Xtant Medical Holdings, Inc.
Form 10-K
March 29, 2017

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, 2016

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	(IRS Employer Identification No.)

incorporation or organization)

664 Cruiser Lane
Belgrade, Montana
(Address of Principal Executive Offices)

59714
(Zip Code)

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

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

Title of each class	Name of each exchange on which registered
Common stock, par value $.000001 per share	NYSE MKT 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, 2016 was $16,420,055 (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 Marketplace).

The number of shares of the Company’s common stock, $0.000001 par value, outstanding as of March 29, 2017 was 18,092,603.

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 class-leading 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 300 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 spinout 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. 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., the Montana corporation, became a wholly owned subsidiary of Bacterin International, Inc., the Nevada corporation. At the end of 2004, management concluded that 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.

We began as a biomaterials testing laboratory and have systematically expanded our strategic vision towards the development of Bacterin-labeled products. Our revenues were initially derived from testing services and milestone payments from collaborative product development agreements with various medical manufacturers. Today we generate most of our revenue from biologics products we manufacture.

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.

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 of Xtant common stock. X-spine is engaged in the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries. As a result of this transaction, X-Spine became a wholly owned subsidiary of the Company.

Before the reverse merger described above, 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 under the ticker symbol "BONE."

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 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.

Products and Services

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

- 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.

- 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.

- BacFast HD facet stabilization dowel is designed with a focus on osteoconductivity and osteoinductive potential. BacFast HD is hyper-demineralized to expose the growth factors and BMPs inherent to cortical bone. With the benefits of HD technology and increased collagen surface area, BacFast® HD also provides the graft with osteoinductive properties without compromising the structural integrity of the graft. These characteristics, coupled with an osteoconductive design through increased surface contact and locking edges to prevent migration, BacFast® HD is engineered with a focus on fusion as well as facet stabilization.

- 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. This was a new addition to Bacterin's biologic products portfolio launched in March 2014.

- hMatrix dermal scaffold is an extension of Bacterin's core biologics technology. hMatrix is an acellular matrix made from donated human dermal tissue that is used to replace a patient's damaged tissue. hMatrix provides a natural collagen tissue scaffold that promotes cellular ingrowth, tissue vascularization and regeneration, and reabsorbs into the patient's dermal tissue for a biocompatible, natural repair.

- 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).

- The Butrex® Anterior Lumbar Buttress Plating System utilizes the patented Resilient Locking Arm Technology to prevent screw back out, while providing repeatable and reliable results. The low profile design, and two point fixation ensures minimal disruption to the local anatomy and high cantilever expulsion resistance. The Butrex System also features an all-in-one drill guide with a plate retaining feature to allow for greater control during plate placement, and to protect adjacent structures.

- 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 provides 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 Zyfix™ Facet Fusion System is a minimally invasive facet fusion system featuring a hollow fenestrated titanium compression screw for bone graft introduction. It is intended for bilateral, transfacet fixation of the facet joint in order to provide stability for fusion.

- The Fixcet® Spinal Facet Screw System is a percutaneous facet screw system offering dual-compression thread and single-thread screws. It is intended for posterior fixation to the lumbar spine (L1 - S1 inclusive). It enables a bilateral, transfacet fixation of the facet joint in order to provide stability for fusion.

- 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 X90® Pedicle Screw System combines unique rotary locking technology and maximum biomechanical performance allowing for simple rod locking without a separate locking cap or set screw. Through its unified design, the X90 Pedicle Screw System is designed to avoid the problems of cross threading, head splay, and cap loosening, endemic to cap type pedicle screw systems.

- 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.

- The X-PORT™ tissue-sparing instrumentation system was designed to maximize surgical access and visualization while minimizing tissue disruption. An ideal partner to the X-spine Fortex pedicle screw system, the radiolucent X-PORT retractor component is integrated with a siderail mounted flexible arm for accurate localization and stability. The X-PORT system includes integral tissue-sparing instrumentation to allow for compression, distraction and rod placement while maintaining anatomic visualization through the retractor component.

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, in an effort 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. Bacterin 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.

We also held patents related to our medical device coatings business. At the end of 2014, the Company made the strategic decision to exit the medical device coatings business and sold the coating equipment and the coating intellectual property in 2015.

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 ®, 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.

Relationship with Zimmer Holdings, Inc.

In January 2014, X-spine entered into a license agreement with Zimmer, under which Zimmer granted to X-spine a royalty-bearing, non-exclusive license under certain Zimmer patents to make, have made, use, practice, offer for sale, sell, export and import certain spinal screw, anchor and rod implants. X-spine is required to pay a royalty on gross sales of products covered by the in-licensed patents. X-spine's license agreement with Zimmer continues so long as there is an enforceable claim in the in-licensed patents. Either X-spine or Zimmer may terminate the agreement for any material breach by the other party that is not cured within a specified time period or in the event of the other party's insolvency.

Also, in January 2014, X-spine entered into a distribution agreement with Zimmer, under which X-spine granted Zimmer a co-exclusive right to distribute certain X-spine products worldwide. X-spine is entitled to receive a royalty in the low-single digits on net sales of products. X-spine also obtained a non-exclusive, perpetual, worldwide license under certain Zimmer patents to distribute certain of X-spine's products. In consideration for the rights granted to X-spine under the agreement, X-spine will be required to pay a royalty on net sales of certain products of 4.0%.

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 developed a hybrid sales force. We have focused our United States sales activities on Orthopedic Surgeons and Neuro Surgeons performing spine procedures, and are working to cover call points with 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 of the American Association of Tissue Banks in good standing. 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.

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 another legally marketed device that was on the market prior to 1976 (known as a Pre-amendments device) or was cleared after 1976 as a 510(k) device. The device(s) to which a substantial equivalence comparison is made is called a "predicate" device. A company cannot claim substantial equivalence to a device approved by FDA under the lengthier, more extensive Premarket Approval process ("PMA"). The standard for approving a PMA device is to establish "reasonable assurance of safety and effectiveness" in an independent and absolute sense, i.e. not by comparing the applicant's device to another device as with a 510(k). 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. The 510(k) process is reserved for low to moderate risk devices. Under the 510(k) process applicants must demonstrate that their device is safe and effective in a comparative sense by comparing itself to a predicate 510(k) device that has been on the market safely and effectively for some time. To establish substantial equivalence to a predicate device, an applicant must demonstrate that it has the 1) same intended use, 2) the same technological characteristics, and 3) if the technological characteristics are different, the applicant must show those differences do not raise different questions of safety and effectiveness. Making this case to FDA requires an extensive submission with a lot of written, telephonic and sometimes face-to-face dialogue with FDA. The applicant must provide data to demonstrate that their device does not diminish safety and effectiveness in comparison to the predicate device. The type of data necessary for a clearance differs for each type of device and the claims the company seeks to make and FDA's expectations for data are often unclear and do change. Companies submit performance data, e.g., bench testing, in vitro and in vivo data, biocompatibility, animal data, etc. The quality and quantity of data needed is usually discussed and negotiated with FDA. In some cases, data from human clinical trials must also be submitted in support of a 510(k) submission.

