Xtant Medical Holdings, Inc.
Form 10-K
April 02, 2018

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, 2017

or

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

For the transition period from _____ to _____

Commission file number: 001-34951

Xtant Medical Holdings, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	20-5313323
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
664 Cruiser Lane Belgrade, Montana	59714
(Address of Principal Executive Offices)	(Zip Code)

(406) 388-0480
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	**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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. x

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," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer ¨
Non-accelerated filer ¨ Smaller reporting company x
(Do not check if a smaller reporting company)

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, 2017 was $5,163,275 (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 April 2, 2018 was 13,077,468.

DOCUMENTS INCORPORATED BY REFERENCE

None

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PART I

Item 1. Business

Overview of Our Business

Xtant Medical Holdings, Inc. develops, manufactures and markets regenerative medicine products and medical devices for domestic and international markets. Xtant 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, tissue grafts for the treatment of orthopedic disorders, and biologics to promote healing following cranial, and foot and ankle surgeries.

Xtant believes the following competitive strengths will be key drivers of future growth of Xtant:

Portfolio of Proprietary Technologies: Xtant has developed 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, Xtant maintains and continues to grow its intellectual property portfolio, with over 100 issued patents globally and over 40 patent applications pending.

Customer Focus: Responding quickly and efficiently to the needs of patients, surgeons and hospitals is central to corporate culture and critical to success. Our supply chain and customer service teams make sure that the right product and instrumentation is in the right place at the right time. Through such vertically integrated processes, we are able to meet the changing needs of our customers.

Multi-channel Distribution Network: Xtant has built a hybrid sales and distribution function calling on Orthopedic Surgeons, Neuro Surgeons, their staff and the hospital administrators that support them. Approximately 420 field agents and distributors in the United States represent some or all of Xtant's products. The distribution channel consists of multiple sub-channels including direct sales, consignment agents, reseller distributors, and private label distributors and technology licensees.

Our Offices

Our headquarter office and manufacturing facility are located at 664 Cruiser Lane, Belgrade, Montana 59714. Our telephone number is (406) 388-0480 and our fax number is (406) 388-1354. 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, one Colorado office located at 363 Centennial Parkway, Suite 220, Louisville, Colorado 80027, and one Ohio office at 452 Alexandersville Road, Miamisburg, Ohio 45342. All our properties are leased.

Our History

We began operations in 1998 as a spin out of the Center for Biofilm Engineering at Montana State University, or the CBE, and we eventually incorporated as “Bacterin, Inc.” in the state of Montana in January 2000. We began as a biomaterial testing laboratory and systematically expanded our strategic vision towards the development of Bacterin-labeled products. Our revenues were initially derived from testing services and milestone payments under collaborative product development agreements with various medical manufacturers.

In March 2004, Bacterin, Inc.’s stockholders entered into a share exchange agreement with a company called Oil & Gas Seekers, Inc., a Nevada corporation (“OGS”) which subsequently changed its name to “Bacterin International, Inc.,” to effectively become a publicly-traded corporation. As a result of this transaction, the stockholders of Bacterin, Inc., the Montana corporation, became stockholders of Bacterin International, Inc., the Nevada corporation, and Bacterin, Inc., became a wholly owned subsidiary of Bacterin International, Inc. At the end of 2004, we concluded this transaction was problematic and did not deliver the expected result. Based on this determination, we entered into an agreement in 2005 to amend the terms of the exchange transaction with the former majority stockholder of OGS. In May 2005, we merged Bacterin, Inc., the Montana corporation, up and into Bacterin International, Inc., the Nevada corporation.

On June 30, 2010, Bacterin International, Inc. merged with and into a wholly-owned Nevada subsidiary of Bacterin International Holdings, Inc. f/k/a K-Kitz Incorporated, a Delaware corporation, and as a result, Bacterin International, Inc. ("Bacterin") became a wholly owned subsidiary of the Company. Before this reverse merger, Bacterin International Holdings, Inc. was known as K-Kitz, Incorporated, with a trading symbol of KKTZ.OB. On June 29, 2010, K-Kitz Incorporated changed its corporate name to "Bacterin International Holdings, Inc." which name change became effective for trading purposes on July 1, 2010, following the reverse merger transaction. Effective July 21, 2010, our trading symbol was changed from KKTZ.OB to BIHI.OB. On March 7, 2011, our common stock began trading on the NYSE Amex, which is 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.

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".

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. Bone is a biologically active tissue and may or may not regenerate depending on the condition of the patient. The damage may be significant enough that a scaffold may be necessary to help regenerate the surgical 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.

CRO Agreement

On May 8, 2017, the Company entered into an agreement (the "CRO Agreement") with Aurora Management Partners Inc. ("Aurora"). Pursuant to the CRO Agreement, David Baker serves as Chief Restructuring Officer of the Company (the "CRO"). The CRO and Aurora personnel, referred to as Deputy Restructuring officers, assisting on this engagement report to the special restructuring committee of the board of directors of the Company and provide periodic updates on progress made in fulfilling the scope of services. The term of the agreement will continue until the engagement is completed or earlier if the engagement is terminated by either party. Aurora is paid the hourly rates set forth on Schedule A to the CRO Agreement and is reimbursed for its expenses actually incurred in providing the services. The CRO Agreement may be terminated by either party, in its sole discretion, for any reason and the termination is effective immediately upon the other party's receipt of written notice of the termination.

Products and Services

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 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 can 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 combining the exceptional cohesive characteristics of OsteoSelect DBM Putty with demineralized cortical chunks. OsteoSelect PLUS delivers differentiated handling properties and insures 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 the Company's 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.

The Company's 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.

In the fixation portfolio, there are numerous product families that are used to treat a variety of spinal and sacroiliac conditions, including trauma, degeneration, deformity and tumor, with an emphasis on Minimally Invasive Surgery (MIS). Some of our key product lines include:

- The Axle® Interspinous Fusion System is a fully modular interspinous device is matched to the patient's individual anatomy and is, available in multiple implantable configurations.

- The Silex® Sacroiliac Joint Fusion System is a sacroiliac fixation system which actively compresses across the SI joint. Sacroiliac dysfunction is increasingly recognized as a frequent contributor to chronic low back pain.

- The Xpress™ Minimally Invasive Pedicle Screw System combines minimally invasive functionality to the most common lumbar fixation procedures — pedicle screw fixation.

- The Certex™ Spinal Fixation System consists of screws, hooks, rods, and cross connectors. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patient anatomy. It is intended to promote fusion of the subaxial cervical spine and cervico-thoracic junction (C3 – T3 inclusive).

- 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.

- Spider® Cervical Plating System. 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.

- 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.

- The Irix-A™ Lumbar Integrated Fusion System consists of an integrated titanium ring, surrounded by an outer PEEK ring and three screws. It is intended for spinal fusion procedures at one or two contiguous levels of the lumbosacral spine (L2 – S1 inclusive) in skeletally mature patients for the treatment of degenerative disc disease.

- The Irix-C™ Cervical Integrated Fusion System consists of an integrated titanium ring, surrounded by an outer PEEK ring and two screws. It is intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for the treatment of degenerative disc disease.

- The Axle-X™ Interspinous Fusion System is an internal fixation device for spinal surgery in the non-cervical spine (T1 – S1 inclusive). It is a minimally invasive, modular interspinous fusion system with angled spikes that allows for adequate L5 – S1 engagement and other variations in patient anatomy. The Axle-X Interspinous Fusion System is designed to provide spinal stability for lumbar fusion procedures, including the treatment of degenerative disc

disease, spinal tumors and trauma.

Technology and Intellectual Property

Patents, trademarks and other proprietary rights are very important to our business. We also rely upon trade secrets, manufacturing know-how, continuing technological innovations and licensing opportunities 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 biomaterial patent efforts are focused on the development of innovative and novel, engineered tissue implants or constructs which employ acellular tissue and processes, and enhanced demineralized bone matrix products. On November 5, 2013, the United States ("U.S.") Patent and Trademark Office issued U.S. Patent No. 8,574,825 entitled "Process for Demineralization of Bone Matrix with Preservation of Natural Growth Factors." The issued claims in the patent are for a method to produce a demineralized cancellous bone matrix, such as Bacterin's OsteoSponge® product line. The Company has a pending divisional application in the United States to pursue protection of other aspects of its bone demineralization technology. We have other provisional applications pending in the United States and other countries that relate to aspects of the technology used in many of our products. 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.

The fixation product portfolio includes over 50 issued patents globally and over 30 patent applications pending. In addition to current product offerings, Xtant continues to invest in the research and development necessary to design, develop and commercialize new surgical solutions for unmet clinical needs.

We believe our patent filings and patent position will facilitate growth and enhance our proprietary core competencies. 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 promote our product in the United States through a hybrid distribution network including direct employees, sales agents and independent distributors.

Our international footprint includes distribution partners in Canada, Mexico, South America, Europe, Middle East, Australia, South Korea, and Taiwan. Xtant continues to evaluate new, global market opportunities and expects to expand the number of international markets served.

Growth Strategy

In an effort to capitalize on our core markets, as well as new market opportunities, we have diversified our supply of donor tissue, expanded our processing capabilities and are further developing a hybrid sales force. We have focused our United States sales activities on Orthopedic Surgeons and Neuro Surgeons performing spine procedures, and development of strategic distribution relationships.

We are pursuing a high-level, national effort to present our products as a value proposition to hospital systems and other purchasing organizations. To this end, we have entered into agreements with Banner Hospitals, Dignity Health, OhioHealth, Franciscan Health System, the Hospital for Special Surgery, Beaumont Health, Providence, Sutter, Community Health Services, Sharp Healthcare, Franciscan Alliance, Pinnacle Health Systems, Proliance Surgeons, Baptist Health South Florida, MedAssets, Novation, Premier, ROi, Health Trust Purchasing Group, Scripps and Bon Secours among others. These agreements are paving the way for our sales representatives to call on additional physicians, as the hospital process has already been approved.

Competition

There are various public and private organizations that offer both, fixation and orthobiologics to their customers. With the growing market, and ongoing pressures to expand and make product portfolios more robust, we expect several new products and new companies will emerge over the coming years. We consider our direct competitors to be orthopedic companies that offer both spinal fixation and biologics, such as NuVasive, RTI Surgical, SeaSpine, Medtronic, OrthoFix, Stryker, Alphatec, Zimmer Biomet, DePuy/Synthes, Medtronic, K2 Medical, and Globus Medical. We also compete with some hardware companies that do not currently market a biologic, such as LDR Holding Company, and tissue banks that do not specialize in spinal fixation materials, such as AlloSource, Lifenet Health, and MTF.

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 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.

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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.

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, recently enacted 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 13485:2003 certification, an organization must demonstrate its ability to provide medical devices that consistently meet applicable customer and regulatory requirements. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. All requirements of ISO 13485:2003 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 13485:2003 certification offers new markets and business opportunities for our products in the global marketplace.

Employees

As of March 19, 2018, Xtant had 174 employees, of whom 62 were in operations, 48 were in sales, 7 were in marketing, 11 were in R&D and Engineering, 21 were in QA/QC, 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.

Facilities

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 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 a 21,000 square foot facility at 732 Cruiser Lane, Belgrade, Montana 59714, where one Class 1,000 (ISO 6) clean room is located.

We lease additional office space of approximately 3,000 square feet located at 363 Centennial Parkway, Suite 220, Louisville, Colorado 80027.

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. The Company intends to sublease or assign the facility for the duration of the lease period.

ITEM 1A. RISK FACTORS

Our business and an investment in our securities 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 securities. 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.

Trends, Risks and Uncertainties Related to Our Business

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 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. Fluctuations in the trading price or liquidity of our common stock may harm the value of your investment in our securities. Factors that may have a significant impact on the market price and marketability of our securities include:

- our ability to make interest payments under our Amended and Restated Credit Agreement;
- our observance of covenants under our Amended and Restated Credit Agreement;
- our quarterly operating results;
- announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with employees, suppliers or collaborative partners;

- acquisitions or divestitures;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling;
- changes in health care policies and practices;
- 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.

Many competitive products exist and more will be developed, and we may not be able to successfully compete because we are smaller and have fewer financial resources.

Our business is in a very competitive and evolving field. Rapid new developments in this field have occurred and are expected to continue to occur. Other companies already have competing products available or may develop products to compete with ours. Many of these products have short regulatory timeframes and our competitors, many with more substantial development resources, may be able to develop competing products that are equal to or better than ours. This may make our products obsolete or undesirable by comparison and reduce our revenue. Our success will depend, in large part, on our ability to maintain a competitive position concerning our intellectual property, and to develop new technologies and new applications for our technologies. Many of our competitors have substantially greater financial and technical resources, as well as greater production and marketing capabilities, and our ability to compete remains uncertain.

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 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.

We are not currently profitable.

We have substantial operating expenses associated with the sales and marketing of our products. The sales and marketing expenses are anticipated to be funded from operating cash flow. There can be no assurance that we will have sufficient access to liquidity or cash flow to meet our operating expenses and other obligations. If we do not increase our revenue or reduce our expenses, we may need to raise additional capital, which would result in dilution to our stockholders, or seek additional loans. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. 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.

We may not be able to raise capital or, if we can, it may not be on favorable terms. We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructuring, bank borrowing or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. If adequate funds are not otherwise available, we would be forced to curtail operations significantly, including reducing our sales and marketing expenses which could negatively impact product sales and we could even be forced to cease operations, liquidate our assets and possibly even seek bankruptcy protection.

Loss of key members of our management whom we need to succeed could adversely affect our business.

We are highly dependent on the services of key members of our management team, and the loss of any of their services could have an adverse effect on our future operations. We do not currently maintain key-man life insurance policies insuring the life of any member of our management team.

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, reducing profitability.

Our revenues will 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 in the United States to fundamental change. The ability of hospitals to pay fees for allograft bone tissue 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 in the procedures in which they are employed. Because there is often no separate reimbursement for our products, the additional cost associated with the use of our products can impact the profit margin of the hospital or other health care facility where the surgery is performed. Some of our target customers may be unwilling to purchase our products if they are able to procure less expensive alternatives. In addition, major third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies, 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.

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

We may incur material liabilities relating to product liability claims, including product liability claims arising out of the use of our products. 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 intend to vigorously defend any existing or future litigation that we may be involved in but 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.

Failure of our information technology systems could disrupt our business.

Our operations depend on the continued performance of our information technology systems. Despite security measures and other precautions, we have taken, our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Sustained failure of our information technology systems could disrupt our business operations. In addition, some of our contracts impose obligations related to information we may have in physical or electronic formats, and any breach or failure of our information technology systems could result in breach of contract claims and other damages.

Failure to protect our intellectual property rights could result in costly and time-consuming litigation and our loss of any potential competitive advantage.

Our success will depend, to a large extent, on our ability to successfully obtain and maintain patents, prevent misappropriation or infringement of intellectual property, maintain trade secret protection, and conduct operations without violating or infringing on the intellectual property rights of third parties. There can be no assurance that our patented and patent-pending technologies will provide us with a competitive advantage, that we will be able to develop or acquire additional technology that is patentable, or that third parties will not develop and offer technologies which are similar to ours. Moreover, we can provide no assurance that confidentiality agreements, trade secrecy agreements or similar agreements intended to protect unpatented technology will provide the intended protection. Intellectual property litigation is extremely expensive and time-consuming, and it is often difficult, if not impossible, to predict the outcome of such litigation. A failure by us to protect our intellectual property could have a materially adverse effect on our business and operating results and our ability to successfully compete in this industry.

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 and successfully defending these patents against third-party challenges. 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 pharmaceutical 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.

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. There can be no assurance that we will prevail in any claims we make to protect our intellectual property.

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;
- 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.

Our success depends on our ability to avoid infringing on the intellectual property rights of third parties, which could expose us to litigation or commercially unfavorable licensing arrangements.

Our commercial success depends in part on our ability and the ability of our collaborators to avoid infringing patents and proprietary rights of third parties. Third parties may accuse us or our collaborators of employing their proprietary

technology in our products, or in the materials or processes used to research or develop our products, without authorization. Any legal action against our collaborators or us claiming damages and/or seeking to stop our commercial activities relating to the affected products, materials and processes could, in addition to subjecting us to potential liability for damages, require our collaborators or us to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. We cannot predict whether we or our collaborators would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If we are unable to obtain such a license, we or our collaborators may be unable to continue to utilize the affected materials or processes or manufacture or market the affected products or we may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if we are able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair our prospects for profitability. Accordingly, we cannot predict whether or to what extent the commercial value of the affected product or products or our prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from our core business. We may be unable to obtain and enforce intellectual property rights to adequately protect our products and related intellectual property.

Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have a significant adverse effect on our prospects.

A third-party may claim an ownership interest in our intellectual property. While we believe we own 100% of the right, title and interest in the patents for which we have applied and our other intellectual property, including that which we license from third parties, we cannot guarantee that a third-party will not, at some time, assert a claim or an interest in any of such patents or intellectual property. A successful challenge or claim by a third party to our patents or intellectual property could have a significant adverse effect on our prospects.

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 (the "Code"), imposes restrictions on the use of a corporation's net operating losses, as well as certain recognized built-in losses and 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 notes that has resulted 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 a ruling from the IRS or 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) and the applicable federal long-term tax-exempt interest rate for the month of the "ownership change."

Except as provided below with respect to net operating carryforwards for losses arising in taxable years beginning after December 31, 2017, the net operating losses generally may be carried forward for up to 20 years, the annual limitation may effectively provide a cap on the cumulative amount of pre-ownership change losses, including certain recognized built-in losses that may be utilized. 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 and United States federal income taxes to be paid earlier than otherwise would be paid if such limitations were not in effect. Further, if for financial reporting purposes the amount or value of these deferred tax assets is may be reduced as a result of the Section 382 limitation. Such reduction could negatively impact the book value of our common stock could result in 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 limitations may be carried forward.

Our ability to deduct interest is limited.

Under the TCJA, 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 by our corporate subsidiaries and treated as business interest paid or accrued in the succeeding taxable year. In addition, the interest paid or incurred with respect to our notes is not deductible.

We may not be able to meet financial or other covenant requirements in our credit facility, and we may not be able to successfully negotiate waivers to cure any covenant violations.

Our credit facility with affiliates of OrbiMed contains representations, warranties, fees, affirmative and negative covenants, including a minimum cash balance, minimum levels of EBITDA, a leverage ratio, and default provisions, which include departures in key management, if not remedied within 90 days. A breach of any of these covenants could result in a default under this agreement. Upon the occurrence of an event of default under our credit facility, our lender could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If our lender accelerates the repayment of borrowings, we may not have sufficient assets to repay our indebtedness. Also, should there be an event of default, or should we need to obtain waivers following an event of default, we may be subject to higher borrowing costs and/or more restrictive covenants in future periods. In addition, to secure the performance of our obligations under the credit facility, we pledged substantially all of our assets, including our intellectual property, to affiliates of OrbiMed. Our failure to comply with the covenants under the credit facility could result in an event of default, the acceleration of our debt and the loss of our assets.

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

We conduct substantially all of our activities through our subsidiaries. We may depend on those subsidiaries for dividends and other payments to generate the funds necessary to meet our financial obligations, including the payment of principal and interest on notes. 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 principal or interest on notes when due.

Breaches in the security of our technology systems and the data we store could compromise proprietary business processes and employee information, exposing the company to liability, causing an adverse effect on our business.

