Xtant Medical Holdings, Inc.
Form 10-K
March 24, 2016

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, 2015

or

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

For the transition period from _____ to _____

Commission file number: 001-34951

Xtant Medical Holdings, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

Title of each class	Name of each exchange on which registered
Common stock, par value $.000001 per share	NYSE 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, 2015 was $25,708,995 (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 OTCQX Marketplace).

The number of shares of the Company's common stock, $0.000001 par value, outstanding as of February 25, 2016 was 11,897,601.

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 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, two Colorado offices located at 8310 S. Valley Highway, Englewood, Colorado 80112, and 10955 Westmoor Drive, Westminster, Colorado 80021, and two Ohio offices at 452 and 444 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.

FDA 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 is 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 implants provide 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 and is pursuing related applications in Canada, Europe and Korea. 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 in the mid-single digits 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 in the range of 4.0% to 6.5% depending on the product.

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, 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, 2016, Xtant had 243 full-time employees and 248 total employees, of whom 89 were in operations, 71 were in sales, 13 were in marketing, 16 were in R&D and Engineering, 30 were in QA/QC, and 29 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 also lease facilities at 452 and 444 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 five-year lease which runs through November 2016 and has a three-year renewal option that the Company is considering.

We lease additional office space under a month-to-month arrangement. One office is located at 10955 Westmoor Drive, Westminster, Colorado 80021and one office is located at 8310 S. Valley Highway, Englewood, Colorado 80112.

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

Pricing pressure and cost containment measures could have a negative impact on our future operating results.

Pricing pressure has increased in our industry due to continued consolidation among healthcare providers, trends toward managed care, the shift towards government becoming the primary payor of healthcare expenses, and government laws and regulations relating to reimbursement and pricing generally. Pricing pressure, reductions in reimbursement levels or coverage or other cost containment measures could unfavorably affect our future operating results and financial condition.

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 over the past few years, 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.

The medical community and the general public may perceive synthetic materials and growth factors as safer, which could have a material adverse effect on our business.

Members of the medical community and the general public may perceive synthetic materials and growth factors as safer than our allograft-based bone tissue products. Our products may be incapable of competing successfully with synthetic bone graft substitutes and growth factors developed and commercialized by others, which could have a material adverse effect on our business, financial condition and results of operations.

Negative publicity concerning methods of human tissue recovery and screening of donor tissue in the industry in which we operate may reduce demand for our allografts and impact the supply of available donor tissue.

Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue may limit widespread acceptance of our allografts. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies. Potential patients may not be able to distinguish our allografts, technologies and the tissue recovery and the processing procedures from those of our competitors or others engaged in tissue recovery. In addition, families of potential donors may become reluctant to agree to donate tissue to for-profit tissue processors.

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.

We will need to continue to innovate and develop new products.

The markets for our products and services are characterized by rapid technological change, frequent new introductions, changes in customers' demands and evolving industry standards. Accordingly, we will need to continue

to innovate and develop additional products. These efforts can be costly, subject to long development and regulatory delays and may not result in products approved for sale. These costs may hurt operating results and may require additional capital. If additional capital is not available, we may be forced to curtail development activities. In addition, any failure on our behalf to react to changing market conditions could create an opportunity for other market participants to capture a critical share of the market within a short period of time.

Our success will depend on our ability to engage and retain qualified technical personnel who are difficult to attract.

Our success will depend on our ability to attract and retain qualified technical personnel to assist in research and development, testing, product implementation, low-scale production and technical support. The demand for such personnel is high and the supply of qualified technical personnel is limited. A significant increase in the wages paid by competing employers could result in a reduction of our technical work force and increases in the wage rates that we must pay or both. If either of these events were to occur, our cost structure could increase and our growth potential could be impaired.

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.

Future revenue will depend on our ability to increase sales.

We currently sell our products through direct sales by our employees and indirectly through distributor relationships. We incurred increased sales and marketing expenses in building and expanding our direct sales force, and there can be no assurance that we will generate increased sales as a result of this effort.

There may be fluctuations in our operating results, which will impact our stock price.

Significant annual and quarterly fluctuations in our results of operations may be caused by, among other factors, our volume of revenues, the timing of new product or service announcements, releases by us and our competitors in the marketplace of new products or services, seasonality and general economic conditions. There can be no assurance that the level of revenues achieved by us in any particular fiscal period will not be significantly lower than in other comparable fiscal periods. Our expense levels are based, in part, on our expectations as to future revenues. As a result, if future revenues are below expectations, net income or loss may be disproportionately affected by a reduction in revenues, as any corresponding reduction in expenses may not be proportionate to the reduction in revenues.

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.

Our operating results will be harmed if we are unable to effectively manage and sustain our future growth.

We might not be able to manage our future growth efficiently or profitably. Our business is unproven on a large scale and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If we are unable to scale our production capabilities efficiently, we may fail to achieve expected operating margins, which would have a material and adverse effect on our operating results. Growth may also stress our ability to adequately manage our operations, quality of products, safety and regulatory compliance. In order to grow, we may be required to obtain additional financing, which may increase our indebtedness or result in dilution to our stockholders. Further, there can be no assurance that we would be able to obtain any additional financing.

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. Company stockholders who collectively own approximately 588,000 shares of our common stock and warrants to purchase additional shares have made claims that our board of directors breached its fiduciary duties in connection with the X-spine acquisition and the financing thereof, which they allege was on commercially unreasonable terms and did not serve the Company's best interests. No lawsuit has been filed. The Company believes the claims are without merit. If we are required to pay a significant amount to resolve a demand from these stockholders, it could have a material adverse effect on our liquidity, business and financial condition, and efforts required to resolve the demand could distract management from operating our business.

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.

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 our recent offering. In addition, affiliates of OrbiMed are significant shareholders and we owe affiliates of OrbiMed approximately $42 million in principal, plus interest and exit fees, pursuant to our Amended and Restated Credit Agreement. 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.

Growth through an acquisition presents certain risks to our business and operations.

The acquisition of X-spine and any other acquisitions we may pursue present numerous risks, including the following:

- the possibility that the expected benefits of the transactions may not materialize in the timeframe expected, or at all, or may be more costly to achieve than anticipated;
- the acquired assets may not produce as expected;
- we may be unable to successfully develop the assets;
- there may be adverse stockholder reaction to the acquisitions; and
- the integration of these transactions may divert the attention of our management and other key employees from ongoing business activities, including the pursuit of other opportunities that could be beneficial to us.

Any one or more of these factors could negatively affect our business, financial condition or results of operations.

We have made certain assumptions relating to the acquisition that may prove to be materially inaccurate.

We have made certain assumptions relating to the acquisition of X-spine that may be inaccurate. Accordingly, we may fail to realize the expected benefits of the acquisition, may incur higher-than-expected transaction and integration costs, may assume unknown liabilities and may experience general economic and business conditions that adversely affect the combined company following the acquisition. These assumptions relate to numerous matters, including:

- projections of X-spine's future results;
- our expected capital structure following the acquisition;
- the amount of goodwill and intangibles that will result from the acquisition;
- certain other purchase accounting adjustments that we expect will be recorded in our financial statements in connection with the acquisition;
- cost, cross-selling and balance sheet synergies;
- acquisition costs, including restructuring charges and transaction costs;
- our ability to maintain, develop and deepen relationships with X-spine's customers; and
- other financial and strategic risks of the acquisition.

There may be risks associated with the post-acquisition integration of X-spine, because X-spine has historically been operated as a privately owned company.

There may be risks associated with the post-acquisition integration of X-spine, because X-spine has historically been operated as a privately owned company. Public companies are subject to significant additional regulatory and reporting requirements. Senior management of public companies may be required to devote more of their time to meeting these additional requirements. X-spine's senior management has historically been actively involved in the revenue-generating activities of its operations. If these individuals are required to devote more time to the additional requirements of managing a public company, and we are unable to successfully transition some or all of their direct

revenue-generating responsibilities to other suitable professionals, our business, results of operations and financial condition may suffer.

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.

We have limited experience with X-spine's product lines.

The product lines acquired in the X-spine transaction are new to us, and we have limited experience with them. The acquired X-spine business is concentrated on developing and manufacturing implants and surgical instruments for surgery of the spine, which business differs from ours. As a result, X-spine's business is comprised of different product lines with which we have limited experience.

We will depend on retaining X-spine management and employees.

We will also be highly dependent on the continued services of key members of X-spine's executive management team. The loss of any one of these individuals could disrupt X-spine's operations or strategic plans. Additionally, X-spine's future success will depend on, among other things, our ability to hire and retain the necessary qualified scientific, technical, sales, marketing and managerial personnel, for whom X-spine competes with numerous other companies, academic institutions and organizations. The loss of members of X-spine's management team, key advisors or personnel, or X-spine's inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on X-spine's business, results of operations and financial condition.

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 2015, Xtant purchased from Norwood Medical 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.