The discussion of what data are 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 PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. A company files for a de novo approval when it does not have a predicate to which it can claim substantial equivalence. Once a de novo application is reviewed and approved, it results in the device having a Class II status and future devices from the company or a competitor may use the company de novo-approved device as a 510(k) predicate. A de novo approval is reserved for Class II moderate risk devices and a company must show that special controls can be created which subsequent applicants can follow to obtain a 510(k) clearance. The advantage of the de novo approval is that it requires less data than a PMA. The disadvantage is that it may require more data than a 510(k) and most often will include human clinical data. FDA is

increasingly moving devices with slightly different proposed indication statements or different technological features off the 510(k) path and on to the de novo path resulting in more time and expense for the company.

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k) or a PMA.

In the future, Xtant may decide to strategically commercialize products in the United States that would require a PMA, but there are no plans to do so at the present time. Clinical trials are almost always required to support a PMA.

Ongoing FDA Regulation

After a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include: establishment registration and device listing with the FDA; the current Good Manufacturing Regulations and Quality Systems Regulations (together the "QSR"), which requires manufacturers to follow stringent design, testing, process control, documentation and other quality assurance procedures; labeling regulations, which prohibit the promotion of products for unapproved, i.e. "off-label," uses and impose other restrictions on labeling; Medical Device Reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (the "FDCA") that may present a risk to health; and requirements to conduct post-market surveillance studies to establish continued safety data.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or PMA of new product versions;
- revocation of 510(k) clearance or PMAs previously granted; and
- criminal prosecution and penalties.

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. For example, the federal government has enforced the Anti-Kickback Statute to reach large settlements with device manufacturers based on allegedly sham consultant arrangements with physicians. 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 practices.

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.

There has also been a recent trend of increased federal and state regulation requiring the public disclosure of payments and transfers of value provided to healthcare professionals or entities. 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 February, 2017, Xtant had 253 full-time employees and 257 total employees, of whom 105 were in operations, 56 were in sales, 14 were in marketing, 14 were in R&D and Engineering, 34 were in QA/QC, and 30 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 which runs through August 2023. The lease also has a ten-year renewal option.

We lease an approximately 14,000 square foot facility at 664 Cruiser Lane, Belgrade, Montana 59714, which was involved in a sale-leaseback transaction in October, 2015 (See Note 12, “Commitments and Contingencies” below). 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 located at 363 Centennial Parkway, Suite 220, Louisville, Colorado 80027.

We also lease facilities at 452 Alexandersville Road, Miamisburg, Ohio 45342. The leased property contains approximately 31,600 square feet, of which approximately 19,260 square feet are office space and approximately 4,740 square feet are warehouse space. The space includes a manufacturing facility with multi-axis CNC machining capacity. The facility specializes in the manufacturing of prototypes, custom instrumentation, test fixtures and key production items. The space includes an advanced biomechanical laboratory and a full bioskills lab for cadaver surgery and clinician training. The facilities are leased under a three-year lease which runs through November 2019.

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

We may not be able to generate enough cash flow to meet our debt obligations.

Our future cash flow may be insufficient to meet our debt obligations and commitments. Any insufficiency could negatively impact our business. A range of economic, competitive, business, regulatory, and industry factors will affect our future financial performance, and, as a result, our ability to generate cash flow from operations and to pay our debt. Many of these factors, such as economic and financial conditions in our industry and the U.S. or the global economy, or competitive initiatives of our competitors, are beyond our control.

If we do not generate enough cash flow from operations to satisfy our debt obligations, we may have to undertake alternative financing plans, such as:

- reducing or delaying capital investments;
- raising additional capital;
- refinancing or restructuring our debt;
- selling assets;
- ceasing our operations; and
- filing for bankruptcy.

We cannot assure you that we would be able to implement alternative financing plans, if necessary, on commercially reasonable terms, or at all, or that implementing any such alternative financing plans would allow us to meet our debt obligations.

If we are unable to meet our debt obligations, we would be in default under the terms of such arrangement, permitting acceleration of the amounts due. If the amounts outstanding under our indebtedness were to be accelerated, we could be forced to file for bankruptcy.

The Company does not have cash on hand to satisfy its current interest obligations under its senior credit facility. Failure of the Company to successfully negotiate its interest obligations will result in the Company being in default under the senior credit facility and, due to the cross defaults thereunder, under the Loan and Security Agreement, dated May 25, 2016, with Silicon Valley Bank.

We will need to secure additional financing in order to continue to finance our operations. If we are unable to secure additional financing on acceptable terms, or at all, we may be forced to curtail or cease our operations.

We will need to secure additional sources of capital to develop our business and product candidates as planned. We are seeking substantial additional financing through our current senior debt holder as well as public and/or private financing, which may include equity and/or debt financings and through other arrangements, including collaborative arrangements. If we are unable to secure additional financing in the near term, we may be forced to:

- curtail or abandon our existing business plans;
- reduce our headcount;
- file for bankruptcy;
- seek to sell some or all of our assets; and/or
- cease our operations.

If we are forced to take any of these steps, any investment in our common stock may be worthless.

Affiliates of OrbiMed may be able to exert significant influence over the Company.

Certain private investment funds for which OrbiMed Advisors LLC serves as the investment manager purchased $52 million of notes in an offering in July of 2015. In addition, affiliates of OrbiMed are significant shareholders and we owe affiliates of OrbiMed approximately $43 million in original principal, plus interest and exit fees, pursuant to our Amended and Restated Credit Agreement and other convertible promissory notes issued to such affiliates. Accordingly, OrbiMed may be able to exert significant influence over the Company. Although OrbiMed has been a

strong supporter of the Company, OrbiMed may have interests that differ, or, in some cases, conflict with, interests of other shareholders.

There is a possibility that we may not be able to continue to operate as a "going concern".

We have adopted ASU No. 2014-15, "Disclosure of Uncertainties about the Entity's Ability to Continue as a Going Concern." We have concluded that there is an uncertainty about our ability to continue as a going concern and our independent registered public accountants have incorporated into their opinion accordingly. This opinion could materially limit our ability to raise additional funds by issuing new debt or equity securities or otherwise. If we fail to raise sufficient capital when needed, we will not be able to complete our proposed business plan. As a result we may have to liquidate our business and investors may lose their investments. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations described herein, obtain financing and eventually attain profitable operations. Investors should consider our independent registered public accountant's comments when deciding whether to invest in the Company.

Our Common Stock may be delisted from the NYSE MKT, and we may move to the OTCQX marketplace.