As a general practice of our business operations, we collect and store sensitive data, including personal information of our employees and information of independent sales distributors. The secure operation of the networks and systems on which this type of information is stored, processed and maintained is critical to our business operations and strategy.

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

Following the Restructuring, 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 a single stockholder, OrbiMed Advisors LLC. As a "controlled company," we are exempt from certain NYSE American rules requiring a board of directors with 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.

Going forward, we plan to rely on NYSE American's controlled company exemptions and do not plan to have a majority independent Board, an independent nomination and governance committee or an independent compensation committee. Consequently, following the consummation of the Restructuring, we disbanded the Compensation and Nominations and Corporate Governance committees of the Board. Accordingly, you will not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the NYSE American.

Trends, Risks and Uncertainties Relating to Our Common Stock

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

Shares of our common stock are common equity interests. This means that our common stock will rank junior to any outstanding shares of our preferred stock that we may issue in the future or to our current credit facility 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.

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 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 our board of directors. Our 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.

Trends, Risks and Uncertainties Related to Federal Regulations

The impact of United States healthcare reform legislation remains uncertain.

In 2010, federal legislation, the Patient Protection and Affordable Care Act, "PPACA" was enacted into law to reform the United States healthcare system. Certain aspects of the law were upheld by a Supreme Court decision announced in June 2012 and in June 2015. PPACA is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the PPACA imposes a 2.3 percent excise tax on medical devices, which applies to United States sales of our medical device products, including our OsteoSelect® DBM putty. Due to multi-year pricing agreements and competitive pricing pressure in our industry, there can be no assurance that we will be able to pass the cost of the device tax on to our customers. Other provisions of the law, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered. We cannot predict the impact of this legislation or other healthcare programs and regulations that may ultimately be implemented at the federal or state level, the effect of any future legislation or regulation in the United States or internationally or whether any changes will have the effect of lowering prices for our products or reducing medical procedure volumes. It is important to note that H.R. 195 (Pub. L. 115-120), signed into law on January 22, 2018, extends for an additional two years the moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Because of the moratorium, the medical device excise tax does not apply to the sale of taxable medical devices by the manufacturer, producer or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2019.

We cannot predict the impact of other healthcare programs and regulations that may ultimately be implemented at the federal or state level, the effect of any future legislation or regulation in the United States or internationally or whether any changes will have the effect of lowering prices for our products or reducing medical procedure volumes.

The sale of our products is subject to regulatory clearances or approvals and our business is subject to extensive regulatory requirements. 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 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 (the "FDCA"), a de novo approval or a Premarket Approval ("PMA"), from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that the proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device. To establish substantial equivalence which allows the device to be marketed, the applicant must demonstrate the device has the: (i) the same intended use; (ii) the same technological characteristics; and (iii) to the extent the technological characteristic are different, that they do not raise different questions of safety and effectiveness. Clinical data are sometimes required to support substantial equivalence, but FDA's expectations for data are often unclear and do change. Another procedure for obtaining marketing authorization for a medical device is the "de novo classification" procedure, pursuant to which FDA may authorize the marketing of a moderate to low risk device that has no predicate. These submissions typically require more information (i.e. non-clinical and/or clinical performance data) and take longer than a 510(k), but require less data and a shorter time period than a PMA. If the FDA grants the de novo request, the device is permitted to enter commercial distribution in the same manner as if 510(k) clearance had been granted, and the device becomes a 510(k) predicate for future devices seeking to call it a "predicate." The PMA pathway requires an applicant to demonstrate reasonable assurance of safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. 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. The 510(k), de novo and PMA processes can be expensive, lengthy and sometimes unpredictable. The processes also entail significant user fees, unless exempt. The FDA's 510(k) clearance process usually takes from six to 18 months, but may take longer if more data are needed. The de novo process can take one to two years or longer if additional data are needed. The PMA pathway is much more costly and uncertain than the 510(k) clearance process and it generally takes from one to five years, or even longer, from the time the application is filed with the FDA until an approval is obtained. 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. 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. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain de novo or PMA processes. Although we do not currently market any devices under PMA and have not gone through the de novo classification for marketing clearance, we cannot assure you that the FDA will not demand that we obtain a PMA 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" 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, 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.

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. Additionally, the FDA and other governmental authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could lead governmental authorities or a court to take action against us, including but not limited to:

- issuing untitled (notice of violation) letters or public warning letters to us;

- imposing fines and penalties on us;

- obtaining an injunction or administrative detention preventing us from manufacturing or selling our products;
- seizing products to prevent sale or transport or export;
- bringing civil or criminal charges against us;
- recalling our products or engaging in a product correction;
- detaining our products at U.S. Customs;
- delaying the introduction of our products into the market;
- delaying pending requests for clearance or approval of new uses or modifications to our existing products; and/or
- withdrawing or denying either approvals or clearances for our products.

If we fail to obtain and maintain regulatory clearances or approvals, our ability to sell our products and generate revenue will be materially harmed.

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. 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. Many of these industry standards 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 U.S. Federal Food, Drug and Cosmetic Act, 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;

- 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 laws have "safe harbors" which allow for certain activities that appear to fall within the scope of the statute to be considered lawful and safe harbored activities. 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 (the "OIG") of the Department of Health and Human Services. This includes, 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 terms of the safe harbor. The same is true for the retention of consultants. Any remuneration paid to a physician acting as a consultant technically meets the definition of remuneration, but is not considered illegal remuneration if it is paid following the provisions of the "Personal Services" 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. 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.

Failure to comply with the U.S. Foreign Corrupt Practices Act could subject us to, among other things, penalties and legal expenses that could harm our reputation and have a material adverse effect on our business, financial condition and operating results.

Our United States operations, including those of our United States operating subsidiaries, are subject to the U.S. Foreign Corrupt Practices Act. 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. We either operate or plan to operate in a number of jurisdictions that pose a high risk of potential violations of the FCPA and other anticorruption laws, such as China and Brazil, and we utilize a number of third-party sales representatives for whose actions we could be held liable under the FCPA. We inform our personnel and third-party sales representatives of the requirements of the FCPA and other anticorruption laws, including, but not limited to their reporting requirements. We also have developed and will continue to develop and implement systems for formalizing contracting processes, performing due diligence on agents and improving our recordkeeping and auditing practices regarding these regulations. However, there is no guarantee that our employees, third-party sales representatives or other agents have not or will not engage in conduct undetected by our processes and for which we might be held responsible under the FCPA or other anticorruption laws.

If our employees, third-party sales representatives or other agents are found to have engaged in such practices, we could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions. During the past few years, the SEC has increased its enforcement of violations of the FCPA against companies, including several medical device companies. Although we do not believe we are currently a target, any investigation of any potential violations of the FCPA or other anticorruption laws by United States or foreign authorities also could have an adverse impact on our business, financial condition and operating results.

Certain foreign companies, including some of our competitors, are not subject to prohibitions as strict as those under the FCPA or, even if subjected to strict prohibitions, such prohibitions may be laxly enforced in practice. If our competitors engage in corruption, extortion, bribery, pay-offs, theft or other fraudulent practices, they may receive preferential treatment from personnel of some companies, giving our competitors an advantage in securing business, or from government officials, who might give them priority in obtaining new licenses, which would put us at a disadvantage.

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.

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 products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Certain of our products are regulated as medical devices by the FDA while others are regulated by the FDA as tissues. 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. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA, unless the device is specifically exempt from those requirements.

The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to a legally marketed device that is not subject to the PMA process, which includes devices that were legally marketed prior to May 28, 1976 (“pre-amendments devices”) for which the FDA has not called for a PMA, devices that have been reclassified from Class III to Class II or Class I, or devices that have been found substantially equivalent through the 510(k) process. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA’s satisfaction the safety and efficacy of the device for its intended use.

Our failure to comply with United States Federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

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). 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.

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.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances, premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are 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. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. 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.

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 efficacy, or that would constitute a major change in its intended use, technology, materials, packaging and certain manufacturing processes, may require a new 510(k) clearance, a de novo, or possibly a PMA. Modifications to our products that have not properly followed FDA regulations and that require new regulatory clearances or approvals, may require us to recall or cease marketing the modified devices until these clearances or approvals are 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 "significantly affects 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 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 are usually conducted every two years. 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 and 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 or a PMA. The issue of whether a product modification is significant enough to require a 510(k), as opposed to a simple "letter-to-file" documenting the change, is in a state of flux. In 1997, FDA issued guidance to address this issue and it is a guidance document with which the FDA and the industry is very familiar. The FDA released new guidance in October 2017 that is more prescriptive in terms of the thresholds that apply to when a new 510(k) should be submitted. The Company has specifically reviewed the literature and has taken the proper steps to ensure continuing compliance.

If the FDA requires us to cease marketing and recall a modified device until we obtain a new 510(k) clearance 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.

In addition to the concerns stated above if the FDA during a routine inspection of our plant discovers we have made modifications by way of letter-to-file, that the FDA believes should have been cleared with a new 510(k), the FDA can also allege that the Company has failed to file with the FDA a Part 806 failure to report the correction or removal of a medical device in addition to requesting that the modified device on the market be recalled, and that a new 510(k) application must be submitted. In addition, the FDA has recently proposed new draft guidance on reporting "enhancements" to medical devices under Part 806 Reports of Corrections and Removals, the practical effect of which may be to alert the FDA to product modifications on an ongoing basis for which the FDA may require a new 510(k). This guidance had not yet been finalized, but may be soon.

The results of our clinical studies may not support our product candidate claims or may result in the discovery of adverse effects.

Our ongoing research and development, pre-clinical testing and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting post-market clinical studies of some of our products to gather information about these products' performance or optimal use. Additionally, in the future we may conduct clinical studies to support clearance or approval of new products. Clinical studies must be conducted in compliance with FDA regulations and local regulations, and according to principles and standards collectively referred to as "Good Clinical Practices." Non-compliance could result in regulatory and legal enforcement action and also could invalidate the data. Even if our clinical studies are completed as planned, we cannot be certain that their results will support our product candidates and/or proposed claims or that the FDA or foreign authorities and notified bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of the later studies will replicate those of earlier or prior studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patient subjects enrolled in our clinical studies of our marketed products will experience adverse side effects that are not currently part of the product candidate's 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.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Future products may require FDA clearance of a 510(k) or approval of a PMA. In addition, future products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Clinical trials can be long, expensive and ultimately uncertain which could jeopardize our ability to obtain regulatory approval and market our products.

Clinical trials are generally required to support a 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 eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials 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. 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, inclusive or 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 efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States.

Our manufacturing operations require us 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 are required to comply with the FDA's current Good Manufacturing (cGMP) and Quality System Regulations, or QSR, which covers 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 inspection resulted in the issuance of a Form FDA-483 listing four inspectional observations. The failure by us or one of our 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)) or approval (de novo or PMA) of new products or modified products;
- withdrawing 510(k) clearances or PMAs that have already been granted;
- refusal to grant export approval 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, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with the FDA's GMP requirements, known as the QSR, for medical devices, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product. Regulatory bodies, such as the FDA, enforce these and other regulations through periodic inspections. The failure by us or one of our 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 and civil penalties;

· unanticipated expenditures to address or defend such actions;

· customer notifications for repair, replacement, refunds;

· recall, detention or seizure of our products;

· operating restrictions or partial suspension or total shutdown of production;

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refusing or delaying our requests for 510(k) clearance or premarket approval of new medical device products or modified medical device products;

- operating restrictions;
- withdrawing 510(k) clearances or PMA that have already been granted;
- refusal to grant export approval for our products; and/or
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. 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 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, and we must comply with medical device reporting requirements, including the reporting of certain adverse events and malfunctions related to 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 changes to labeling, restrictions on such products or manufacturing processes, withdrawal 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, suspension of regulatory approvals, 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) clearance 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. 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 materials, 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 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.

Further, the advertising and promotion of our products is subject to EEA Member States laws implementing Directive 93/42/EEC concerning Medical Devices, or the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, 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.

In addition, 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. Surgeons also may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. 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, or 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 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.

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, or NCARs. The Medical Device Vigilance System is further intended to facilitate a direct, early and harmonized implementation of Field Safety Corrective Actions, or 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.

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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 the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. 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 classifications of recalls 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.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

Our promotional materials and training methods for physicians must comply with the FDA and other applicable laws and regulations. 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. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training 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 that event, our reputation could be damaged and adoption of the products would be impaired.

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; Good Tissue Practice, or GTP, 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 to recipients. 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 for a homologous use; (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 such an effect, it is intended for autologous use or allogeneic use in close relatives 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 FD&C Act 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 recipients.

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. 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 the Current Good Tissue Practices, 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 effect. 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 NOTA. 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 EU as well, should we enter that market. In the European Union, or EU, 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 EU, 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. For example, in 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-clearance or approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the “Refuse to Accept” guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. 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.

Item 1B. Unresolved Staff Comments

Not applicable.

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.

As of October 2015, we lease a 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.

We also lease space 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 additional office space of approximately 3,000 square feet located at 363 Centennial Parkway, Suite 220, Louisville, Colorado 80027.

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. The Company intends to sublease or assign the facility for the duration of the lease period.

Item 3. Legal Proceedings

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 $972,283. Xtant filed a motion to dismiss on September 15, 2017, and is awaiting the court's ruling. The Company recorded reserves for outstanding net receivables due from Axis and consigned assets in Axis' possession totaling $1,342,049 in the third quarter ended September 30, 2017.

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." From April 9, 2015 until October 19, 2015, our common stock traded on the OTCQX marketplace under the ticker symbol "BONE," and from March 7, 2011 to April 8, 2015, our common stock was listed on the NYSE American under the ticker symbol "BONE." The following table sets forth the range of high and low prices per share of our common stock for each quarter, as reported by the NYSE American (which was previously known as the NYSE MKT) and the OTCQX marketplace, as applicable, for the periods indicated below. Prices have been adjusted to reflect the Company's July 25, 2014 1:10 reverse split and the February 13, 2018 1:12 reverse stock split.

	High	Low
First Quarter 2016 (January 1, 2016 - March 31, 2016)	$45.00	$24.24
Second Quarter 2016 (April 1, 2016 - June 30, 2016)	$32.64	$18.12
Third Quarter 2016 (July 1, 2016 - September 30, 2016)	$24.60	$11.16
Fourth Quarter 2016 (October 1, 2016 - December 31, 2016)	$14.64	$5.40
First Quarter 2017 (January 1, 2017 - March 31, 2017)	$14.16	$3.48
Second Quarter 2017 (April 1, 2017 - June 30, 2017)	$10.56	$4.32
Third Quarter 2017 (July 1, 2017 - September 30, 2017)	$14.52	$7.20
Fourth Quarter 2017 (October 1, 2017 - December 31, 2017)	$10.08	$5.64

Holders of Record

As of March 19, 2018, we had 179 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 amended and restated credit agreement precludes us from paying dividends.

Recent Sales of Unregistered (and Registered) Securities

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 6. Selected Financial Data

Not required.

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

Safe Harbor Declaration

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 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 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;

- our ability to pay dividends; and

- our ability to issue preferred stock.

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 our 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.

Comparison of Year Ended December 31, 2017 and December 31, 2016

	Year Ended December 31, 2017		2016	
	Amount	% of Revenue	Amount	% of Revenue
Revenue				
Orthopedic product sales	$82,513,128	99.9 %	$89,388,145	99.3 %
Other revenue	98,973	0.1 %	614,591	0.7 %
Total Revenue’	82,612,101	100.0 %	90,002,736	100.0 %
Cost of Sales	32,511,120	39.4 %	27,710,014	30.8 %
Gross Profit	50,100,981	60.8 %	62,292,722	69.2 %
Operating Expenses				
General and administrative	15,245,926	18.6 %	15,762,531	17.5 %
Sales and marketing	40,511,434	49.0 %	44,055,813	48.9 %
Research and development	2,441,062	3.0 %	3,410,600	3.8 %
Depreciation and amortization	5,485,280	6.6 %	4,940,955	5.5 %
Acquisition and integration related expenses	-	0.0 %	1,401,366	1.6 %
Impairment intangible assets	17,586,071	21.3 %	-	0.0 %
Restructuring expenses	4,679,645	5.7 %	-	0.0 %
Separation related expenses	1,901,187	2.3 %	-	0.0 %
Non-cash consulting expenses	84,697	0.1 %	266,721	0.3 %
Total Operating Expenses	87,935,302	106.4 %	69,837,986	77.6 %
Loss from Operations	(37,834,321)	(45.8)%	(7,545,264)	(8.4)%
Other Income (Expense)				
Interest expense	(14,704,751)	(17.8)%	(12,262,750)	(13.6)%
Change in warrant derivative liability	202,519	0.2 %	716,738	0.8 %
Other income (expense)	(74,709)	(5.6)%	(351,914)	(0.4)%
Total Other Income (Expense)	(14,576,941)	(17.6)%	(11,897,926)	(13.2)%
Net Loss from Operations Before (Provision) Benefit for Income Taxes	(52,411,262)	(63.4)%	(19,443,190)	(21.6)%
Benefit (Provision) for Income Taxes				
Current and Deferred	-	0.0 %	(50,362)	(0.1)%
Net Loss	$(52,411,262)	(63.4)%	$(19,493,552)	(21.7)%

Revenue

Total revenue for the year ended December 31, 2017 decreased 8.2% to $82,612,101 compared to $90,002,736 in the prior year. The decrease of $7,390,635 is primarily due to lower fixation revenue as a result of changes to our sales channels to eliminate unprofitable distributor relationships with high commission rate structures, the highly competitive environment in the fixation sector and no new fixation product introductions in 2017, offset by above-market growth in biologics revenue.

Cost of sales

Costs of sales consist primarily of manufacturing and product purchase costs and depreciation of surgical trays. Cost of sales increased by 17.3% or $4,801,106 to $32,511,120 for the year ended December 31, 2017 from $27,710,014 for the year ended December 31, 2016. Cost of sales as a percent of total sales was 39.4% of revenues for the year ended December 31, 2017, compared to 30.8% in the prior year. Cost of sales includes an increase in reserves for estimated excess inventory, inventory on consignment that may be missing and not returned, and impairment charges for estimated missing and damaged consigned surgical instruments of $4,044,347 in 2017. In addition, additional inventory reserves and surgical instrument impairment of $927,875 was recorded in 2017 related to litigation with a distributor. Excluding the additional reserves recorded in 2017, Cost of sales as a percent of total sales is 33.8% which is 3.0% higher than 2016 due to the change in sales mix towards biologics which have higher Cost of sales than fixation.

Operating Expenses

Operating expenses include general and administrative expenses, sales and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 25.9%, or $18,097,316 for the year ended December 31, 2017, compared to the year ended December 31, 2016, primarily due to the reasons set forth below.

General and Administrative

General and administrative expenses consist principally of personnel costs for corporate employees, cash based and stock option compensation related costs and corporate expenses for legal, accounting and other professional fees as well as occupancy costs. General and administrative expenses decreased 3.3%, or $516,605 to $15,245,926 for the year ended December 31, 2017, compared to the same period of 2016. The Company reduced its rent and office expenses by $1.5 million as it relocated and closed one office and distribution location as announced on October 6, 2017. Offsetting these reductions was write-off totaling $414,174 in 2017 related to litigation with a distributor.

