Xtant Medical Holdings, Inc.
Form 10-K
April 01, 2019

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, 2018

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 (State or other jurisdiction of incorporation or organization)	20-5313323 (IRS Employer Identification No.)
664 Cruiser Lane Belgrade, Montana (Address of Principal Executive Offices)	59714 (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	**Name of each exchange on which registered**
Common stock, par value $.000001 per share	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 Exchange 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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ]	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, 2018 was $21.9 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 29, 2019 was 13,161,762.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference information (to the extent specific sections are referred to herein) from the registrant's definitive proxy statement for its 2019 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K, in any case, to be filed within 120 days of the end of the period covered by this report.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 10-K that are not purely historical are forward-looking statements within the meaning of applicable securities laws. 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 simi may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements in this Form 10-K may include, for example, statements about:

- our ability to comply with the covenants in our amended and restated credit agreement;
- our ability to maintain sufficient liquidity to fund our operations;
- our ability to obtain financing on reasonable terms;
- our ability to increase or maintain revenue;
- the ability of our sales force to achieve expected results;
- our ability to remain competitive;
- government regulations;
- our ability to innovate and develop new products;
- our ability to obtain donor cadavers for our products;
- our ability to engage and retain qualified technical personnel and members of our management team;
- the availability of our facilities;
- government and third-party coverage and reimbursement for our products;
- our ability to obtain and maintain regulatory approvals;
- our ability to successfully integrate future business combinations or acquisitions;
- our ability to use our net operating loss carry-forwards to offset future taxable income;
- our ability to deduct all or a portion of the interest payments on the notes for U.S. Federal income tax purposes;

our ability to service our debt;

product liability claims and other litigation to which we may be subjected;

product recalls and defects;

timing and results of clinical studies;

our ability to obtain and protect our intellectual property and proprietary rights;

infringement and ownership of intellectual property;

our ability to remain accredited with the American Association of Tissue Banks; and

our ability to maintain our stock listing on the NYSE American Exchange.

The forward-looking statements contained in this Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. 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 “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 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 of Our Business

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 implants. Our products are used by orthopedic spine surgeons and neurosurgeons to treat a variety of spinal disorders in the cervical, thoracolumbar, and interbody spine.

Our Offices

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

Our Corporate History

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. (“Bacterin”), which on March 7, 2011, began trading our common stock 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. X-spine is engaged in the development, manufacturing and sale of implants and medical devices for use in orthopedic spinal surgeries. As a result of this transaction, X-spine became a wholly owned subsidiary of Bacterin International Holdings, Inc.

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At the close of business on July 31, 2015, we changed our corporate name to “Xtant Medical Holdings, Inc.” On August 6, 2015, Xtant formed a new wholly owned subsidiary, Xtant Medical, Inc., a Delaware corporation to facilitate the integration of Bacterin and X-spine. On October 15, 2015, our common stock began trading on the NYSE MKT under the ticker symbol “XTNT.” X-spine is engaged in the development, manufacturing and sale of implants and medical devices for use in orthopedic spinal surgeries. Xtant, Bacterin and X-spine are jointly referred to herein as the “Company”.

On May 8, 2017, the Company entered into an agreement with Aurora Management Partners Inc. (“Aurora”) to assist us in restructuring efforts. Pursuant to this agreement, David Baker served as Chief Restructuring Officer of the Company and certain additional Aurora personnel, referred to as Deputy Restructuring Officers, assisted in the restructuring efforts. As part of our restructuring, we completed a significant debt restructuring in the beginning of 2018 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. Although our agreement with Aurora terminated on November 8, 2018 and David Baker no longer serves as Chief Restructuring Officer, certain Aurora personnel continue to provide financial and accounting assistance to us under a separate agreement.

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. Over 300 commissioned independent agents and stocking agents in the United States represent some or all of Xtant's 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.

Our Orthobiologics Products

Our biomaterial products include OsteoSponge®, OsteoSponge® SC, OsteoSelect® DBM putty, OsteoSelect Plus DBM putty, OsteoWrap®, OsteoSTX®, and our new 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 provides a natural scaffold for cellular in-growth and exposes 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 completely 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 engineered with the surgeon in mind. With outstanding handling characteristics, OsteoSelect is designed to be easily molded into any shape and compressed into bony voids. Bacterin has validated a low-dose, low-temperature gamma sterilization process 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 combines the exceptional cohesive characteristics of OsteoSelect DBM Putty with demineralized cortical chunks. OsteoSelect PLUS is designed to deliver differentiated handling properties and insure 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 can wrap around non-union fractures to assist with fusion, can act as a biologic plate or can be used in conjunction with a hardware plate system. Additionally, this product provides the surgeon with superior handling characteristics as the allograft can be easily sized using surgical scissors or a scalpel and will 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. Bacterin's 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.

All of our biologics are 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 related biologic products are described in multiple physician-initiated studies that continue to prove expanded indications for their use. These documents are available through our website at www.xtantmedical.com. Information contained on our website does not constitute part of this Form 10-K.

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 CertexTM 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 XpressTM 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-XTM 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-CTM 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-ATM 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.

Technology and Intellectual Property

We rely upon patents, trademarks, and trade secrets 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.

Patents

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, 2018, 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 under the Bacterin name: 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®, Capless® and X-spine's square design logo.

Trade Secrets

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.

Donor Procurement

We have agreements with multiple recovery agencies, and we continue 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.

Sales and Marketing

We distribute our products in the United States through a distribution network of over 300 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.

Our international footprint includes distribution partners in Canada, Mexico, South America, Europe, Australia, and certain Pacific region countries.

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.

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 or have received 510(k) clearances.

Human Tissue

Human tissue products have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second 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. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and communicable disease transmission to recipients. Several of our products including OsteoSponge and OsteoWrap are regulated as HCT/Ps as determined by the Tissue Reference Group and regulated under Section 361 of the Public Health Service Act ("PHSA") and 21 CFR Part 1271.

Medical Devices

Our medical devices require the clearance of the FDA prior to sale within the United States. The FDA process requires a premarket notification, or a 510(k) submission, to the FDA to demonstrate that the medical device is safe and effective and is substantially equivalent to a legally marketed device that is not subject to premarket approval. Applicants must compare the device to one or more similar devices that are commercially available in the United States (known as the "predicate device") and make and support a claim of substantial equivalency to such predicate device. Support for such claims must include descriptive data and, when necessary, performance data. In some cases, data from clinical trials must also be submitted in support of a 510(k) submission. The FDA must then issue an order finding substantial equivalency before the devices may be commercially distributed in the United States. The Center for Devices and Radiological Health Division of the FDA governs HCT/Ps that are regulated as medical devices, including our OsteoSelect DBM putty.