On August 15, 2016, we received a letter from NYSE MKT notifying us that we are not in compliance with NYSE MKT's continued listing standards. Specifically, we are not in compliance with Section 1003(a)(i) of the Company Guide with stockholders' equity of less than $2,000,000 and net losses in two of our three most recent fiscal years, Section 1003(a)(ii) with stockholders' equity of less than $4,000,000 and net losses in three of our four most recent fiscal years and Section 1003(a)(iii) of the Company Guide with stockholders' equity of less than $6,000,000 and net losses in five of our most recent fiscal years. Therefore, we have become subject to the procedures and requirements of Section 1009 of the Company guide and submitted a plan of compliance addressing how we intend to regain compliance with Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the Company Guide by February 15, 2018.

This notice has no effect on the listing of our common stock at this time, subject to compliance with other NYSE MKT continued listing standards; however, the consolidated tape now includes a ".BC" indicator, which will be removed at such time as the Company is deemed compliant with NYSE MKT's continued listing standards.

If we are delisted from the NYSE MKT, we anticipate that our common stock will trade on the OTCQX marketplace. If our common stock is delisted from the NYSE MKT, our stock price and liquidity may be negatively affected, some shareholders may sell their shares, and we may not be able to attract institutional investors in future financing transactions. In addition, under current SEC rules, our common stock must be listed on a national securities exchange in order to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3, or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). If we were unable to utilize a Form S-3 registration statement for primary and secondary offerings of our common stock, we would be required to file a Form S-1 registration statement, which could delay our ability to raise funds in the future, may limit the type of offerings of common stock we could undertake, and could increase the expenses of any offering, as, among other things, registration statements on Form S-1 are subject to SEC review and comments whereas take downs pursuant to a previously effective Form S-3 are not. There can be no assurance that our common stock will remain listed on the NYSE MKT.

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 senior credit facility;
- our observance of covenants under our credit facilities, including the March 31, 2017 covenants on revenue, minimum liquidity and consolidated senior leverage ratio;
- our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our operating expenses;
- 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 MKT;
- 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 and we will need to raise additional funds in the future; however, additional funds may not be available on acceptable terms, or at all.

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 and we may be have to pay out-of-pocket.

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 to offset future taxable income may become 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 carryforwards, 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. It is possible that the issuance of common stock upon conversion of our notes could result in an ownership change under Section 382, and there can be no assurance that this will not happen. If an "ownership change" occurs, Section 382 would impose an annual limit on the amount of pre-change net operating losses and other losses 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."

Because United States federal 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. In addition, if an ownership change were to occur, it is possible that the limitations imposed on our ability to use pre-ownership change losses and certain recognized built-in losses could cause a net increase in our United States federal income tax liability 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 reduced, such reduction could negatively impact the book value of our common stock.

The business acquired from X-spine depends, in part, on a key distributor arrangement.

Certain of X-spine's former shareholders, who now own over 10% of our common stock, own a controlling share of X-spine's largest supplier, Norwood Tool Company d/b/a Norwood Medical. In 2016, Xtant purchased from Norwood Medical less than 10% and in 2015, approximately 12% of its operating products. X-spine's dependence on Norwood Medical exposes us to risks, including limited control over pricing, availability and delivery schedules. If Norwood Medical ceases to provide X-spine with sufficient quantities of products in a timely manner or on terms acceptable to X-spine, or ceases to manufacture products of acceptable quality, X-spine would have to seek alternate sources of supply. Because of the nature of X-spine's regulatory and quality control requirements, and the proprietary nature of its products, it may not be able to quickly engage additional or replacement suppliers. Any such disruption could harm X-spine's business, results of operations or financial condition.

We may not be able to deduct all or a portion of the interest payments on notes for U.S. federal income tax purposes.

The deduction for all or a portion of the interest paid or incurred on indebtedness classified as "corporate acquisition indebtedness" for U.S. federal income tax purposes may be disallowed. A convertible debt instrument may be classified as "corporate acquisition indebtedness" under the Code if the proceeds thereof are used, directly or indirectly, to finance an acquisition and certain other conditions are met. The convertible notes we issued to finance a portion of the acquisition may be treated as corporate acquisition indebtedness. Accordingly, the deduction for all or a portion of the interest paid or incurred on notes may be disallowed. If we were not entitled to deduct interest on our notes, our after-tax operating results could be adversely affected.

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 agreement with affiliates of OrbiMed contains representations, warranties, fees, affirmative and negative covenants, including a minimum cash balance, a leverage ratio and minimum revenue amounts by quarter, 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 these agreements. Upon the occurrence of an event of default under our debt agreements, 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 need to use 50% of the net proceeds from future offerings to make a mandatory prepayment on our loan.

Subject to the discretion of our lender, our credit agreement with affiliates of OrbiMed includes an obligation on our part to use 50% of the net proceeds from equity offerings above $50 million in the aggregate to make a mandatory prepayment on our loan. This provision could reduce the net proceeds to us in future financing transactions, which may affect our ability to raise capital in the future.

Despite our current consolidated debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.

Despite our current consolidated debt levels, we and our subsidiaries may be able to incur substantial additional debt in the future, including secured debt. The indenture governing some of our notes permits us and our subsidiaries to incur additional indebtedness or to take a number of other actions that could diminish our ability to make payments on such notes.

We may not have the ability to raise the funds necessary to pay interest on notes or to repurchase notes upon a fundamental change.

In certain circumstances, we are obligated to pay additional interest or special interest on notes. In addition, if a fundamental change occurs, holders of notes may require us to repurchase all or a portion of their notes in cash. Any of the cash payments described above could be significant, and we may not have enough available cash or be able to obtain financing so that we can make such payments when due. In addition, our ability to repurchase our notes, to pay additional interest or special interest on notes, or to pay cash upon conversions of notes may be limited by law or by agreements governing our existing or future indebtedness. For example, under the amended and restated credit facility that we entered into in connection with the initial issuance of notes, we are restricted from making any payment or distribution with respect to, or purchasing, redeeming, defeasing, retiring or acquiring, our notes, other than payments of scheduled interest on notes, issuance of conversion shares, and payment of cash in lieu of fractional shares.

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.

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 agreement and any future indebtedness we may incur and to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our board of directors or a duly authorized committee of our board of directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders 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 5,000,000 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, we have a staggered board of directors and advanced notice is required prior to stockholder proposals, which might further delay a change of control.

Future sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of our notes.

In the future, we may sell shares of our common stock or equity-related securities to raise capital. In addition, as of December 31, 2016, 7,497,244 shares of our common stock are reserved for issuance upon the exercise of stock options and warrants and additional amounts are reserved for issuance upon conversion of notes. At December 31, 2016, we also have reserved 1,071,629 shares of common stock for issuance pursuant to a common stock purchase agreement with Aspire Capital Fund, LLC. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock or equity-related securities, or the perception that such issuances and sales may occur, could adversely affect the trading price of our notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

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, as amended by the Health Care and Education Reconciliation Act (collectively "PPACA"), to reform the United States healthcare system was enacted into law. 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. X-spine products also are subject to this excise tax. 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 recent federal legislation suspended the collection of the 2.3 percent excise tax on medical devices for two years. The tax will then resume unless the tax is permanently repealed.