Sales and Marketing

Sales and marketing expenses primarily consist 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 8.0%, or $3,544,379, to $40,511,434 for the year ended December 31, 2017, compared to $44,055,813 for the same period of 2016. As a percentage of revenue, sales and marketing expenses were 49.0% in 2017 as the 48.9% in the prior year. Reductions in personnel and related travel costs were approximately $2.7 million offset by an increase in commission expense of approximately $1.3 million.

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 $969,538 or 28.4% from $3,410,600 for the year ended December 31, 2016 to $2,441,062 for the same period of 2017. The decrease is primarily due to a reduction in royalty expense of $0.3 million, reduction in personnel of $0.2 million and other research related costs of $0.5 million.

Depreciation and Amortization

Depreciation and amortization expense consists of depreciation and amortization of long-lived intangible assets, patents, leasehold improvements and equipment. Depreciation and amortization expense increased $544,325 to $5,485,280 for the year ended December 31, 2017, from $4,940,955 for the same period in 2016 primarily due to surgical instrument purchases in 2016.

Acquisition and Integration Related Expenses

There were no acquisition and integration related expenses for the year ended December 31, 2017 and $1,401,366 for the same period in 2016. Acquisition related expenses consisted of investment banking, accounting, consulting, legal fees and miscellaneous expenses associated with the due diligence and execution of the 2015 X-spine acquisition. 2016 integration related expenses consist of samples, travel, retention bonuses and software.

Impairment Intangible Assets

The Company recorded an impairment charge in 2017 of $14,910,083 related to Technology and $2,675,988 related to Tradename 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.

Separation Related Expenses

Separation related expenses are $1,901,187 for the year ended December 31, 2017 with no expense incurred during the same period in 2016. The expense consists of those items related to reductions in personnel as part of the restructuring of the Company and closure of our Dayton facility.

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 decreased $182,024 to $84,697 for the year ended December 31, 2017, from $266,721 for the same period in the prior year.

Interest Expense

Interest expense is related to interest incurred from our debt instruments. Interest expense for the year ended December 31, 2017 increased $2,442,001 to $14,704,751 as compared to $12,262,750 in fiscal year 2016. The increase in interest expense is due to increased long-term and convertible debt and compounding of non-cash interest.

Change in Warrant Derivative Liability

For the year ended December 31, 2017, the Company recorded a gain in its non-cash warrant derivative liability of $202,519 which was primarily driven by change in the closing price of the Company’s common stock at December 31, 2017. The liability is associated with the issuance of warrants as part of the Company’s prior convertible debt

financing, the Company's 2010 financing and the Company's 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

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 common stock rights offering and other debt transactions. At December 31, 2017, we had $2.9 million of cash, $12.7 million of net accounts receivable and $22.2 million of inventory. The Company also had approximately $2.2 million of funds available to draw down on its delayed draw term loan (See note 6, "Debt" below).

Xtant has reduced its accounts payable from $11.1 million at December 31, 2016, to $9.5 million as of December 31, 2017. Accrued liabilities of $15.8 million at December 31, 2017 rose from $9.0 million at December 31, 2016 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 include approximately $70.8 million of convertible debt and $67.1 million of long-term debt due to Orbimed Advisors' affiliates.

Net cash used by operating activities for the year ended December 31, 2017 was $543,180 from various operating activities. For the comparable period of 2016, net cash used by operating activities was $14,407,296. The improvement in cash used for operating activities is the result of restructuring efforts in 2017 to improve liquidity, reduce inventory, convert receivables to cash and reduce payables and accrued liabilities. The amendments to the Company's debt agreements to allow for the non-payment of interest currently due has increased accrued interest on long-term debt by $5.6 million in the year ended December 31, 2017.

Net cash used by investing activities for the year ended December 31, 2017 was $1,608,166 due to the purchase of property and equipment.

Net cash provided by financing activities was $2,429,038 in 2017 due to proceeds from new debt less payments on capital leases and the revolving line of credit.

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.

Cash Requirements

The Company entered into a private placement with Orbimed on February 15, 2018 which provided a cash inflow of $4,843,097, net of related expenses. We believe that our December 31, 2017 cash on hand, accounts receivable balance of $15,570,345 along with proceeds of the private placement and anticipated net operating cash receipts and available amended and restated credit agreement capacity are sufficient to meet our anticipated cash requirements through March 31, 2019.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Xtant Medical Holdings, Inc.

Belgrade, Montana

OPINION ON THE CONSOLIDATED FINANCIAL STATEMENTS

We have audited the accompanying consolidated balance sheets of Xtant Medical Holdings, Inc. and Subsidiaries (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' deficit, and cash flows, for each year in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each year in the two-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

BASIS FOR OPINION

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ EKS&H LLLP

April 2, 2018

Denver, Colorado

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

XTANT MEDICAL HOLDINGS, INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2017	2016
Revenue		
Orthopedic product sales	$82,513,128	$89,388,145
Other revenue	98,973	614,591
Total Revenue	82,612,101	90,002,736
Cost of Sales	32,511,120	27,710,014
Gross Profit	50,100,981	62,292,722
Operating Expenses		
General and administrative	15,245,926	15,762,531
Sales and marketing	40,511,434	44,055,813
Research and development	2,441,062	3,410,600
Depreciation and amortization	5,485,280	4,940,955
Acquisition and integration related expenses	-	1,401,366
Impairment intangible assets	17,586,071	-
Restructuring expenses	4,679,645	-
Separation related expenses	1,901,187	-
Non-cash consulting expense	84,697	266,721
Total Operating Expenses	87,935,302	69,837,986
Loss from Operations	(37,834,321)	(7,545,264)
Other Income (Expense)		
Interest expense	(14,704,751)	(12,262,750)
Change in warrant derivative liability	202,519	716,738
Other expense	(74,709)	(351,914)
Total Other Expense	(14,576,941)	(11,897,926)
Net Loss from Operations Before Provision for Income Taxes	(52,411,262)	(19,443,190)
Provision for Income Taxes		
Current and Deferred	-	(50,362)
Net Loss	$(52,411,262)	$(19,493,552)
Net loss per share:		
Basic	$(34.76)	$(18.46)

Dilutive	$(34.76)	$(18.46)
Shares used in the computation:		
Basic	1,507,769	1,055,937
Dilutive	1,507,769	1,055,937

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2017	As of December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$2,855,959	$2,578,267
Trade accounts receivable, net of allowance for doubtful accounts of $2,135,339 and $1,653,385, respectively	12,714,386	18,991,872
Current inventories, net	22,228,587	26,266,457
Prepaid and other current assets	1,705,963	1,149,615
Total current assets	39,504,895	48,986,211
Non-current inventories, net	194,061	971,854
Property and equipment, net	9,913,439	15,840,730
Goodwill	41,534,626	41,534,626
Intangible assets, net	13,826,373	35,940,810
Other assets	731,189	827,374
Total Assets	$105,704,583	$144,101,605
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$9,315,424	$10,471,944
Accounts payable - related party (note 14)	160,381	640,442
Revolving line of credit	-	10,448,283
Accrued liabilities	15,845,421	8,982,187
Warrant derivative liability	131,094	333,613
Current portion of capital lease obligations	365,476	244,847
Total current liabilities	25,817,796	31,121,316
Long-term Liabilities:		
Capital lease obligation, less current portion	623,297	832,152
Long-term convertible debt, less issuance costs	70,853,485	68,937,247
Long-term debt, less issuance costs	67,108,997	50,284,187
Total Liabilities	164,403,575	151,174,902
Commitments and Contingencies (note 9)		
Stockholders' Equity (Deficit):		
Preferred stock, $0.000001 par value; 10,000,000 shares authorized; no shares issued and Outstanding	-	-
	2	1

Common stock, $0.000001 par value; 50,000,000 shares authorized; 1,514,899 shares issued and outstanding as of December 31, 2017 and 1,437,442 shares issued and outstanding as of December 31, 2016		
Additional paid-in capital	86,246,792	85,461,226
Accumulated deficit	(144,945,786)	(92,534,524)
Total Stockholders' Equity (Deficit)	(58,698,992)	(7,073,297)
Total Liabilities & Stockholders' Equity (Deficit)	$105,704,583	$144,101,605

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock Shares	Amount	Additional Paid-In-Capital	Retained Deficit	Total Shareholders' Equity (deficit)
Balance at December 31, 2015	991,466	$ 1	$ 81,917,498	$(73,040,972)	$ 8,876,527
Stock-based compensation	-	-	256,266	-	256,266
Issuance of restricted stock	4,901	-	200,000	-	200,000
Issuance of common stock	7,295	-	225,000	-	225,000
Net proceed from the rights issuance	421,280	-	2,562,462	-	2,562,462
Issuance of stock to Aspire Capital	12,500	-	300,000	-	300,000
Net loss	-	-		(19,493,552)	(19,493,552)
Balance at December 31, 2016	1,437,442	$ 1	$ 85,461,226	$(92,534,524)	$ (7,073,297)
Stock-based compensation	-	-	127,112	-	127,112
Issuance of restricted stock	7,183	-	178,455	-	178,455
Issuance of common stock	70,274	1	479,999	-	480,000
Net loss	-	-		(52,411,262)	(52,411,262)
Balance at December 31, 2017	1,514,899	$ 2	$ 86,246,792	$(144,945,786)	$ (58,698,992)

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2017	2016
Operating activities:		
Net loss	$(52,411,262)	$(19,493,552)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,408,594	7,241,870
Loss on intangible impairment and disposal of fixed assets	21,242,247	-
Non-cash interest	14,684,712	6,784,785
Loss on sale of fixed assets	10,469	25,458
Non-cash consulting expense/stock option expense	211,809	522,987
Provision for losses on accounts receivable and inventory	4,212,582	223,538
Change in derivative warrant liability	(202,519)	(716,738)
Changes in operating assets and liabilities:		
Trade accounts receivable	4,746,876	(2,680,405)
Inventories	2,122,274	(4,074,086)
Prepaid and other assets	(460,162)	(484,061)
Accounts payable	(1,636,580)	319,091
Accrued liabilities	(1,472,220)	(2,076,183)
Net cash used in operating activities	(543,180)	(14,407,296)
Investing activities:		
Purchases of property and equipment and intangible assets	(1,640,666)	(5,832,690)
Proceeds from sale of fixed assets	32,500	16,400
Net cash used in investing activities	(1,608,166)	(5,816,290)
Financing activities:		
Proceeds from long-term and convertible debt, net of deferred and financing costs	12,787,094	3,238,166
Payments on capital leases	(88,228)	(144,600)
Net proceeds from the revolving line of credit	(10,448,283)	10,252,809
Net proceeds from issuance of stock and warrants	178,455	3,087,462
Net cash provided by financing activities	2,429,038	16,433,837
Net change in cash and cash equivalents	277,692	(3,789,749)
Cash and cash equivalents at beginning of year	2,578,267	6,368,016
Cash and cash equivalents at end of year	$2,855,959	$2,578,267

See notes to audited consolidated financial statements.

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Notes to Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Xtant Medical Holdings, Inc., formerly known as Bacterin International Holdings, Inc., a Delaware corporation, and its wholly owned subsidiaries, Xtant Medical, Inc., a Delaware corporation, Bacterin International, Inc., ("Bacterin") a Nevada corporation and X-Spine Systems, Inc. ("X-spine"), an Ohio corporation, (Xtant Medical Inc., Bacterin and X-spine are jointly referred to herein as "Xtant" or the "Company"). All intercompany balances and transactions have been eliminated in consolidation. Xtant products serve the combined specialized needs of orthopedic and neurological surgeons, including orthobiologics for the promotion of bone healing, implants and instrumentation for the treatment of spinal disease, tissue grafts for the treatment of orthopedic disorders to promote healing following spine, cranial and foot surgeries and the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries.

The markets in which the Company competes are highly competitive and rapidly changing. Significant technological advances, changes in customer requirements, or the emergence of competitive products with new capabilities or technologies could adversely affect the Company's operating results. The Company's business could be harmed by a decline in demand for, or in the prices of, its products or as a result of, among other factors, any change in pricing or distribution methods, increased price competition, changes in government regulations or a failure by the Company to keep up with technological change. Further, a decline in available donors could have an adverse impact on our business.

Reverse Stock Split

The Company completed a 1:12 reverse split of its common stock, effective at the open of business on Wednesday, February 14, 2018. The reverse stock split was approved by the Company's shareholders at the Special Meeting of Shareholders on February 13, 2018. All references to common shares, stock option, restricted stock units, warrants, and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Concentrations and Credit Risk

The Company's accounts receivables are from a variety of health care organizations and distributors throughout the world. No single customer accounted for more than 10% of revenue or accounts receivable in the fiscal years 2017 or 2016. The Company provides for uncollectible amounts when specific credit issues arise. Management believes that all significant credit risks have been identified at December 31, 2017.

In the years ended December 31, 2017 and 2016, Xtant purchased from Norwood Medical less than 10% of its operating products (See Note 14, "Related Party Transactions" below).

Use of Estimates

The preparation of the financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period. Significant estimates include the carrying amount of property and equipment (including surgical instruments), goodwill, and intangible assets and liabilities; valuation allowances for trade receivables, inventory valuation, and deferred income tax assets and liabilities; valuation of the warrant derivative liability; inventory and estimates for the fair value of stock options grants and other equity awards upon which the Company determines stock-based compensation expense. Actual results could differ from those estimates.

Cash and Cash Equivalents

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

Trade Accounts Receivable

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

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, 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. The Company does not have any off-balance sheet credit exposure related to its customers.

Inventories

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

Property and Equipment

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

Intangible Assets

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

In 2015 with the acquisition of X-spine, the Company established a fair value for the technology, tradenames and intangible assets which was determined based upon a “relief from royalty” approach. The amortization of these assets is consistent with the valuation method used to establish their fair value which in turn was based on the assets’ future cash flow.

Other Assets

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

Long-Lived Assets

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

Goodwill

Goodwill represents the excess of costs over fair value of assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, instead they are tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. In its evaluation of goodwill, the Company performs an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired. The results from the assessment and a step 1 analysis allowed the Company to conclude that goodwill was not impaired as of December 31, 2017. The Company conducts its impairment test on an annual basis and will review the analysis assumptions on a quarterly basis.

Revenue Recognition

Revenue is recognized when all of the following criteria are met: a) the Company has entered into a legally binding agreement with the customer; b) the products or services have been delivered; c) the Company's fee for providing the products and services is fixed or determinable; and d) collection of the Company's fee is probable.

The Company's policy is to record revenue net of any applicable sales, use, or excise taxes. If an arrangement includes a right of acceptance or a right to cancel, revenue is recognized when acceptance is received or the right to cancel has expired.

The Company ships to certain customers under consignment arrangements whereby the Company's product is stored by the customer. The customer is required to report the use to the Company and upon such notice, the Company invoices the customer and revenue is recognized when the above criteria have been met.

Research and Development

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

Other Expense

Other income (expense) primarily consists of non-recurring items that are outside of normal Company's operations such as gain or loss on the sale of fixed assets.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net loss per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and warrants using the treasury stock method. Diluted net loss per share was the same as basic net loss per share for the years ended December 31, 2017 and 2016, as shares issuable upon the exercise of stock options and warrants were anti-dilutive as a result of the net losses incurred for those periods. Dilutive loss per share are not reported as their effects of including 587,382 and 624,769 outstanding stock options and warrants for the years ended December 31, 2017 and 2016, respectively, are anti-dilutive.

Fair Value of Financial Instruments

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

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

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

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

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

A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. During the years ended December 31, 2017 and 2016, there was no reclassification in financial assets or liabilities between Level 1, 2 or 3 categories.

The following table sets forth by level, within the fair value hierarchy, our liabilities as of December 31, 2017 and 2016 that are measured at fair value on a recurring basis:

Warrant derivative liability

	As of December 31, 2017	As of December 31, 2016
Level 1	-	-
Level 2	-	-
Level 3	$ 131,094	$ 333,613

The valuation technique used to measure fair value of the warrant liability is based on a lattice valuation model and significant assumptions and inputs determined by us (See Note 8, “Warrants” below).

Level 3 Changes

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the years ended December 31, 2017 and 2016:

Warrant derivative liability

Balance at January 1, 2016	$1,050,351
Gain recognized in earnings	(716,738)
Balance at January 1, 2017	$333,613
Gain recognized in earnings	(202,519)
Balance at December 31, 2017	$131,094

During the year ended December 31, 2017, the Company did not change any of the valuation techniques used to measure its liabilities at fair value.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers* (Topic 606) (ASU 2014-09). Using a five-step framework set forth in ASC 606, ASU 2014-09 requires entities to recognize revenue at an amount that the entity expects to be entitled to upon transferring control of goods or services to a customer, as opposed to when risks and rewards transfer to a customer under the existing revenue recognition guidance. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 for one year, which makes the guidance effective for the Company's first fiscal year beginning after December 15, 2017. Additionally, the FASB is permitting entities to early adopt the standard, which allows for either full retrospective or modified retrospective methods of adoption, for reporting periods beginning after December 15, 2016. We will adopt the provisions of ASU 2014-09 effective January 1, 2018 using the modified retrospective method given we expect the timing of our revenues to remain generally the same. As of December 31, 2017, we finalized our assessment of the impact of the standard on the consolidated financial statements. The updated guidance will require additional disclosure regarding our revenue transactions.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. While we are still evaluating the impact of our pending adoption of the new standard on our financial statements, we expect that upon adoption we will recognize ROU assets and lease liabilities and that the amounts could be material.

In June 2016, the FASB issued ASU 2016-13 *Financial Instruments - Credit losses: Measurement of Credit Losses on Financial Instruments*, which amends certain provisions of ASC 326, *Financial Instruments-Credit Loss*. The ASU changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held to maturity debt securities, loans and other instruments, entities will be required to use a new forward-looking "expected loss" model that generally will result in the earlier recognition of allowances for losses. The ASU is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those annual periods, and will be applied as a cumulative effect adjustment to retained earnings as of the beginning of the first reporting period for which the guidance is effective. We currently do not expect that the adoption of these provisions will have a material effect on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flow -Restricted Cash* (ASU 2016-18). ASU 2016-18 requires that an entity's statement of cash flows explain the change during the period in that entity's total cash and cash equivalents, including amounts generally described as restricted cash or restricted cash equivalents.

Additionally, an entity is to reconcile its cash and cash equivalents as per its balance sheet to the cash and cash equivalent balances presented in its statement of cash flows. ASU 2016-18 is effective for the Company's first fiscal year beginning after December 15, 2017. Given that the Company has historically had little to no restricted cash, we expect our consolidated statements of cash flows to remain generally the same. Nonetheless, we will continue to evaluate the impact of ASU 2016-18 and we will adopt the provisions of ASU 2016-18 effective January 1, 2019.

(2) Inventories

Inventories consist of the following:

	December 31, 2017	December 31, 2016
Current inventories		
Raw materials	$ 4,276,773	$ 4,833,403
Work in process	1,515,085	1,891,380
Finished goods	23,269,805	23,878,040
Gross current inventories	29,061,663	30,602,823
Reserve for obsolescence	(6,833,076)	(4,336,366)
Current inventories, total	22,228,587	26,266,457
Non-current inventories		
Finished goods	1,071,956	1,385,017
Reserve for obsolescence	(877,895)	(413,163)
Non-current inventories, total	194,061	971,854
Total inventories	$ 22,422,648	$ 27,238,311

The Company provides implants and biologic inventory on consignment through its various sales channels to logistically place the inventory near the anticipated surgical location. Consigned inventory was approximately $12.0 million and $11.2 million at December 31, 2017 and December 31, 2016, respectively.