The discussion of what data is needed is sometimes conducted in a formal 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. The Center for Devices and Radiological Health division of the FDA governs the clearance 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.

Another procedure for obtaining marketing authorization for a medical device is the "de novo classification" procedure. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. 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 premarket approval or "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. A company files for a de novo approval when it does not have a predicate to which it can claim substantial equivalence. Once a de novo application is reviewed and approved, it results in the device having a Class II status and future devices from the company or a competitor may use the company de novo-approved device as a 510(k) predicate. A de novo approval is reserved for Class II moderate risk devices and a company must show that special controls can be created which subsequent applicants can follow to obtain a 510(k) clearance. The advantage of the de novo approval is that it 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. FDA is increasingly moving devices with slightly different proposed indication statements or different technological features off the 510(k) path and on to the de novo path resulting in more time and expense for the company.

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. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k) or a PMA.

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. Clinical trials are almost always required to support a PMA.

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, 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. There can be no assurance that we will be able to remediate this matter on a timeline that is satisfactory to the Notified Body. If this risk were to materialize, we may be required to remove the effected products from the EU market countries until remediation is complete.

The new European 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, 2018, Xtant had 166 employees, of whom 75 were in operations, 39 were in sales and marketing, 8 in research and development and engineering, 19 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 relations with employees and service partners to be good.

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 furnishes 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 trading 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 operating losses and at December 31, 2018, we had an accumulated deficit of $215.0 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 and market acceptance of our products; competing technologies and market developments; regulatory requirements and delays; ability to attract and retain key personnel; and pending litigation. 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 will 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.

We have substantial operating expenses associated with the sales and marketing of our products. Although it is difficult for us to predict our future liquidity requirements, we believe that our cash and cash equivalents balance of approximately $6.8 million, as of December 31, 2018, together with existing credit availability and $10.0 million in availability under our Second Amended and Restated Credit Facility dated March 29, 2019 will be sufficient to meet our anticipated cash requirements through the end of March 2020. Although we recently increased availability under our Second Amended and Restated Credit Agreement, we still believe we may require additional funds to fund our future operations and business strategy. 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 and we could even be required to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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 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 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, including, as of December 31, 2018, $77.9 million in aggregate principal plus additional 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;

NYSE compliance;

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, financial performance, and sales results. 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. While an event of default 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.

We rely on our subsidiaries for funds necessary to meet our financial obligations.

We conduct substantially all of our activities through our subsidiaries. We depend on those subsidiaries for dividends and other payments to generate the funds necessary to meet our financial obligations, including our outstanding indebtedness. The ability of our subsidiaries to make payments to us may be restricted by, among other things, applicable state corporation or similar statutes and other laws and regulations. The earnings from, or other available assets of, our subsidiaries may be insufficient to enable us to pay the outstanding principal or interest due on our outstanding indebtedness when due.

Risks Related to Our Business

Many competitive products exist and more will be developed. Our operating results have suffered due to intense competition and we may not be able to successfully compete because we are smaller and have fewer financial resources.

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. Intense competition adversely affected our operating results during 2018. In addition, 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 continue to develop and market new products and technologies, we may experience a decrease in demand for our products, or our products could become obsolete, and our business and operating results would suffer.

Due to lack of funding, our research and development efforts 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.

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. Any disruption in the supply of this crucial raw material could have significant consequences for our revenue, operating results and continued operations.

Our inability to attract and retain key personnel could adversely affect our business and results of operations.

Our success is highly dependent upon the services of our executives. However, we have experienced a high level of turnover among our executive team over the past year, including the departure of our interim CEO and our CFO during the first quarter of 2019. Most of the members of our management team have joined the Company in the past year. Currently, our Vice President of Finance, Greg Jensen, is serving as our interim Chief Financial Officer and our principal executive officer as we search for qualified replacements. The loss of Mr. Jensen, or the loss of any of the

remaining key members of our management team, such as our Chief Commercial Officer and Chief Operations Officer, could have a material adverse effect on our future operations. We do not currently maintain key-person life insurance policies insuring the life of any member of our management team.

Our future success also depends, in part, upon our ability to retain and motivate key managerial, sales, and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. We compete for such personnel with other companies, academic institutions, governmental entities, and other organizations. There can be no assurance that we will be successful in retaining our current personnel or in hiring or retaining qualified personnel in the future. Any unanticipated loss or interruption of services of our management team and our key personnel could significantly reduce our ability to meet our strategic objectives due to extended time required for us to find appropriate replacement personnel, if at all, should the need arise. Loss of key personnel or the inability to hire or retain qualified personnel in the future could have a material adverse effect on our ability to operate successfully.

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

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 relevant with respect to our Calix Lumbar Spine Implant System recall initiated in December 2018. 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.

Litigation may result in financial loss and/or impact our ability to sell our products going forward.

We are subject to certain pending litigation and dispute matters. For example, in December 2018, a complaint was filed by RSB Spine, LLC against us which claims that some of our products, including the Irix-ATM Lumbar Integrated Fusion System and the Irix-CTM Cervical Integrated Fusion System, infringe certain of RSB Spine’s patents. The complaint seeks, among other relief, an injunction against future infringement, unspecified damages for infringement, and treble damages for willful infringement. Our pending litigation is discussed in Note 9 to our consolidated financial statements. Although we intend to vigorously defend any existing or future litigation or dispute

in which we may be involved, there can be no assurance that we will prevail in these matters. An unfavorable judgment or settlement may result in a financial burden on us. An unfavorable judgment or settlement may also result in restrictions on our ability to sell certain products and therefore may impact future operating results. Moreover, costs, fees, expenses, settlement amounts, judgments or other liabilities associated with such matters may not be covered by our insurance.

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 them 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 or 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 and non-compete obligations or agreements by employees of 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.

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 future results.

Our quarterly operating results may vary significantly due to a combination of factors, many of which are beyond our control. These factors include:

- demand for 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 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 the healthcare 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 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.