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 new 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 under the U.S. Federal Food, Drug and Cosmetic Act, the Anti-Kickback Statute, the Federal False Claims Act, the Physician Payments Sunshine Act, 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 (the “HHS”). 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. Because of the nature of our business, we are involved from time to time in lawsuits, claims, audits and investigations, including whistleblower actions by private parties and subpoenas from governmental agencies such as OIG and HHS. In February 2013, we received a subpoena from the OIG seeking documents in connection with an investigation into possible false or otherwise improper claims submitted to Medicare. The subpoena requested documents related to physician referral programs operated by the Company, which we believe refers to the Company’s prior practice of compensating physicians for performing certain educational and promotional services on behalf of the Company during 2009 and 2010. We later learned that this subpoena resulted from a qui tam action that was dismissed without prejudice in November 2013 after the Department of Justice declined to intervene. 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.

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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. 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 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 a guidance to address this issue and it is a guidance document with which FDA and industry is very familiar. FDA has announced they are about to issue a new draft guidance for public comment. We are unclear how dramatic the proposed changes may be. Until then, manufacturers may continue to adhere to the FDA's 1997 guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device, but the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

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 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 FDA during a routine inspection of our plant discovers we have made modifications by way of letter-to-file, that FDA believes should have been cleared with a new 510(k), the FDA can also allege that the company has failed to file with 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, 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 FDA to product modifications on an ongoing basis for which 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 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 FDA's observations related to our documentation of corrective and preventative actions, procedures for receiving, reviewing and evaluating complaints, procedures to control product that does not conform to specified requirements and procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. Although we believe we have corrected all of these observations, the FDA could disagree with our conclusion and corrective and remedial measures. 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 current good manufacturing practice, or GMP requirements, known as the Quality System Regulation, or 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;
- 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.

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 Public Health Service Act ("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 the National Organ Transplant Act, or 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 that was the result of a sale-leaseback transaction (See Note 12, “Commitments and Contingencies” below).

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 located at 363 Centennial Parkway, Suite 220, Louisville, Colorado 80027.

We also lease facilities at 452 Alexandersville Road, Miamisburg, Ohio 45342. The leased property contains approximately 31,600 square feet, of which approximately 19,260 square feet are office space and approximately 4,740 square feet are warehouse space. The space includes a manufacturing facility with multi-axis CNC machining capacity. The facility specializes in the manufacturing of prototypes, custom instrumentation, test fixtures and key production items. The space includes an advanced biomechanical laboratory and a full bioskills lab for cadaver surgery and clinician training. The facility is leased under a three-year lease which runs through November 2019.

Item 3. Legal Proceedings

We are engaged in ordinary routine litigation incidental to our business from time to time, including product liability disputes.

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 MKT 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 MKT 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 MKT and the OTCQX marketplace, as applicable, for the periods indicated below.

	High	Low
First Quarter 2015 (January 1, 2015 - March 31, 2015)	$4.50	$2.75
Second Quarter 2015 (April 1, 2015 - June 30, 2015)	$4.49	$2.55
Third Quarter 2015 (July 1, 2015 - September 30, 2015)	$4.49	$2.70
Fourth Quarter 2015 (October 1, 2015 - December 31, 2015)	$3.50	$2.28
First Quarter 2016 (January 1, 2016 - March 31, 2016)	$3.75	$2.02
Second Quarter 2016 (April 1, 2016 - June 30, 2016)	$2.72	$1.51
Third Quarter 2016 (July 1, 2016 - September 30, 2016)	$2.05	$0.93
Fourth Quarter 2016 (October 1, 2016 - December 31, 2016)	$1.30	$0.45

Holders of Record

As of March 15, 2017, we had 208 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 senior credit facility and to make the interest payment deferred to March 31, 2017;

- our ability to maintain sufficient liquidity to fund our operations;

- our ability to remain listed on the NYSE MKT;

- our ability to obtain financing on reasonable terms;

- our ability to increase revenue;

- our ability to continue as a going concern;

- our ability to maintain sufficient liquidity to fund our operations;

- 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 recent and 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.

- influence by our management;

- 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, 2016 and December 31, 2015

	Year Ended December 31,					
	2016			2015		
	Amount	% of Revenue		Amount	% of Revenue	
Revenue						
Orthopedic product sales	$89,388,145	99.3	%	$58,194,249	98.1	%
Other revenue	614,591	0.7	%	1,151,468	1.9	%
Total Revenue	90,002,736	100.0	%	59,345,717	100.0	%
Cost of Sales	27,710,014	30.8	%	20,262,728	34.1	%
Gross Profit	62,292,722	69.2	%	39,082,989	65.9	%
Operating Expenses						

General and administrative	15,762,531	17.5	%	12,993,307	21.9	%
Sales and marketing	44,055,813	48.9	%	28,731,184	48.4	%
Research and development	3,410,600	3.8	%	2,546,362	4.3	%
Depreciation and amortization	4,940,955	5.5	%	3,819,588	6.4	%
Acquisition and integration related expenses (Note 2)	1,401,366	1.6	%	4,935,755	8.3	%
Extinguishment of debt	-	0.0	%	(2,345,019)	(4.0)	%
Impairment of assets	-	0.0	%	233,748	0.4	%
Non-cash consulting expense	266,721	0.3	%	246,165	0.4	%
Total Operating Expenses	69,837,986	77.6	%	51,161,090	86.2	%
Loss from Operations	(7,545,264)	(8.4)	%	(12,078,101)	(20.4)	%
Other Income (Expense)						
Interest expense	(12,262,750)	(13.6)	%	(7,733,748)	(13.0)	%
Change in warrant derivative liability	716,738	0.8	%	270,020	0.5	%
Non-cash consideration associated with stock purchase agreement	-	0.0	%	(558,185)	(0.9)	%
Other income (expense)	(351,914)	(0.4)	%	388,176	0.7	%
Total Other Income (Expense)	(11,897,926)	(13.2)	%	(7,633,737)	(12.9)	%
Net Loss from Operations Before (Provision) Benefit for Income Taxes	(19,443,190)	(21.6)	%	(19,711,838)	(33.2)	%
Benefit (Provision) for Income Taxes						
Current	(50,362)	(0.1)	%	-	0.0	%
Deferred	-	0.0	%	17,537,408	29.6	%
Net Loss	$(19,493,552)	(21.7)	%	$(2,174,430)	(3.7)	%

As with all the annual comparisons stated below, the results only include X-spine results as of the Acquisition Date, July 31, 2015 (See Note 2, “Business Combination” below) in the results for the year ended December 31, 2016.