(3) Property and Equipment, Net

Property and equipment, net are as follows:

	December 31, 2017	**December 31, 2016**
Equipment	$ 4,471,198	$ 4,629,754
Computer equipment	489,718	416,233
Computer software	523,526	529,726
Furniture and fixtures	214,770	181,566
Leasehold improvements	4,030,010	4,053,837
Vehicles	10,000	10,000
Surgical instruments	11,461,798	13,876,757
Total cost	21,201,020	23,697,873
Less: accumulated depreciation	(11,287,581)	(7,857,143)

$ 9,913,439	$ 15,840,730

The Company deploys certain surgical instruments through its 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 $6.6 million and $8.2 million at December 31, 2017 and December 31, 2016, respectively. An impairment charge of $1,614,793 was recorded in 2017 for instruments on consignment which may not be recoverable.

Depreciation expense related to property and equipment, including property under capital lease, for the year ending 2017 and 2016 was $3,765,314 and $2,431,619, respectively.

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of December 31, 2017, the Company has recorded $1,585,366 gross capital lease assets within Equipment, and $500,092 of accumulated depreciation.

(4) Intangible Assets

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

The following table sets forth information regarding intangible assets:

	December 31, 2017	December 31, 2016
Patents	$ 847,436	$ 747,249
Acquisition related intangibles:		
Technology	13,788,617	28,698,700
Customer relationships	9,911,000	9,911,000
Tradename	1,867,312	4,543,300
Non-compete	40,500	40,500
Accumulated amortization	(12,628,492)	(7,999,939)
Net carrying value	$ 13,826,373	$ 35,940,810
Aggregate amortization expense:	$ 4,628,558	$ 4,479,010

The following is a summary of estimated future amortization expense for intangible assets as of December 31, 2017:

2018	$ 2,053,485
2019	2,005,419
2020	1,969,073
2021	1,855,794
2022	1,758,531
Thereafter	4,184,071
Total	$ 13,826,373

The Company recorded an impairment charge in 2017 of $14,910,083 related to Technology and $2,675,988 related to Tradename 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.

(5) Accrued Liabilities

Accrued liabilities consist of the following:

December 31, 2017	December 31, 2016

Accrued interest payable	$ 10,834,641	$ 3,090,585
Wages/commissions payable	2,830,946	3,330,578
Accrued stock compensation	120,000	213,758
Other accrued liabilities	2,059,834	2,347,266
Accrued Liabilities	$ 15,845,421	$ 8,982,187

(6) Debt

Convertible Note Indenture

In connection with the Restructuring (defined below), effective on February 14, 2018, all of the Notes (defined below) and the Additional Notes (defined below) were converted or exchanged into shares of our common stock and the Indenture (defined below) was discharged. Please see Note 16, "Subsequent Events" below for a further description of such conversions and exchanges of the Notes and the Additional Notes.

On July 31, 2015, we completed an offering of $65 million aggregate principal amount of 6.00% convertible senior unsecured notes due 2021 (the "Notes") in a private offering to qualified institutional buyers, as defined in Rule 144A under the Securities Act of 1933, as amended, when we entered into an Indenture with Wilmington Trust, National Association (the "Indenture"). ROS Acquisition Offshore LP ("ROS") and OrbiMed Royalty Opportunities II, LP ("Royalty Opportunities") initially purchased $49 million aggregate principal amount of the Notes directly from the Company, while Bruce Fund, Inc. ("Bruce Fund"), Park West Partners International, Limited ("PWPI"), Park West Investors Master Fund, Limited ("PWIMF"), and Telemetry Securities, L.L.C. ("Telemetry" and, together with ROS, Royalty Opportunities, Bruce Fund, PWPI and PWIMF, collectively, the "Holders"), collectively purchased the remaining $16 million of the Notes. On August 10, 2015, ROS and Royalty Opportunities exercised their option with respect to an additional $3 million aggregate principal amount of the Notes, for a total aggregate principal amount of $52 million of the Notes in the offering.

On April 14, 2016, we entered into a securities purchase agreement with ROS and Royalty Opportunities and issued $2,238,166 aggregate principal amount of convertible senior unsecured notes (the "2016 Notes") in a private placement. The proceeds were utilized to pay interest due for both the Notes and the Credit Facility (described below) on April 15, 2016. The 2016 Notes may be converted into shares of our common stock at an initial conversion price of approximately $34.80 per share.

On January 17, 2017, the Company entered into securities purchase agreements with Bruce Fund, PWPI, PWIMF and Telemetry, to satisfy interest obligations that were owed to such parties under the Notes issued to them under the Indenture. Pursuant to such agreements, the parties agreed to purchase from the Company a total of 70,274 shares of our common stock at a price of $6.83 per share.

On January 17, 2017, the Company entered into securities purchase agreements and certain related documents with ROS and Royalty Opportunities to satisfy interest obligations that the Company owed to them pursuant to the Notes and the 2016 Notes. Pursuant to such agreements, ROS and Royalty Opportunities agreed to purchase from the Company a new series of 6% Convertible Senior Notes Due 2021 in the aggregate original principal amount of up to

$1,560,000 for the Notes, and $67,145 for the 2016 Notes (collectively, the “2017 Notes” and together with the 2016 Notes, the “Additional Notes”). The 2017 Notes are convertible into our common stock at a conversion price of $9.11 per share.

The Additional Notes and the Notes bear interest at a rate equal to 6.00% per year. Interest on the Additional Notes and the Notes will be payable semiannually in arrears on January 15 and July 15 of each year. Interest accrues on the Additional Notes and the Notes from the last date to which interest has been paid or duly provided for. Unless earlier converted or repurchased, the Additional Notes and the Notes will mature on July 15, 2021.

Effective March 31, 2017, the Company, ROS and Royalty Opportunities entered into a waiver letter (the “Indenture Waiver”) of the Indenture. Under the Indenture Waiver, ROS and Royalty Opportunities waived any non-compliance with the covenant set forth in Section 6.01(a)(vii) of the Indenture due to the going concern qualification included in the Company’s audit report for the year ended December 31, 2016.

ROS and Royalty Opportunities also entered into a waiver (the “Notes Waiver”) for defaults that occurred under multiple convertible promissory notes (including the Notes and the Additional Notes). Under the Notes Waiver, ROS and Royalty Opportunities waived any non-compliance with the covenants set forth in Section 6.01(a)(vii) of their respective notes due to the going concern qualification included in the Company’s audit report for the year ended December 31, 2016.

Effective July 15, 2017, the Holders entered into an omnibus waiver which deferred interest accrued on the Notes (the “Omnibus Waiver”). Under the Omnibus Waiver and pursuant to Section 9.02 of the Indenture and Section 10.13 of the Notes, the interest due July 15, 2017 on the Notes was deferred until August 15, 2017, to be paid in cash together with interest accrued on such interest from July 15, 2017 to the date of the payment thereof at a rate equal to 6.00% per annum plus 100 basis points. Also under the Omnibus Waiver, the Holders waived any event of default that has occurred under the Indenture or the Notes as a result of the Company’s failure to pay interest accrued on the Notes on July 15, 2017. The convertible interest due on July 15, 2017 under the Company’s various convertible promissory notes was deferred by the holders of such notes until August 15, 2017.

Effective August 15, 2017, September 29, 2017, October 31, 2017, November 30, 2017 and December 28, 2017, the Company, ROS and Royalty Opportunities entered into the Amendment and Waiver, and the Second, Third, Fourth and Fifth Amendment and Waiver, respectively, which amended the Additional Notes by moving the payment date of interest accrued on the Additional Notes as follows: (a) for interest accrued on the Additional Notes that was originally required to be paid on July 15, 2017, from July 15, 2017 to January 31, 2018, and (b) for interest accrued on the Additional Notes that is required to be paid on January 15, 2018, from January 15, 2018 to January 31, 2018. The amendment also waived any event of default that may have occurred as a result of the non-payment of interest on July 15, 2017 or January 15, 2018. The interest payment due on January 31, 2018 includes interest accrued on such interest from July 15, 2017 and January 15, 2018, respectively, to the date of payment thereof at a rate equal to 6.00% per annum plus 100 basis points.

Effective August 16, 2017, October 2, 2017, October 31, 2017, December 1, 2017 and December 29, 2017, the Company and Wilmington Trust, National Association, entered into the Amendment Numbers 1, 2, 3, 4 and 5 to the Indenture, respectively, which amended the existing Indenture. The amendments amended the Indenture by moving the payment date of interest accrued on the Notes issued under the Indenture as follows: (a) for interest accrued on the Notes that was originally required to be paid on July 15, 2017, from July 15, 2017 to January 31, 2018, and (b) for interest accrued on the Notes that is required to be paid on January 15, 2018, from January 15, 2018 to January 31, 2018. Amendment Number 5 to the Indenture also set the record dates for the January 31, 2018 interest payments at June 30, 2017 and December 31, 2017, respectively, and waived any event of default that may have occurred as a result of the non-payment of interest on July 15, 2017 or January 15, 2018. The interest payments due on January 31, 2018 includes interest accrued on such interest from July 15, 2017 and January 15, 2018, respectively, to the date of payment thereof at a rate equal to 6.00% per annum plus 100 basis points.

Amended and Restated Credit Agreement

In connection with the Restructuring, effective February 14, 2018, a substantial amendment was made to the Amended and Restated Credit Agreement (the “Credit Facility”). Please see Note 16, “Subsequent Events” below for a further description of such amendment to the Credit Facility.

On July 31, 2015 the Company recorded $42 million of principal debt pursuant to the Credit Facility with ROS and Royalty Opportunities, which has a maturity date of July 31, 2020 (the “Maturity Date”). Interest under the Credit Facility is bifurcated into a “cash pay” portion and a “payment-in-kind” portion. Until June 30, 2018 (the “First Period”), interest on loans outstanding under the Credit Facility will accrue at a rate equal to the sum of (a) 9% per annum, which portion of interest will be payable in cash, plus (b) additional interest (“PIK Interest”) in an amount equal to (i) the sum of 14% per annum, plus the higher of (x) the LIBO Rate and (y) 1% per annum, minus (ii) 9% per annum, which portion of interest will be payable “in kind”. On or after June 30, 2018 until the Credit Facility is repaid in full (the “Second Period”), interest on loans outstanding under the Credit Facility will accrue at a rate equal to the sum of (a) 12% per annum, which portion of interest will be payable in cash, plus (b) PIK Interest in an amount equal to the difference of (i) the sum of 14% per annum, plus the higher of (x) the LIBO Rate and (y) 1% per annum, minus (ii)

12% per annum, which portion of interest will be payable “in kind.” In both the First Period and the Second Period, the portion of accrued interest constituting PIK Interest will not be payable in cash but will instead be added to the principal amount outstanding under the Credit Facility. However, at our option, we may choose to make any “payment-in-kind” interest payment in cash. Until the third anniversary of the closing date of the Credit Facility, we will not be allowed to voluntarily prepay the Credit Facility. Whenever loans outstanding under the Credit Facility are prepaid or paid, whether voluntarily, involuntarily or on the Maturity Date, a fee of 7.5% on the amount paid will be due and payable.

The Credit Facility contains financial and other covenant requirements, including, but not limited to, financial covenants that require the Company to maintain revenue and liquidity at levels set forth in the Credit Facility and ensure that the Company’s senior consolidated leverage ratio does not exceed levels set forth in the Credit Facility. The Credit Facility also restricts us from making any payment or distribution with respect to, or purchasing, redeeming, defeasing, retiring or acquiring, the Notes other than payments of scheduled interest on the Notes, issuance of shares of our common stock upon conversion of the Notes, and payment of cash in lieu of fractional shares. The loans under the Credit Facility are guaranteed by the Company and its current and future subsidiaries and are secured by substantially all of the current and future assets of the Company and its subsidiaries.

Approximately $4.9 million of expenses were incurred in conjunction with the acquisition, the issuance of convertible debt and the amendment and restatement of our credit facility with ROS and Royalty Opportunities. Of that amount, approximately $4.7 million of debt issuance costs was capitalized and is being amortized over the life of the debt.

We have entered into several amendments to the Credit Facility, and the material provisions of such amendments that have been subsequently modified or restated are summarized below.

On July 29, 2016 we entered into the fourth amendment to the Credit Facility which provided for an additional "Tranche A Commitment" in an amount up to $1,000,000 from ROS and Royalty Opportunities, which was made available to us on July 29, 2016 for a total of $43 million loan payable to ROS and Royalty Opportunities.

On September 27, 2016, we entered into the sixth amendment to the Credit Facility which increased the fee on any amounts paid under the Credit Facility from 7.5% to 9.0%. Under the sixth amendment, regular interest will not accrue during the period from July 1, 2016 to September 30, 2016; however, during such period, PIK Interest will accrue at a rate per annum equal to 9.00%, and such PIK Interest will be added to the outstanding principal amount of the loans at September 30, 2016. The sixth amendment also modified the negative covenants of the Credit Facility by increasing the amount of purchase money indebtedness and capitalized lease liabilities allowed to be incurred by us.

The seventh amendment (effective December 31, 2016), eighth amendment (effective January 13, 2017), ninth amendment (effective January 31, 2017), tenth amendment (effective February 14, 2017), eleventh amendment (effective February 28, 2017), twelfth amendment (effective March 31, 2017), thirteenth amendment (effective April 30, 2017), fourteenth amendment (effective May 11, 2017), fifteenth amendment (effective June 30, 2017), sixteenth amendment (effective July 15, 2017), seventeenth amendment (effective August 11, 2017), eighteenth amendment (effective September 29, 2017), nineteenth amendment (effective October 31, 2017), twentieth amendment (effective November 30, 2017), and twenty-first amendment (effective December 28, 2017) deferred our accrued interest payment date for the fiscal quarters ended on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017 and December 31, 2017 until January 31, 2018.

The interest due on January 31, 2018 for the fiscal quarter ended on December 31, 2016 is $1,147,329, plus interest accrued on such interest from January 2, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate (as defined in the Credit Facility) for the fiscal quarter ended on December 31, 2016, or 1%. The interest due on January 31, 2018 for the fiscal quarter ended on March 31, 2017 is $1,139,597, plus interest accrued on such interest from April 1, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on March 31, 2017, or 1%. The interest due on January 31, 2018 for the fiscal quarter ended on June 30, 2017 is $1,303,935, plus interest accrued on such interest from July 1, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on June 30, 2017, or 1%. The interest due on January 31, 2018 for the fiscal quarter ended on September 30, 2017 is $1,482,406, plus interest accrued on such interest from October 2, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on September 30, 2017, or 1%. The interest due on January 31, 2018 for the fiscal quarter ended on December 31, 2017 is $1,521,262, plus interest accrued on such interest from January 2, 2018 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on December 31, 2017, or 1%.

The twelfth amendment waived any non-compliance with the covenant set forth in Section 7.1(c) of the Credit Facility due to the going concern qualification included in the Company's audit report for the year ended December 31, 2016.

The fourteenth amendment to the Credit Facility amended the guarantors to the Company, X-Spine and Xtant Medical, collectively, and listed X-Spine as the Additional Delayed Draw Borrower of new term loans. The fourteenth amendment allowed for X-Spine to make additional term loans with ROS and Royalty Opportunities in an aggregate amount of up to $15,000,000. Total 2017 additional term loans in 2017 were $12,787,094, allowing for an additional $2,212,906 after 2017. The amount of each loan draw made by X-Spine is subject to the Company's production of a thirteen-week cash flow forecast that is approved by ROS and Royalty Opportunities. The funding of each Additional Delayed Draw Loan by ROS and Royalty Opportunities is subject to the satisfaction (or waiver in writing by each lender) of conditions precedent, including closing certificate, delivery of budget, the hiring of a CRO, a payoff letter from the Bank (see below), and other satisfactory documents.

The twentieth amendment modified the consolidated senior leverage ratio financial covenant of the Credit Facility by moving the commencement date of the covenant from the most recent four fiscal quarters ended December 31, 2017, to the most recent four fiscal quarters ended March 31, 2018. The twentieth amendment waived any non-compliance with the covenant set forth in Section 7.1(b) of the Credit Facility with respect to the timely filing of the Company's quarterly report on Form 10-Q for the quarterly period ended September 30, 2017.

Effective November 14, 2017, Bacterin, the Company, X-Spine, Xtant Medical, ROS and Royalty Opportunities, entered into a Waiver to Amended and Restated Credit Agreement, which waived any non-compliance with the minimum revenue base covenant for the quarter ending September 30, 2017.

The twenty-first amendment modified the minimum liquidity financial covenant of the Credit Facility by allowing the Company and its subsidiaries to maintain a liquidity amount of not less than $100,000 until January 31, 2018. At all times after January 31, 2018, the liquidity of the Company and its subsidiaries must not be less than $5,000,000.

Revolving Credit Line Loan and Security Agreement

On May 25, 2016, we entered into a Loan and Security Agreement (the "LSA") with Silicon Valley Bank, a California corporation (the "Bank"), pursuant to which the Bank agreed to provide us with a revolving line of credit in the aggregate principal amount of $6,000,000.

On August 12, 2016, we entered into a First Loan Modification Agreement (the "Modification Agreement") with the Bank, which amended certain provisions of the LSA. Pursuant to the terms of the Modification Agreement, the Bank increased the aggregate principal amount of the revolving line of credit to $11,000,000.

On May 12, 2017, we paid off all obligations under the LSA with funds from the Credit Facility and terminated the LSA with Silicon Valley Bank.

Long-term debt consists of the following:

	December 31, 2017	December 31, 2016
Loan payable to ROS Acquisition Offshore (See details above)	$55,787,094	$43,000,000
PIK Interest payable to ROS	11,582,306	7,648,776
6% convertible senior unsecured notes due 2021 (See details above)	71,865,311	70,238,166
Gross long-term debt	139,234,711	120,886,942
Less: capitalized debt issuance costs	(1,272,229)	(1,665,508)
Long-term debt, less issuance costs	$137,962,482	$119,221,434

The following is a summary of maturities due on the debt as of December 31, 2017:

2018	$-
2019	-
2020	67,369,400
2021	71,865,311
2022	-
Thereafter	-
Total	$139,234,711

(7) Stock-Based Compensation

The Amended and Restated Xtant Medical Equity Incentive Plan ("the Plan") provides for stock awards, including options and performance stock awards, to be granted to employees, consultants, independent contractors, officers and directors. The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and, on occasion, independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by our Board of Directors. Stock options granted under the Plan are generally not transferable, vest in installments over the requisite service period and are exercisable during the stated contractual term of the option only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. 158,333 shares are authorized under the Plan and at December 31, 2017, we had approximately 64,000 shares available for issuance which are authorized, but unissued or reacquired shares.

Stock compensation expense recognized in the statement of operations for the year ended December 31, 2017 and 2016 is based on awards ultimately expected to vest and reflects an estimate of awards that will be forfeited. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. No stock options were issued or exercised in 2017 or 2016.

