as part of their offer packages. Annual cash incentive bonus payouts based on performance against pre-established performance goals are reported in the "Non-equity incentive plan compensation" column.

(2) Amounts reported represent the aggregate grant date fair value for restricted stock unit 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 date immediately prior to the grant date.

(3) Amounts reported represent the aggregate grant date fair value for option awards granted to each named executive officer computed in accordance with FASB ASC Topic 718. The grant date fair value is determined based on our Black-Scholes option pricing model. The table below sets forth the specific assumptions used in the valuation of each such option award:

Grant Date	Grant Date Fair Value Per Share	Risk Free Interest Rate	Expected Life	Expected Volatility	Expected Dividend Yield
10/15/2019	$ 2.09	1.65%	6.50 years	92.55%	—
08/15/2019	2.11	1.45%	6.25 years	92.76%	—
01/15/2019	1.95	2.70%	10.00 years	90.90%	—
08/15/2018	5.37	2.84%	10.00 years	89.92%	—

(4) Amounts reported represent payouts under our annual bonus plan and for each year reflect the amounts earned for that year but paid during the following year.

(5) The table below provides information concerning amounts reported in the "All Other Compensation" column of the Summary Compensation Table for 2019 with respect to each named executive officer. Additional detail on these amounts is provided in the table below.

Name	401(k) Match	Reimbursement of Health Benefits	Commuting Expenses	Total
Sean E. Browne	$ 1,851	$ —	$ 8,119	$ 9,970
Michael Mainelli	—	4,500	6,359	10,859
Greg Jensen	10,581	—	52,592	63,173
Kevin D. Brandt	17,416	—	—	17,416
Ronald G. Berlin	11,873	—	—	11,873

(6) Mr. Browne was appointed our President and Chief Executive Officer effective October 7, 2019.

(7) Mr. Mainelli resigned as Interim Chief Executive Officer and a director effective March 18, 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. Upon the resignation of Mr. Mainelli effective March 18, 2019 until the appointment of Mr. Browne as President and Chief Executive Officer effective October 7, 2019, Mr. Jensen served in the capacity as our principal executive officer.

(9) Mr. Brandt was appointed our Chief Commercial Officer effective July 9, 2018.

(10) Mr. Berlin was appointed our Vice President and Chief Operations Officer effective January 1, 2019 and our General Manager in March 2019.

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, which was prorated for 2019. 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 a restricted stock 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. The stock option has a 10-year term and a per share exercise price equal to the "fair market value" (as defined in the 2018 Plan) of our common stock on the grant date. The option and restricted stock unit award will vest in equal annual installments over five years or earlier in the event the award is not continued, assumed or substituted with an equivalent award in connection with a "change in control" of the Company or Mr. Browne's employment is terminated by the Company without "cause" or by Mr. Browne for "good reason" within one year of a "change in control" of the Company (as such terms are defined in the stock option or restricted stock unit award agreement or Plan). We also agreed to grant Mr. Browne additional stock options and restricted stock unit awards, in the same proportionate split, in the event OrbiMed Advisors LLC (including its affiliates) converts any of our outstanding indebtedness into equity of the Company within five years. The employment agreement contains standard confidentiality, non-competition, non-solicitation and assignment of intellectual property provisions. The agreement also contains standard severance and change in control provisions, which are described under *"—Potential Payments upon Termination or Change in Control."*

We entered into an interim executive employment agreement with Michael Mainelli, our former Interim Chief Executive Officer, on October 12, 2018. This agreement provided for an annual base salary of $525,000 with a target annual bonus opportunity of 75% of his annual base salary, subject to proration based on his start date, and reimbursement of monthly individual family health insurance policy premiums incurred, which reimbursement was capped at $1,500 per month. We also agreed to pay or promptly reimburse Mr. Mainelli for reasonable out-of-pocket business expenses incurred by him in connection with his employment, including all reasonable travel, lodging and meal expenses incurred by him on account of his travel to the Company's offices in Belgrade, Montana, and other travel conducted by him for the purpose of facilitating the performance of his duties and responsibilities. In addition, we agreed to grant Mr. Mainelli an option to purchase 240,000 shares of our common stock, which option was scheduled to vest monthly over 24 months, commencing on November 15, 2018, assuming continued employment as Interim Chief Executive Officer through the vesting date. The agreement also contained standard confidentiality, non-competition, non-solicitation, and assignment of intellectual property provisions.