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

The business acquired from X-spine is dependent, in part, on a key distributor arrangement. For the years ended December 31, 2015 and 2014, net sales to this one large distributor exceeded 10% of X-spine's net sales. X-spine's results of operations are directly dependent on the sales and marketing efforts of its distributors and other sales agents and employees. If X-spine's key distributor were to reduce its efforts or cease to do business with X-spine, X-spine's sales could be adversely affected. In such a situation, X-spine may need to seek alternative distributors or increase its reliance on existing direct sales employees, sales agent and other distributors, which we may be unable to do in a timely and efficient manner, if at all.

The business acquired from X-spine depends, in part, on a relationship with a key supplier, which is a related party.

The business acquired from X-spine relies on third-party suppliers to supply substantially all of its products. For X-spine to be successful, its suppliers must be able to provide it with products in substantial quantities, in compliance

with regulatory requirements, in accordance with agreed-upon specifications, at acceptable costs and on a timely basis. If X-spine is unable to obtain sufficient quantities of high quality products to meet demand on a timely basis, it may lose customers, and our business and reputation may suffer.

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 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; and

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.

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.

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.

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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 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.

Trends, Risks and Uncertainties Relating to Our Common Stock

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 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:

- announcements of technological innovations or new commercial products by us, our collaborative partners or our present or potential competitors;
- 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;
- 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;

- suspension of trading of our common stock;

- 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, 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.

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 do not anticipate, and may be prevented from, paying dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, our amended and restated credit facility precludes us from paying dividends.

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, 2015, 1,942,647 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, 2015, we also have reserved 1,221,629 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.

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 and, consequently, the trading price of our notes 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 and, consequently, the trading price of our notes to decline.

Trends, Risks and Uncertainties Relating to Our Indebtedness

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.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to service our substantial debt obligations depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and other fixed charges, fund working capital needs and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

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.

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.

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.

An active trading market may never develop for our notes.

There has been no trading market for our notes, and we do not intend to apply to list our notes on any securities exchange or to have them quoted on any automated dealer quotation system. In addition, the liquidity of the trading market in notes, and the trading price of our notes, may be adversely affected by changes in the overall market for this type of security and by changes in our financial performance or prospects or in the prospects for companies in our industry generally. As a result, we cannot assure you that an active trading market will develop for our notes. If an active trading market does not develop or is not maintained, the trading price and the liquidity of our notes may be adversely affected. In that case, you may not be able to sell your notes at a particular time, if at all, or you may not be able to sell your notes at a favorable price.

Item 1B. Unresolved Staff Comments

We have unresolved comments from the staff (the "Staff") of the Securities and Exchange Commission pursuant to a letter from the Staff to us, dated January 15, 2016, with respect to our Registration Statement on Form S-1 (File No. 333-208677), currently in review with the Securities and Exchange Commission but not yet effective. We have not yet responded to this letter, but are in the process of doing so.

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 (See Note 12, "Commitments and Contingencies" below). 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 also lease facilities at 452 and 444 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 five-year lease which runs through November 2016 and has a monthly lease payment of $21,379 plus CAM charges and taxes. The lease has a three-year renewal option that the Company is considering.

We lease additional office space under a month-to-month arrangement. One office is located at 10955 Westmoor Drive, Westminster, Colorado 80021and one office is located at 8310 S. Valley Highway, Englewood, Colorado 80112.

Item 3. Legal Proceedings

On March 17, 2014, a complaint was served on the Company in the following state court action in the District Court for the County of Arapahoe, State of Colorado: Robert Taggart v. Guy Cook, Bacterin International, Inc., a Nevada Corporation and Bacterin International Holdings, Inc., a Delaware corporation, Civil Action No. 14CV30401. The complaint involves claims under an employment agreement between plaintiff and the Company seeking commissions on Company sales, a commission on funds obtained by the Company as a result of a reverse merger and vesting of certain stock options. Plaintiff seeks damages in excess of $5 million. The Company believes this case lacks legal merit and has filed counterclaims for plaintiff's breach of his employment agreement and breach of his duty of loyalty to the Company, asserting the right to recover all compensation paid to Plaintiff during his employment as well as other damages.

We are also 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. Prices have been adjusted to reflect the Company's July 25, 2014 1:10 reverse stock split.

	High	Low
First Quarter 2014 (January 1, 2014 - March 31, 2014)	$14.10	$4.80
Second Quarter 2014 (April 1, 2014 - June 30, 2014)	$8.50	$6.30
Third Quarter 2014 (July 1, 2014 - September 30, 2014)	$7.40	$4.07
Fourth Quarter 2014 (October 1, 2014 - December 31, 2014)	$4.75	$2.19
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

Holders of Record

As of January 14, 2016, we had 220 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 integrate the acquisition of X-spine Systems, Inc. and any other business combinations or acquisitions successfully;
- 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 comply with the covenants in our credit facility;
- 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, 2015 and December 31, 2014

	Year Ended December 31,			
	2015		**2014**	
	Amount	**% of Revenue**	**Amount**	**% of Revenue**
Revenue				
Orthopedic product sales	$58,194,249	98.06 %	$34,569,160	97.84 %

Other revenue	1,151,468	1.94	%	762,652	2.16	%
Total Revenue	59,345,717	100.00	%	35,331,812	100.00	%
Cost of Sales	20,262,728	34.14	%	13,034,314	36.89	%
Gross Profit	39,082,989	65.86	%	22,297,498	63.11	%
Operating Expenses						
General and administrative	12,993,307	21.89	%	8,886,972	25.15	%
Sales and marketing	28,731,184	48.41	%	16,912,865	47.87	%
Research and development	2,546,362	4.29	%	1,443,018	4.08	%
Depreciation and amortization	3,819,588	6.44	%	271,748	0.77	%
Acquisition and integration related expenses (Note 2)	4,935,755	8.32	%	-	0.00	%
Extinguishment of debt	(2,345,019)	(3.95)%		-	0.00	%
Impairment of assets	233,748	0.39	%	912,549	2.58	%
Non-cash consulting expense	246,165	0.41	%	135,075	0.38	%
Total Operating Expenses	51,161,090	86.21	%	28,562,227	80.84	%
Loss from Operations	(12,078,101)	(20.35)%		(6,264,729)	-17.73	%
Other Income (Expense)						
Interest expense	(7,733,748)	(13.03)%		(5,660,357)	-16.02	%
Change in warrant derivative liability	270,020	0.45	%	1,736,053	4.91	%
Non-cash consideration associated stock agreement	(558,185)	(0.94)%		-	0.00	%
Other income (expense)	388,176	0.66	%	(318,836)	-0.90	%
Total Other Income (Expense)	(7,633,737)	(12.86)%		(4,243,140)	-12.01	%
Net Loss from Operations Before (Provision) Benefit for Income Taxes	(19,711,838)	(33.21)%		(10,507,869)	-29.74	%
Benefit (Provision) for Income Taxes						
Current	-	0.00	%	-	0.00	%
Deferred	17,537,408	29.55	%	-	0.00	%
Net Loss	$(2,174,430)	(3.66)%		$(10,507,869)	-29.74	%

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, 2015.

Revenue

Total revenue for the year ended December 31, 2015 increased approximately 68.3% to $59,345,717 compared to $35,331,812 in the prior year. The increase of $24,013,905 is due partly to the X-spine acquisition and internal growth of approximately 12.2% from continuing improved sales force productivity.

Cost of sales

Costs of sales consist primarily of manufacturing costs and depreciation of surgical trays. Costs of sales increased by 55.5% or $7,228,414 to $20,262,728 for the year ended December 31, 2015 from $13,034,314 for the year ended 2014. Cost of sales as a percent of total sales was 34.1% of revenues for the year ended December 31, 2015 compared to 36.9% in the year ended 2014. The decrease is the result of improved manufacturing efficiencies including the impact of new products and a change in product and customer mix between the two periods.

Operating Expenses

Operating expenses include general and administrative expenses, selling and marketing expenses, depreciation, research and development expenses, and compensation costs, including incentive compensation. Operating expenses increased 79.1%, or $22,598,863 for the year ended December 31, 2015 compared to the year ended December 31, 2014, primarily due to the reasons set forth below and the expenses due to X-spine acquisition which includes “Acquisition and integration related expenses” and “Extinguishment of debt”.

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 46.2%, or $4,106,355, to $12,993,307 for the year ended December 31, 2015 compared to the same period of 2014. Almost all of the increase is due to the acquisition of

X-spine. The remaining increase is due to additional head count in operations as a result of increased sales activity and a onetime entry of bad debt expense.

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. In addition, stock option compensation expense associated with our sales force is also included in sales and marketing expenses. Sales and marketing expenses increased 69.9%, or $11,818,319, to $28,731,184 for the year ended December 31, 2015 compared to $16,912,865 for the same period of 2014. The increase is almost all due to the acquisition of X-spine. The remaining increase is due to increased commissions tied to increased revenues and the addition of the increased number of sales assets. As a percentage of revenue, sales and marketing expenses increased to 48.4% in the year ended 2015 from 47.9% in the prior year.