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

	2017			2016		
	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date
Outstanding at January 1	100,492	$ 62.52	$ 33.84	55,340	$ 127.64	$ 63.84
Granted	-	-	-	59,040	19.44	14.04
Cancelled or expired	(33,027)	45.13	30.74	(13,888)	138.48	68.64
Outstanding at December 31	67,465	$ 71.03	$ 36.85	100,492	$ 62.52	$ 33.84
Exercisable at December 31	32,750	$ 128.39	$ 62.23	31,258	$ 141.96	$ 68.76

The aggregate intrinsic value of options outstanding as of December 31, 2017 was zero because the closing price of the stock at year end was less than the strike price of all options outstanding. As of December 31, 2017, there were 34,714 unvested options with a weighted average fair value at the grant date of $22.92 per option. As of December 31, 2017, we had approximately $224,000 in compensation expense related to unvested awards not yet recognized.

From time to time we may grant stock options and restricted stock unit grants to directors and consultants. We account for consultant stock options in accordance with ASC 505-50. Consulting expense for the grant of stock options to consultants is determined based on the estimated fair value of the stock options at the measurement date as defined in ASC 505-50 and is recognized over the vesting period. The Company recognized restricted stock unit expense for the year ended December 31, 2017 and 2016 of $84,697 and $266,721 respectively, as Non-cash consulting expense.

Total option activity expense recognized in 2017 was $127,112 and $221,261 in 2016. The total stock compensation recognized for employees, directors and consultants was $211,809 and $487,982 for the year ended December 31, 2017 and 2016, respectively.

On July 25, 2017, the Company granted 25,974 restricted stock units to the independent Directors of the Company. These restricted shares will be vested on July 25, 2018 and were granted when the stock price was $9.24

On October 6, 2016, we issued an option to purchase 25,000 shares of our common stock at $13.32 per share to our Chief Executive Officer.

On July 5, 2016, the Company granted 6,700 restricted stock units to four of the independent Directors of the Company (Messrs. Lopach, Swanson, Deedrick and Buckman). These restricted shares vested on July 5, 2017 and were granted when the stock price was $23.88 per share. The total expense of $160,000 was recognized ratably over the period as Non-cash consulting expense. In the year ended December 31, 2016, $52,000 was expensed with the remaining expensed in 2017.

On July 5, 2016, the Company granted 4,950 stock options to two of the independent Directors of the Company (Messrs. Mazzocchi and Timko). These stock options vest on July 5, 2017 and were granted when the stock price was $23.88 per share. The total expense of $32,444 is being recognized ratably over the period as Non-cash consulting expense. In the year ended December 31, 2016, $10,000 was expensed with the remaining expensed in 2017.

(8) Warrants

The following table summarizes our warrant activities for the period ended December 31, 2017:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding as of January 1, 2016	106,547	$ 101.40
Issued	421,278	10.80
Expired	(3,548)	380.76
Outstanding at January 1, 2017	524,277	$ 26.76
Expired	(4,360)	135.36
Outstanding at December 31, 2017	519,917	$ 25.68

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The valuation model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of $202,519 resulting from the change in the fair value of the warrant derivative liability for the year ended 2017. Under the terms of some of our warrant agreements, at any time while the warrant is outstanding, the exercise price per share can be reduced to the price per share of future subsequent equity sales of our common stock or a common stock equivalent that is lower than the exercise price per share as stated in the warrant agreement.

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

	Year Ended December 31,	
	2017	2016
Value of underlying common stock (per share)	$6.84	$6.60
Risk free interest rate	2.12 %	1.93 %
Expected term	4.6 years	5.6 years
Volatility	92 %	84 %
Dividend yield	0 %	0 %

The following table summarizes our activities related to warrants accounted for as a derivative liability for the years ended December 31, 2017 and 2016:

	2017	2016
Balance at January 1	1,125,119	1,125,119
Derivative warrants issued	-	-
Derivative warrants exercised	-	-
Expired	-	-
Balance at December 31	1,125,119	1,125,119

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(9) Commitments and Contingencies

Operating Leases

We lease five office facilities under non-cancelable operating lease agreements with expiration dates between 2019 and 2025. We have the option to extend the five leases for up to another ten year term and we have the right of first refusal on any sale.

Future minimum payments for the next five years and thereafter as of December 31, 2017, under these operating leases, are as follows:

2018	$806,747
2019	668,807
2020	396,263
2021	375,289
2022	354,003
Thereafter	684,413
Total	$3,285,522

Rent expense was $795,321 and $845,845 for the years ended December 31, 2017 and 2016, respectively. Rent expense is determined using the straight-line method of the minimum expected rent paid over the term of the agreement. We have no contingent rent agreements.

Capital Leases

Future minimum payments for the next five years and thereafter as of December 31, 2017, under these capital leases, are as follows:

2018	$522,869
2019	462,544
2020	181,714
2021	-
2022	-

Thereafter	-
Total minimum lease payments	1,167,127
Less amount representing interest	(178,354)
Present value of obligations under capital leases	988,773
Less current portion	(365,476)
Long-term capital lease obligations	$623,297

Indemnifications

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

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

Litigation

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 $972,283. Xtant filed a motion to dismiss on September 15, 2017, and is awaiting the court's ruling. The Company recorded reserves for outstanding net receivables due from Axis and consigned assets in Axis' possession totaling $1,342,049 in the third quarter of 2017.

(10) Income Taxes

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

The components of income loss before provision for income taxes consist of the following:

	Year Ended December 31,	
	2017	2016
United States	$(52,411,262)	$(19,443,552)
Total	$(52,411,262)	$(19,443,552)

The components of the income tax provision are as follows:

	Year Ended December 31,	
	2017	2016
Current:		
Federal	$ -	$ -
State	-	50,362
Total current	-	50,362
Deferred:		

Federal	-	-
State	-	-
Total deferred	-	-
Total Provision for Income Taxes	$ -	$ 50,362

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The reconciliation of income tax attributable to operations computed at the U.S. Federal statutory income tax rate of 35% to income tax expense is as follows:

	Year Ended December 31,	
	2017	2016
Statutory Federal tax rate	$(18,314,681)	$(6,822,743)
Valuation allowance	6,390,359	3,133,196
State income taxes, net of Federal benefit	(2,817,493)	(721,362)
Change in state income tax rate	755,459	267,836
Change in warrant derivative liability	(70,882)	(277,381)
Stock compensation adjustment and other reconciling items	(189,834)	2,470,052
Tax Cuts and Jobs Act	11,771,772	-
Nondeductible interest	1,472,784	1,915,018
Restructuring expenses	950,857	-
Other	-	(1,038)
Nondeductible meals and entertainment expense	51,659	86,784
Total Provision for Income Taxes	$-	$50,362

Deferred tax components are as follows:

	At December 31,	
	2017	2016
Deferred tax assets:		
Accrued liability for vacation	$81,076	$132,646
Accrued commissions and bonuses / compensation	59,722	43,538
Accrued contingencies	68,344	135,452
Bad debt reserve	579,844	639,868
Charitable contributions carryforward	7,656	10,673
Inventory reserve	2,075,107	1,760,691
Net operating loss carryovers	23,173,536	27,863,368
Stock warrants	-	132,543
Stock option compensation	559,868	899,990
Other	42,266	57,435
Total deferred tax assets	26,647,419	31,676,204
Valuation allowance	(22,588,729)	(16,198,372)
Total net deferred tax assets	4,058,690	15,477,832
Deferred tax liabilities:		
Depreciation	(703,666)	(2,046,350)
Amortization	(3,355,024)	(13,431,482)

Total deferred tax liabilities	(4,058,690)	(15,477,832)
Net deferred tax assets	$-	$-

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management does not believe it is more likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a valuation allowance equal to the net realizable deferred tax assets. The valuation allowance increased by $6,390,357 in 2017 and increased by $3,133,196 in 2016.

At December 31, 2017 and 2016, the Company had total domestic Federal and state net operating loss carryovers of approximately $164,847,000 and $136,630,000, respectively. Federal and state net operating loss carryovers both expire at various dates between 2025 and 2037.

Under the Tax Reform Act of 1986, as amended, the amounts of and benefits from net operating loss carryovers and research and development credits may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three-year period. The Company does not believe that such an ownership change has occurred in 2017 and 2016.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*. Prior U.S. GAAP required an entity to recognize excess tax benefit or deficiency as additional paid-in capital. To simplify the presentation of stock compensation, the amendments in this Update require that the excess tax benefit or deficiency is recognized as expense. For non-public business entities, the amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. The Company is adopting the Update as of January 1, 2017. Due to a full valuation allowance, there was no qualitative impact to the tax provision upon adoption.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into legislation. At December 31, 2017, the Company has not yet completed its accounting assessment for the tax effects of the enactment of the Act; however, as described below, the Company has made a reasonable estimate of the effects on the existing deferred tax balances.

As a result of the lower enacted corporate tax rate, the Company has 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 provisional amount recorded related to the remeasurement of the Company's deferred tax balance was $11.8 million, that is 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, the Company has 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 is still analyzing certain aspects of the Act and refining its calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts. Additional analysis of the law and the impact to the Company will be performed and any impact will be recorded in the respective quarter in 2018.

The 2014 through 2016 tax years remain open to examination by the Internal Revenue Service and various other state tax agencies. These taxing authorities have the authority to examine those tax years until the applicable statute of limitations expire.

The Company did not recognize any material interest or penalties related to income taxes for the years ended December 31, 2017 and 2016.

(11) Equity

We entered into the Purchase Agreement on March 16, 2015, as amended and restated on April 17, 2015, with Aspire Capital, which provided that, upon the terms and subject to the conditions and limitations set forth therein. In 2016, we issued 12,500 shares of our common stock to Aspire Capital for $300,000 in aggregate proceeds. The Purchase Agreement has expired with no further purchases in 2017.

Related to the acquisition, on October 8, 2015 the Company granted 6,542 restricted stock units to five X-spine employees at $38.28 a share for a total cost of $250,447 to be expensed ratably over twelve months in Acquisition and integration related expenses from the acquisition date.

Effective October 6, 2016, our board of directors appointed Carl O'Connell to serve as the President of the Company. In connection with the hiring of Mr. O'Connell, we issued him an option to purchase 25,000 shares of our common stock at $13.32 per share which start vesting 5,000 shares on October 6, 2017 and then vest 1,250 shares per quarter on January 6, 2018 until October 6, 2021.

On October 31, 2016, the Company distributed to holders of its Common Stock and to holders of its convertible notes, at no charge, non-transferable subscription rights to purchase units. Each unit consisted of one share of Common Stock and one tradeable warrant representing the right to purchase one share of Common Stock ("Tradeable Warrants"). The offering of units pursuant to the subscription rights is referred to as the "Rights Offering." On October 31, 2016, the Company entered into a dealer-manager agreement (the "Dealer-Manager Agreement") with Maxim Group LLC ("Maxim"), to engage Maxim as dealer-manager for the Rights Offering.

In the Rights Offering, holders received two subscription rights for each share of Common Stock, or each share of Common Stock underlying our convertible notes owned on the record date, October 21, 2016. Subscribers whose subscriptions otherwise would have resulted in their beneficial ownership of more than 4.99% of the Company's Common Stock could elect to receive, in lieu of shares of Common Stock in excess of that threshold, pre-funded warrants to purchase the same number of shares of Common Stock for $0.12 ("Pre-Funded Warrants"), and the subscription price per unit consisting of a Pre-Funded Warrant in lieu of a share of Common Stock was reduced by the $0.12 exercise price but no Pre-Funded Warrants were sold.

The Rights Offering closed on November 14, 2016. The units were priced at $9.00 per unit with gross proceeds from the Rights Offering of approximately $3.8 million and the net proceeds from the Rights Offering of approximately $2.5 million after deducting fees and expenses payable, and after deducting other expenses payable by us and excluding any proceeds received upon exercise of any Tradeable Warrants issued in the offering. The Tradeable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $10.80 per share. The Tradeable Warrants associated with the equity raised was subject to an analysis that resulted in the Tradeable Warrants being recorded as equity with the Common Stock in stockholder's equity. After the one-year anniversary of issuance, we may redeem the Tradeable Warrants for $0.01 per Tradeable Warrant if the volume weighted average price of our Common Stock is above $27.00 for each of 10 consecutive trading days.

In connection with the Rights Offering, the Company paid to Maxim a cash fee equal to 7% of the gross proceeds received by us directly from exercises of Subscription Rights. We also reimbursed Maxim $75,000 for expenses incurred in connection with the Rights Offering.

(12) Employee Benefit Plans

The Company combined the previous two plans for Bacterin and X-spine in 2017. Under the combined plan, the employee becomes qualified upon starting employment. Terms for the plan are as follows:

Discretionary Match: 3%

Contribution Limit: $18,000 or the statutorily prescribed limit

Enrollment Period: Begins at time of employment

(13) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Year Ended December 31,	
	2017	2016
Cash paid during the period for:		
Interest	$627,213	$5,477,965
Non-cash activities:		
Issuance of capital leases	$173,227	$1,178,660
Issuance of shares associated with legal settlement	$-	$225,000
Interest converted into common stock	$480,000	$-

(14) Related Party Transactions

As discussed in Note 16 below, the Company entered into the Restructuring Agreement with the Holders. Other than as described above with respect to (i) ROS and OrbiMed and (ii) PWPI and PWIMF, the Holders do not constitute a "group" as such term is defined in Section 13(d) of the Exchange Act.

Furthermore, as discussed in Note 16 below, the Company entered into the Support Agreement with the Holders, the Company's executive officers and directors and certain of the Company's stockholders.

Certain of X-spine's former shareholders, who own over 10% of our common stock as of December 31, 2017, also have a controlling interest in one of X-spine's major suppliers, Norwood Tool Company d/b/a Norwood Medical. In 2017, Xtant purchased less than 10% of its operating supplies from Norwood Medical. The related party accounts payable balance as of December 31, 2017 and 2016 was $160,381 and $640,442, respectively.

The Audit Committee or the disinterested members of the full Board of Directors reviews and approves all related party transactions.

(15) Segment and Geographic Information

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

The Company attributes revenues to geographic areas based on the location of the customer. Approximately 97% and 95% of sales were in the United States, respectively, for the years ended December 31, 2017 and 2016. Total revenue by major geographic area is as follows:

	Year Ended December 31,	
	2017	**2016**
United States	$79,738,169	$85,618,087
Rest of World	2,873,932	4,384,649
Total	$82,612,101	$90,002,736

(16) Subsequent Events

Restructuring Agreement

On January 11, 2018, we entered into a Restructuring and Exchange Agreement (the "Restructuring Agreement") with the Holders. The Restructuring Agreement set forth several obligations and approvals that we needed to complete in order to close the Restructuring Agreement and the transaction contemplated thereby (the "Restructuring"), which are described throughout this Note 16.

Under the Restructuring Agreement, we agreed to several standard representations, warranties and covenants. Further, we agreed to indemnify certain of our officers and representatives and certain affiliates and representatives of the Holders for all damages arising from any losses based upon any act related to us, the Restructuring, the Restructuring Agreement or any related documents.

Pursuant to the Restructuring Agreement, and following the execution of the Sixth Amendment to the 2017 Notes, described below, on January 17, 2018, ROS and Royalty Opportunities converted the 2017 Notes, plus accrued and unpaid interest, at the $9.11 per share conversion rate originally provided thereunder, into 189,645 shares of our

common stock (of which 121,045 of such shares of common stock were issued to ROS and 68,600 of such shares of common stock were issued to Royalty Opportunities) (the "Tier 1 Transaction").

In connection with the Restructuring Agreement, we also set a special meeting of the stockholders (the "Special Meeting"), to approve certain items related to the Restructuring Agreement and the Restructuring. We held the Special Meeting on February 13, 2018, and at such meeting our stockholders approved all three proposals related to the Restructuring, which were as follows:

- Approval of the issuance of shares of common stock for purposes of Sections 713(a) and 713(b) of the NYSE American Company Guide.

- Approval of an amendment to our certificate of incorporation ("Charter") to affect a Reverse Stock Split (defined below), to change the number of authorized shares of common stock and preferred stock available for issuance and to make such other changes as are described below.

- Approval of John Bakewell, Michael Eggenberg, Michael Mainelli, Robert McNamara, Jeffrey Peters and Matthew Rizzo as the new directors to the Board to serve until the 2018 Annual Meeting of Stockholders and until they or respective successors have been duly elected and qualified.

After giving effect to the Reverse Stock Split and upon approval of the stockholders at the Special Meeting, on February 14, 2018, the remaining $70.238 million aggregate principal amount of our outstanding 6.00% convertible senior unsecured notes due 2021 held by the Holders (the "Remaining Notes"), consisting of the Notes and the 2016 Notes, plus accrued and unpaid interest, were exchanged for newly-issued shares of our common stock at an exchange rate of 138.8889 shares per $1,000 principal amount of the Remaining Notes, for an exchange price of $7.20 per share (the "Notes Exchange"). This resulted in the issuance of 10,401,309 shares of our common stock to the Holders as follows:

Holder	Common Stock issued in Notes Exchange
ROS	5,126,534
Royalty Opportunities	2,905,396
Bruce Fund	296,172
PWPI	153,828
PWIMF	1,104,905
Telemetry	814,474

Upon the completion of the Notes Exchange, all outstanding obligations under the Remaining Notes were satisfied in full and the Indenture and the 2016 Notes were discharged.

Support Agreement

On January 11, 2018, the Holders, our executive officers and directors and certain of our stockholders (collectively the "Support Equityholders"), entered into a support agreement (the "Support Agreement") simultaneously with the execution of the Restructuring Agreement. Under the Support Agreement, the Support Equityholders agreed to vote their shares of common stock in favor of the approval of: (i) the amendment to our Charter and the issuance of common stock pursuant to the Notes Exchange, (ii) any proposal to adjourn or postpone the meeting to a later date, if there were not sufficient votes for the approval of the such proposals on the date on which such meeting is held, and (iii) any other proposal included in the proxy statement for the Special Meeting that relates to the consummation of the Restructuring that the Board recommended our stockholders approve. The Support Equityholders also appointed ROS and Royalty Opportunities as attorney-in-fact and proxy to vote all applicable shares of the Support Equityholders consistent with the provisions of the Support Agreement. The Support Equityholders made standard representations and warranties related to their ownership of common stock.

Sixth Amendment to the 2017 Notes

Effective January 17, 2018, we entered into the Sixth Amendment with ROS and Royalty Opportunities, which amended the 2017 Notes. The amendment amended the 2017 Notes by removing the limitations on stock ownership that prevented ROS, Royalty Opportunities or any of their affiliates from effecting a conversion of the 2017 Notes if such conversion would result in the holder or any of its affiliates beneficially owning in excess of 9.99% of the then outstanding shares of our common stock and providing that the Conversion Consideration (as defined therein) due upon conversion of the 2017 Notes shall account for any accrued and unpaid interest on the 2017 Notes.

Twenty-Second Amendment to Amended and Restated Credit Agreement

Effective January 30, 2018, Bacterin, the Company, X-Spine, Xtant Medical, ROS and Royalty Opportunities, entered into the Twenty-Second Amendment to Amended and Restated Credit Agreement, which amended the Credit Facility. The amendment further deferred Bacterin's accrued interest payment date for the fiscal quarters ended on December 31, 2016, March 31, 2017, June 30, 2017, September 30, 2017 and December 31, 2017 until February 28, 2018.