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 future performance. We cannot assure you that our revenue will increase or be sustained in future periods or that we will be profitable in any future period. Any shortfalls in revenue or earnings from levels expected by industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period.

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

A significant portion of our product revenue is made 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 recent notification of the termination of a consulting agreement effective on March 22, 2019 will likely adversely affect our operating results beginning with the first quarter of 2019.

In December 2018, we received notification of the termination of 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. As a result of this notification, this agreement will terminate effective March 22, 2019. We anticipate that the termination of this agreement will negatively impact our revenues based on our ability to continue to sell products through our distribution channels to our customers affiliated with this entity.

Worldwide economic instability could adversely affect our net sales, 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 sales, 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 5% of our total revenue for our year ended December 31, 2018. 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:

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;

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;

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;

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 government of the United Kingdom formally gave notice of its intent to withdraw from the European Union. Serving this notice began a two-year period for the United Kingdom to negotiate terms for its 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. Although it is unknown what those terms will be, it is possible that 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. Brexit could 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 what implications the withdrawal of the United Kingdom from the European Union will have and how such withdrawal could affect, or whether it could have a material adverse effect on, our business, financial condition and 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 of 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, 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. We continue to consolidate and integrate the number of systems we operate, and we plan to continue system roll-outs in the future and to otherwise upgrade and expand our IT system capabilities. 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 ship and track product orders, project inventory requirements, manage our supply chain, and otherwise adequately service our customers, and 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. 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.

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 timely, 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 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.

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. The integration of combined or acquired businesses is likely to 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 light of anticipated changes in accounting standards and in the context of acquisitions of other businesses.

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 shareholder 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 ordinary shares 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. For example, recently, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases*, that amend the accounting standards and related disclosure requirements related to lease accounting. 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. 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 IRS 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. In addition, the interest paid or incurred with respect to our prior convertible notes is not deductible.

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 ("PMA"), from the FDA, unless an exemption applies. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

Most of our currently commercialized products have received premarket clearances under Section 510(k) of the FDCA. In the future, the FDA may determine that our products will require the more costly, lengthy and uncertain de novo or PMA processes. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our revenue to decline. Although we do not currently market any devices under PMA and have not gone through the de novo classification 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 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, we 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 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 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 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 Federal False Claims Act) which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal 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 the Anti-Kickback Statue and the Federal False Claims Act 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 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 “safe harbors” which if met will protect certain arrangements from liability. For example, the Anti-Kickback Statute allows for payments that would technically fall under the definition of “remuneration” and be illegal, are allowed because they meet a safe harbor 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 companies to provide discounts to their customers in many forms (such as rebates, volume discounts, etc.) as long as they meet the requirements of the safe harbor. Certain safe harbors under the Anti-Kickback Statute may also apply to consulting and other arrangements for personal services which may apply to relationships we have with physician consultants. 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. Therefore, 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, physicians and other healthcare providers, some of whom 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.

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.

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. There can be no assurance that we will be able to remediate this matter on a timeline that is satisfactory to the Notified Body. If this risk were to materialize, we may be required to remove the effected products from the EU market countries until remediation is complete.

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. Up until recently, companies looked to a 1997 guidance document from FDA regarding when a change to a cleared device required a new 510(k) clearance. FDA and manufacturers were very familiar with this guidance document. The FDA released new guidance, in October 2017, that superseded the 1997 guidance. 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 or PMA application and are sometimes required for 510(k) clearance. Such trials generally require an investigational device exemption application, or 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 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 and future profits. 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 our ability to generate profits. 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 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 by 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 or procedure 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 fine 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 if surgeons attempt to use our products off-label. 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.

There may be increased risk of injury and product liability if surgeons misuse our products or do not follow recommended user and 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. Any of these events could harm our business and operating results.

If our products cause or contribute to a death or a 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 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, or results in permanent impairment of a body function or permanent damage to body structure. 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, inspection or 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 or product enhancements and modifications, 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. 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 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. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

In December 2018, we initiated a Class 2 recall of our Calix Lumbar Spine Implant System due to a risk of compromised sterilization of the product. There were no device related adverse events reported for this product and we are working with the FDA on this recall and expect to have it closed out in 2019.

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 restrictions or withdrawal from the market.

The FDA has statutory authority to regulate HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient, 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 principally 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 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 Practice, or cGTP, when processing, storing, labeling and distributing HCT/Ps, including required labeling

information; stringent recordkeeping; and adverse event reporting. The FDA has also proposed extensive 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)) or approval (de novo or PMA).

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

An HCT/P is eligible for regulation solely as a 361 HCT/P if it is: (i) minimally manipulated; (ii) intended for homologous use as 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 effector 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 comprehensive regulations that address manufacturer activities associated with HCT/Ps. The first requires that companies that produce and distribute 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 marketing 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 Practices" 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.

At the time they came into effect approximately fifteen 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 comply, or will comply on a timely basis, 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 some of our HCT/Ps meet the criteria for marketing solely under Section 361 of the PHSA, and therefore do not 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 will be 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 products may be subject to regulation in the European Union ("EU") 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.

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

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 expand our business.

Product pricing (and, therefore, profitability) is subject to regulatory control which could impact our revenue and financial performance.

The pricing and profitability 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 and/or profitability 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 financial performance.

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 hospitals to purchase our products depends in part on the extent to which reimbursement for the costs of such materials and related treatments 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. If third-party payor reimbursement to providers for procedures involving our products decreases, some of our target customers may be unwilling to purchase our products in favor of purchasing less expensive alternatives. In addition, third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies and amounts, which can result in 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. 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 failures 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 Our Intellectual Property

If we lose any existing or 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. In December 2018, a complaint was filed by RSB Spine, LLC against us which claims that some of our products, including the Irix-ATM Lumbar Integrated Fusion System and the Irix-CTM Cervical Integrated Fusion System, infringe certain of RSB Spine's patents. The complaint seeks, among other relief, an injunction against future infringement, unspecified damages for infringement, and treble damages for willful infringement. Legal proceedings, regardless of the outcome, could drain our financial resources and divert the time and effort of our management. If we lose one of these proceedings, 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 or selling our products. 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 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 the 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.

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 would 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. 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 or a duly authorized committee of 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. 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 own, in the aggregate, approximately 70% of our outstanding common stock, and beneficially own, with their warrants, approximately 75%, and hold all of our outstanding indebtedness and therefore can exert significant influence or control over our corporate matters.