Research and Development

Research and development expenses consist primarily of internal costs for the development of new technologies and processes for our regenerative orthopedic product lines. Research and development expenses increased $1,103,344 or 76.5% from $1,443,018 for the year ended December 31, 2014 to $2,546,362 for the same period of 2015. 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 $3,547,840 to $3,819,588 for the year ended December 31, 2015 from $271,748 in the same period in 2014. 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 $4,935,755 for the year ended 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. We anticipate additional expenses to occur during the first and second quarters of 2016.

Extinguishment of Debt

Extinguishment of Debt expenses are $2,345,019 for the year ended December 31, 2015 and are related to the Amended and Restated Credit Agreement with ROS Acquisition Offshore LP (“ROS”) and is recorded in accordance with ASC Subtopic 470-50, Debt Modifications and Extinguishments and ASC Subtopic 470-60, Troubled Debt Restructuring by Debtors. The expense consists of the write-off of the royalty liability offset by the debt discount and capitalized expenses associated with the issuance of the original debt agreement, including amendments, with ROS.

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 $111,090 to $246,145 for the year ended December 31, 2015 from $135,075 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, 2015 increased $2,073,391 to $7,733,748 as compared to $5,660,357 in the year ended 2014. 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, 2015, the Company recorded a gain in its non-cash warrant derivative liability of $270,020 which was primarily driven by an decrease in the closing price of the Company’s common stock from December 31, 2014 to December 31, 2015. 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 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 income for the year ended December 31, 2015 was $388,176 as compared to an expense of $318,836 in the same period in 2014.

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, 2015, we received $68 million from the issuance of the Notes, and we borrowed an additional $18 million under an amended and restated credit facility with ROS (See Note 9, “Long-Term Debt” below). After payment of the consideration and expenses related to the acquisition and related financing transactions, our cash on hand increased by approximately $8.6 million.

We also received $2,137,439 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, 2015, we had $21,753,234 of cash and cash equivalents and accounts receivable.

Net cash used in operating activities for the year ended December 31, 2015 was $9,099,868 primarily related to funds required to finance the Company’s operations. For comparable period of 2014, net cash used in operating activities was $7,324,059.

Net cash used in investment activities for the year ended December 31, 2015 was $73,571,038 due mostly to the acquisition of X-spine and also to the sale/retirement/purchase of property and equipment.

Net cash provided by financing activities was $84,570,714 for the December 31, 2015, primarily due to proceeds from the sale of equity securities and the issuance of common stock, senior convertible notes and amended and restated credit facility associated with the acquisition of X-spine (See Note 3, “Equity” and Note 9, “Long-Term Debt” below) and the sale-leaseback transaction for the property located at 664 Cruiser Lane, Belgrade, Montana, 59714 (See Note 12, “Commitments and Contingencies” below).

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, 2015 cash on hand and accounts receivable balance of $21,753,234 along with anticipated cash receipts from sales expected from operations and proceeds from the Aspire Capital financing will be sufficient to meet our anticipated cash requirements through December 31, 2016. If we do not meet our revenue objectives, we may need to sell additional equity securities, which could result in dilution to our stockholders, or seek additional loans or alternative sources of financing. 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 limit our ability to expand our business operations and could harm our overall business prospects.

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, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for 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 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 consolidated 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, 2015 and 2014, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ EKS&H LLLP

March 24, 2016

Denver, Colorado

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XTANT MEDICAL HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2015	As of December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$6,368,016	$4,468,208
Trade accounts receivable, net of allowance for doubtful accounts of $2,579,634 and $1,392,989, respectively	15,385,218	4,427,081
Inventories, net	22,684,716	9,558,648
Prepaid and other current assets	985,471	654,140
Total current assets	45,423,421	19,108,077
Non-current inventories	1,607,915	1,934,258
Property and equipment, net	11,816,629	4,654,527
Goodwill	41,534,626	-
Intangible assets, net	40,237,289	655,490
Other assets	2,439,558	1,598,539
Total Assets	$143,059,438	$27,950,891
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$9,386,531	$3,876,760
Accounts payable - related party	1,406,763	250,629
Accrued liabilities	9,595,851	1,921,301
Warrant derivative liability	1,050,351	1,320,371
Current portion of capital lease obligations	35,139	61,970
Current portion of royalty liability	-	1,000,750
Current portion of long-term debt	-	50,671
Total current liabilities	21,474,635	8,482,452
Long-term Liabilities:		
Capital lease obligation, less current portion	7,800	11,808
Long-term royalty liability, less current portion	-	6,361,216
Long-term convertible debt	68,000,000	-
Long-term debt, less current portion	44,700,476	20,870,330
Total Liabilities	134,182,911	35,725,806
Commitments and Contingencies		
Stockholders' Equity (Deficit)		
	-	-

Preferred stock, $0.000001 par value; 5,000,000 shares authorized; no shares issued and Outstanding		
Common stock, $0.000001 par value; 95,000,000 shares authorized; 11,897,601 shares issued and outstanding as of December 31, 2015 and 6,679,646 shares issued and outstanding as of December 31, 2014	11	7
Additional paid-in capital	81,917,488	63,091,620
Accumulated deficit	(73,040,972)	(70,866,542)
Total Stockholders' Equity (Deficit)	8,876,527	(7,774,915)
Total Liabilities & Stockholders' Equity	$143,059,438	$27,950,891

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2015	2014
Revenue		
Orthopedic product sales	$58,194,249	$34,569,160
Other revenue	1,151,468	762,652
Total Revenue	59,345,717	35,331,812
Cost of Sales	20,262,728	13,034,314
Gross Profit	39,082,989	22,297,498
Operating Expenses		
General and administrative	12,993,307	8,886,972
Sales and marketing	28,731,184	16,912,865
Research and development	2,546,362	1,443,018
Depreciation and amortization	3,819,588	271,748
Acquisition and integration related expenses (Note 2)	4,935,755	-
Extinguishment of debt	(2,345,019)	-
Impairment of assets	233,748	912,549
Non-cash consulting expense	246,165	135,075
Total Operating Expenses	51,161,090	28,562,227
Loss from Operations	(12,078,101)	(6,264,729)
Other Income (Expense)		
Interest expense	(7,733,748)	(5,660,357)
Change in warrant derivative liability	270,020	1,736,053
Non-cash consideration associated stock agreement	(558,185)	-
Other income (expense)	388,176	(318,836)
Total Other Income (Expense)	(7,633,737)	(4,243,140)
Net Loss from Operations Before Benefit (Provision) for Income Taxes	(19,711,838)	(10,507,869)
Benefit (Provision) for Income Taxes		
Current	-	-
Deferred	17,537,408	-
Net Loss	$(2,174,430)	$(10,507,869)
Net loss per share:		

Basic	$(0.24)	$(1.76)
Dilutive	$(0.24)	$(1.76)
Shares used in the computation:		
Basic	9,055,483	5,954,195
Dilutive	9,055,483	5,954,195

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, 2013	5,348,282	$ 5	$ 56,516,491	$ (60,358,673)	$ (3,842,177)
Stock-based compensation	38,364	-	935,316	-	935,316
Net proceeds from the issuance of stock	1,143,000	2	5,869,633	-	5,869,635
Issuance of restricted stock to employees	-	-	136,977	-	136,977
Issuance of warrants in conjunction with the issuance of stock	-	-	(1,461,796)	-	(1,461,796)
Issuance of stock to ROS to amend Credit agreement to borrow additional $4 million	150,000	-	1,094,999	-	1,094,999
Net loss	-	-	-	(10,507,869)	(10,507,869)
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 proceeds from the issuance of stock	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

See notes to audited consolidated financial statements.

XTANT MEDICAL HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2015	2014
Operating activities:		
Net loss	$(2,174,430)	$(10,507,869)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,889,272	952,320
Purchase accounting valuation allowance	(17,537,408)	-
Non-cash interest	4,107,225	814,374
Impairment of Assets	956,395	912,549
(Gain)/Loss on sale of fixed assets	(596,883)	25,269
Amortization of debt discount	707,281	1,632,245
Non-cash consulting expense/stock option expense	836,741	935,316
Provision for losses on accounts receivable and inventory	700,234	647,765
Change in derivative warrant liability	(270,020)	(1,736,053)
Non-cash consideration associated with stock purchase agreement	558,185	-
Extinguishment of debt	(2,345,019)	-
Changes in operating assets and liabilities:		
Accounts receivable	(5,512,429)	283,624
Inventories	(545,713)	(17,392)
Prepaid and other assets	(1,044,962)	(455,048)
Accounts payable	644,149	715,706
Accrued liabilities	7,527,514	(1,526,865)
Net cash used in operating activities	(9,099,868)	(7,324,059)
Investing activities:		
Acquisition of X-spine Systems, Inc.	(72,975,200)	
Purchases of property and equipment and intangible assets	(2,263,033)	(299,978)
Proceeds from sale of fixed assets	1,667,195	1,626
Net cash used in investing activities	(73,571,038)	(298,352)
Financing activities:		
Proceeds from long-term and convertible debt, net of deferred and financing costs	83,897,361	4,000,000
Net proceeds from equity private placement	515,395	-
Payment of royalty obligation	(542,905)	
Payments on long-term debt	(1,325,814)	(653,397)
Payments on capital leases	(101,760)	(171,957)
Proceeds from exercise of options	11,500	-
Net proceeds from issuance of stock	2,116,937	5,869,633
Net cash provided by financing activities	84,570,714	9,044,279
Net change in cash and cash equivalents	1,899,808	1,421,868

Cash and cash equivalents at beginning of period	4,468,208	3,046,340
Cash and cash equivalents at end of period	$6,368,016	$4,468,208

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, 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. As of December 31, 2014, the Company made a strategic decision to discontinue the medical device coatings business which resulted in an impairment of related assets (See Note 5, "Impairment of Assets" below).