The interest due on February 28, 2018 for the fiscal quarter ended on December 31, 2016, is $1,147,329, plus interest accrued on such interest from January 2, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate (as defined in the Credit Facility) for the fiscal quarter ended on December 31, 2016, or 1%. The interest due on February 28, 2018 for the fiscal quarter ended on March 31, 2017 is $1,139,597, plus interest accrued on such interest from April 1, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on March 31, 2017, or 1%. The interest due on February 28, 2018 for the fiscal quarter ended on June 30, 2017 is $1,303,935, plus interest accrued on such interest from July 1, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on June 30, 2017, or 1%. The interest due on February 28, 2018 for the fiscal quarter ended on September 30, 2017 is $1,482,406, plus interest accrued on such interest from October 2, 2017 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on September 30, 2017, or 1%. The interest due on February 28, 2018 for the fiscal quarter ended on December 31, 2017 is $1,521,262, plus interest accrued on such interest from January 2, 2018 until paid at a rate equal to 14% plus the higher of the LIBO Rate for the fiscal quarter ended on December 31, 2017, or 1%.

The amendment also modified the minimum liquidity financial covenant of the Credit Facility by allowing the Company and its subsidiaries to maintain a liquidity amount of not less than $100,000 until February 28, 2018. At all times after February 28, 2018, the liquidity of the Company and its subsidiaries must not be less than $5,000,000.

Amendment Number 6 to Indenture

Effective January 30, 2018, we entered into the Amendment Number 6 to Indenture with Wilmington Trust, National Association, which amended the Indenture. The amendment amended the Indenture by moving the payment date of interest accrued on the Notes issued under the Indenture as follows: (a) for interest accrued on the such Notes that was originally required to be paid on July 15, 2017, from January 31, 2018 to February 28, 2018, and (b) for interest accrued on the such Notes that is required to be paid on January 15, 2018, from January 31, 2018 to February 28, 2018. The Indenture Amendment also set the record dates for the February 28, 2018 interest payments at June 30, 2017 and December 31, 2017, respectively, and waived any event of default that may have occurred as a result of the non-payment of interest on July 15, 2017 or January 15, 2018. The interest payments due on February 28, 2018 includes interest accrued on such interest from July 15, 2017 and January 15, 2018, respectively, to the date of payment thereof at a rate equal to 6.00% per annum plus 100 basis points.

Sixth Amendment and Waiver to the 2016 Notes

Effective January 30, 2018, we entered into the Sixth Amendment and Waiver with ROS and Royalty Opportunities, which amended the 2016 Notes. The amendment amended the 2016 Notes by moving the payment date of interest accrued on the 2016 Notes as follows: (a) for interest accrued on the 2016 Notes that was originally required to be paid on July 15, 2017, from January 31, 2018 to February 28, 2018, and (b) for interest accrued on the 2016 Notes that is required to be paid on January 15, 2018, from January 31, 2018 to February 28, 2018. The amendment also waived any event of default that may have occurred as a result of the non-payment of interest on July 15, 2017 or January 15, 2018. The interest payment due on February 28, 2018 includes interest accrued on such interest from July 15, 2017 and January 15, 2018, respectively, to the date of payment thereof at a rate equal to 6.00% per annum plus 100 basis points.

Amended and Restated Certificate of Incorporation

On February 13, 2018, following the Special Meeting, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Charter (the "Certificate Amendment") to affect the Reverse Stock Split. The Certificate Amendment amended and restated our Charter, to, among other things:

· effect a reverse stock split at a ratio of 1-for-12 (the "Reverse Stock Split");

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after giving effect to the Reverse Stock Split, decrease the number of authorized shares of common stock available for issuance from 95,000,000 to 50,000,000 and increase the number of authorized shares of preferred stock available for issuance from 5,000,000 to 10,000,000;

- authorize the Board to increase or decrease the number of shares of any series of our capital stock, provided that such increase or decrease does not exceed the number of authorized shares or be less than the number of shares then outstanding;

- authorize the Board to issue new series of preferred stock without approval of the holders of common stock or other series of preferred stock, with such powers, preferences and rights as may be determined by the Board;

- authorize a majority of the Board to fix the number of our directors;

- indemnify the members of the Board to the fullest extent permitted by law;

- remove the classification of the Board to require all directors to be elected annually;

- provide that special meetings of our stockholders may only be called by the Board, the chairman of the Board or our chief executive officer;

- provide that no stockholder will be permitted to cumulative voting at any election of directors;

- elect not to be governed by Section 203 of the Delaware General Corporation Law (the “DGCL”);

- elect the Court of Chancery of the State of Delaware to be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of a fiduciary duty owed by any of our directors, officers or other employees, any action under the DGCL, our Charter or bylaws or any actions governed by the internal affairs doctrine; and

- require the vote of at least two-thirds of the voting power of the then outstanding shares of our capital stock to amend or repeal certain provisions of our Charter.

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

Twenty-Third Amendment to Amended and Restated Credit Agreement

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

The amendment also made the following modifications to the financial covenants of the Credit Facility:

- The minimum revenue base covenant was removed in its entirety.

- The minimum liquidity financial covenant of the Credit Facility was revised to allow the Company and its subsidiaries to maintain a liquidity amount of not less than $500,000 at all times after February 14, 2018.

- The maximum consolidated senior leverage ratio covenant was modified as follows:

Four Fiscal Quarters Ended	**Consolidated Senior Leverage Ratio**
June 30, 2019	10.00:1.00

September 30, 2019	10.00:1.00
December 31, 2019	8.00:1.00
March 31, 2020	7.00:1.00
June 30, 2020	7.00:1.00

·A new minimum Consolidated EDITDA covenant was added as follows:

Testing Period	**Minimum Consolidated EBITDA**
Three quarter period ended September 30, 2018	$2.2 million
Four quarter period ended December 31, 2018	$4.0 million
Four quarter period ended March 31, 2019	$5.5 million
Four quarter period ended June 30, 2019	$7.0 million
Four quarter period ended September 30, 2019	$8.5 million
Four quarter period ended December 31, 2019	$10 million
Four quarter period ended March 31, 2020	The greater of (a) $10 million or (b) 75% of projected Adjusted EBITDA for such period pursuant to projections, based on good faith estimates and assumptions believed to be reasonable at the time made, delivered to ROS no later than December 31, 2019
Four quarter period ended June 30, 2020	The greater of (a) $10 million or (b) 75% of projected Adjusted EBITDA for such period pursuant to projections, based on good faith estimates and assumptions believed to be reasonable at the time made, delivered to ROS no later than December 31, 2019

Private Placement SPA

On February 14, 2018, we entered into a Securities Purchase Agreement (the "Private Placement SPA") with ROS and Royalty Opportunities. Pursuant to the Private Placement SPA, on February 14, 2018, ROS and Royalty Opportunities purchased from us a total of 945,819 shares of our common stock, at a price of $7.20 per share, for aggregate proceeds of $6,809,896. Under the Private Placement SPA, 603,687 of such shares of our common stock were issued to ROS and 342,132 of such shares of common stock were issued to Royalty Opportunities.

Investor Rights Agreement

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

For so long as the Ownership Threshold is met, we must obtain the approval of ROS and Royalty Opportunities to proceed with the following actions: (i) issue new securities; (ii) incur over $250,000 of debt in a fiscal year; (iii) sell or transfer over $250,000 of our assets or businesses or our subsidiaries in a fiscal year; (iv) acquire over $250,000 of assets or properties in a fiscal year; (v) make capital expenditures over $125,000 individually, or $1,500,000 in the aggregate during a fiscal year; (vi) approve our annual budget; (vii) hire or terminate our chief executive officer; (viii) appoint or remove the chairperson of the Board; and (ix) make, loans to, investments in, or purchase, or permit any subsidiary to purchase, any stock or other securities in another entity in excess of $250,000 in a fiscal year. As long as the Ownership Threshold is met, we may not increase the size of the Board beyond seven directors without the approval of a majority of the directors nominated by ROS and Royalty Opportunities.

The Investor Rights Agreement Grants Royalty Opportunities, ROS, PWPI and PWIMF the right to purchase from us a pro rata amount of any new securities that we may propose to issue and sell. The Investor Rights Agreement may be terminated (a) upon the mutual written agreement of all the parties, (b) upon written notice of the Company, ROS or Royalty Opportunities, if ROS and Royalty Opportunities' ownership percentage of our then outstanding common stock is less than 10%, or (c) upon written notice of ROS and Royalty Opportunities. PWPI and PWIMF's right to purchase from us a pro rata amount of any new securities will also terminate at such time as their aggregate ownership percentage of our then outstanding common stock is less than 8.5%.

Registration Rights Agreement

Effective February 14, 2018, we entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Holders. The Registration Rights Agreement requires us to, among other things, file with the SEC a shelf registration statement (which, initially, will be on Form S-1 and, as soon as we are eligible, will be on Form S-3) covering the resale, from time to time, of our common stock issued: (i) under the Tier 1 Transaction, (ii) upon the Notes Exchange, or (iii) under the Private Placement SPA, within 90 days of the date of the Registration Rights Agreement. We agree to use our best efforts to cause the shelf registration statement to become effective under the Securities Act no later than the 180th day after such demand; provided, that if the SEC notifies us that it will not review or has no comments to such initial registration statement within 110 days after the date of the Registration Rights Agreement, we will use our best efforts to cause such registration statement to become effective under the Securities Act no later than the 120th day after the date of the Registration Rights Agreement.

Second Amended and Restated Bylaws

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

- provide for annual and special meetings of stockholders to be held through remote communications;
- provide for the election of any directors not elected at an annual meeting of stockholders to be elected at a special meeting of stockholders;
- declassify the Board into one group of directors that will hold office until the subsequent annual meeting of stockholders and until the election and qualification of such directors' respective successors;

- provide for the filling of a new directorship or director vacancy by the affirmative vote of the holders of a majority of the voting power of our shares of stock;

- allow for a majority of the Board present to adjourn a Board meeting if a quorum is not met;

- unless otherwise restricted in the Amended Bylaws or our Charter, provide the Board with the authority to fix the compensation of directors, including without limitation, compensation for services as members of Board committees;

- allow us to enter into an agreement with a stockholder to restrict the transfer of shares held by such stockholder in any manner not prohibited by the DGCL);

- allow the Board to declare dividends on our capital stock, subject to any provisions of our Charter and applicable law;

- allow us to maintain insurance on behalf of any of our directors or officers; and

- allow us to provide electronic notice to our stockholders, if consented to by such stockholder in accordance with Section 232 of the DGCL.

Compliance with NYSE American Continued Listing Standards

On February 15, 2018, we filed a Current Report on Form 8-K with the SEC to disclose our unaudited pro forma stockholders' equity of approximately $47,362,434 as of February 15, 2018, which reflected the: (i) Tier 1 Transaction, (ii) the Notes Exchange, (iii) the shares issued under the Private Placement SPA, and (iv) results of operations. Subsequently, we received correspondence from the NYSE American LLC, dated February 15, 2018, confirming that we had resolved our previous stockholders' equity deficiency and had regained full compliance with the NYSE American LLC's continued listing standard.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management with the participation of our chief executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2017. Based upon that evaluation, our chief executive officer and principal financial officer concluded that as of December 31, 2017, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in rule 13a-15 (f) under the Securities and Exchange Act of 1934 as amended. Under the supervision and with the participation of senior and executive management, we conducted an evaluation of our internal controls over financial reporting based upon the framework Internal Control - Integrated Framework (2013) as outlined by COSO, the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of an evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Based on our evaluation under the framework Internal Control - Integrated Framework (2013), management concluded that our internal control over financial reporting was effective as of December 31, 2017.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2017, we implemented the following changes in our internal control over financial reporting to enhance our overall financial control environment and to address the reported material weakness related to internal control on property and equipment from the quarters ended March 31, 2017 and June 30, 2017:

- The Company has changed supervisory personnel and improved the accounting review processes in connection with the presentation and disclosure of the recognition of property and equipment and related accumulated depreciation.

- The Company has also exercised additional review and oversight in the recording of property and equipment activity.

Except as described above, there were no changes in the Company's internal control over financial reporting during the year ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Executive Officers and Directors

Name	Age	Position
Carl O'Connell	54	Chief Executive Officer
John Bakewell	56	Director
Michael Eggenberg	48	Director
Michael Mainelli	56	Director

Robert McNamara	61	Director
Jeffrey Peters	49	Director
Matthew Rizzo	45	Director

The business experience of our executive officer and directors for the past five years is summarized below.

Carl O'Connell, President (Director, Chief Executive Officer, was most recently the Vice President Global Marketing - Extremities for Wright Medical, a recognized leader in the global foot and ankle market. Mr. O'Connell lead marketing teams and initiatives that were instrumental in achieving U.S. growth initiatives that exceeded 28% and 23% globally. He also lead the completion of marketing integration of three acquired businesses within a year, recruited top talent to his team, and supported the launch of multiple product line extensions and new products, including the successful launch of the market leading Infinity Total Ankle. During his tenure as Global Vice President Marketing for Stryker Spine, Mr. O'Connell drove marketing leadership and brand differentiation programs to support a 20% growth imperative, which was achieved through strategic cross divisional collaboration and the successful launches of line extensions and product upgrades. Mr. O'Connell served as the President and CEO of MedSurg - ITOCHU International, a division of ITOCHU Corporation, the 3rd largest Japanese trading corporation with over $70B in sales transactions, where he was responsible for the reorganization of three recently impaired acquisitions by supporting success attributes, acquiring new vendor contracts, stabilizing and growing top line sales at double digit growth rates, and driving the division to profitability.

John K. Bakewell is a consultant to the medical technology industry. Mr. Bakewell served as the Chief Financial Officer of Exact Sciences Corporation, a molecular diagnostics company, from January 2016 to November 2016. Mr. Bakewell previously served as the Chief Financial Officer of Lantheus Holdings, Inc., a diagnostic medical imaging company, from June 2014 to December 2015 and as Chief Financial Officer of Interline Brands, Inc., a distributor and direct marketer of broad-line maintenance, repair and operations products, from June 2013 to May 2014. Mr. Bakewell previously was the Executive Vice President and Chief Financial Officer of RegionalCare Hospital Partners, an owner and operator of non-urban hospitals, from January 2010 to December 2011. In addition, Mr. Bakewell held the position of Chief Financial Officer with Wright Medical Group, Inc., an orthopaedic medical device company, from 2000 to 2009, with Altra Energy Technologies, Inc. from 1998 to 2000, with Cyberonics, Inc. from 1993 to 1998 and with Zeos International, Ltd. from 1990 to 1993. Mr. Bakewell previously served on the board of directors of Entellus Medical, Inc., a public ENT-focused medical device company, until its acquisition by Stryker Corp.; ev3 Inc., a public endovascular medical device company, until its acquisition by Covidien plc; and Corindus Vascular Robotics, Inc., a public cardiovascular robotics medical technology company. Since July 2008, Mr. Bakewell has served on the board of directors of Keystone Dental, Inc., a private medical device company. Mr. Bakewell holds a Bachelor of Arts in Accounting from the University of Northern Iowa and is a certified public accountant (inactive). Mr. Bakewell's financial experience as a chief financial officer of several publicly traded medical technology companies and his background and sophistication in finance and accounting contributes valuable experience to our Board of Directors.

Michael Eggenberg is a Managing Director with OrbiMed Advisors LLC since December 2016, focused on healthcare royalty and structured finance investments. Previously, Mr. Eggenberg was a Managing Director at Fortress Investment Group, focused on Special Opportunities Funds from May 2005 to December 2016. Prior to Fortress, Mr. Eggenberg held positions at CIT, Wells Fargo and Nations Bank. Mr. Eggenberg received his B.S. in Finance and General Business from Drexel University. Mr. Eggenberg brings valuable experience in the life science industry and finance experience to the Board of Directors.

Michael Mainelli has worked in the medical device industry for over twenty-five years, serving the diagnostic imaging, surgical, and orthopedic markets. He has extensive international experience having led operations in the UK and Israel. Most recently, he served as President and CEO of Stanmore Implants Worldwide, LTD from 2013 to 2016, a UK based specialty orthopaedics company, and led the sale of the company to Stryker Corporation. Prior to Stanmore, he was the CEO of Active Implants Corporation, an early stage company developing an innovative meniscal implant, from 2008 to 2011. Prior to Active Implants, he was the Group President of the Medical Device Segment of Intermagnetics General Corporation from 2005 to 2006 before the company was acquired by Royal Philips. Prior to employment by Intermagnetics, Mr. Mainelli was with Stryker Corporation serving in the positions of VP-Corporate Development, Assistant to the Chairman, President-Stryker Japan and President-Stryker Spine. Prior to Stryker, he was employed by General Electric in various management roles. He has served on the board of directors of Orthofix International, a publicly traded medical device company, and Active Implants Corporation and Stanmore Implants, which were VC-backed privately-owned companies. He currently serves on the board of directors of Autocam Medical, a privately-owned medical device contract manufacturing company. He earned a MBA from the University of Chicago, a MSE from the University of Pennsylvania and a BSME from Northeastern University. Mr. Mainelli brings strong experience in the implant and medical device industries to the Board of Directors.

Robert McNamara brings over 25 years experience within the medical device and high technology industries. He served as Executive Vice President of the spine company, LDR Holdings, since January 2013 and as the Chief Financial Officer for LDR Holdings since April 2012 up until its acquisition by Zimmer Biomet in July 2016. From September 2010 to April 2012, Mr. McNamara served as a financial consultant, working primarily in the medical device and biotechnology industries. From May 2009 to September 2010, he served as Chief Financial Officer of Purfresh, Inc., a privately held clean technology company. In addition, Mr. McNamara has previously served as the Senior Vice President and Chief Financial Officer for several publicly traded medical device companies including Accuray, Inc. (ARAY), Somnus Medical Technologies (SOMN) and Target Therapeutics (TGET). In addition, he has served as a member of the Board of Directors and Audit Committee of Northstar Neurosciences (NSTR). Mr. McNamara holds a B.S. in Accounting from the University of San Francisco and an M.B.A. in Finance from The Wharton School at the University of Pennsylvania. He is a Certified Public Accountant (inactive) and is the former Mayor of Menlo Park, CA. Mr. McNamara brings valuable finance and accounting experience in the medical device industry to the Board of Directors.

Jeffrey Peters has over 25 years of medical device experience and currently serves as the president and chief executive officer of Cardialen, a private medical device company developing low-energy therapy for cardiac arrhythmias. Previously, Mr. Peters was the chief executive officer of Anulex Technologies (2011-2014), a company developing minimally invasive spine therapies. He also served as the chief technology officer of ev3 (now Medtronic)

from 2001-2007. Mr. Peters' financial roles include portfolio manager at Black River Asset Management, entrepreneur-in-residence at Foundation Medical, and stock analyst at Dain Rauscher Wessels. Mr. Peters received his B.S. and M.B.A. from the University of Minnesota. Mr. Peters brings experience in the medical device and life science industries to the Board of Directors.

Matthew S. Rizzo is a Partner with OrbiMed Advisors LLC, having joined the firm in April 2010, and is focused on healthcare royalty and structured finance investments. Previously, Mr. Rizzo was at Ikaria Holdings as a Senior Director in business development for pharmaceutical licensing and acquisitions. Prior to Ikaria, Mr. Rizzo was a Vice President at Fortress Investment Group, focused on healthcare investments in the Drawbridge Special Opportunities Funds. Prior to Fortress, he was at GlaxoSmithKline where he worked in business and commercial analysis. Mr. Rizzo received his M.B.A. from Duke University and his B.S. from the State University of New York at Buffalo. Mr. Rizzo brings valuable experience in the life science industry and finance experience to the Board of Directors.