Funds affiliated with OrbiMed Advisors LLC, OrbiMed Royalty Opportunities II, LP ("Royalty Opportunities") and ROS Acquisition Offshore LP ("ROS"), own approximately 70% of our outstanding common stock and beneficially own, with their warrants, approximately 75% of our outstanding common stock. Pursuant to an Investor Rights Agreement, dated as of February 14, 2018 ("Investor Rights Agreement"), by and among the Company and certain stockholders, including without limitation, Royalty Opportunities and ROS, for so long as the Ownership Threshold (as defined in the Investor Rights Agreement) is met, these funds are entitled to nominate such individuals to the Board of Directors constituting a majority of the directors. Michael Eggenberg, Matthew Rizzo and Jeffrey Peters are currently the three director representatives per the terms of the Investor Rights Agreement. In addition, Royalty Opportunities and ROS are the lenders under our Second Amended and Restated Credit Agreement and hold all of our outstanding indebtedness thereunder and hold warrants to purchase in the aggregate an additional 2,407,309 shares of our common stock. 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, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. This concentration of ownership may delay or prevent a change in control otherwise favored by our other stockholders and could depress our stock price.

We are a “controlled company” within the meaning of the NYSE American rules and rely on exemptions from various corporate governance requirements.

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, an independent nomination and governance committee or an independent compensation committee. Accordingly, you 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 subject to the continued listing standards of the NYSE American and our failure to satisfy these criteria 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 shareholders’ equity and a minimum number of public shareholders. In addition to these objective standards, the NYSE American 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 the NYSE American considers a “low selling price” and the issuer fails to correct this via a reverse split of shares after notification by the NYSE American; or (vi) if any other event occurs or any condition exists which makes continued listing on the NYSE America, 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, 2018 reflect stockholders’ deficit of $43.8 million. According to Section 1003(a) of the Company Guide, the NYSE American will normally consider providing an exemption for entities not in compliance with Section 1003(a)(iii) of the Company Guide if the entity is in compliance with the following standards: (1) total value of market capitalization of at least $50,000,000; or total assets and revenue of $50,000,000 each in its last fiscal year, or in two of its last three fiscal years; and (2) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least $15,000,000 and 400 round lot shareholders. No assurance can be provided, however, that the Company will be able to meet this exemption.

If we fail to meet these continued listing requirements, we may receive a deficiency notice by the NYSE American that we are not in compliance with the requirements set forth in the NYSE American Company Guide. In response to this notice, we would likely submit to the NYSE American a plan to regain compliance with the requirements. If NYSE Regulation does not approve our plan or if we are unable to regain compliance by the end of the cure period which we expect to receive or if the NYSE American determines that we are not making progress consistent with the plan during the plan period, the NYSE American may initiate suspension and delisting procedures. 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 the NYSE American 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 your investment 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 2018, the sale price of our common stock ranged from $1.61 to $11.50 per share, after giving effect to the one-for-12 reverse stock split effected on February 13, 2018. 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 your investment in our common stock. Factors that may have a significant impact on the market price and marketability of our common stock include:

the terms of any potential future debt restructuring or reorganization;

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. In addition, if outstanding options or warrants or 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 securities could adversely affect their market price.

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 stocks 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, our stock price 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 our trading volume and the market price of our common stock to decline.

We could issue “blank check” preferred stock without stockholder approval with the effect of diluting interests of then-current stockholders and impairing their voting rights, and provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

Our Amended and Restated Certificate of Incorporation provides for the authorization to issue up to 10,000,000 shares of “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by the Board of Directors. The Board of Directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. In addition, advanced notice is required prior to stockholder proposals, which might further delay a change of control.

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. 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 your sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

This Item 1B is inapplicable to Xtant as a smaller reporting company.

Item 2. Properties

We lease approximately 17,700 square feet in a building located at 600 Cruiser Lane, Belgrade, Montana 59714. 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. The lease also has a ten-year renewal option.

We lease an approximately 14,000 square foot facility at 664 Cruiser Lane, Belgrade, Montana 59714. 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 21,000 square feet in a building located at 732 Cruiser Lane, Belgrade, Montana 59714, where one Class 1,000 (ISO 6) clean room is located.

We lease office space of approximately 225 square feet located at 9990 Coconut Road, Bonita Springs, FL 34135.

We lease office space of approximately 1,800 square feet located at 6363 Poplar Avenue, Suite 400, Memphis TN 38119 We plan to allow this lease to expire on August 1, 2019.

We lease office space of approximately 3,000 square feet located at 363 Centennial Parkway, Suite 220, Louisville, Colorado 80027. The Company intends to assign this lease to a third party.

We also lease a facility at 452 Alexandersville Road, Miamisburg, Ohio 45342. The leased property contains approximately 31,600 square feet. The Company's offices and operations at this facility were transferred to the Company's facilities in Belgrade, Montana in the fourth quarter of 2017. The facilities are leased under a three-year lease which runs through November 2019. As of February 28, 2019, we terminated our Miamisburg, OH lease, which was set to expire December 1, 2019.

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-ATM Lumbar Integrated Fusion System and the Irix-CTM 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 intend to vigorously defend the claims in this action. Because this matter is in early stages and because of the complexity of the case, we cannot estimate the possible loss or range of loss, if any, associated with its resolution. However, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition or results of operations.

On August 10, 2017, a civil suit complaint was filed against Xtant in the United States District Court, District of Nevada by Axis Spine NV, LLC (“Axis”), Case No. 2:17-CV-02147-APG-VCF. The complaint alleges breach of contract, breach of the implied covenant of good faith and fair dealing, and tortious interference with prospective economic advantage with respect to an alleged medical device distribution relationship between the parties. Specifically, Axis alleges that Xtant owes payments to Axis for its medical device distributions. Axis seeks relief in the form of damages in an amount in excess of $1.0 million. On March 6, 2019, the Court granted Xtant’s motion for summary judgment on Axis’s claims for breach of contract, and breach of the covenant of good faith and fair dealing but denied Xtant’s motion for summary judgment on Axis’s unjust enrichment claim. Xtant is evaluating its alternatives in light of the court order. Because this matter is in early stages and because of the complexity of the case, we cannot estimate the possible loss or range of loss, if any, associated with its resolution. However, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition or results of operations.