Going Concern

The Company has incurred losses since its inception. The terms, conditions and amounts outstanding under the Company’s debt agreements as described in Footnotes 9 and 18 raises substantial doubt about the Company’s ability to continue as a going concern. The Company has established a special committee of its board of directors to evaluate restructuring alternatives, assist in related negotiations with the Company’s lenders and consider alternatives for raising new capital. The Company also is evaluating various cost-reduction and cash flow improvement measures. However, there can be no assurance that the Company will be successful in these efforts.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern; however, the above conditions raise substantial doubt about the Company’s ability to do so. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

Revenue

Total revenue for the year ended December 31, 2016 increased approximately 51.7% to $90,002,736 compared to $59,345,717 in the prior year. The increase of $30,657,019 is due mostly to the X-spine acquisition and the impact of new products.

Cost of sales

Costs of sales consist primarily of manufacturing costs and depreciation of surgical trays. Costs of sales increased by 36.8% or $7,447,286 to $27,710,014 for the year ended December 31, 2016 from $20,262,728 for the year ended 2015. Cost of sales as a percent of total sales was 30.8% of revenues for the year ended December 31, 2016 compared to 34.1% in the year ended 2015. The decrease is primarily the result of changes in product mix and increased economies of scale.

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 36.5%, or $18,676,896 for the year ended December 31, 2016 compared to the year ended December 31, 2015, primarily due to the reasons set forth below and the expenses due to X-spine acquisition which includes “Acquisition and integration related expenses”.

General and Administrative

General and administrative expenses consist principally of corporate personnel, 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 increased 21.3%, or $2,769,224, to $15,762,531 for the year ended December 31, 2016 compared to the same period of 2015. Almost all of the increase is due to the acquisition of X-spine and the absorption of the general and administrative infrastructure for the full year in 2016 as opposed to five months of activity in the 2015 fiscal year.

Sales and Marketing

Sales and marketing expenses primarily consist of costs for sales and marketing personnel, sales commissions, costs for trade shows, sales conventions and meetings, travel expenses, advertising and other sales and marketing related costs. Sales and marketing expenses increased 53.3%, or $15,324,629, to $44,055,813, for the year ended December 31, 2016 compared to $28,731,184 for the same period of 2015. As a percentage of revenue, sales and marketing expenses increased slightly to 48.9% in the year ended 2016 from 48.4% in the prior year. The increase is substantially due to the absorption of the X-spine sales and marketing infrastructure for a full year as opposed to just five months activity in the 2015 fiscal year.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new technologies and processes for our orthopedic product lines. Research and development expenses increased $864,238 or 33.9% from $2,546,362 for the year ended December 31, 2015 to $3,410,600 for the same period of 2016. All of the increase is due to the acquisition of X-spine.

Depreciation and Amortization

Depreciation and amortization expense consists of depreciation of long-lived property and equipment, patents and intangible assets that resulted from the acquisition of X-spine. Depreciation and amortization expense increased $1,121,367 to $4,940,955 for the year ended December 31, 2016 from $3,819,588 in the same period in 2015. Almost all of the increase is due to the amortization of the intangible assets that resulted from the acquisition of X-spine.

Acquisition and Integration Related Expenses

Acquisition and Integration related expenses are $1,401,366 for the year ended December 31, 2016 as compared to $4,935,755 for the year ending December 31, 2015. Acquisition related expenses consisted of investment banking, accounting, consulting, legal fees and miscellaneous expenses associated with the due diligence and execution of the acquisition. Integration related expenses consist of samples, travel and meeting, severance due to reduction in force, retention bonuses and software.

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 increased $20,556 to $266,721 for the year ended December 31, 2016 from $246,165 in the same period in the prior year.

Interest Expense

Interest expense is from our debt instruments. Interest expense for the year ended December 31, 2016 increased $4,529,002 to $12,262,750 as compared to $7,733,748 in the year ended 2015. The increase in interest expense is due to increased long-term and convertible debt issued in part to finance the acquisition of X-spine.

Change in Warrant Derivative Liability

For the year ended December 31, 2016, the Company recorded a gain in its non-cash warrant derivative liability of $716,738 which was primarily driven by a decrease in the closing price of the Company’s common stock from December 31, 2015 to December 31, 2016. 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.

Non-Cash Consideration Associated with Stock Agreement

In the first quarter of 2015 we issued 154,189 shares of our common stock which were valued at $3.62 per share or $558,185 to Aspire Capital as a commitment fee.

Other Income (Expense)

Other expense for the year ended December 31, 2016 was $351,914 as compared to an income of $388,176 in the same period in 2015. Other income (expense) includes legal settlement expense, gain or loss on the sale of fixed assets along with other miscellaneous items.

Benefit (Provision) for Income Taxes

For the year ended December 31, 2016, the Company recorded approximately $50,400 in state and local income taxes. For the year ended December 31, 2015, the Company recorded roughly $17.45 million of a deferred tax benefit in conjunction with the acquisition of X-spine (See note 13, “Income taxes” below).

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 and other debt transactions.

For the year ended December 31, 2016, we received $300,000 and $2,675,126 in the same period last year from the sale of our common stock to Aspire Capital pursuant to a Purchase Agreement. See Note 3, “Equity” below, describing the Purchase Agreement with Aspire Capital. At December 31, 2016, we had $21,570,139 of cash and cash equivalents and accounts receivable.

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 $0.01 ("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 $0.01 exercise price but no Pre-Funded Warrants were sold.

The Rights Offering closed on November 14, 2016. The units were priced at $0.75 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 to Maxim, 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 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. The Tradeable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $0.90 per share. 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 $2.25 for each of 10 consecutive trading days (See Note 3, "Equity" below).

Net cash used in operating activities for the year ended December 31, 2016 was $14,407,296 from various operating activities. For the comparable period of 2015, net cash used in operating activities was $9,099,868.

Net cash used in investing activities for the year ended December 31, 2016 was $5,816,290 due mostly to the purchase of property and equipment which includes additional trays for future sales and additions to our clean room facilities in Montana. For the comparable period of 2015, net cash used in investing activities was $73,571,038 of which $72,975,200 was related to the acquisition of X-spine.

Net cash provided by financing activities was $16,433,837 for the December 31, 2016, primarily from issuance of senior and convertible debt, common stock rights offering and the revolving line of credit. For the comparable period of 2015, net cash provided by financing activities was $84,570,714.

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

We believe that our December 31, 2016 cash on hand and accounts receivable balance of $21,570,139 along with anticipated operating cash receipts from sales expected from operations and our line of credit may not be sufficient to meet our anticipated cash requirements through December 31, 2017. We do not anticipate that we will have sufficient cash funds to service current interest obligations under our senior credit facility and convertible debt.

The Company has incurred losses since its inception. The terms, conditions and amounts outstanding under the Company's debt agreements as described in Footnotes 9 and 18 raises substantial doubt about the Company's ability to continue as a going concern. The Company has established a special committee of its board of directors to evaluate restructuring alternatives, assist in related negotiations with the Company's lenders and consider alternatives for raising new capital. The Company also is evaluating various cost-reduction and cash flow improvement measures. However, there can be no assurance that the Company will be successful in these efforts.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern; however, the above conditions raise substantial doubt about the Company's ability to do so. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

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

We have audited the accompanying consolidated balance sheets of Xtant Medical Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Xtant Medical Holdings, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has recurring losses from operations and has operational and financial uncertainties that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the

outcome of this uncertainty. Our opinion is not modified with respect to that matter.