In connection with Mr. Jensen's appointment as Vice President, Finance and Interim Chief Financial Officer in February 2019, we entered into an employment agreement with him which provided for an annual base salary of $325,000 and a target annual bonus opportunity equal to 50% of his annual base salary. The employment agreement also contained standard confidentiality, non-competition, non-solicitation and assignment of intellectual property provisions. In April 2019, the Board increased Mr. Jensen's annual base salary to $400,000. Effective with the release of our second quarter 2019 financial results, the Board approved the appointment of Mr. Jensen as non-interim Chief Financial Officer, and on August 8, 2019, the Company and Mr. Jensen executed an amended and restated employment agreement pursuant to which Mr. Jensen serves as Vice President, Finance and Chief Financial Officer. This agreement provides for an annual base salary of $400,000, a target annual bonus opportunity equal to 50% of his annual base salary and certain severance and change in control benefits, which are described under *"—Potential Payments upon Termination or Change in Control."*

Effective January 1, 2019, we entered into an employment agreement with Ronald G. Berlin, our Vice President, Chief Operations Officer and General Manager, which provides for an initial annual base salary of $265,000 (which was subsequently increased to $400,000 in April 2019), a target annual bonus opportunity equal to 40% (which was subsequently increased to 50% in April 2019) of his annual base salary, and a $50,000 signing bonus, which was required to be paid back if Mr. Berlin terminated his employment with Xtant prior to the one-year anniversary of his hire date. In addition, the agreement provided for the grant of a stock option to purchase 100,000 shares of our common stock, which option vests on an annual basis over four years, assuming continued employment. The agreement also provides that Mr. Berlin is eligible to receive an additional equity award in 2021, subject to the approval of the Board. The agreement contains standard confidentiality, non-competition, non-solicitation, and assignment of intellectual property provisions. The agreement also contains standard severance and change in control provisions, which are described under *"—Potential Payments upon Termination or Change in Control."*

Effective July 9, 2018, we entered into an employment agreement with Kevin D. Brandt, our Chief Commercial Officer, which provided for an initial annual base salary of $400,000 (which was subsequently increased to $415,000 in April 2019) with a target annual bonus of 50% of his annual base salary, subject to proration based on his start date, 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 a restricted stock unit 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. The agreement contains standard confidentiality, non-competition, non-solicitation, and assignment of intellectual property provisions. The agreement also contains standard severance and change in control provisions, which are described under *"—Potential Payments upon Termination or Change in Control."*

Indemnification Agreements

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

401(k) Retirement Plan

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

Outstanding Equity Awards at Fiscal Year-End

The table below provides information regarding unexercised option awards and unvested stock awards held by each of our named executive officers that remained outstanding at our fiscal year-end, December 31, 2019. All of the outstanding equity awards described below were granted under the 2018 Plan.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date[1]	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares or Units of Stock that Have Not Vested[2]
Sean E. Browne	—	329,044 [3]	$ 2.70	10/15/2029	329,044 [4]	$526,470
Michael Mainelli	—	—	—	—	—	—
Greg Jensen	—	39,063 [5]	2.76	08/15/2029	33,898 [6]	54,237
Kevin D. Brandt	7,692	23,078 [7]	6.20	08/15/2028	40,000 [8]	64,000
	—	40,527 [5]	2.76	08/15/2029	35,169 [6]	56,270
Ronald G. Berlin	—	100,000 [9]	2.24	01/15/2029	—	—

(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, 2019 ($1.60), 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. If Mr. Browne's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

(4) This restricted stock unit award vests in nearly equal installments annually over a five-year period beginning on October 15, 2020. In addition, this restricted stock unit 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. If Mr. Browne's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

(5) 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. If Mr. Brandt's or Mr. Jensen's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

(6) This restricted stock unit award vests in nearly equal installments annually over a four-year period beginning on August 15, 2020. In addition, this restricted stock unit 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. If Mr. Brandt's or Mr. Jensen's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

(7) 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. If Mr. Brandt's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

(8) This restricted stock unit 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 restricted stock unit 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. If Mr. Brandt's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

(9) This stock option vests with respect to 25,000 of the underlying shares on each of January 15, 2020, January 15, 2021, January 15, 2022 and January 15, 2023. 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. If Mr. Berlin's employment is terminated by reason of death, a pro rata percentage of the award will vest immediately.

Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan

In 2018, the Board approved and the Company's stockholders approved and adopted the Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan and subsequently approved an amendment to the plan in 2019 (as amended, 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, restricted stock units, 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 2,807,747 shares. To date, the Company has granted stock options, restricted stock and restricted stock units under the 2018 Plan. As of December 31, 2019, 1,650,005 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, other than Mr. Mainelli, 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 restricted stock unit awards will vest and become immediately issuable as to a pro rata percentage of the unvested portion of the restricted stock unit awards scheduled to vest on the next applicable vesting date and the unvested portion of the restricted stock unit 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 restricted stock unit 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 restricted stock unit 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 restricted stock unit 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 restricted stock unit 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 restricted stock unit awards every two years.

The table below sets forth the annual cash retainers for 2019:

Description	Annual Cash Retainer January 1 through April 30	Annual Cash Retainer May 1 through December 31
Non-Employee Director	$ 50,000	$ 50,000
Chairman of the Board Premium	12,500	32,500
Audit Committee Chair Premium	12,500	32,500
Compensation Committee Chair Premium	12,500	32,500

The equity compensation component is intended to match the dollar value of the annual cash retainers. Because the Compensation Committee Chair position was a new position during 2019 and because the annual cash retainers for our Chairman of the Board, Audit Committee Chair and Compensation Committee Chair increased during 2019, each of these directors received an additional restricted stock unit award during 2019. Mr. McNamara, as Compensation Committee Chair, received a restricted stock unit award valued at $23,109 for 9,027 shares of our common stock, and Mr. Peters, as Chairman of the Board, and Mr. Bakewell, as Audit Committee Chair, each received a restricted stock unit award valued at $14,221 for 5,555 shares of our common stock. In addition, initially it was believed that the two Investor Designees who are employees of OrbiMed Advisors, LLC would not receive equity grants in consideration for their director services. This changed and on October 30, 2019, each of Messrs. Eggenberg and Rizzo received a restricted stock unit award covering 20,833 shares of our common stock, which is the same number of shares underlying the initial restricted stock or restricted stock unit awards received by our other directors in 2018. All of these restricted stock unit awards became fully vested on February 15, 2020.

Director Compensation Table for Fiscal 2019

The table below describes the compensation earned by our directors during fiscal 2019, 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	$ 75,925	$ 14,221	—	—	$ 90,146
Michael Eggenberg	50,000	43,333	—	—	93,333
Robert McNamara	75,925	23,109	—	—	99,034
Jeffrey Peters	75,925	14,221	—	—	90,146
Matthew Rizzo	50,000	43,333	—	—	93,333

(1) The amount reported in the "Stock Awards" column represents the aggregate grant date fair value for the restricted stock unit awards granted to our non-employee directors in 2019. The grant date fair value for the restricted stock unit awards was determined based on the closing sale price of our common stock on the date immediately prior to the grant date.

(2) As of December 31, 2019, each non-employee director held the following number of unvested stock awards (all of which are in the form of either restricted stock awards or restricted stock unit awards): Mr. Bakewell (18,576); Mr. Eggenberg (20,833); Mr. McNamara (19,444); Mr. Peters (18,576); and Mr. Rizzo (20,833).

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, 54th Floor New York, NY 10022	11,655,987	74.6%
Common Stock	Park West Asset Management LLC[(3)] 900 Larkspur Landing Circle, Suite 165 Larkspur, CA 94939	1,258,733	9.5%
Common Stock	Telemetry Investments, L.L.C.[(4)] 545 Fifth Avenue, Suite 1108 New York, NY 10017	752,915	5.7%

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

(1) Percent of class is based on 13,223,565 shares of our common stock outstanding as of March 1, 2020.

(2) Based solely on information contained in a Schedule 13D/A filed with the SEC on April 4, 2019. Includes 5,917,609 shares of common stock and 1,539,293 shares of common stock issuable upon exercise of warrants held of record by ROS Acquisition Offshore LP. OrbiMed Advisors LLC ("OrbiMed"), 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.àr.l., 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 3,331,069 shares of common stock and 868,016 shares of common stock issuable upon exercise of warrants 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.

(3) Based solely on information contained in a Schedule 13G/A filed with the SEC on February 14, 2019. Includes 1,104,905 shares of common stock held by Park West Investors Master Fund, Limited ("PWIMF") and 153,828 shares of common stock held by Park West Partners International, Limited ("PWPI"). PWIMF and PWPI are directly or indirectly controlled by Park West Asset Management LLC. Peter S. Park, manager of Park West Asset Management LLC, has sole voting and investment power over the shares owned by PWIMF and PWPI.