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 approximately 4.24 million 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. X-spine is engaged in the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries.

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

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Reverse Stock Split

Xtant completed a 1:10 reverse split of its common stock, effective at the close of business on Friday, July 25, 2014 and in effect for trading purposes on Monday, July 28, 2014. The reverse stock split was approved by Xtant shareholders at the 2014 Annual Meeting of Shareholders on June 11, 2014. All references to common stock, stock options, restricted stock units, warrants, and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Public Offering

In August 2014, Xtant offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock valued at $1,461,796 in Additional paid-in-capital at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and were used for working capital and general corporate purposes. The offering closed on August 6, 2014. The warrants have a five year term and expire on August 6, 2019. We utilize a valuation model to determine the fair market value and account for these warrants as a derivative liability (See "Derivative Instruments" below and See Note 11, "Warrants" below).

Aspire Capital Transaction

We entered into a Common Stock Purchase Agreement on March 16, 2015, as amended and restated on April 17, 2015 (the "Purchase Agreement"), with Aspire Capital Fund, LLC ("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 on the Statement of Operations to Aspire Capital as a commitment fee. In the second quarter of 2015, following the effectiveness of our Registration Statement on Form S-1, 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 (See Note 3, "Equity" below).

Private Placement Offering

During the third quarter of 2015, we issued 140,053 shares of our common stock to certain members of our Board of Directors at the closing price on September 4, 2015, for aggregate proceeds of $515,395 (See Note 3, “Equity” below).

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% and 98% of sales were in the United States, respectively, for the year ended 2015 and 2014. 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, 2015.

In 2015, Xtant purchased from Norwood Medical approximately 12% of its operating products (See Note 16, “Related Party Transactions” below).

Revenue by geographical region is as follows:

	Year Ended December 31,	
	2015	2014
United States	$56,750,372	$34,643,571
Rest of World	2,595,345	688,241
	$59,345,717	$35,331,812

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 reserve; royalty liability; 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.

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 or 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 tissue and medical devices sales. Inventories where the sales cycle is estimated to be beyond twelve months are classified as Non-current inventories.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to seven years for computers and equipment, and 30 years for buildings. 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.

Other Assets

Other Assets consist of the short-term and the long-term portion of prepaid expenses, security deposits, the capitalized portion of debt related issuance costs and kits that are used in the implantation of certain biologic products. The items are stated at cost and in the case of debt related issuance costs and 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 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 and whether it is necessary to perform the two-step goodwill impairment. The Company conducts its annual impairment test on December 31 of each year.

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.

The Company also receives royalty revenue from third parties related to licensing agreements which represented less than 1% of total revenue for the years ended December 31, 2015 and 2014.

Advertising Costs

The Company expenses advertising costs as incurred. The Company had advertising expense of $224,297 and $34,970 for the years ended December 31, 2015 and 2014.

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.

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, 2015 and 2014, 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 1,942,647 and 2,350,656 outstanding stock options and warrants for the year ended December 31, 2015 and 2014, respectively, are anti-dilutive.

Fair Value of Financial Instruments

The carrying values of financial instruments, including trade accounts receivable, accounts payable, other accrued expenses 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, 2015 and 2014, 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, 2015 and December 31, 2014 that are measured at fair value on a recurring basis:

Warrant derivative liability

	As of December 31, 2015	**As of December 31, 2014**
Level 1	-	-
Level 2	-	-
Level 3	$ 1,050,351	$ 1,320,371

The valuation technique used to measure fair value of the warrant liability is based on a lattice 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 year ended December 31, 2015:

Warrant derivative liability

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

During the year ended December 31, 2015, 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 when to adopt the new standard, 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, pursuant to a Stock Purchase Agreement (the “Purchase Agreement”). X-spine was engaged in the development, manufacturing and sale of medical devices for use in orthopedic spinal surgeries. The primary reasons for the X-spine acquisition are to combine the Company’s product lines into regenerative orthopedic product lines, leverage customer call points, expand sales and marketing coverage, increase revenue, and drive operating efficiencies.

Under the terms of the Purchase Agreement, the Company paid the former X-spine stockholders consideration of approximately $60 million in cash and approximately 4.24 million shares of Xtant common stock. The Company also repaid approximately $13 million of X-spine debt.

The cash consideration was financed in part using the net proceeds from the Company’s offering of $68 million aggregate principal amount of 6% Convertible Senior Notes due 2021 (See Note 9, “Long-Term Debt” below).

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. Goodwill is primarily attributable to the benefits the Company expects to realize by expanding its product offerings and addressable markets, thereby contributing to an expanded revenue base. The Company will also increase the size of its sales organization, while realizing cost synergies associated with eliminating redundant positions, primarily in selling, general and administrative functions.

The assets and liabilities assumed in the acquisition have been included in the Company's consolidated balance sheet as of December 31, 2015. The results of X-spine operations were included in the Company's consolidated financial statements from the Acquisition Date.

The Company's management reviews financial results and manages the business on an aggregate basis. Therefore, financial results are reported in a single operating segment (See Note 17, "Segment and Geographic Information" below).

Acquisition Costs

Acquisition-related expenses were $4.9 million for the year ended December 31, 2015, and primarily included investment banking, accounting, consulting, legal fees and integration expenses. Integration expenses include samples, travel and meetings, severance due to reduction in force, retention bonuses and software. We anticipate additional integration expenses to occur during the first quarter of 2016.

Taxes

The Company did not acquire X-spine's net operating loss carryforwards for federal tax purposes because X-spine was an S-corporation tax filer prior to the acquisition and any carryforwards were taken by the former shareholders of X-spine in their federal tax filings. The Company has evaluated the realizability of the net deferred tax assets acquired net of the deferred tax liabilities that arose from the recording of intangible assets as part of the purchase price allocation (See Note 13, "Income Taxes" below).

Given its significant prior accumulated tax losses, the Company does not expect to incur U.S. federal tax expense in the year ended December 31, 2015 or the foreseeable future. The Company does, however, expect to incur state tax expense during 2015.

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, 2014. 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.

	Year Ended December 31,	
	2015	**2014**
Revenue	$86,517,599	$77,651,056
Net loss	$(5,845,125)	$(15,565,081)

(3) Equity

During the first quarter of 2014, the Company issued 150,000 shares of common stock to an affiliate of ROS Acquisition Offshore LP (“ROS”) pursuant to a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional $4 million under our Credit Agreement (See Note 9, “Long-Term Debt” below).

In August 2014, the Company offered 1,143,000 shares of its common stock at $5.70 per share and warrants to purchase 571,500 shares of its common stock at an exercise price of $7.12 per share to the public. Gross proceeds of the offering were approximately $6.5 million. Net proceeds from the offering were approximately $5.9 million and were used for working capital and general corporate purposes. The offering closed on August 6, 2014. The warrants have a five year term and expire on August 6, 2019. The Company utilizes a valuation model to determine the fair market value and accounts for these warrants as a derivative liability (See Note 1, “Fair Value of Financial Instruments” above and See Note 11, “Warrants” below).

We entered into a Common Stock Purchase Agreement on March 16, 2015, as amended and restated 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 in shares of our common stock over the 24-month term. The stock purchase transactions are at the Company’s option. Pursuant to the terms and conditions in the Common Stock Purchase Agreement, in the first quarter of 2015, we issued 207,182 shares of our common stock for $750,000 in aggregate proceeds, along with 154,189 shares of our common stock valued at $558,185 as a commitment fee. In the second quarter of 2015, following the effectiveness of our Registration Statement on Form S-1, 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. The Company did not issue any shares to Aspire Capital in the six months ended December 31, 2015.

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.