/s/ EKS&H LLLP

March 29, 2017

Denver, Colorado

XTANT MEDICAL HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2016	As of December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$2,578,267	$6,368,016
Trade accounts receivable, net of allowance for doubtful accounts of $1,653,385 and $2,579,634, respectively	18,991,872	15,385,218
Current Inventories, net	26,266,457	22,684,716
Prepaid and other current assets	1,149,615	601,697
Total current assets	48,986,211	45,039,647
Non-current inventories, net	971,854	1,607,915
Property and equipment, net	15,840,730	11,816,629
Goodwill	41,534,626	41,534,626
Intangible assets, net	35,940,810	40,237,289
Other assets	827,374	791,221
Total Assets	$144,101,605	$141,027,327
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$10,471,944	$9,386,531
Accounts payable - related party (note 16)	640,442	1,406,763
Revolving line of credit	10,448,283	-
Accrued liabilities	8,982,187	9,595,851
Warrant derivative liability	333,613	1,050,351
Current portion of capital lease obligations	244,847	35,139
Total current liabilities	31,121,316	21,474,635
Long-term Liabilities:		
Capital lease obligation, less current portion	832,152	7,800
Long-term convertible debt, less issuance costs	68,937,247	66,436,647
Long-term debt, less issuance costs	50,284,187	44,231,718
Total Liabilities	151,174,902	132,150,800
Commitments and Contingencies (note 12)		
Stockholders' Equity (Deficit):		
Preferred stock, $0.000001 par value; 5,000,000 shares authorized; no shares issued and Outstanding	-	-
	17	11

Common stock, $0.000001 par value; 95,000,000 shares authorized; 17,249,315 shares issued and outstanding as of December 31, 2016 and 11,897,601 shares issued and outstanding as of December 31, 2015		
Additional paid-in capital	85,461,210	81,917,488
Accumulated deficit	(92,534,524)	(73,040,972)
Total Stockholders' Equity (Deficit)	(7,073,297)	8,876,527
Total Liabilities & Stockholders' Equity (Deficit)	$144,101,605	$141,027,327

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2016	**2015**
Revenue		
Orthopedic product sales	$89,388,145	$58,194,249
Other revenue	614,591	1,151,468
Total Revenue	90,002,736	59,345,717
Cost of Sales	27,710,014	20,262,728
Gross Profit	62,292,722	39,082,989
Operating Expenses		
General and administrative	15,762,531	12,993,307
Sales and marketing	44,055,813	28,731,184
Research and development	3,410,600	2,546,362
Depreciation and amortization	4,940,955	3,819,588
Acquisition and integration related expenses (Note 2)	1,401,366	4,935,755
Extinguishment of debt	-	(2,345,019)
Impairment of assets	-	233,748
Non-cash consulting expense	266,721	246,165
Total Operating Expenses	69,837,986	51,161,090
Loss from Operations	(7,545,264)	(12,078,101)
Other Income (Expense)		
Interest expense	(12,262,750)	(7,733,748)
Change in warrant derivative liability	716,738	270,020
Non-cash consideration associated with stock purchase agreement	-	(558,185)
Other income (expense)	(351,914)	388,176
Total Other Income (Expense)	(11,897,926)	(7,633,737)
Net Loss from Operations Before Benefit (Provision) for Income Taxes	(19,443,190)	(19,711,838)
Benefit (Provision) for Income Taxes		
Current	(50,362)	-
Deferred	-	17,537,408
Net Loss	$(19,493,552)	$(2,174,430)
Net loss per share:		

Basic	$(1.54)	$(0.24)
Dilutive	$(1.54)	$(0.24)
Shares used in the computation:		
Basic	12,671,685	9,055,483
Dilutive	12,671,685	9,055,483

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, 2014	6,679,646	$ 7	$ 63,091,620	$(70,866,542)	$ (7,774,915)
Stock-based compensation	-	-	569,705	-	569,705
Issuance of restricted stock	39,312	-	120,000	-	120,000
Issuance of common stock	17,564	-	11,500	-	11,500
Net proceed from the rights issuance	140,053	-	515,395	-	515,395
Issuance of stock related to acquisition	4,242,655	4	14,934,142	-	14,934,146
Issuance of stock to Aspire Capital	778,371	-	2,675,126	-	2,675,126
Net loss	-	-		(2,174,430)	(2,174,430)
Balance at December 31, 2015	11,897,601	$ 11	$ 81,917,488	$(73,040,972)	$ 8,876,527
Stock-based compensation	-	-	256,266	-	256,266
Issuance of restricted stock	58,820	-	200,000	-	200,000
Issuance of common stock	87,549	-	225,000	-	225,000
Net proceeds from the issuance of stock rights	5,055,345	6	2,562,456	-	2,562,462
Issuance of stock to Aspire Capital	150,000	-	300,000	-	300,000
Net loss	-	-		(19,493,552)	(19,493,552)
Balance at December 31, 2016	17,249,315	$ 17	$ 85,461,210	$(92,534,524)	$ (7,073,297)

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2016	**2015**
Operating activities:		
Net loss	$(19,493,552)	$(2,174,430)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,241,870	4,889,272
Purchase accounting valuation allowance	-	(17,537,408)
Non-cash consideration associated with stock purchase agreement	-	558,185
Impairment of Assets	-	956,395
Non-Cash interest	6,784,785	4,814,506
Loss (Gain) on sale of fixed assets	25,458	(596,883)
Non-cash consulting expense/stock option expense	522,987	836,741
Provision for losses on accounts receivable and inventory	223,538	700,234
Change in derivative warrant liability	(716,738)	(270,020)
Extinguishment of debt	-	(2,345,019)
Changes in operating assets and liabilities:		
Trade accounts receivable	(2,680,405)	(5,512,429)
Inventories	(4,074,086)	(545,713)
Prepaid and other assets	(484,061)	(1,044,962)
Accounts payable	319,091	644,149
Accrued liabilities	(2,076,183)	7,527,514
Net cash used in operating activities	(14,407,296)	(9,099,868)
Investing activities:		
Acquisition of X-spine Systems, Inc.	-	(72,975,200)
Purchases of property and equipment and intangible assets	(5,832,690)	(2,263,033)
Proceeds from sale of fixed assets	16,400	1,667,195
Net cash used in investing activities	(5,816,290)	(73,571,038)
Financing activities:		
Proceeds from long-term and convertible debt, net of deferred and financing costs	3,238,166	83,897,361
Payments on long-term debt	-	(1,325,814)
Net proceeds from equity private placement	-	515,395
Payment of royalty obligation	-	(542,905)
Payments on capital leases	(144,600)	(101,760)
Net proceeds from the revolving line of credit	10,252,809	-
Proceeds from exercise of options	-	11,500
Net proceeds from issuance of stock and warrants	3,087,462	2,116,937
Net cash provided by financing activities	16,433,837	84,570,714
Net change in cash and cash equivalents	(3,789,749)	1,899,808

Cash and cash equivalents at beginning of year	6,368,016	4,468,208
Cash and cash equivalents at end of year	$2,578,267	$6,368,016

See notes to audited consolidated financial statements.