(4) Based solely on information contained in a Schedule 13G/A filed with the SEC on February 13, 2020. Includes 752,915 shares of common stock held by Telemetry Securities, L.L.C. ("Telemetry Securities"). Telemetry Investments, L.L.C. ("Telemetry") is a registered investment advisor and the investment manager to Telemetry Securities. Andrew J. Schorr and Daniel P. Schorr are each managers of Telemetry. As such, Telemetry, Andrew J. Schorr and Daniel P. Schorr share voting and investment power over the securities held by Telemetry Securities.

Security Ownership of Management

The table below sets forth information relating to the beneficial ownership of our common stock as of March 1, 2020, 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 March 1, 2020, through the exercise of any stock option, warrants, or other rights or the vesting of any restricted stock 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 13,223,565 shares of our common stock outstanding as of March 1, 2020. Shares of our common stock that a person has the right to acquire within 60 days of March 1, 2020, 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	Percent of Class
Common Stock	John Bakewell	31,597	*
Common Stock	Michael Eggenberg	—	—
Common Stock	Robert McNamara	29,860	*
Common Stock	Jeffrey Peters	31,597	*
Common Stock	Matthew Rizzo	—	—
Common Stock	Sean E. Browne	—	—
Common Stock	Greg Jensen	—	—
Common Stock	Ron Berlin	25,000 (1)	*
Common Stock	Kevin D. Brandt	7,692 (1)	*
Common Stock	All executive officers and directors as a group (9 persons)	125,746	*

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

(1) Consists of options to purchase shares of our common stock.

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, 2019.

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	1,102,880	$ 6.07	1,650,005
Equity compensation plans not approved by security holders	—	—	—
Total	1,102,880	$ 6.07	1,650,005

(1) Amount includes shares of our common stock issuable upon the exercise of stock options granted under the 2018 Plan and the Prior Plan and shares of our common stock issuable upon the vesting of restricted stock unit awards granted under the 2018 Plan.

(2) Not included in the weighted-average exercise price calculation are 499,914 restricted stock unit awards.

(3) Amount includes 1,650,005 shares of our common stock remaining available for future issuance under the 2018 Plan. No shares remain available for grant under the Prior Plan since such plan has been terminated with respect to future grants.

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

Policies and Procedures for Review and Approval of Related Party Transactions

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

Related Party Transactions

Investor Rights Agreement

Effective February 14, 2018, in connection with the debt restructuring, we entered into an Investor Rights Agreement with Royalty Opportunities, ROS, Park West Investors Master Fund, Limited and Park West Partners International, Limited. Under the Investor Rights Agreement, ROS and Royalty Opportunities 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 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 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 or Directors beyond seven directors without the approval of a majority of the directors nominated by ROS and Royalty Opportunities.

The Investor Rights Agreement grants Royalty Opportunities, ROS, PWPI and PWIMF 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 ROS and Royalty Opportunities' ownership percentage of our then outstanding common stock is less than 10%, or (c) upon written notice of ROS and Royalty Opportunities. The right of PWPI and PWIMF to purchase from us a pro rata amount of any new securities will terminate at such time as their aggregate ownership percentage of our then outstanding common stock is less than 8.5%.

Second Amended and Restated Credit Agreement and Warrant Issuance

On March 29, 2019, Xtant Medical Holdings, Inc., 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, 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 Amended and Restated Credit Agreement, the Prior Credit Agreement was amended to provide that:

- X-spine Systems, Inc. may request additional term loans from the Investors 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 Amended and Restated Credit Agreement, and may request new additional term loans in an aggregate amount of up to $10,000,000, the making of each such Loan to be subject to the discretion of the Investors and the Company's production of a thirteen-week cash flow forecast that is approved by the Investors 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 will accrue on the loans under the Second Amended and Restated Credit Agreement from and after January 1, 2019 until March 31, 2020;

- Beginning April 1, 2020 through the maturity date of the Second Amended and Restated Credit Agreement, interest payable in cash will accrue on the loans under the Second Amended and Restated 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 Amended and Restated Credit Agreement) and (y) 2.3125%;

- The maturity date of the loans is 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 to specific executives.

On April 1, 2019, Xtant issued warrants to purchase an aggregate of 1.2 million shares of Company 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 Amended and Restated Credit Agreement. The number of shares of Xtant common stock issuable upon exercise of these warrants is subject to standard and customary anti-dilution provisions for stock splits, stock dividends, or similar transactions.