(4) Inventories

Inventories consist of the following:

	December 31, 2015	December 31, 2014
Current inventories		
Raw materials	$4,860,914	$3,836,635
Work in process	2,720,707	2,484,635
Finished goods	18,289,674	5,163,458
	25,871,295	11,484,728
Reserve for obsolescence	(3,186,579)	(1,926,080)
Current inventories, total	22,684,716	9,558,648
Non-current inventories		
Finished goods	2,021,077	2,860,248
Reserve for obsolescence	(413,162)	(925,990)
Non-current inventories, total	1,607,915	1,934,258
Total inventories	$24,292,631	$11,492,906

(5) Impairment of Assets

During the fourth quarter of 2014, management decided to dispose of a group of components because of a shift in strategy for the Company. The component groups consisted of the inventory and fixed assets associated with the Device Coatings and Cranial Maxillofacial Fixation (CMF) lines of business. Sales for these product lines represented less than 1% of total revenue in both the years ending 2015 and 2014. Gross profit associated with these product lines was less than 1% of total gross profit for both periods. Total assets associated with the two lines at December 31, 2014 included $80,042 of related fixed assets, net of depreciation, and related inventory of $832,507 for a total value of $912,549. These assets were transferred to Assets held for Sale and are classified on the balance sheet at December 31, 2014 as part of “Prepaid and other current assets”. After the impairment provision, the net balance of the Assets Held for Sale was $0 at December 31, 2014.

The sale of the CMF inventory occurred during the first quarter of 2015 and did not result in any tangible payment to the Company. The sale of the Device Coatings line of business occurred in the third quarter of 2015. The terms of the sale called for cash consideration to the Company of approximately $250,000, and additional contingent cash consideration of $100,000, both of which are secured by promissory notes. The gain on the sale will only be recognized when payment on the promissory notes is received. The final terms of the sale of the Device Coatings line of business resulted in an impairment gain of $51,476.

During the third quarter of 2015, Intangible Assets were reviewed and found to be impaired. The impact, net of amortization, was $285,224.

(6) Property and Equipment, Net

Property and equipment, net are as follows:

	December 31, 2015	December 31, 2014
Buildings	$ -	$ 1,657,579
Equipment	5,368,567	4,724,608
Computer equipment	348,404	225,009
Computer software	503,587	345,039
Furniture and fixtures	174,215	153,834
Leasehold improvements	2,661,802	2,380,617
Vehicles	10,000	41,099
Surgical instruments	8,175,578	-
Total cost	17,242,153	9,527,785
Less: accumulated depreciation	(5,425,524)	(4,873,258)
	$ 11,816,629	$ 4,654,527

The Company provides surgical instruments to surgeons to use during surgical procedures. Instruments are classified as non-current assets and are recorded as property, plant and equipment. Instruments are carried at cost and are held at book value (cost less accumulated depreciation). Depreciation is calculated using the straight-line method using a five year useful life.

The Company leases certain equipment under capital leases. For financial reporting purposes, minimum lease payments relating to the assets have been capitalized. As of December 31, 2015, the Company has recorded $349,162 gross assets in Equipment, and $147,980 of accumulated depreciation relating to assets under capital leases.

Maintenance and repairs expense for the year ended 2015 and 2014 was $366,323 and $293,707, respectively. Depreciation expense related to property and equipment, including property under capital lease for the year ended 2015 and 2014 was $676,540 and $570,726, respectively.

(7) Intangible Assets

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

The following table sets forth information regarding intangible assets:

	December 31, 2015	December 31, 2014
Patents	564,717	1,036,580
Acquisition related intangibles:		
Technology	28,698,700	-
Customer relationships	9,911,000	-
Tradename	4,543,300	-
Non-compete	40,500	-
Accumulated amortization	(3,520,928)	(381,090)
Net carrying value	$ 40,237,289	$ 655,490
Aggregate amortization expense:	$ 3,438,596	$ 77,022

The following is a summary of estimated future amortization expense for intangible assets as of December 31, 2015:

2016	$4,481,492
2017	4,641,781
2018	4,656,956
2019	4,547,754
2020	4,462,079
Thereafter	17,447,227
Total	$40,237,289

(8) Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2015	December 31, 2014
Accrued stock compensation	$ 147,037	$ -
Wages/commissions payable	3,994,714	1,434,743
Accrued integration expense	646,860	-
Accrued interest payable	1,716,167	-
Other accrued expenses	3,969,684	486,558
	$ 10,474,462	$ 1,921,301

(9) Long-Term Debt

On March 6, 2014, we entered into a Sixth Amendment to our Credit Agreement with ROS whereby we borrowed an additional $4.0 million under our Credit Agreement with ROS and issued 150,000 shares to an affiliate of ROS. We used the proceeds for working capital and general corporate purposes.

On July 31, 2015, concurrent with the acquisition of X-spine, we completed an offering of $65.0 million aggregate principal amount of 6.00% convertible senior unsecured notes due 2021 (the “Notes”) in a private offering to qualified institutional buyers, as defined in Rule 144A under the Securities Act of 1933, as amended. Certain private investment funds for which OrbiMed Advisors LLC, serves as the investment manager, purchased $52.0 million aggregate principal amount of the Notes directly from the Company in the offering. On August 10, 2015, the initial purchaser exercised its option with respect to an additional $3 million aggregate principal amount of Notes.

The Notes bear interest at a rate equal to 6.00% per year. Following the first interest payment date, which will be on April 15, 2016, interest on the Notes will be payable semiannually in arrears on January 15 and July 15 of each year. Interest will accrue on the Notes from the last date to which interest has been paid or duly provided for or, if no interest has been paid or duly provided for, from July 31, 2015. Unless earlier converted or repurchased, the Notes will mature on July 15, 2021.

At any time prior to the close of business on the second business day immediately preceding the maturity date, holders may convert their Notes into shares of Xtant common stock (together with cash in lieu of fractional shares) at an initial conversion rate of 257.5163 shares per $1,000 principal amount of Notes (which represents an initial conversion price of approximately $3.88 per share). However, a Note will not be convertible to the extent that such

convertibility or conversion would result in the holder of that Note or any of its affiliates being deemed to beneficially own in excess of 9.99% of the then-outstanding shares of Xtant common stock. The conversion rate will be subject to an adjustment as described in the Indenture for certain events, including, among others:

- the issuance of certain share and cash dividends on our common stock;
- the issuance of certain rights or warrants;
- certain subdivisions and combinations of our capital stock;
- certain distributions of capital stock, indebtedness or assets; and
- certain tender or exchange offers.

We will not adjust the conversion rate for other events, such as for an issuance of our common stock for cash or in connection with an acquisition that may dilute our common stock thereby adversely affecting its market price. In addition, Xtant will, in certain circumstances, increase the conversion rate for holders who convert their Notes in connection with a “make-whole fundamental change” (as defined in the Indenture). No sinking fund is provided for the Notes. Xtant may not redeem the Notes at its option prior to their maturity. If a “fundamental change” (as defined in the Indenture) occurs, holders will have the right, at their option, to require us to repurchase their Notes at a cash price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date, subject to the right of holders of Notes on a record date to receive accrued and unpaid interest.

The Notes are Xtant's senior, unsecured obligations, rank equal in right of payment with its existing and future unsecured indebtedness that is not junior to the Notes, are senior in right of payment to any of its existing and future indebtedness that is expressly subordinated to the Notes, and are effectively subordinated to its existing and future secured indebtedness to the extent of the value of the collateral securing such indebtedness. The Notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent Xtant is not a holder thereof) preferred equity, if any, of its subsidiaries.

Amended and Restated Credit Agreement

On July 31, 2015, we refinanced approximately $24 million in existing term loans and borrowed an additional $18 million pursuant to an Amended and Restated Credit Agreement with ROS (the "New Facility"). The maturity date of the New Facility is July 31, 2020 (the "Maturity Date"). Interest under the New Facility is bifurcated into a "cash pay" portion and a "payment-in-kind" ("PIK") portion. Until June 30, 2018 (the "First Period"), interest on loans outstanding under the New Facility will accrue at a rate equal to the sum of (a) 9% per annum, which portion of interest will be payable in cash, plus (b) additional interest ("PIK Interest") in an amount equal to (i) the sum of 14% per annum, plus the higher of (x) LIBOR and (y) 1% per annum, minus (ii) 9% per annum, which portion of interest will be payable "in kind." During the portion of the First Period before December 31, 2015 (the "Optional PIK Period"), we may elect at our option to have all or any portion of interest on loans outstanding under the New Facility to accrue during the Optional PIK Period at a rate equal to the sum of 14% per annum, plus the higher of (x) LIBOR and (y) 1% per annum, which portion of interest will be payable "in kind." On or after June 30, 2018 until the New Facility is repaid in full (the "Second Period"), interest on loans outstanding under the New Facility will accrue at a rate equal to the sum of (a) 12% per annum, which portion of interest will be payable in cash, plus (b) PIK Interest in an amount equal to the difference of (i) the sum of 14% per annum, plus the higher of (x) LIBOR and (y) 1% per annum, minus (ii) 12% per annum, which portion of interest will be payable "in kind." In both the First Period and the Second Period, the portion of accrued interest constituting PIK Interest will not be payable in cash but will instead be added to the principal amount outstanding under the New Facility. However, at our option, we may choose to make any "payment-in-kind" interest payment in cash. Until the third anniversary of the closing date of the New Facility, we will not be allowed to voluntarily prepay the New Facility. Whenever loans outstanding under the New Facility are prepaid or paid, whether voluntarily, involuntarily or on the Maturity Date, a fee of 7.5% on the amount paid will be due and payable. The New Facility contains financial and other covenant requirements, including, but not limited to, financial covenants that require the Company to maintain revenue and liquidity at levels set forth in the New Facility and ensure that the Company's senior consolidated leverage ratio does not exceed levels set forth in the New Facility. The New Facility also restricts us from making any payment or distribution with respect to, or purchasing, redeeming, defeasing, retiring or acquiring, the Notes other than payments of scheduled interest on the Notes, issuance of shares of our common stock upon conversion of the Notes, and payment of cash in lieu of fractional shares. The loans under the New Facility are guaranteed by Xtant and its current and future subsidiaries and are secured by substantially all of the current and future assets of Xtant and its subsidiaries. The additional amount borrowed under the New Facility was used to pay a portion of the X-spine acquisition, with the balance being available for general corporate purposes.