Notes to Consolidated Financial Statements

(1) Business Description and Summary of Significant Accounting Policies

Business Description

The accompanying consolidated financial statements include the accounts of Xtant Medical Holdings, Inc. ("Xtant"), 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, Bacterin and X-spine are jointly referred to herein as the "Company"). All intercompany balances and transactions have been eliminated in consolidation. Xtant develops, manufactures and markets regenerative orthopedic products for domestic and international markets and fixation devices. 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 Company also previously developed and licensed coatings for various medical device applications which the company discontinued in 2014.

On July 31, 2015, Xtant acquired all of the outstanding capital stock of X-spine Systems, Inc. for approximately $60 million in cash, repayment of approximately $13 million of X-spine debt, and 4,242,655 shares of Xtant common stock (See Note 2, "Business Combination" below). Following the closing of the acquisition, on July 31, 2015 Bacterin International Holdings, Inc. changed its 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.

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.

Going Concern

The Company has incurred losses since its inception. The terms, conditions and amounts outstanding under the Company's debt agreements as described in Footnotes 9 and 18 raises substantial doubt about the Company's ability to continue as a going concern. The Company has established a special committee of its board of directors to evaluate restructuring alternatives, assist in related negotiations with the Company's lenders and consider alternatives for raising new capital. The Company also is evaluating various cost-reduction and cash flow improvement measures. However, there can be no assurance that the Company will be successful in these efforts.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern; however, the above conditions raise substantial doubt about the Company's ability to do so. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

Concentrations and Credit Risk

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the world. Approximately 95% of sales were in the United States, for the year ended 2016 and 2015. No single customer accounted for more than 10% of revenue or accounts receivable for the comparable periods. The Company provides for uncollectible amounts when specific credit issues arise. Management's estimates for uncollectible amounts have been adequate during prior periods, and management believes that all significant credit risks have been identified at December 31, 2016.

Revenue by geographical region is as follows:

	Year Ended December 31,	
	2016	2015
United States	$85,618,087	$56,750,372
Rest of World	4,384,649	2,595,345
	$90,002,736	$59,345,717

Use of Estimates

The preparation of the financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period. Significant estimates include the carrying amount of property and equipment, goodwill, and intangible assets and liabilities; valuation allowances for trade receivables, inventory 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 market. 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 twelve 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. 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 must be 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 valuation method used to establish its 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, security deposits and kits that are used in the implantation of certain biologic products. The items are stated at cost and in the case of kits are amortized on a straight line basis over their estimated useful lives.

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 (See Note 5, “Impairment of Assets” below).

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 the end of 2016. The Company conducts its impairment test on December 31 of each year 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 above criteria have been met.

Advertising Costs

The Company expenses advertising costs as incurred. The Company had advertising expense of $179,126 and $224,297 for the years ended December 31, 2016 and 2015.

Research and Development

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

Other Income (Expense)

Other income (expense) primarily consists of non-recurring items that are outside of the normal Company's operations such as other related legal expenses, gain or loss on the sale of fixed assets and miscellaneous minor adjustments to account balances.

Net Loss Per Share

Basic net income (loss) per share is computed by dividing net income (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 income (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, 2016 and 2015, 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 earnings per share are not reported as their effects of including 7,497,244 and 1,942,647 outstanding stock options and warrants for the year ended December 31, 2016 and 2015, 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, 2016 and 2015, 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, 2016 and December 31, 2015 that are measured at fair value on a recurring basis:

Warrant derivative liability

	As of December 31, 2016	As of December 31, 2015
Level 1	-	-
Level 2	-	-
Level 3	$ 333,613	$ 1,050,351

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 11, "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 periods ended December 31, 2016:

Warrant derivative liability

Balance at January 1, 2015	$1,320,371
Gain recognized in earnings	(270,020)
Balance at January 1, 2016	$1,050,351
Gain recognized in earnings	(716,738)
Balance at December 31 , 2016	$333,613

During the year ended December 31, 2016, 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 No. 2014-09, Revenue from Contracts with Customers. The new standard was originally effective for reporting periods beginning after December 15, 2016 and early adoption was not permitted. On August 12, 2015, the FASB approved a one year delay of the effective date to reporting periods beginning after December 15, 2017, while permitting companies to voluntarily adopt the new standard as of the original effective date. The comprehensive new standard will supersede existing revenue recognition guidance and require revenue to be recognized when promised goods or services are transferred to customers in amounts that reflect the consideration to which the company expects to be entitled in exchange for those goods or services. Adoption of the new rules could affect the timing of revenue recognition for certain transactions. The guidance permits two implementation approaches, one requiring retrospective application of the new standard with restatement of prior years and one requiring prospective application of the new standard with disclosure of results under old standards. The Company is currently evaluating the impacts of adoption and the implementation approach to be used.

In April 2015, the FASB issued ASU 2015-3, to simplify the presentation of debt issuance costs. This update requires that debt issuance costs be presented in the balance sheet as a direct deduction from the carrying amount of the associated debt liability, consistent with the required presentation for debt discounts. This update is effective for

interim and annual periods beginning after December 15, 2015. ASU 2015-3 is not expected to have a material impact.

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.

(2) Business Combination

On July 31, 2015 (the "Acquisition Date"), the Company completed its acquisition of 100% of the outstanding common stock of X-spine. During the year ended December 31, 2016, the Company recorded $1,401,366 of integration related expenses and $4,433,398 of amortization of the intangible assets associated with the acquisition in the consolidated statements of operations. During the year ended December 31, 2015, the Company recorded $4,935,755 of Acquisition and integration related expenses and $3,405,124 of amortization of the intangible assets associated with the acquisition in the consolidated statements of operations.

Unaudited Supplemental Pro Forma Financial Information

The unaudited pro forma results presented below include the combined results of both entities as if the acquisition had been consummated as of January 1, 2015. Certain pro forma adjustments have been made to reflect the impact of the purchase transaction, primarily consisting of amortization of intangible assets with determinable lives and interest expense on long-term debt. In addition, certain historical expenses, such as warrant expense and interest expense associated with debt that was immediately repaid, were eliminated from these pro-forma results. The pro forma information does not necessarily reflect the actual results of operations had the acquisition been consummated at the beginning of the fiscal reporting period indicated nor is it indicative of future operating results. The pro forma information does not include any adjustment for potential revenue enhancements, cost synergies or other operating efficiencies that could result from the acquisition. Shown below are the actual results for the year ending December 31, 2016 and the pro forma results for the year ended December 31, 2015.