Board Composition and Terms of Office

We are a controlled company, and as such, we rely on NYSE American's controlled company exemptions and do not have a majority independent Board, an independent nomination and governance committee or an independent compensation committee.

OrbiMed and ROS control a majority of the combined voting power of all classes of our outstanding voting stock. As a result, we are a "controlled company" within the meaning of the NYSE American corporate governance standards. Under the NYSE American rules, a company of which more than 50% of the voting power is held by another person or group of persons acting together is a controlled company and may elect not to comply with certain NYSE American corporate governance requirements, including the requirements that:

- a majority of the board of directors consist of independent directors;
- the board has a nomination and governance committee composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- the board has a compensation committee composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities.

All directors hold office for one-year terms and until the election and qualification of their successors. Officers are elected by, and serve at the discretion of, the board of directors.

Audit Committee

The members of the Company's Audit Committee are Messers. Mainelli, Bakewell and McNamara, all of which are independent under the NYSE American standards of independence as well as under rules adopted by the SEC pursuant to the Sarbanes-Oxley Act of 2002. Mr. Bakewell serves as the Chairman of the Audit Committee. The purpose of the Audit Committee is to assist the oversight of our Board of Directors with the integrity of our financial statements, our compliance with legal and regulatory matters, our internal audit function, and our independent auditor's qualifications, independence, and performance. The primary responsibilities of the Audit Committee are set forth in its charter, which is posted on our website at www.xtantmedical.com, and include various matters with respect to the oversight of our accounting and financial reporting process and audits of our financial statements. The Audit Committee also selects the independent auditor, reviews the proposed scope of the audit, reviews our accounting and financial controls with the independent auditor and financial accounting staff, and reviews and approves transactions between us and our directors, officers, and their affiliates.

Under the NYSE American listing standards, all audit committee members must be "financially literate," as that term is determined by the Board in its business judgment. Further, under SEC rules, the Board must determine whether at least one member of the audit committee is an "audit committee financial expert," as defined by the SEC's rules. The Board has determined that all current members of the Audit Committee are "financially literate" and all current members of the Audit Committee qualify as an "audit committee financial expert" in accordance with applicable rules and

regulations of the SEC.

Nominations to the Board of Directors

Our directors take a critical role in guiding our strategic direction and overseeing the management of our company. Board candidates are considered based upon various criteria, such as their broad-based business and professional skills and experiences, a global business and social perspective, concern for the long-term interests of the stockholders, diversity, personal integrity and judgment.

In addition, directors must have time available to devote to board activities and to enhance their knowledge in the growing business. Accordingly, we seek to attract and retain highly qualified directors who have sufficient time to attend to their substantial duties and responsibilities.

Family Relationships

There are no family relationships among our directors and executive officers.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) requires directors, executive officers and holders of more than 10% of an equity security registered pursuant to Section 12 of the Exchange Act of 1934 to file various reports with the SEC.

To the Company’s knowledge, based solely on our review of the Section 16 reports furnished to us with respect to 2017, we believe all reports required pursuant to Section 16(a) were filed on a timely basis.

Code of Ethics

We have adopted a Code of Conduct and a Code of Ethics for our CEO and Senior Financial Officers, both of which are posted on our website at www.xtantmedical.com. We intend to disclose any changes in, or waivers from, these codes by posting such information on the same website or by filing a Form 8-K. The contents of our website are not incorporated by reference into this annual report on Form 10-K.

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Procedures for Shareholder Recommendation of Nominees to the Board of Directors

The procedures by which shareholders may recommend nominees to the Board of Directors are contained in our Bylaws.

Item 11. Executive Compensation

The table below summarizes the compensation earned for services rendered to the Company for the fiscal years indicated, by our Chief Executive Officer and two most highly-compensated named executive officers other than our Chief Executive Officer.

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (1)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Carl O'Connell (2)	2017	502,692	55,000	-	-	-	-	-	557,692
Chief Executive Officer	2016	65,385	20,000 (3)	-	274,052	-	-	-	359,437
Christopher Valois	2017	295,975	18,900	-	-	-	-	-	314,875
Vice President Sales and Marketing	2016	219,661	8,000	-	-	-	-	-	227,661
Kevin O'Dare	2017	200,000	-	-	-	-	-	147,688 (4)	347,688
Area Vice President-East	2016	180,298	-	-	128,365	-	-	103,728 (4)	412,391
Daniel Goldberger (5)	2017	154,250	-	-	-	-	-	130,000 (6)	284,250
Chief Executive Officer (From August 14, 2013 to January 21, 2017)	2016	518,486	-	-	-	-	-	-	518,486
David Kirschman	2017	-	-	-	-	-	-	-	-
Executive Vice President and Chief Scientific Officer (From July 31,2015 to July 2, 2016)	2016	259,615	-	-	-	-	-	-	259,615
John Gandolfo (7)	2017	298,926	36,000	-	-	-	-	129,808	464,734
Chief Financial Officer (From July 6, 2010 to August 25,2017)	2016	360,000	-	-	-	-	-	-	360,000
Robert Di Silvio	2017	-	-	-	-	-	-	-	-
President (From July 1, 2014 to January 8, 2016)	2016	-	-	-	-	-	-	224,500 (6)	224,500

(1) Key assumptions used to estimate the grant date fair value of restricted stock and option awards are contained in Note 7 of this Annual Report on Form 10-K.

(2) Effective February 17, 2017, Mr. O'Connell was appointed Chief Executive Officer and a director of the Company after serving as Interim Chief Executive Officer since January 21, 2017, and the President of the Company since October 6, 2016.

(3) Signing bonus.

(4) Commissions.

(5) Effective January 21, 2017, Daniel Goldberger resigned as Chief Executive Officer and a director of the Company.

(6) Consulting fees.

(7) Effective August 25, 2017, John Gandolfo resigned as Chief Financial Officer of the Company. Mr. Gandolfo is receiving one year of severance shown as “All Other Compensation” above.

Employment Agreements

Employment agreements for our current executive officers are set forth as exhibits to this Form 10-K. The employment agreements require each of the executives to perform such duties as are customarily performed by one holding their positions and provide for a fixed annual base salary. In addition, each executive is entitled to receive certain cash bonuses and grants under our equity incentive plan as may be determined by the compensation committee of our board of directors.

The employment agreements contain covenants (a) restricting the executives from engaging in any activity competitive with our business, (b) prohibiting the executive from disclosing confidential information regarding our company, and (c) requiring that all intellectual property developed by the executive and relating to our business constitutes our sole and exclusive property. The employment agreements also contain severance provisions in the event of termination without cause, resignation for good reason, or termination in connection with a change of control.

Amended and Restated Xtant Medical Equity Incentive Plan and Inducement Grants

We have granted stock options, shares of common stock and restricted stock units under our Amended and Restated Xtant Medical Equity Incentive Plan (the "Plan"), as well as an inducement grant, consisting of an option to purchase 25,000 shares of our common stock at $13.32 to our Chief Executive Officer granted outside of our Plan. The following is a summary of the material terms of our Plan and the inducement grants:

The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the Board of Directors. The administrator of the Plan has the power to determine the terms of any stock options granted under the Plan, including the exercise price, the number of shares subject to the stock option and conditions of exercise. Stock options granted under the Plan are generally not transferable, vest in installments and are exercisable during the lifetime of the optionee only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant.

There are 158,333 shares of our common stock authorized to be issued under the Plan. As of December 31, 2017, we had outstanding options (excluding non-plan options) to purchase 67,465 shares and 25,974 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 64,000 shares available for

issuance thereunder.

We also granted stock options to Mr. O'Connell, our Chief Executive Officer and former President, outside of our Plan as inducement material to entering into employment with the company pursuant to Section 711(a) of the NYSE MKT Company Guide, which is now known as the NYSE American Company Guide. The inducement grant to Mr. O'Connell was approved by the Compensation Committee of our Board of Directors and granted outside of the Plan as an inducement material to entering into employment with the Company pursuant to Section 711(a) of the NYSE American Company Guide. The inducement grant to Mr. O'Connell consists of a stock option to purchase up to 25,000 shares of our common stock, with a per share exercise price of $13.32, which was the adjusted closing price of the Company's common stock on the October 6, 2016 grant date. Mr. O'Connell's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in sixteen (16) equal quarterly installments as to 1,250 underlying shares, beginning October 6, 2017. The inducement grant to our former Chief Executive Officer consisted of a stock option to purchase up to 16,666 shares of our common stock, with a per share exercise price of $72.00, which was the adjusted closing price of our common stock on the July 1, 2014 grant date. Our former Chief Executive Officer inducement grant stock option vested over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 2,777 underlying shares, beginning September 15, 2014, and one final installment as to 2,775 underlying shares.

Except for the Plan and the inducement grants to Mr. O'Connell discussed above, we do not have any other stock option plans or other similar incentive compensation plans for officers, directors and employees.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2017)

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	**Number of shares or units of stock that have not vested**[(1)]	**Market value of shares or units of stock that have not vested**[(2)]
Carl O'Connell	25,000	25,000	$ 13.32	10/6/26	18,750	-
Kevin O'Dare	8,333	8,333	21.24	7/20/26	6,666	-
	416	416	48.00	8/05/25	187	
Chris Valois	-	-	-	N/A	-	-

(1) This table includes stock options which are unvested 60 days past December 31, 2017.

(2) The market value for all stock awards set forth on this table have been valued at $0 as the exercise prices for all such stock awards exceed the current stock price of the Company as of December 31, 2017.

Potential Payments Upon Termination or Change-in-Control

All of our named executive officers have employment agreements that provide for severance payments for termination in connection with a change in control.

Mr. O'Connell's employment agreement provides an annual base salary of $520,000, which is subject to annual increases based on periodic reviews, along with other incentive compensation as determined by the Board of Directors, with a bonus target of 50% of Mr. O'Connell's annual base salary. Mr. O'Connell's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for six (6) months severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control. Mr. O'Connell is also entitled to receive a special recognition bonus for 2016 of $85,000 by April 30, 2017 which is still due and payable as of December 31, 2017.

Retirement Plans

The Company combined the previous two plans for Bacterin and X-spine in 2017. Under the combined plan, the employee becomes qualified upon starting employment. Terms for the plan are as follows:

Discretionary Match:	3%
Contribution Limit:	$18,000 or the statutorily prescribed limit
Enrollment Period:	Begins at time of employment

Director Compensation

Compensation to the members of our board of directors in office during 2017 was as follows:

Name	Fees Earned or Paid in Cash (1)	**Stock Awards** (2)	**Option Awards** (2)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Kent Swanson	$ 60,000	$ 40,000	$ -	$ -	$ -	$ -	$100,000
Michael Lopach	$ 56,500	$ 40,000	$ -	$ -	$ -	$ -	$96,500
Paul Buckman	$ 73,500	$ 40,000	$ -	$ -	$ -	$ -	$113,500
Eric Timko	$ 53,000	$ 40,000	$ -	$ -	$ -	$ -	$93,000
John Deedrick	$ 71,500	$ 40,000	$ -	$ -	$ -	$ -	$111,500
Rudy Mazzocchi	$ 55,500	$ 40,000	$ -	$ -	$ -	$ -	$95,500

(1) Compensation during 2017 for our independent Board members was as follows: independent directors receive an annual retainer of $40,000 per year, the independent Chairman of our Board receives an additional $20,000 per year, the Audit Committee Chair, other Committee members received $4,000 per year and all independent directors received an annual equity grant valued at $40,000. In addition, the Chair of our Business Development Committee received $12,500 per year and all other members of the Business Development Committee received $5,000 per year.

(2) Key assumptions used to estimate the grant date fair value are contained in Note 9, “Stock-Based Compensation” above.

Compensation Committee Interlocks and Insider Participation

No interlocking relationship exists between our board of directors and the board of directors or compensation committee of any other company, nor has any interlocking relationship existed in the past.

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

The following table sets forth information regarding the beneficial ownership of our common stock as of December 31, 2017 by (a) each of our former directors and named executive officers, (b) and our executive officers, and (c) each person who is known by us to beneficially own more than 5% of our common stock.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned[2]		Percentage of Shares Beneficially Owned[3]	
Former Directors and Named Executive Officers[1]:				
Carl O'Connell	6,250	(4)		*
Kent Swanson	38,066	(5)	2.5	%
Michael Lopach	6,145	(6)		*
Paul Buckman	1,675	(7)		*
John Deedrick	4,712	(8)		*
Eric Timko	2,475	(9)		*
Rudy Mazzocchi	2,475	(10)		*
David Kirschman, M.D.	141,421	(11)	9.3	%
Our executive officers and former directors as a group (8 persons)	203,220		13.4	%
Five Percent Stockholders:				
OrbiMed Advisors LLC 601 Lexington Ave., 54th Floor New York, NY 10022	236,575	(12)	15.6	%
Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998 9485 Gulfshore Drive, B-201 Naples, FL 34108	106,066	(13)	7.0	%
Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998 P.O. Box 421 15643 Captive Drive Captiva, FL 33924	106,066	(14)	7.0	%

* Less than 1% of outstanding shares of Common Stock.

(1) The address for directors and named executive officers is c/o Xtant Medical Holdings, Inc., 664 Cruiser Lane, Belgrade, Montana 59714.

(2) Unless otherwise indicated, includes shares owned by a spouse, minor children and relatives sharing the same home, as well as entities owned or controlled by the named person. Also includes shares that the named person has the right to acquire within 60 days after January 18, 2018, by the exercise or conversion of any warrant, stock

option or convertible preferred stock. Unless otherwise noted, shares are owned of record and beneficially by the named person and the persons named in the table have sole voting and investment power with respect to the shares beneficially owned by them as set forth opposite their respective names.

(3) The calculation in this column is based on 1,514,899 shares of Common Stock outstanding on December 31, 2017. The shares of Common Stock underlying warrants and stock options are deemed outstanding for purposes of computing the percentage of the person holding them, but are not deemed outstanding for the purpose of computing the percentage of any other person.

(4) Consists of options to purchase 6,250 shares of our Common Stock.

(5) Consists of (a) 10.066 shares of our Common Stock held directly, (b) 1,666 shares held by a family limited partnership, (c) warrants to purchase 416 shares of our Common Stock, (d) options to purchase 916 shares of our Common Stock, (e) 12,500 stock right shares purchased November 17, 2017, (f) 12,500 stock right warrants purchased November 17, 2017, and (g) 0 of the 4,329 restricted stock units ("RSUs") of the annual board award on July 25, 2017 vesting on July 27, 2018.

(6) Consists of (a) 3,454 shares of our Common Stock held directly, (b) 1,118 shares held by a 401(k) plan, (c) warrants to purchase 169 shares of our Common Stock, (d) options to purchase 1,333 shares of our Common Stock, and (e) 0 of the 4,329 RSUs of the annual board award on July 25, 2017 vesting on July 25, 2018.

(7) Consists of (a) 1,675 shares of our Common Stock held directly, and (b) 0 vested of the 4,329 RSUs of annual board award on July 25, 2017 vesting on July 25, 2018.

(8) Consists of (a) 3,879 shares of our Common Stock, (b) options to purchase 833 shares of our Common Stock, and (c) 0 of the 4,329 RSUs of the annual board award on July 25, 2017 vesting on July 25, 2018.

(9) Consists of (a) options to purchase 2,475 shares of our common shares, and (b) 0 of the 4,329 RSUs annual board award on July 25, 2017 vesting on July 25, 2018.

(10) Consists of (a) options to purchase 2,475 shares of our common shares, and (b) 0 of the 4,329 RSUs annual board award on July 25, 2017 vesting on July 25, 2018.

(11) Consists of 141,421 shares of our Common Stock acquired in connection with our acquisition of X-spine, which are no longer subject to a lock-up agreement and escrow agreement.

(12) Based on Schedule 13D filed with the SEC on May 30, 2017, as well as our knowledge regarding recent purchases of the Notes by affiliates of OrbiMed Advisors LLC ("OrbiMed Advisors"). Includes 39,619 shares of our Common Stock and warrants to purchase 7,309 shares of our Common Stock held by ROS, an entity managed by OrbiMed Advisors. Affiliates of OrbiMed Advisors also purchased $52.0 million aggregate principal amount of the Notes, which are convertible into shares of our Common Stock. However, the indenture prevents note holders from converting their Notes to the extent that such conversion would result in beneficial ownership by the note holder or any of its affiliates in excess of 9.99% of the then-outstanding shares of our Common Stock. OrbiMed Advisors, an investment advisor, and Samuel D. Isaly, its managing member and a control person, each have shared voting and dispositive power with respect to shares of our Common Stock and notes held by ROS and OrbiMed.

(13) Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 106,066 shares of our Common Stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement. Kenneth J. Hemmelgarn, Jr. is a beneficiary of and the sole trustee of the Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998, which may be revoked by Kenneth J. Hemmelgarn, Jr. Kenneth J. Hemmelgarn, Jr. and Brian J. Hemmelgarn are brothers and may be deemed to be members of a "group" for purposes of Section 13(d)(3) of the Exchange Act, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

(14)

Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 106,066 shares of our Common Stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement. Brian J. Hemmelgarn is a beneficiary of and the sole trustee of the Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998, which may be revoked by Brian J. Hemmelgarn. Kenneth J. Hemmelgarn, Jr. and Brian J. Hemmelgarn are brothers and may be deemed to be members of a “group” for purposes of Section 13(d)(3) of the Exchange Act, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

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Securities authorized for issuance under equity compensation plans

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	37,515	$ 115.68	69,166	(1)
Equity compensation non-plan, not approved by security holders (2)	25,000	$ 13.32	N/A	
Total	62,515	$ 74.76	69,166	

(1) In addition to options outstanding, the Company also has 25,974 shares of restricted stock outstanding that have been issued under the Plan.

(2) For a description of certain inducement grants not approved by security holders, see “Amended and Restated Xtant Medical Equity Incentive Plan and Inducement Grants” below.

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

Transactions with Related Persons, Promoters and Certain Control Persons

As discussed in Note 17 above, the Company entered into the Restructuring Agreement with the Holders. Other than as described above with respect to (i) ROS and OrbiMed and (ii) PWPI and PWIMF, the Holders do not constitute a "group" as such term is defined in Section 13(d) of the Exchange Act.

Furthermore, as discussed in Note 17 above, the Company entered into the Support Agreement with the Holders, the Company's executive officers and directors and certain of the Company's stockholders

Certain former X-spine shareholders, who each now own less than 10% of our common stock, own a controlling interest in Norwood Tool Company d/b/a Norwood Medical, one of X-spine's larger suppliers. In 2017, Xtant purchased less than 10% of its operating products from Norwood Medical.

David Kirschman's sister, Deborah Kirschman Klopsch, served as Xtant's Corporate Counsel and Director of Corporate Compliance through July 2017. Compensation paid to Ms. Klopsch was $120,000 and $50,327 in 2017 and 2016, respectively. Ms. Klopsch also received 1,005 of the restricted stock units at $3.19 a share for a total cost of approximately $3,000 to be expensed ratably over the vesting period as General and administrative expense (See Note 7, "Stock-Based Compensation" above).

The Audit Committee or the disinterested members of the full Board of Directors reviews and approves all related party transactions.

Director Independence

The following board members are independent directors, as defined under the independence standards of the NYSE American: John Bakewell, Michael Mainelli, Robert McNamara. The additional, non-management, current board members include Jeffrey Peters, Matthew Rizzo and Michael Eggenberg. Our sole committee, the Audit Committee is comprised solely of non-management directors, and the composition of our Audit Committees is described in Item 10 of this Form 10-K.