We accounted for the Notes and for the New Facility with ROS in accordance with ASC Subtopic 470-50, Debt Modifications and Extinguishments, and ASC Subtopic 470-60, Troubled Debt Restructurings by Debtors. Based on

the facts and circumstances surrounding the changes to the loan and applying the calculation methodology per the above mentioned ASC Subtopics, the Company recognized a gain from the extinguishment of debt of $2,345,019. The expense consists of the write-off of the royalty liability offset by the debt discount and capitalized expenses associated with the original debt agreement, including amendments, with ROS.

In addition, the Company calculated a fair value of the New Facility on a non-recurring basis by taking the five year cash flow and discounting it at a market interest rate. There was no significant difference between the calculated value and the stated value of the New Facility.

Approximately $4.8 million of expenses were incurred in conjunction with the acquisition, the issuance of convertible debt and the amendment and restatement of our credit facility with ROS. Of that amount, approximately $2.2 million of debt issuance costs will be capitalized and amortized over the life of the debt and we expensed approximately $2.5 million in 2015 related to the acquisition itself.

Prior to the issuance of the New Facility, the Company was required to pay a royalty of 1.75% on the first $45,000,000 of net sales, plus 1.0% of net sales in excess of $45,000,000. The estimate of the royalty component of the facility over the life of the agreement resulted in a debt discount and a royalty liability of approximately $7.4 million at the time of the issuance of the New Facility. The debt discount was amortized to interest expense over the seven year term of the loan using the effective interest method. The royalty liability was to be accreted to $12.3 million through interest expense over the ten year term of the royalty agreement using the effective interest method. With the issuance of the New Facility, both the Debt Discount and Royalty Liability were written off as part of the $2.3 million credit related to the Extinguishment of Debt expense.

Long-term debt consists of the following:

	December 31, 2015	**December 31, 2014**
Loan payable to ROS Acquisition Offshore (See details above)	$ 42,000,000	$ 24,000,000
Adjustment fee was payable to ROS Acquisition Offshore, due in August 2019	-	700,000
6% convertible senior unsecured notes due 2021 (See details above)	68,000,000	
PIK Interest payable to ROS	2,700,476	
6.00% loan payable to Valley Bank of Belgrade secured by a building that was sold and leased back in the fourth quarter of 2015	-	1,325,814
	112,700,476	26,025,814
Less: current portion	-	(50,671)
Debt discount	-	(5,104,813)
Long-term debt	$ 112,700,476	$ 20,870,330

The following is a summary of maturities due on the debt as of December 31, 2015:

2016	$-
2017	-
2018	-
2019	-
2020	44,700,476
Thereafter	68,000,000
Total	$112,700,476

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(10) Stock-Based Compensation

The Amended and Restated Xtant Medical Equity Incentive Plan ("the Plan") provides for stock awards, including options and performance stock awards, to be granted to employees, consultants, independent contractors, officers and directors. The purpose of the Plan is to enable us to attract, retain and motivate key employees, directors and, on occasion, independent consultants, by providing them with stock options and restricted stock grants. Stock options granted under the Plan may be either incentive stock options to employees, as defined in Section 422A of the Internal Revenue Code of 1986, or non-qualified stock options. The Plan is administered by the compensation committee of our Board of Directors. Stock options granted under the Plan are generally not transferable, vest in installments over the requisite service period and are exercisable during the stated contractual term of the option only by such optionee. The exercise price of all incentive stock options granted under the Plan must be at least equal to the fair market value of the shares of common stock on the date of the grant. 1,400,000 shares are authorized under the Plan and at December 31, 2015, we had approximately 470,000 shares available for issuance which are authorized, but unissued or reacquired shares.

Stock compensation expense recognized in the statement of operations for the year ended December 31, 2015 and 2014 is based on awards ultimately expected to vest and reflects an estimate of awards that will be forfeited. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The estimated fair value of stock options granted is done using the Black-Scholes-Merton method applied to individual grants. Key assumptions used to estimate the fair value of stock awards are as follows:

	Year Ended December 31, 2015		**Year Ended December 31, 2014**	
Risk-free interest rate	1.75	%	1.92	%
Expected volatility	80	%	57	%
Expected term	6.3	Years	5.4	Years
Expected forfeiture rate	20	%	20	%
Dividend yield	0	%	0	%

In July 2014, the Company granted the President of Bacterin an option to purchase 55,000 shares of our common stock outside of the Plan, and in August 2013, the Company granted our Chief Executive Officer an option to purchase 200,000 shares of our common stock outside of the Plan (collectively the "Non-Plan Grants").

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

	2015			2014		
	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date	Shares	Weighted Average Exercise Price	Weighted Average Fair Value at Grant Date
Outstanding at January 1	695,336	$ 11.09	$ 5.35	758,328	$ 14.90	$ 8.60
Granted	45,000	4.00	2.81	169,300	5.78	2.65
Exercised	(11,500)	1.00	2.96	(6,666)	10.00	0.04
Cancelled or expired	(64,755)	12.58	6.31	(225,626)	11.38	6.07
Outstanding at December 31	664,081	$ 10.64	$ 5.32	695,336	$ 11.09	$ 5.35
Exercisable at December 31	381,988	$ 13.65	$ 6.50	311,080	$ 15.25	$ 7.35

The aggregate intrinsic value of options outstanding as of December 31, 2015 was zero because the closing price of the stock at year end was less than the strike price of all options outstanding. As of December 31, 2015, there were 282,093 unvested options with a weighted average fair value at the grant date of $3.72 per option. As of December 31, 2015, we had approximately $699,000 in compensation expense related to unvested awards not yet recognized.

From time to time we may grant stock options and stock grants to consultants. We account for consultant stock options in accordance with ASC 505-50. Consulting expense for the grant of stock options to consultants is determined based on the estimated fair value of the stock options at the measurement date as defined in ASC 505-50 and is recognized over the vesting period. The Company recognized expenses for the year ended December 31, 2015 and 2014 of $246,165 and $135,075, respectively, as Non-cash consulting expense.

Total share based compensation recognized for employees, directors and consultants was $569,705 and $935,316 for the year ended December 31, 2015 and 2014, respectively.

On November 10, 2014, the Company granted 39,312 shares of restricted stock units to the independent Directors of the Company. These restricted shares vested on July 1, 2015 and were issued when the stock price was $4.07 per share. The total expense of $160,000 was recognized ratably over the period as Non-cash consulting expense.

On July 1, 2015, the Company granted 58,820 restricted stock units to the independent Directors of the Company. These restricted shares vest on July 1, 2016 and were granted when the stock price was $3.40 per share. The total expense of $200,000 is being recognized ratably over the period as Non-cash consulting expense. In the year ended December 31 2015, $100,000 was expensed.

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 from the Acquisition Date over the vesting period as Acquisition and integration related expense. In the year ended December 31, 2015, $25,045 was expensed.

Also, On October 8, 2015, the Company granted 20,000 restricted stock units to four Xtant area sales vice presidents at $3.19 a share for a total cost of $65,550 to be expensed ratably over the vesting period as General and administrative expense. In the year ended December 31, 2015, $5,296 was expensed.

(11) Warrants

The following table summarizes our warrant activities for the period ended December 31, 2015:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding as of January 1, 2014	1,087,820	$ 16.20
Issued	571,500	7.12
Expired	(4,000)	20.00
Outstanding at January 1, 2015	1,655,320	$ 13.06
Issued	-	-
Expired	(376,754)	22.87
Outstanding at December 31, 2015	1,278,566	$ 8.45

We utilize a lattice model to determine the fair market value of the warrants accounted for as liabilities. The valuation model accommodates the probability of exercise price adjustment features as outlined in the warrant agreements. We recorded an unrealized gain of $270,020 resulting from the change in the fair value of the warrant derivative liability for the year ended 2015. Under the terms of some of our warrant agreements, at any time while the warrant is outstanding, the exercise price per share can be reduced to the price per share of future subsequent equity sales of our common stock or a common stock equivalent that is lower than the exercise price per share as stated in the warrant agreement.