	Year Ended December 31,	
	2016	2015
Revenue	$90,002,736	$86,517,599
Net loss	$(19,493,552)	$(5,845,125)

The Company accounted for the acquisition as a business combination and recorded the assets acquired, liabilities assumed, and the estimated future obligations at their respective fair values as of the Acquisition Date. The assets acquired and liabilities assumed were recorded as of the Acquisition Date at their respective fair values and consolidated with those of the Company. The reported consolidated balance sheet of the Company after completion of the acquisition reflects these fair values. The results of X-spine operations from the Acquisition Date contributed $288,824 of net profit to the Company’s consolidated financial statements for the fiscal year ended December 31, 2015.

The components of the aggregate preliminary purchase price for the acquisition were as follows:

Cash	$73,033,018
Fair value of Xtant shares	14,934,146
Total purchase price	$87,967,164

Net Assets Acquired

The transaction has been accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their fair values as of the Acquisition Date. The following table summarizes the allocation of assets acquired and liabilities assumed as of the Acquisition Date:

	Allocation of purchase price	Amortization period (in years)
Accounts receivable	$5,989,904	
Inventories	13,132,697	
Prepaids and other current assets	208,116	
Property and equipment, net	7,409,667	
Cash	57,818	
Total tangible assets acquired	26,798,202	
Less: liabilities assumed	23,559,164	
Net tangible assets less liabilities	$3,239,038	
Intangible assets:		
Technology	28,698,700	10
Customer relationships	9,911,000	14
Tradename	4,543,300	10
Non-compete agreements	40,500	3
Goodwill	41,534,626	
Total purchase price	$87,967,164	

The assets acquired and liabilities assumed were recorded at their estimated fair values as of the Acquisition Date. We determined the fair value of the inventory based on its estimated selling price less cost to sell and normal profit margin.

The fair value of the technology and tradename intangible assets were determined based upon a “relief from royalty” approach. The “relief from royalty” method is based on the premise that a third party would be willing to pay a royalty to use these assets owned by the subject company. The projected royalties are converted into their present value equivalents through the application of a risk adjusted discount rate. The customer relationships were valued based on an “excess earnings method.” The “excess earnings method” measures the historical customer churn analysis and discussions with management extended until excess earning cash flow approximates zero. The non-compete agreements were valued based on a “with and without” approach. The “with and without” method measures an asset value by estimating the difference in cash flows generated by the business with the asset in-use versus without the asset. The difference in cash flows is attributable to incremental earnings or cost savings associated with the asset. These fair value measurements are based on significant unobservable inputs, based on management’s estimates and assumptions.

The fair value of the identifiable assets, including the intangible assets noted above, may be impacted by the Company’s evaluation of deferred taxes as further discussed below and possibly by future factors that may or may not impact the fair value of the identifiable assets, including the intangible assets noted above.

The Company recorded the excess of the aggregate purchase price over the estimated fair values of the identifiable assets acquired as goodwill, which is not deductible for tax purposes.

(3) Equity

We entered into the Purchase Agreement on March 16, 2015, as amended and restated on April 17, 2015, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the approximately 24-month term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, in the first quarter of 2015 we issued 207,182 shares of our common stock to Aspire Capital for $750,000 in aggregate proceeds, along with 154,189 shares of our common stock which were valued at $3.62 per share and included as $558,185 in the consolidated statements of operations as a commitment fee. In 2016, we issued 150,000 shares of our common stock to Aspire Capital for $300,000 in aggregate proceeds. In 2015, we issued 417,000 shares of our common stock to Aspire Capital for $1,366,941 in aggregate proceeds, which were used for working capital and general corporate purposes.

Under the Common Stock Purchase Agreement, we have the right, at our sole discretion, to present Aspire Capital with purchase notices, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock, per trading day, provided that the aggregate price of each such purchase shall not exceed $500,000 per trading day, at a per share price equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- The arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, we also have the right to present Aspire Capital with volume-weighted average price purchase notices directing Aspire Capital to purchase an amount of our common stock equal to up to 30% of the aggregate shares of our common stock on the next trading day, subject to the terms, conditions and limitations in the Purchase Agreement.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The Purchase Agreement also provides for customary events of default, upon the occurrence of which Aspire Capital may terminate the Purchase Agreement. Aspire Capital has agreed that neither it nor any of its agents, representatives or affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. Any proceeds we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.

On July 31, 2015, the Company acquired all of the outstanding capital stock of X-spine for approximately $60 million in cash, repayment of approximately $13 million in debt and 4,242,655 shares of our common stock.

Related to the acquisition, on October 8, 2015 the Company granted 78,510 restricted stock units to five X-spine employees at $3.19 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.

On September 4, 2015, the Company sold an aggregate of 140,053 shares of our common stock to certain members of our Board of Directors in a private placement transaction for aggregate cash proceeds of $515,395.

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 300,000 shares of our common stock at $1.11 per share which start vesting 60,000 shares on October 6, 2017 and then vest 15,000 shares per quarter on January 6, 2018 until October 6, 2021 (See Note 18, "Subsequent Events" below).

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 $0.01 ("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 $0.01 exercise price but no Pre-Funded Warrants were sold.

The Rights Offering closed on November 14, 2016. The units were priced at $0.75 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 $0.90 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 $2.25 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.

Under the terms and subject to the conditions contained in the Dealer-Manager Agreement, the Company agreed not to issue or announce the issuance of any shares of Common Stock or Common Stock equivalents until 90 days after the closing date of the Rights Offering, without the consent of Maxim, subject to certain exceptions including a pre-existing agreement, equity awards, conversion of derivative securities and in connection with any acquisitions, partnerships or strategic transactions.

(4) Inventories

Inventories consist of the following:

	December 31, 2016	December 31, 2015
Current inventories		
Raw materials	$ 4,833,403	$ 4,860,914
Work in process	1,891,380	2,720,707
Finished goods	23,878,040	18,289,674
Gross current inventories	30,602,823	25,871,295
Reserve for obsolescence	(4,336,366)	(3,186,579)
Current inventories, total	26,266,457	22,684,716
Non-current inventories		
Finished goods	1,385,017	2,021,077
Reserve for obsolescence	(413,163)	(413,162)
Non-current inventories, total	971,854	1,607,915
Total inventories	$ 27,238,311	$ 24,292,631

(5) Impairment of Assets

For the year ended December 31, 2016, there were no indications of impairment of assets. During the third quarter of 2015, Intangible Assets were reviewed and found to be impaired. The impact, net of amortization, was $233,748.

(6) Property and Equipment, Net

Property and equipment, net are as follows:

	December 31, 2016	December 31, 2015
Equipment	$ 4,629,754	$ 5,368,567
Computer equipment	416,233	348,404
Computer software	529,726	503,587
Furniture and fixtures	181,566	174,215
Leasehold improvements	4,053,837	2,661,802
Vehicles	10,000	10,000
Surgical instruments	13,876,757	8,175,578

Total cost	23,697,873	17,242,153
Less: accumulated depreciation		