In October 2016, Phoenix Surgical, Inc., a former distributor sued Xtant for its alleged participation in a scheme orchestrated by a former Phoenix Surgical sales representative to divert sales away from Phoenix Surgical to another entity. The other entity diverted approximately $285,000 in sales (or approximately $205,000 in gross profit) that would otherwise have gone to Phoenix Surgical. Phoenix Surgical alleges that Xtant and one of its former employees participated in this diversion of sales and that Xtant is liable to Phoenix Surgical for its loss, with treble damages for violation of a Connecticut statute. Xtant claims that the other entity was a legitimate distributor, its former employee acted on his own and Xtant had no way of knowing the other parties were diverting sales. Phoenix initially sued Xtant in Connecticut and in federal bankruptcy court because some other individuals involved have filed bankruptcy. Xtant was dismissed from those actions, and the dispute is now subject to arbitration in Colorado. The arbitration is scheduled for July 2019.

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 29, 2019, we had 174 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

On March 29, 2019, we entered into the Second Amended and Restated Credit Agreement with OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP (collectively, the "Investors"), as described in Item 9B below. As a condition to the effectiveness of the Second Amended and Restated Credit Agreement, on April 1, 2019, the Company will issue warrants to purchase an aggregate of 1.2 million shares of our Common Stock to the Investors, with an exercise price of $0.01 per share and an expiration date of April 1, 2029 (collectively, the "2019 Warrants"). The issuance of the 2019 Warrants was exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Section 4(a)(2) thereof and/or Regulation D promulgated thereunder. The issuance of any shares of our Common Stock in connection with the exercise of the 2019 Warrants is also expected to be exempt from the registration requirements of the Securities Act, pursuant to Section 4(a)(2) thereof and/or Regulation D promulgated thereunder.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

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 Operation

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 our products in the United States largely through independent distributors and stocking agents, augmented by direct employees.

During the first quarter of 2018, we effected a significant restructuring pursuant to which we converted an aggregate of $71.9 million of aggregate principal amount of debt into equity by issuing an aggregate of 10,590,954 shares of our common stock, in cancellation thereof; issued an additional 945,819 shares of our common stock in a private placement for an aggregate purchase price of $6.8 million, completed a 1-for-12 reverse split of our common stock after the close of business on February 13, 2018, and replaced our entire Board of Directors. We completed this restructuring during the second quarter of 2018 with a common stock stockholder rights offering, which expired on June 18, 2018 and resulted in the issuance of an additional 129 shares of common stock. Upon completion of this restructuring and as of December 31, 2018, two funds affiliated with OrbiMed, which held a significant portion of our converted indebtedness and continue to hold all of our currently outstanding debt, own approximately 70% of our outstanding common stock. Because of this significant ownership, we are a "controlled company" within the meaning of the NYSE American corporate governance standards.

During 2018, we experienced reduced revenues due primarily to company-initiated discontinued distributor arrangements and challenges in channel management, the highly competitive fixation distribution network, and no new product introductions over the past two years. We focused on reducing our operating expenses during 2018, which resulted in a 19.3% decrease in general and administrative expenses, a 20.9% decrease in sales and marketing expenses and a 30.5% decrease in research and development expenses compared to 2017. These decreases, however, were offset by a significant non-cash impairment of goodwill charge of $38.3 million and impairment of intangible

assets charge of $9.8 million during the fourth quarter of 2018 relating primarily to assets acquired in connection with our 2015 X-spine acquisition.

As of December 31, 2018, our cash and cash equivalents were $6.8 million.

On March 29, 2019, we entered into a Second Amended and Restated Credit Agreement with our lenders (the “Second Amended and Restated Credit Agreement”), which amended and restated our 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 may request additional term loans with ROS and Royalty Opportunities in the remaining amount available as Additional Delayed Draw Loans, and may make a request for new term loans in an aggregate amount of up to $10,000,000, the amount of each loan draw to be subject to our production of a thirteen-week cash flow forecast that is approved by ROS and Royalty Opportunities and 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 lender) 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 (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 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 Kevin Brandt and Ron Berlin.

Comparison of Years Ended December 31, 2018 and December 31, 2017 (in thousands):

The following table sets forth our results of operations for 2018 and 2017.

	Year Ended December 31,					
	2018			2017		
	Amount	% of Revenue		Amount	% of Revenue	
Revenue						
Orthopedic product sales	$71,814	99.5	%	$82,513	99.9	%
Other revenue	389	0.5	%	99	0.1	%
Total Revenue	72,203	100.0	%	82,612	100.0	%
Cost of Sales	28,717	39.8	%	32,511	39.4	%
Gross Profit	43,486	60.2	%	50,101	60.6	%
Operating Expenses						
General and administrative	12,881	17.0	%	15,246	18.5	%
Sales and marketing	32,059	44.4	%	40,511	49.0	%
Research and development	1,702	2.4	%	2,441	3.0	%
Depreciation and amortization	4,118	5.7	%	5,485	6.6	%
Impairment of goodwill and intangible assets	48,146	66.7	%	17,586	21.3	%
Restructuring expenses	2,970	4.1	%	4,680	5.7	%
Separation related expenses	1,568	2.2	%	1,901	2.3	%
Non-cash consulting expenses	120	1.0	%	85	0.1	%
Total Operating Expenses	103,564	143.4	%	87,935	106.4	%
Loss from Operations	(60,078)	(83.2	)%	(37,834)	(45.8	)%
Other Income (Expense)						
Interest expense	(10,145)	(14.1	)%	(14,705)	(17.8	)%
Change in warrant derivative liability	121	0.2	%	203	0.2	%
Other income (expense)	3	0.0	%	(75)	(0.0	)%
Total Other Income (Expense)	(10,021)	(13.9	)%	(14,577)	(17.6	)%
Net Loss from Operations Before (Provision) Benefit for Income Taxes	(70,099)	(97.1	)%	(52,411)	(63.4	)%
Benefit (Provision) for Income Taxes						
Current	-	0.0	%		0.0	%
Deferred	-	0.0	%	-	0.0	%

Net Loss	$(70,099)	(97.1)%	$(52,411)	(63.4)%

Revenue

Total revenue for the year ended December 31, 2018 decreased 12.6% to $72.2 million compared to $82.6 million in the prior year. The decrease of $10.4 million is primarily due to company-initiated discontinued distributor arrangements and challenges in channel management the highly competitive fixation distribution network, and no new product introductions over the past two years.