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

	Year Ended December 31,	
	2015	**2014**
Value of underlying common stock (per share)	$2.80	$3.03
Risk free interest rate	1.02%	0.80%
Expected term	4.08 years	5.00 years
Volatility	79 %	75 %
Dividend yield	0 %	0 %

The following table summarizes our activities related to warrants accounted for as a derivative liability for the year ended December 31, 2015 and 2014:

	2015	**2014**
Balance at January 1,	1,171,692	600,192
Derivative warrants issued	-	571,500
Derivative warrants exercised	-	-
Expired	(46,573)	-
Balance at December 31,	1,125,119	1,171,692

(12) Commitments and Contingencies

Operating Leases

We lease four office facilities under non-cancelable operating lease agreements with expiration dates in 2016, 2019, 2023 and 2025. We have the option to extend the four leases for up to another ten year term and for one facility, and we have the right of first refusal on any sale. We lease additional office space under a month-to-month arrangement.

On October 23, 2015, the Company entered into a sale-leaseback transaction for the property located at 664 Cruiser Lane, Belgrade, Montana, 59714 which formerly secured the 6% loan payable to Valley Bank of Belgrade (See Note 9, “Long-Term Debt” above). Our new lease agreement has a ten year term with an option to extend for two additional five year terms for a total of ten years.

Future minimum payments for the next five years and thereafter as of December 31, 2015, under these leases, are as follows:

2016	$775,141
2017	451,327
2018	462,678
2019	348,141
2020	342,638
Thereafter	1,386,653
Total	$3,766,578

Rent expense was $544,000 and $365,000 for the year ended December 31, 2015 and 2014, respectively. Rent expense is determined using the straight-line method of the minimum expected rent paid over the term of the agreement. We have no contingent rent agreements.

Indemnifications

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

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

Litigation

On March 17, 2014, a complaint was served on the Company in the following state court action in the District Court for the County of Arapahoe, State of Colorado: Robert Taggart v. Guy Cook, Bacterin International, Inc., a Nevada Corporation and Bacterin International Holdings, Inc., a Delaware corporation, Civil Action No. 14CV30401. The complaint involves claims under an employment agreement between plaintiff and the Company seeking commissions on Company sales, a commission on funds obtained by the Company as a result of a reverse merger and vesting of certain stock options. Plaintiff seeks damages in excess of $5 million. The Company believes this case lacks legal merit and has filed counterclaims for plaintiff's breach of his employment agreement and breach of his duty of loyalty to the Company, asserting the right to recover all compensation paid to Plaintiff during his employment as well as other damages. The parties recently underwent court mandated mediation.

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

(13) Income Taxes

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

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

	Year Ended December 31,	
	2015	2014
United States	$(19,711,838)	$(10,507,869)
	$(19,711,838)	$(10,507,869)

The components of the income tax provision are as follows:

	Year Ended December 31,

	2015	2014
Current:		
Federal	$-	$ -
State	-	-
Total current	-	-
Deferred:		
Federal	(15,117,246)	-
State	(2,420,162)	-
Total deferred	(17,537,408)	-
	$(17,537,408)	$ -

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

	Year Ended December 31,	
	2015	2014
Statutory Federal tax rate	$(6,898,830)	$(3,677,754)
Valuation allowance	7,089,311	4,909,776
State income taxes, net of Federal benefit	(1,104,199)	(368,826)
Purchase accounting valuation reversal	(17,537,408)	-
Change in state income tax rate	(1,277,303)	277,076
Provision to return adjustment	-	(505,423)
Change in Warrant Derivative Liability	(109,633)	(668,554)
Other deferred tax adjustment	581,444	-
Acquisition expenses	527,646	-
Non-cash interest	1,096,446	-
Other	1,762	-
Nondeductible meals, entertainment and other expense	93,356	33,705
	$(17,537,408)	$-

Deferred tax assets and liabilities are as follows:

	At December 31,	
	2015	2014
Deferred tax assets:		
Current deferred tax assets		
Accrued liability for vacation	$139,162	$102,643
Accrued commissions and bonuses/compensation	1,369,265	-
Accrued contingencies	142,107	-
Bad debt reserve	1,047,382	536,440
Charitable contributions carryforward	38,283	33,124
Inventory reserve	1,461,566	1,098,333
Reserve - assets held for sale	-	351,423
Net operating loss carryovers	22,698,555	18,200,823
Stock warrants	139,056	131,891
Stock option compensation	2,058,631	1,594,460
Goodwill amortization	-	82,212
Debt discount and waiver amortization	1,577,347	1,076,926
Depreciation	-	244,004
Amortization	-	30,290
Other	47,593	-
Total non-current deferred tax assets	30,718,947	23,482,569
Valuation allowance	(13,065,176)	(23,482,569)
Net non-current deferred tax assets	17,653,771	-
Deferred tax liabilities:		
Depreciation	(1,566,381)	-
Amortization	(16,087,390)	-
Total deferred tax liabilities	(17,653,771)	-
Net deferred tax assets	$-	$-

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management does not believe it is more likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a valuation allowance equal to the net realizable deferred tax assets. The valuation allowance decreased by $10,417,393 and increased by $4,909,776 in 2015 and 2014, respectively.

During 2015, the Company acquired intangible assets of $43,193,500 in a purchase business combination related to existing customer base and contracts for which there is no tax basis. Accordingly, the recognition of the intangible asset created a deferred tax liability at the close of the purchase business combination resulting in a reduction of the valuation allowance equal to the tax affected intangible asset. In accordance with ASC 805-740-30-3, the resulting valuation allowance reversal is considered a current year deferred income tax benefit of $17,537,408 as reported on the consolidated statement of income.

At December 31, 2015 and 2014, the Company had total domestic Federal and state net operating loss carryovers of approximately $55,905,000 and $47,263,000, respectively. Federal net operating loss carryovers expire at various dates between 2025 and 2035, while state net operating loss carryovers expire between 2025 and 2035.

Under the Tax Reform Act of 1986, as amended, the amounts of and benefits from net operating loss carryovers and research and development credits may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period. The Company does not believe that such an ownership change has occurred in 2015 or 2014.

The 2012 through 2014 tax years remain open to examination by the Internal Revenue Service and the 2010 to 2014 tax years remain open to the Montana Department of Revenue and various other state tax agencies. These taxing authorities have the authority to examine those tax years until the applicable statute of limitations expire.

The Company did not recognize any interest or penalties related to income taxes for the years ended December 31, 2015 and 2014.

At December 31, 2015 the Company early adopted Accounting Standards Update (ASU) No. 2015-17, “Balance Sheet Classification of Deferred Taxes” (Topic 740), which provides for a simplified reporting and balance sheet classification of current and non-current deferred tax assets and liabilities. The adopted ASU requires all deferred tax assets and liabilities, and the related valuation allowance, be presented as non-current on the balance sheet. Accordingly, the 2015 and 2014 deferred tax assets and liabilities have been reclassified to conform to the ASU’s required presentation. No change in any prior year net deferred tax accounts was reported as all prior year deferred tax accounts have been fully reserved.

(14) Employee Benefit Plans

Xtant currently has two 401(k) retirement plans for its employees. Under both plans, the employee becomes qualified after six months of employment. The Company is in the process of integrating the two plans. Terms for the two plans are as follows:

	Bacterin	X-Spine
Matching	2%	None
Contribution Limit	$18,000 or the statutorily prescribed limit	$18,000 or $24,000 if over the age of 50
Enrollment Period	Twice a year	Four times a year

(15) Supplemental Disclosure of Cash Flow Information

Supplemental cash flow information is as follows:

	Year Ended December 31,	
	2015	**2014**
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$2,279,919	$3,192,854
Non-cash activities:		
Issuance of warrants related to stock issuance	-	1,461,796
Issuance of shares related to debt issuance	$-	$1,094,999
Issuance of shares for non-cash consulting expense	$-	$81,924
Issuance of restricted stock to employees	$-	$136,977
Issuance of shares in conjunction with the acquisition of X-spine	$14,934,146	$-
Issuance of capital leases	$70,921	$-

(16) Related Party Transactions

Darrel Holmes, our former Chief Operating Officer, and Mitchell Godfrey, a former director, serve on the board of American Donor Services Inc. (“ADS”), and Mr. Godfrey also serves as secretary and treasurer for ADS. Messrs. Godfrey and Holmes each receive $5,000 per year for their service to ADS. ADS recovers tissue from donors and we reimburse ADS for its recovery fees, which are comprised primarily of labor costs. The approximate aggregate amount of all transactions with ADS for the year ended December 31, 2015 and 2014 was $1,853,457 and $2,406,926, respectively. Our relationship with ADS has benefited us, as ADS provides us with current donors and a pipeline for future donors, which is necessary to our success.

Certain of X-spine’s former shareholders, now own over 10% of our common stock as of the Acquisition Date, and have owned a controlling interest of X-spine’s largest supplier, Norwood Tool Company d/b/a Norwood Medical. In 2015, Xtant purchased from Norwood Medical approximately 12% of its operating products (See ITEM 1A. RISK FACTORS - Trends, Risks and Uncertainties Related to Our Business, *“The business acquired from X-spine depends, in part, on a relationship with a key supplier, which is a related party” above).*

Unless delegated to the Compensation Committee by the Board of Directors, the Audit Committee or the disinterested members of the full Board of Directors reviews and approves all related party transactions.