The Investors, which collectively own approximately 70% of our outstanding common stock, and beneficially own, with their warrants, approximately 75% of our outstanding common stock, are the sole holders of our outstanding long-term debt.

Sublease Agreement

On April 5, 2019, we entered into a Sublease Agreement with Cardialen, Inc., under which we lease a portion of Cardialen's office space in Plymouth, Minnesota. The Sublease Agreement was subsequently amended effective as of August 1, 2019 to reduce the amount of office space and monthly rent. Under the amended Sublease Agreement, we agreed to pay rent of $2,100 per month for the months of April through July 2019, $1,250 per month for the months of August 2019 through December 2019, $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 the following two Board members are currently "independent directors," as defined under the independence standards of the NYSE American: John Bakewell and Robert McNamara.

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, 2019 and 2018. However, effective October 1, 2018, EKS&H LLLP ("EKS&H") combined with Plante Moran. As a result, EKS&H resigned as our independent registered public accounting firm. Upon the resignation of EKS&H, the Audit Committee engaged Plante Moran as our new independent registered public accounting firm for the remainder of 2018 and to audit our books and accounts for the fiscal year ended December 31, 2018.

The table below presents the aggregate fees billed for professional services rendered by Plante Moran and EKS&H for the years ended December 31, 2019 and December 31, 2018.

	2019	2018
Audit fees	$ 297,300	$ 282,000
Audit-related fees	20,000	16,500
Tax fees	—	—
All other fees	9,357	28,203
Total fees	$ 326,657	$ 326,703

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. "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 and EKS&H during 2019 and 2018.

Change in Independent Registered Public Accounting Firm

As previously disclosed, effective October 1, 2018, EKS&H LLLP combined with Plante Moran. As a result, EKS&H resigned as the Company's independent registered public accounting firm. Upon the resignation of EKS&H, the Audit Committee engaged Plante Moran as the Company's new independent registered public accounting firm for the remainder of 2018.

The audit reports of EKS&H on the Company's financial statements for the years ended December 31, 2017 and 2016 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope, or accounting principles. During the two most recent fiscal years ended December 31, 2017 and 2016 and through the subsequent interim period preceding EKS&H's resignation, there were no disagreements between the Company and EKS&H on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of EKS&H, would have caused them to make reference thereto in their reports on the Company's financial statements for such years. During the two most recent fiscal years ended December 31, 2017 and 2016 and through the subsequent interim period preceding EKS&H's resignation, there were no reportable events within the meaning set forth in Item 304(a)(1)(v) of Regulation S-K.

During the two most recent fiscal years ended December 31, 2017 and 2016 and through the subsequent interim period preceding Plante Moran's engagement, the Company did not consult with Plante Moran on either (1) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that may be rendered on the Company's financial statements, and Plante Moran did not provide either a written report or oral advise to the Company that Plante Moran concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing, or financial reporting issue; or (2) any matter that was either the subject of a disagreement, as defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event, as defined in Item 304(a)(1)(v) of Regulation S-K.

The Company previously disclosed this information in its Current Report on Form 8-K filed with the SEC on October 9, 2018, provided EKS&H with a copy of the disclosures, and requested that EKS&H furnish it with a letter addressed to the SEC stating whether or not it agrees with the Company's statements therein. A copy of the letter dated October 8, 2018 was filed as an exhibit to such Form 8-K.

PART IV

Item 15. Exhibits, 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
2.1	Stock Purchase Agreement dated July 27, 2015 among Bacterin International Holdings, Inc., X-spine Systems, Inc. and the sellers named therein (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 28, 2015 (SEC File No. 0-34941) and incorporated by reference herein)
3.1	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. 0-34941) and incorporated by reference herein)
3.2	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. 0-34941) and incorporated by reference herein)
3.3	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. 0-34941) and incorporated by reference herein)
4.1*	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
4.2	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)
4.3	Form of Warrant to Purchase Common Stock (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 5, 2013 (SEC File No. 0-34941) and incorporated by reference herein)
4.4	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. 0-34941) and incorporated by reference herein)