Cost of Sales

Costs of sales consist primarily of manufacturing and product purchase costs and depreciation of surgical trays. 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 11.7%, or $3.8 million, to $28.7 million for the year ended December 31, 2018 from $32.5 million for the year ended December 31, 2017. This was primarily due to manufacturing cost savings achieved during 2018 as a result of the consolidation of facilities following the closure of our Dayton, Ohio operations in early 2018 and cost reduction initiatives to fully integrate hardware and biologics operations at the beginning of 2018. Cost of sales as a percent of total revenue was 39.8% of revenue for the year ended December 31, 2018, compared to 39.4% for the prior year. Reserves for estimated excess inventory, inventory on consignment that may be missing and not returned, and estimated missing and damaged consigned surgical instruments were $4.6 million in 2018 and $4.0 million in 2017. The reserve for 2018 was due primarily to the significant decrease in fixation sales and our change in estimate for determining excess and obsolete inventory to include 100% of fixation products with quantity on hand greater than two years of sales. The reserve for 2017 was due, in part, to litigation with a certain distributor.

Operating Expenses

Operating expenses include general and administrative expenses, sales and marketing expenses, research and development expenses, depreciation and amortization, impairment of goodwill and intangible assets, restructuring expenses and compensation costs, including separation related expenses and incentive compensation. Operating expenses increased 17.8%, or $15.6 million, for the year ended December 31, 2018 compared to the year ended December 31, 2017, primarily due to the $48.1 million impairment of goodwill and intangible assets. Almost all other components of operating expenses decreased during 2018 compared to 2017.

General and Administrative

General and administrative expenses consist principally of personnel costs for corporate employees, cash based and stock-based compensation related costs and corporate expenses for legal, accounting and other professional fees, as well as occupancy costs. General and administrative expenses decreased 15.5%, or $2.4 million, to $12.9 million for the year ended December 31, 2018, compared to the year ended December 31, 2017. The reduction in expenses is largely the result of decreased bad debt expense, personnel costs, and legal expenses incurred in 2018 compared to 2017.

Sales and Marketing

Sales and marketing expenses consist primarily of sales commissions, personnel costs for sales and marketing employees, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. Sales and marketing expenses decreased 20.9%, or $8.5 million, to $32.1 million for the year ended December 31, 2018, compared to $40.5 million for of the year ended December 31, 2017. As a percentage of revenue, sales and marketing expenses were 44.4% in 2018 and 49.0% in the prior year. This reduction in sales and marketing expenses as a percent of revenue was primarily the result of changes made to the commission rate structure under certain distribution agreements, lower sales commissions, personnel reductions and a decline of other direct marketing expenses.

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 $0.7 million, or 30.3%, to $1.7 million for the year-ended December 31, 2018 from $2.4 million for the year ended December 31, 2017. The decrease is primarily due to the consolidation of the Dayton, Ohio, facility and the corresponding reduction in headcount.

Depreciation and Amortization

Depreciation and amortization expense consist of depreciation and amortization of long-lived intangible assets, patents, leasehold improvements and equipment. Depreciation and amortization expense decreased $1.4 million to $4.1 million for the year ended December 31, 2018, from $5.5 million for the year ended December 31, 2017 primarily due to lower new capital investments in 2018.

Impairment of Goodwill and Intangible Assets

The Company recorded an impairment charge in 2018 of $38.3 million to Goodwill based on the analysis performed in comparing the carrying value of assets, including cash, and non-interesting bearing liabilities to the derived enterprise value of the business.

The Company also recorded an impairment charge in 2018 of $9.8 million to Tradenames, Technology and Customer Relationships and in 2017 of $17.6 million related to Technology and Tradenames based on the carrying amount exceeding the future net cash flows expected to be generated by these intangible assets acquired through the X-spine acquisition.

See Note 4 to the consolidated financial statements for more information regarding these charges.

Restructuring expenses

Restructuring expenses decreased $1.7 million to $3.0 million for the year ended December 31, 2018, from $4.7 million for the year-ended December 31, 2017. Restructuring costs were incurred by the Company related to our recapitalization and performance improvement measurements.

Separation Related Expenses

Separation related expenses decreased $0.3 million to $1.6 million for the year ended December 31, 2018, from $1.9 million for the year ended December 31, 2017. Separation related expenses consist 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.

Non-cash Consulting Expense

Non-cash consulting expense consists of non-cash expense associated with granting restricted stock and stock to directors and consultants. Non-cash consulting expense was $0.1 million for the year ended December 31, 2018, remaining consistent to the $0.1 million for the year ended December 31, 2017.

Interest Expense

Interest expense is related to interest incurred on our debt instruments. Interest expense for the year ended December 31, 2018 decreased $4.6 million to $10.1 million as compared to $14.7 million for the year ended December 31, 2017. The decrease in interest expense is due to the 24th and 25th amendments to the Prior Credit Agreement, resulting in lower effective interest rates on outstanding debt.

Change in Warrant Derivative Liability

For the year ended December 31, 2018, we recorded a gain in our non-cash warrant derivative liability of $0.1 million, and a gain in the year ended December 31, 2017 of $0.2 million were primarily driven by a change in the closing price of our common stock at December 31, 2018 and 2017, respectively. The liability is associated with the issuance of warrants as part of our prior convertible debt financing, our 2010 financing and our 2014 equity financing which contains certain provisions requiring the Company to record a change in the fair value of the warrant derivative liability from period to period.

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,	
	2018	2017
Cash and cash equivalents	$6,797	$2,856
Accounts receivable, net	9,990	12,714
Inventories, net	17,301	22,423
Total current assets	34,677	39,699
Accounts payable	6,465	9,476
Accrued liabilities	5,150	15,845
Total current liabilities	12,051	25,818
Total working capital	22,626	13,881
Long-term debt, less issuance costs	77,939	137,962

Xtant has reduced its accounts payable from $9.5 million at December 31, 2017, to $6.5 million as of December 31, 2018. Accrued liabilities of $5.2 million at December 31, 2018 decreased from $15.8 million at December 31, 2017 primarily due to the accumulation of accrued interest on long-term debt, the payment of which has been delayed or converted to equity as noted in recent amendments of the Company’s long-term debt agreements.