Item 14. Principal Accountant Fees and Services

EKS&H LLLP ("EKS&H") served as the independent registered public accounting firm to audit our books and accounts for the fiscal years ending December 31, 2017 and December 31, 2016. The following table presents the aggregate fees billed for professional services rendered by EKS&H for the years ended December 31, 2017 and December 31, 2016.

	2017	2016
Audit fees	$283,000	$234,000
Audit-related fees	14,500	41,364
Tax fees	45,000	33,705
All other fees	28,869	2,581
Total fees	$371,369	$311,650

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

Audit Committee's Pre-Approval Policy

It is the Audit Committee's policy to approve in advance the types and amounts of audit, audit-related, tax and any other services to be provided by our independent accountants. In situations where it is not possible to obtain full Audit Committee approval, the Audit Committee has delegated authority to the Chairman of the Audit Committee to grant pre-approval of auditing, audit-related, tax and all other services. Any pre-approved decisions by the Chairman are required to be reviewed with the Audit Committee at its next scheduled meeting.

The Audit Committee approved 100% of the services provided by EKS&H.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of or are included in this Annual Report on Form 10-K:

1. Financial statements included in Item 8 of this Annual Report; and

2. Exhibits listed in the Exhibit Index filed as part of this Annual Report.

Item 16. Form 10-K Summary

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XTANT MEDICAL HOLDINGS, INC.

By: /s/ Laura Kendall
Name: Laura Kendall
Title: Deputy Restructuring Officer
(serving as principal financial officer)
Date: April 2, 2018

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on April 2, 2018.

Signature	**Title**
/s/ Carl O'Connell Carl O'Connell	Chief Executive Officer (Principal Executive Officer)
/s/ John Bakewell John Bakewell	Director
/s/ Michael Eggenberg Michael Eggenberg	Director
/s/ Michael Mainelli Michael Mainelli	Director
/s/ Robert McNamara Robert McNamara	Director
/s/ Jeffrey Peters Jeffery Peters	Director
/s/ Matthew Rizzo Matthew Rizzo	Director

/s/ Laura Kendall	Deputy Restructuring Officer
Laura Kendall	(serving as principal financial officer)

Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of June 30, 2010, by and among K-Kitz, Inc., KB Merger Sub, Inc. and Bacterin International, Inc. (filed as Exhibit 2.1 to the Registrant's Form 8-K filed with the SEC on June 30, 2010 and incorporated by reference herein).
2.2	Common Stock Purchase Agreement, dated March 16, 2015, by and between Bacterin and Aspire Capital Fund, LLC (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on March 17, 2015 and incorporated by reference herein).
2.3	Amended and Restated Common Stock Purchase Agreement, dated April 17, 2015, by and between Bacterin and Aspire Capital Fund, LLC (filed as Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 filed with the SEC on April 17, 2015 and incorporated by reference herein).
2.4	Stock Purchase Agreement, dated July 27, 2015, by and among Bacterin, X-spine Systems, Inc. and the sellers named therein (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on July 28, 2015 and incorporated by reference herein).
3.1	Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Registrant's Form 10-Q filed with the SEC on November 14, 2011 and incorporated by reference herein).
3.2	Certificate of Amendment to Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on July 25, 2014 and incorporated by reference herein).
3.3	Certificate of Amendment to Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on August 3, 2015 and incorporated by reference herein).
3.4	Amended and Restated Bylaws (filed as Exhibit 3.2 to the Registrant's Form 8-K filed with the SEC on October 1, 2015 and incorporated by reference herein).
4.1	Form of Warrant to Purchase Common Stock (filed as Exhibit 4.1 to the Registrant's Form 8-K filed with the SEC on July 31, 2014, and Exhibit 4.1 to the Registrant's Form 8-K filed with the SEC on June 5, 2013 and incorporated by reference herein).
4.2	Form of Warrant Certificate for Warrants underlying Units (filed as Exhibit 4.1 to the Registrant's Form 10-Q filed with the SEC on November 10, 2016 and incorporated by reference herein).
4.3	Form of Pre-Funded Warrant (filed as Exhibit 4.3 to the Registrant's Form 10-Q filed with the SEC on November 10, 2016 and incorporated by reference herein).
4.4	Form of Common Stock Certificate (filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 filed with the SEC on December 21, 2015 and incorporated by reference herein).
4.5	Form of Common Stock Certificate (filed as Exhibit 4.2 to the Registrant's Form 10-Q filed with the SEC on November 10, 2016 and incorporated by reference herein).
4.6	Registration Rights Agreement, dated March 16, 2015, by and between Bacterin and Aspire Capital Fund, LLC (filed as Exhibit 4.1 to the Registrant's Form 8-K filed with the SEC on March 17, 2015 and incorporated by reference herein).
4.7	Registration Rights Agreement, dated July 31, 2015, by and among Bacterin, Leerink Partners LLC, OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP (filed as Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on August 3, 2015 and incorporated by reference herein).
4.8	Registration Rights Agreement, dated April 14, 2016, among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.4 to the Registrant's Form 8-K filed with the SEC on April 19, 2016 and incorporated by reference herein).
4.9	

	Registration Rights Agreement (for Common Stock underlying the Indenture Notes), dated January 17, 2017, among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.9 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
4.10	Registration Rights Agreement (for Common Stock underlying the PIK Notes), dated January 17, 2017, among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.13 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
4.11	Indenture, dated July 31, 2015, by and between Bacterin and Wilmington Trust, National Association (filed as Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on August 3, 2015 and incorporated by reference herein).

4.12	Waiver Letter, dated as of March 31, 2017, by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.2 to Form 8-K filed April 6, 2017 and incorporated by reference herein).
4.13	Amendment Number 1 to Indenture, dated as of August 16, 2017, by and between Xtant Medical Holdings, Inc. and Wilmington Trust, National Association (filed as Exhibit 10.2 to Form 8-K filed August 17, 2017 and incorporated by reference herein).
4.14	Amendment Number 2 to Indenture, dated as of October 2, 2017, by and between Xtant Medical Holdings, Inc. and Wilmington Trust, National Association (filed as Exhibit 10.2 to Form 8-K filed October 3, 2017 and incorporated by reference herein).
4.15	Amendment Number 3 to Indenture, dated as of October 31, 2017, by and between Xtant Medical Holdings, Inc. and Wilmington Trust, National Association (filed as Exhibit 10.2 to Form 8-K filed October 31, 2017 and incorporated by reference herein).
4.16	Amendment Number 4 and Waiver to Indenture, dated as of December 1, 2017, by and between Xtant Medical Holdings, Inc. and Wilmington Trust, National Association (filed as Exhibit 10.2 to Form 8-K filed December 4, 2017 and incorporated by reference herein).
4.17	Amendment Number 5 to Indenture, dated as of December 29, 2017, by and between Xtant Medical Holdings, Inc. and Wilmington Trust, National Association (filed as Exhibit 10.2 to Form 8-K filed December 29, 2017 and incorporated by reference herein).
4.18	Form of 6.00% Convertible Senior Note due 202 (filed as Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on August 3, 2015 and incorporated by reference herein).
4.19	Amendment and Waiver, dated as of August 15, 2017, by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.3 to Form 8-K filed August 17, 2017 and incorporated by reference herein).
4.20	Second Amendment and Waiver, dated as of September 29, 2017, by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.3 to Form 8-K filed October 3, 2017 and incorporated by reference herein).
4.21	Third Amendment and Waiver, dated as of October 31, 2017, by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.3 to Form 8-K filed October 31, 2017 and incorporated by reference herein).
4.22	Fourth Amendment and Waiver, dated as of November 30, 2017, by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.3 to Form 8-K filed December 4, 2017 and incorporated by reference herein).
4.23	Fifth Amendment and Waiver, dated as of December 28, 2017, by and among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.3 to Form 8-K filed December 29, 2017 and incorporated by reference herein).
10.1•	Form of Indemnification Agreement for directors (filed as Exhibit 10.6 to the Registrant's Form 10-Q filed with the SEC on November 21, 2017 and incorporated by reference herein).
10.2•	Amended and Restated Xtant Medical Equity Incentive Plan (filed as Exhibit 10.8 to the Registrant's Form 10-Q filed with the SEC on November 16, 2015 and incorporated by reference herein).
10.3•	Form of Stock Option Agreement (filed as Exhibit 10.23 to the Registrant's Form 10-Q filed with the SEC on May 4, 2012 and incorporated by reference herein).
10.4•	Form of Amended and Restated Restricted Stock Agreement (filed as Exhibit 10.4 to the Registrant's Form 10-K filed with the SEC on March 24, 2016 and incorporated by reference herein).
10.5•	Daniel Goldberger Employment Agreement (filed as Exhibit 10.25 to the Registrant's Form 8-K filed with the SEC on August 15, 2013 and incorporated by reference herein).
10.6•	Separation Agreement and General Release dated January 21, 2017 by and between Daniel S. Goldberger and Bacterin International, Inc., and Xtant Medical Holdings, Inc. (filed as Exhibit 10.1 to Form 8-K filed January

23, 2017 and incorporated by reference herein).

10.7• John Gandolfo Employment Agreement (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on July 29, 2014 and incorporated by reference herein).

10.8	•	Amendment No. 2 to John Gandolfo Employment Agreement, dated effective as of February 17, 2017, between Bacterin International, Inc. and John Gandolfo (filed as Exhibit 10.2 to Form 8-K filed February 23, 2017 and incorporated by reference herein).
10.9	•	Carl O'Connell Employment Agreement (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on October 6, 2016 and incorporated by reference herein).
10.10	•	Carl O'Connell Stock Option Agreement (filed as Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on October 6, 2016 and incorporated by reference herein).
10.11	•	Amendment No. 1 to Carl O'Connell Employment Agreement, dated effective as of February 17, 2017, between Xtant Medical Holdings, Inc. and Carl O'Connell (filed as Exhibit 10.1 to Form 8-K filed February 23, 2017 and incorporated by reference herein).
10.12		Form of Board of Director Services Agreement (filed as Exhibit 10.3 to the Registrant's Form 10-Q filed with the SEC on August 10, 2016 and incorporated by reference herein).
10.13		Amended and Restated Credit Agreement dated July 27, 2015 by and between Bacterin and ROS Acquisition Offshore LP (filed as Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on July 28, 2015 and incorporated by reference herein).
10.14		First Amendment to Amended and Restated Credit Agreement, dated March 31, 2016, by and among Bacterin International, and Orbimed Royalty Opportunities II, LP and ROS Acquisition Offshore LP (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on April 4, 2016 and incorporated by reference herein).
10.15		Amendment to Amended and Restated Credit Agreement, dated as of April 14, 2016, by and among Bacterin International, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.5 to the Registrant's Form 8-K filed with the SEC on April 19, 2016 and incorporated by reference herein).
10.16		Fourth Amendment to Amended and Restated Credit Agreement, dated as of July 29, 2016, by and among Bacterin International, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on August 2, 2016 and incorporated by reference herein).
10.17		Sixth Amendment to Amended and Restated Credit Agreement, dated as of September 27, 2016, by and among Bacterin International, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on September 28, 2016 and incorporated by reference herein).
10.18		Seventh Amendment to Amended and Restated Credit Agreement, dated as of December 31, 2016, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on January 6, 2017 and incorporated by reference herein).
10.19		Eighth Amendment to Amended and Restated Credit Agreement, dated as of January 13, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.20		Ninth Amendment to Amended and Restated Credit Agreement, dated as of January 31, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed February 1, 2017 and incorporated by reference herein).
10.21		Tenth Amendment to Amended and Restated Credit Agreement, dated as of February 14, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed February 15, 2017 and incorporated by reference herein).
10.22		Eleventh Amendment to Amended and Restated Credit Agreement, dated as of February 28, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc.,

	ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed March 2, 2017 and incorporated by reference herein).
10.23	Twelfth Amendment and Waiver to Amended and Restated Credit Agreement, dated as of March 31, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed April 6, 2017 and incorporated by reference herein).

10.24	Thirteenth Amendment to Amended and Restated Credit Agreement, dated as of April 30, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.1 to Form 8-K filed May 4, 2017 and incorporated by reference herein).
10.25	Fourteenth Amendment to Amended and Restated Credit Agreement, dated as of May 11, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.1 to Form 8-K filed May 12, 2017 and incorporated by reference herein).
10.26	Fifteenth Amendment to Amended and Restated Credit Agreement, dated as of June 30, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.1 to Form 8-K filed July 7, 2017 and incorporated by reference herein).
10.27	Sixteenth Amendment to Amended and Restated Credit Agreement, dated as of July 15, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.1 to Form 8-K filed July 20, 2017 and incorporated by reference herein).
10.28	Seventeenth Amendment and Waiver to Amended and Restated Credit Agreement, dated as of August 11, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed August 17, 2017 and incorporated by reference herein).
10.29	Eighteenth Amendment to Amended and Restated Credit Agreement, dated as of September 29, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed October 3, 2017 and incorporated by reference herein).
10.30	Nineteenth Amendment to Amended and Restated Credit Agreement, dated as of October 31, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed October 31, 2017 and incorporated by reference herein).
10.31	Waiver, dated as of November 14, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed November 14, 2017 and incorporated by reference herein).
10.32	Twentieth Amendment and Waiver to Amended and Restated Credit Agreement, dated as of November 30, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed December 4, 2017 and incorporated by reference herein).
10.33	Twenty-First Amendment to Amended and Restated Credit Agreement, dated as of December 28, 2017, by and among Bacterin International, Inc., Xtant Medical Holdings, Inc., X-Spine Systems, Inc., Xtant Medical, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to Form 8-K filed December 29, 2017 and incorporated by reference herein).
10.34	Securities Purchase Agreement dated July 27, 2015 by and between Bacterin and the investors named therein (filed as Exhibit 10.4 to the Registrant's Form 8-K filed with the SEC on July 28, 2015 and incorporated by reference herein).
10.35	Distribution Agreement dated January 23, 2014 by and between X-spine Systems, Inc. and Zimmer Spine, Inc., as amended (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on August 3, 2015 and incorporated by reference herein).
10.36	

	Loan and Security Agreement, dated May 25, 2016, among Xtant Medical Holdings, Inc., Bacterin International Inc., X-spine Systems, Inc., Xtant Medical, Inc. and Silicon Valley Bank (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on May 31, 2016 and incorporated by reference herein).
10.37	First Loan Modification Agreement, dated August 12, 2016, among Xtant Medical Holdings, Inc., Bacterin International, Inc., X-spine Systems, Inc., Xtant Medical, Inc. and Silicon Valley Bank (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on August 16, 2016 and incorporated by reference herein).

10.38	Intellectual Property Security Agreement, dated May 25, 2016, among Xtant Medical Holdings, Inc., Bacterin International, Inc., Xtant Medical, Inc. and Silicon Valley Bank (filed as Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on May 31, 2016 and incorporated by reference herein).
10.39	Forbearance Agreement, dated April 17, 2017, among Xtant Medical Holdings, Inc., Bacterin International, Inc., X-spine Systems, Inc., Xtant Medical, Inc. and Silicon Valley Bank (filed as Exhibit 10.1 to Form 8-K filed April 19, 2017 and incorporated by reference herein).
10.40	Forbearance Agreement, dated April 21, 2017, among Xtant Medical Holdings, Inc., Bacterin International, Inc., X-spine Systems, Inc., Xtant Medical, Inc. and Silicon Valley Bank (filed as Exhibit 10.1 to Form 8-K filed April 24, 2017 and incorporated by reference herein).
10.41	Forbearance Agreement, dated April 30, 2017, by and among Xtant Medical Holdings, Inc., Bacterin International, Inc., X-spine Systems, Inc., Xtant Medical, Inc. and Silicon Valley Bank (filed as Exhibit 10.2 to Form 8-K filed May 4, 2017 and incorporated by reference herein).
10.42	Securities Purchase Agreement, dated April 14, 2016, among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on April 19, 2016 and incorporated by reference herein).
10.43	Convertible Promissory Note, dated April 14, 2016, made by Xtant Medical Holdings, Inc. in favor of ROS Acquisition Offshore LP (filed as Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on April 19, 2016 and incorporated by reference herein).
10.44	Convertible Promissory Note, dated April 14, 2016, made by Xtant Medical Holdings, Inc. in favor of OrbiMed Royalty Opportunities II, LP (filed as Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on April 19, 2016 and incorporated by reference herein).
10.45	Securities Purchase Agreement, dated January 17, 2017, between Xtant Medical Holdings, Inc. and Bruce Fund, Inc. (filed as Exhibit 10.2 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.46	Securities Purchase Agreement, dated January 17, 2017, between Xtant Medical Holdings, Inc. and Park West Partners International, Limited. (filed as Exhibit 10.3 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.47	Securities Purchase Agreement, dated January 17, 2017, between Xtant Medical Holdings, Inc. and Park West Investors Master Fund, Limited. (filed as Exhibit 10.4 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.48	Securities Purchase Agreement, dated January 17, 2017, between Xtant Medical Holdings, Inc. and Telemetry Securities, L.L.C. (filed as Exhibit 10.5 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.49	Securities Purchase Agreement (for sale of the Indenture Notes), dated January 17, 2017, among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.6 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.50	Convertible Promissory Note in the principal amount of $995,700, dated January 17, 2017, made by Xtant Medical Holdings, Inc. in favor of ROS Acquisition Offshore LP. (filed as Exhibit 10.7 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.51	Convertible Promissory Note in the principal amount of $564,300, dated January 17, 2017, made by Xtant Medical Holdings, Inc. in favor of OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.8 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.52	Securities Purchase Agreement (for sale of the PIK Notes), dated January 17, 2017, among Xtant Medical Holdings, Inc., ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.10 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.53	Convertible Promissory Note in the principal amount of $42,856.59, dated January 17, 2017, made by Xtant Medical Holdings, Inc. in favor of ROS Acquisition Offshore LP. (filed as Exhibit 10.11 to Form 8-K filed January 20, 2017 and incorporated by reference herein).

10.54	Convertible Promissory Note in the principal amount of $24,288.41, dated January 17, 2017, made by Xtant Medical Holdings, Inc. in favor of OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.12 to Form 8-K filed January 20, 2017 and incorporated by reference herein).
10.55	Waiver, dated as of March 31, 2017, by ROS Acquisition Offshore LP and OrbiMed Royalty Opportunities II, LP. (filed as Exhibit 10.3 to Form 8-K filed April 6, 2017 and incorporated by reference herein).
10.56	Agreement, dated May 8, 2017, between Xtant Medical Holdings, Inc. and Aurora Management Partners Inc. (filed as Exhibit 10.2 to Form 8-K filed May 12, 2017 and incorporated by reference herein).

21.1	Subsidiaries of the Registrant (filed as Exhibit 21.1 to the Registrant's Post-Effective Amendment No. 1 to Form S-1 Registration Statement filed with the SEC on August 25, 2015 and incorporated by reference herein).
23.1*	Consent of Independent Accounting Firm, EKS&H LLLP
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1**	Section 1350 Certification of Chief Executive Officer
32.2**	Section 1350 Certification of Chief Financial Officer
101.INS	XBRL INSTANCE DOCUMENT
101.SCH	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

•Indicates a management contract or compensatory plan.
*Filed herewith.
**Furnished herewith.