Exhibit No.	Description
4.5	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. 0-34941) and incorporated by referenced herein)
4.6	Form of Pre-Funded Warrant (filed as Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016 (SEC File No. 0-34941) and incorporated by reference herein)
4.7	Warrant dated as of September 17, 2018 issued by Xtant Medical Holdings, Inc. to ROS Acquisition Offshore LP (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 17, 2018 (SEC File No. 0-34941) and incorporated by reference herein)
4.8	Warrant dated as of September 17, 2018 issued by Xtant Medical Holdings, Inc. to OrbiMed Royalty Opportunities II, LP (filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 17, 2018 (SEC File No. 0-34941) and incorporated by reference herein)
4.9	Warrant dated as of April 1, 2019 issued by Xtant Medical Holdings, Inc. to ROS Acquisition Offshore LP (filed as Exhibit 4.11 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018 (SEC File No. 0-34941) and incorporated by reference herein)
4.10	Warrant dated as of April 1, 2019 issued by Xtant Medical Holdings, Inc. to OrbiMed Royalty Opportunities II, LP (filed as Exhibit 4.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018 (SEC File No. 0-34941) and incorporated by reference herein)
4.11	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. 0-34941) and incorporated by reference herein)
4.12	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. 0-34941) and incorporated by reference herein)
4.13	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. 0-34941) and incorporated by reference herein)
4.14	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. 0-34941) and incorporated by reference herein)

Exhibit No.	Description
10.1•	Xtant Medical Holdings, Inc. 2018 Equity Incentive Plan, as amended (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 31, 2019 (SEC File No. 0-34941) 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. 0-34941) 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. 0-34941) 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. 0-34941) 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. 0-34941) and incorporated by reference herein)
10.6•	Form of Stock Option Agreement under Amended and Restated Xtant Medical Equity Incentive Plan (filed as Exhibit 10.23 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 (SEC File No. 0-34941) and incorporated by reference herein)
10.7•	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. 0-34941) and incorporated by reference herein)
10.8•	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. 0-34941) and incorporated by reference herein)
10.9•	Interim Executive Employment Agreement dated as of October 12, 2018 between Xtant Medical Holdings, Inc. and Michael Mainelli (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 15, 2018 (SEC File No. 0-34941) and incorporated by reference herein)
10.10•	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. 0-34941) and incorporated by reference herein)
10.11•*	Employment Agreement effective as of January 1, 2019 between Xtant Medical Holdings, Inc. and Ronald Berlin
10.12•	Amended and Restated Employment Agreement effective as of August 8, 2019 between Xtant Medical Holdings, Inc. and Greg Jensen (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 (SEC File No. 0-34941) and incorporated by reference herein)

Exhibit No.	Description
10.13	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. 0-34941) and incorporated by reference herein)
10.14	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. 0-34941) and incorporated by reference herein)
10.15	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. 0-34941) 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. 0-34941) 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. 0-34941) and incorporated by reference herein)
21.1	Subsidiaries of the Registrant (filed as Exhibit 21.1 to the Registrant's Post-Effective Amendment No. 1 to Form S-1 Registration Statement filed with the SEC on August 25, 2015 (SEC File No. 333-203492 and incorporated by reference herein)
23.1*	Consent of Independent Registered Public Accounting Firm, Plante & Moran, PLLC
31.1*	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
31.2*	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
32.1**	Certification of Chief Executive Officer and 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
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

Exhibit No.	Description

- 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.

March 5, 2020

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 March 5, 2020.

Signature	**Title**
/s/ Sean E. Browne Sean E. Browne	President and Chief Executive Officer (principal executive officer)
/s/ Greg Jensen Greg Jensen	Vice President, Finance and Chief Financial Officer (principal financial and accounting officer)
/s/ John Bakewell John Bakewell	Director
/s/ Michael Eggenberg Michael Eggenberg	Director
/s/ Robert McNamara Robert McNamara	Director
/s/ Jeffrey Peters Jeffrey Peters	Director
/s/ Matthew Rizzo Matthew Rizzo	Director

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BOARD OF DIRECTORS

Jeffrey Peters
Chairman of the Board

John Bakewell

Sean E. Browne

Michael Eggenberg

Robert McNamara

Matthew Rizzo

EXECUTIVE OFFICERS

Sean E. Browne
President and Chief Executive Officer

Kevin D. Brandt
Chief Commercial Officer

Greg Jensen
Vice President, Finance and Chief Financial Officer

CORPORATE INFORMATION

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Telephone: (800) 468-9716

Legal Counsel
Fox Rothschild LLP
Minneapolis, Minnesota

Independent Registered Public Accounting Firm
Plante & Moran, PLLC
Denver, Colorado

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