Total liabilities as of December 31, 2018 include $77.9 million of long-term debt due to the lenders under our credit facility.

Cash Flows

Net cash provided by operating activities for the year ended December 31, 2018 was $1.2 million driven primarily from management of working capital. For the comparable period of 2017, net cash used in operating activities was $0.5 million. The improvement in cash provided by operating activities is the result of our restructuring efforts in 2017 to improve liquidity, convert receivables to cash and reduce payables and accrued liabilities. The amendments to our Prior Credit Agreement during 2018 to allow for the non-payment of then current interest decreased our accrued interest on long-term debt by $5.9 million in the year ended December 31, 2018.

Net cash used in investing activities for the year ended December 31, 2018 was $0.4 million, primarily representing purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2017 was $1.6 million, primarily representing purchases of property and equipment, partially offset by proceeds from the sale of fixed assets.

Net cash provided by financing activities was $3.1 million for the year-ended December 31, 2018 due to $6.8 million in proceeds from a private placement, partially offset by $3.4 million in costs associated therewith and our debt conversion.

Second Amended and Restated Credit Agreement

On March 29, 2019, we entered into a Second Amended and Restated Credit Agreement (the "Second Amended and Restated Credit Agreement") with OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP. (collectively, the "Investors"), 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").

The Second Amended and Restated Credit Agreement amended the Prior Credit Agreement to provide that X-Spine may request term loans with the Investors in an amount equal to the remaining commitment for additional delayed draw loans, which was approximately $2,200,000 as of the date of the Second Amended and Restated Credit Agreement, and request additional term loans in an aggregate amount of up to $10,000,000, 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 $1,500,000, 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. In addition, the Second Amended and Restated Credit Agreement provides that (i) 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; (ii) 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%; (iii) the maturity date of the Loans is March 31, 2021; (iv) 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 (v) the key person event default provision was revised to refer specifically to Kevin Brandt and Ron Berlin.

Under the terms of the Prior Credit Agreement we were required to comply with a minimum liquidity covenant, a consolidated leverage ratio covenant and a minimum consolidated EBITDA covenant. We were in compliance with all covenants under the Prior Credit Agreement as of December 31, 2018. As of December 31, 2018, we had $55.8 million in borrowings outstanding under the Prior Credit Agreement and $2.2 million in unused availability under the Prior Credit Agreement. As a result of the Second Amended and Restated Credit Agreement, as of March 29, 2019 we added an additional $10 million in unused availability under our Credit Facility.

Cash Requirements

We believe that our December 31, 2018 cash and cash equivalents of $6.8 million, together with the subsequent availability of $10.0 million under our new Second Amended and Restated Credit Agreement, will be sufficient to

meet our anticipated cash requirements through the end of March 2020. However, we may require additional funds to fund our future operations and business strategy. 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 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 the Investors, and no assurance can be provided that the Investors would provide such consent, which could limit our ability to raise additional financing.

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 the 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 the 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 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 auditors. 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. On an annual basis, or more frequently upon the occurrence of certain events, we test for goodwill impairment. In conducting the impairment test, we first assessed qualitative factors to determine whether it was more likely than not that the fair value of a reporting unit was less than its carrying amount as a basis for determining whether it was necessary to perform the two-step goodwill impairment test. If the qualitative step was not passed, we performed a two-step impairment test whereby in the first step, we would compare the fair value of the reporting unit with its carrying amount. If the carrying amount exceeded its fair value, we performed the second step of the goodwill impairment test to determine the amount of impairment. The second step, measuring the impairment

loss, compared the implied fair value of the goodwill with the carrying value of the goodwill. Any excess of the goodwill carrying value over the implied fair value would be recognized as an impairment loss.

In our evaluation of goodwill, we performed an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired. We considered factors such as, but not limited to, macroeconomic conditions, industry and market considerations, and financial performance, including the planned revenue and earnings of X-spine. The results from the assessment and a Step 1 analysis allowed us to conclude that a further valuation of goodwill was necessary, as indicators of impairment existed as of December 31, 2018. As part of the Step 1 analysis, we updated the discounted cash flow analysis used to determine our initial fair value as of December 31, 2018. Based on the results of the impairment test and analysis, we concluded that the fair value of the Company was less than its carrying amount.

Based on the results of the impairment test and analysis, we concluded that a Step 2 goodwill impairment test was needed to determine the amount of impairment loss, if any. We engaged a third-party specialist to assist in the valuation. We 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 fourth quarter of 2018. The remaining Goodwill is valued at $3.2 million as of December 31, 2018.

During the fourth quarter of 2018, a few things changed in our business that 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 abandoned 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 reaping 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 were inaccurate and likely would not prove out to be true in the near future in light of our business priorities, international regulatory issues and anticipated funding requirements.

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

Given the level of impairment initially indicated by the Step 1 analysis, an ASC 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 to Tradenames, Technology and Customer Relationships based on the carrying amount exceeding the future net cash flows expected to be generated by these intangible assets. We also recorded an impairment charge in 2017 of $17.6 million related to Technology and Tradenames.

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 future demand for its 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 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 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 the inventory reserves result in a corresponding expense, which is recorded to cost of sales.

Total charges incurred to write down excess and obsolete inventory to net realizable value included in Cost of sales were approximately $4.6 million and $4.0 million for the years ended December 31, 2018 and 2017. During the year ended December 31, 2018, due primarily to the significant decrease in fixation sales, we changed our estimate for determining excess and obsolete inventory to include 100% of fixation products with quantity on hand greater than two years of sales which resulted in our excess and obsolete inventory reserve being much larger than in prior periods.

In the future, if additional inventory write-downs are required, we would recognize additional cost of goods sold at the time of such determination. Regardless of changes in our estimates of future product demand, we do not increase the value of our inventory above its adjusted cost basis. Therefore, although we make every effort to ensure the accuracy of our forecasts of future product demand, significant unanticipated decreases in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results.

Instruments

We deploy certain surgical instruments through various sales channels for use with purchased implants during surgical procedures. The instruments are classified as non-current assets within property and equipment and depreciated using the straight-line method over a five-year useful life. The net book value of consigned surgical instruments was approximately $4.4 million and $6.6 million at December 31, 2018 and December 31, 2017, respectively. We review instruments for impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to an asset are less than the asset’s carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value. An impairment charge of $1.6 million was recorded for the year ended December 31, 2017 for instruments on consignment which were determined not to be recoverable. No impairment was recorded for the year ended December 31, 2018.

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, customer's 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. 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 problems 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 sales and marketing expense in the period that we made such a determination.

Our allowance for doubtful accounts was $2.1 million at December 31, 2018 and 2017.

Valuation of Deferred Tax Assets and Liabilities and Uncertain Tax Positions

We account for income taxes in accordance with provisions which set forth an asset and liability approach that requires the recognition of deferred tax assets and deferred tax liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Realization of deferred tax assets in each taxable jurisdiction is dependent on our ability to generate future taxable income sufficient to realize the benefits. Management evaluates deferred tax assets on an ongoing basis and provides valuation allowances to reduce net deferred tax assets to the amount that is more likely than not to be realized.

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, we have established a valuation allowance equal to the net realizable deferred tax assets. Our valuation allowance balances totaled $29.9 million and $22.6 million at December 31, 2018 and 2017, respectively. The valuation allowance increased by $7.3 million in 2018 and increased by $6.4 million in 2017.

As a multinational corporation, we are subject to taxation in many jurisdictions and the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in various taxing jurisdictions. In accordance with ASC 740, *Income Taxes*, we recognize the tax effects of an income tax position only if they are “more-likely-than-not” to be sustained based solely on the technical merits as of the reporting date. If we ultimately determine that the payment of these liabilities will be unnecessary, we will reverse the liability and recognize a tax benefit in the period in which we determine the liability no longer applies. Conversely, we record additional tax charges in a period in which we determine that a recorded tax liability is less than we expect the ultimate assessment to be. The company has not recorded any uncertain tax positions for the years ended December 31, 2018 and December 31, 2017.

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 we 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. We do not believe that such an ownership change has occurred in 2018 and 2017.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act"), was signed into legislation. As a result of the lower enacted corporate tax rate, we have remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The amount recorded at December 31, 2017 related to the remeasurement of our deferred tax balance was $11.8 million, that was fully offset by a corresponding decrease to the valuation allowance.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118"), was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, we have provisionally determined that there is no tax deferred tax benefit or expense with respect to the remeasurement of certain deferred tax assets and liabilities due to the full valuation allowance against net deferred tax assets. The Company analyzed certain aspects of the Act further and refined its calculations during 2018. The Company has completed their analysis of the impact of the Tax Act at December 31, 2018 and has incorporated it into the current year provision. The most significant impact as a result of the Act, beginning in tax year 2018, is the limitation placed on the deductibility of interest expense.

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; ability to attract and retain key personnel; and pending litigation.

Management's evaluation of going concern was conducted as part of the multiple discussions with the review by the Board of Directors of our 2019 Annual Operating Plan. The Company and OrbiMed have entered into a Second Amended and Restated Credit Agreement and commitment for up to an additional $10 million in debt capital. Management believes these actions, along with the $16.7 million of cash and accounts receivable on the balance sheet as of December 31, 2018, will enable the Company to continue as a going concern through the end of March 2020.

Although we recently increased availability under our Second Amended and Restated Credit Agreement we still believe we may require additional funds to fund our future operations and business strategy. 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 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

The following items are included herein:

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

Xtant Medical Holdings, Inc.

Belgrade, Montana

OPINIONS ON THE CONSOLIDATED FINANCIAL STATEMENTS

We have audited the accompanying consolidated balance sheet of Xtant Medical Holdings, Inc. (the "Company") as of December 31, 2017, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows, for the year ended December 31, 2017, 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, 2017, and the results of its operations and its cash flows for the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

BASIS FOR OPINION

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

/s/ EKS&H LLLP

April 2, 2018

Denver, Colorado

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Xtant Medical Holdings, Inc. (the “Company”) as of December 31, 2018, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year ended December 31, 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, 2018, and the results of its operations and its cash flows for the year ended December 31, 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Plante & Moran, PLLC

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

Denver, Colorado

April 1, 2019

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XTANT MEDICAL HOLDINGS, INC.

Consolidated Statements of Operations

(In thousands, except number of shares and per share amounts)

	Year Ended December 31,	
	2018	2017
Revenue		
Orthopedic product sales	$71,814	$82,513
Other revenue	389	99
Total Revenue	72,203	82,612
Cost of Sales	28,717	32,511
Gross Profit	43,486	50,101
Operating Expenses		
General and administrative	12,881	15,246
Sales and marketing	32,059	40,511
Research and development	1,702	2,441
Depreciation and amortization	4,118	5,485
Impairment of goodwill and intangible assets	48,146	17,586
Restructuring expenses	2,970	4,680
Separation related expenses	1,568	1,901
Non-cash consulting expense	120	85
Total Operating Expenses	103,564	87,935
Loss from Operations	(60,078)	(37,834)
Other Income (Expense)		
Interest expense	(10,145)	(14,705)
Change in warrant derivative liability	121	203
Other income (expense)	3	(75)
Total Other Expense	(10,021)	(14,577)
Net Loss from Operations Before Provision for Income Taxes	(70,099)	(52,411)
Provision for Income Taxes		
Current and Deferred	-	-
Net Loss	$(70,099)	$(52,411)
Net loss per share:		

Basic	$(5.97)	$(34.76)
Dilutive	$(5.97)	$(34.76)
Shares used in the computation:		
Basic	11,740,550	1,507,769
Dilutive	11,740,550	1,507,769

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, 2018	As of December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,797	$ 2,856
Trade accounts receivable, net of allowance for doubtful accounts of $2,140 and $2,135, respectively	9,990	12,714
Inventories, net	17,301	22,423
Prepaid and other current assets	589	1,706
Total current assets	34,677	39,699
Property and equipment, net	7,174	9,913
Goodwill	3,205	41,535
Intangible assets, net	573	13,826
Other assets	793	732
Total Assets	$ 46,422	$ 105,705
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 6,465	$ 9,316
Accounts payable - related party	-	160
Accrued liabilities	5,150	15,845
Warrant derivative liability	10	131
Current portion of capital lease obligations	426	366
Total current liabilities	12,051	25,818
Long-term Liabilities:		
Capital lease obligation, less current portion	204	624
Long-term convertible debt, less issuance costs	-	70,853
Long-term debt, less issuance costs	77,939	67,109
Total Liabilities	90	