(17) Segment and Geographic Information

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

The Company attributes revenues to geographic areas based on the location of the customer. Total revenue by major geographic area is reported in Note 1, "Business Description and Significant Accounting Policies" above.

(18) Subsequent Events

As previously disclosed in a Form 8-K filed with the SEC on January 22, 2016, effective January 8, 2016, Robert Di Silvio ceased to be President and a named executive officer of the Company; however, Mr. Di Silvio will continue to work with the Company as a consultant.

In connection with the restructuring of the Company following the acquisition of X-Spine, effective February 24, 2016, Darrel Holmes ceased serving as our Chief Operating Officer. Going forward, Mr. Holmes will continue to serve as the Chief Operating Officer of Bacterin, but will no longer be a named executive officer of the Company.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2015. Based upon that evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2015, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

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

Based on our evaluation under the framework Internal Control - Integrated Framework (2013), management concluded that our internal control over financial reporting was effective as of December 31, 2015.

This report does not include an attestation report of the Company's independent public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the

Company to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

In connection with the restructuring of the Company following the acquisition of X-Spine, effective February 24, 2016, Darrel Holmes ceased serving as our Chief Operating Officer. Going forward, Mr. Holmes will continue to serve as the Chief Operating Officer of Bacterin, but will no longer be a named executive officer of the Company.

PART III

Item 10. Directors and Executive Officers of the Registrant

Executive Officers and Directors

The names, ages and positions of our executive officers and directors are as follows:

Name	Age	Position
Daniel Goldberger	57	Director, Chief Executive Officer
Kent Swanson	71	Chairman of the Board
Michael Lopach	67	Director
Jon Wickwire	72	Director
John Deedrick	53	Director
David Goodman, M.D.	60	Director
David L. Kirschman, M.D.	45	Director, Executive Vice President and Chief Scientific Officer
John Gandolfo	55	Chief Financial Officer

The principal occupations for the past five years (and, in some instances, for prior years) of each of our executive officers and directors are as follows.

Daniel Goldberger, Director, Chief Executive Officer, has more than 25 years of experience as a leader of both publicly traded and privately held medical technology companies, with a proven track record of building revenue and profits through the introduction of market changing product innovations. He was most recently Chief Executive Officer and a director of Sound Surgical Technologies from April 2007 through its merger with Solta Medical (Nasdaq: SLTM) in February 2013. Previously, he was President/Chief Executive Officer and a director of Xcorporeal (Amex XCR) an innovator in portable dialysis and Glucon (private) a developer of glucose measurement technology and several other successful enterprises. Mr. Goldberger is a named inventor on more than 60 US patents. He holds a B.S. in Mechanical Engineering from the Massachusetts Institute of Technology and an MS in Mechanical

Engineering from Stanford University. Mr. Goldberger contributes medical industry and management experience to the board of directors.

Kent Swanson, Chairman of the Board, was with Accenture for over 32 years, retiring from the firm in 2001 as a Senior Partner. He held global leadership and management positions in a wide range of industries and geographies. From 2001 to 2008, he was the board chair of ALN Medical Management; providing outsourced services for clinic-based physician practices. Also from 2001 to 2008, he was board chair for Boys Hope Girls Hope of Colorado, a charitable organization providing a home and scholarship education for disadvantaged children with significant capabilities and promise. From 2002 to 2009, he was a board member, audit committee member and compensation committee chair for MPC Computers. Mr. Swanson graduated with distinction from the University of Minnesota earning an M.S. in Business and received an M.B.A. from the University of Chicago in 1969. Mr. Swanson contributes significant management experience to the board of directors.

Michael Lopach, Director, is a certified public accountant with over 40 years of accounting experience. Mr. Lopach spent 27 years of his career with Galusha, Higgins, Galusha & Co. (1981-1991), the largest privately held accounting firm in Montana and northern Idaho, where he served as president and Chief Executive Officer. In 1999, Mr. Lopach founded Lopach & Carparelli PC, an accounting firm that focuses on medical practitioners. Mr. Lopach received his MBA from the University of Notre Dame. Mr. Lopach serves as chairman of the audit committee. Mr. Lopach contributes significant accounting experience to the board of directors.

Jon Wickwire, Director, is an attorney and founding shareholder of Wickwire Gavin, P.C., a national construction law firm which merged with Akerman Senterfitt, one of the top 100 law firms in the United States. Mr. Wickwire served as lead counsel on major infrastructure litigation and alternative dispute resolutions, both domestically and internationally, throughout his 35 year career, and was the founding fellow of the American College of Construction Lawyers. Mr. Wickwire also served as the founding chairman of the College of Scheduling, an organization dedicated to advancing the techniques, practice and profession of project scheduling, and has authored several books and articles on construction and public contract law, including Construction Management: Law and Practice and The Construction Subcontracting Manual: Practice Guide with Forms. Mr. Wickwire currently serves on the advisory board for Crunchies Food Company. Mr. Wickwire is a graduate of the University of Maryland and Georgetown University Law Center. Mr. Wickwire serves as chairman of the nominations and corporate governance committee. Mr. Wickwire contributes legal experience to the board of directors.

John Deedrick, Director, is an experienced senior executive with 30 years of experience in healthcare, defense, and business consulting. He was a co-founder and managing director for Accuitive Medical Ventures (2003-2012) and a corporate venture capitalist for Mayo Clinic (1997-2003). Mr. Deedrick currently serves as President and Chief Executive Officer of CHIP Solutions (2012-present) and is founder and chairman of GreatDeeds (2001-present), a Minnesota non-profit organization. Mr. Deedrick has served on the board of numerous early, mid and growth stage healthcare companies over the last 17 years, including LAFORGE Optical (2016-present) GreatDeeds (2001-present) and Ironwood Springs Ranch (2014-present). Mr. Deedrick received his undergraduate degree from the University of Northwestern St. Paul (Roseville, MN) and his MBA from St. Thomas University (St. Paul, MN). Mr. Deedrick contributes significant financial, management and industry experience to the board of directors.

David Goodman, M.D., Director, has devoted his career to improving health through the development and integration of innovative technologies into clinical practice. Dr. Goodman currently serves as co-founder and Chief Medical Officer of FirstVitals Health & Wellness, a technology-enabled service company focused on preventing complications such as foot ulcers and lower extremity amputations in people with diabetes. Dr. Goodman also serves on the board of directors of NEUROMetrix (Nasdaq: NURO), a neurotechnology company focused on the early detection of diabetic peripheral neuropathy (DPN) and treatment of painful diabetic neuropathy (PDN). In addition, Dr. Goodman served as a director of Sound Surgical Technologies LLC, a private manufacturer of aesthetic surgical tools until its successful acquisition by Solta Medical (Nasdaq: SLTM) in 2013. Dr. Goodman has a long track record of accomplishment in executive management as well as through his own entrepreneurial efforts. As an executive, Dr. Goodman served as Chief Executive Officer of SEDLine, an EEG-based brain monitoring company as well as the EVP of Business Development for Masimo (Nasdaq: MASI), a leading company in non-invasive patient monitoring. As an entrepreneur, Dr. Goodman was the founding Chief Executive Officer of LifeMasters Supported SelfCare, a pioneering disease management company, and Aradigm, a developer of electronic aerosol drug delivery systems. Dr. Goodman began his career as the first engineer at Nellcor, the company that developed modern pulse oximetry. He holds a B.A.S. in applied science and bioengineering and a M.S.E. in bioengineering from the University of Pennsylvania. Dr. Goodman also received an M.D. cum laude from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology. Dr. Goodman completed his internship at the University of California, San Francisco (UCSF) in the Department of Medicine. He holds 18 issued and 4 pending US patents and maintains clinical practices in California and Hawaii. Dr. Goodman contributes medical and industry experience to the board of directors.

David L. Kirschman, M.D., Director, Executive Vice President and Chief Scientific Officer, is an inventor and entrepreneur with a background in the medical device industry. He completed training in neurosurgery with a specialization in instrumented spinal surgery. Dr. Kirschman retired from the practice of medicine in 2006. Dr. Kirschman has issued and pending patents for a wide range of spinal devices and has been the President of X-spine since 2004. In connection with the acquisition of X-spine by the Company on July 31, 2015, Dr. Kirschman became a member of our board of directors and our Executive Vice President and Chief Scientific Officer. Dr. Kirschman also serves on the board of directors of Aerobiotix, Inc. He received his B.S. in Biological Science cum laude from Colorado State University and M.D. from the University of Colorado School of Medicine. Dr. Kirschman contributes medical, management and industry experience to the board of directors, as well as an in-depth understanding of the X-spine business.

John Gandolfo, Chief Financial Officer, joined us as our interim Chief Financial Officer on a part-time basis, effective June 4, 2010, and filled this position full time commencing on July 6, 2010. Mr. Gandolfo also served as Interim Co-Chief Executive Officer from April 5, 2013 to August 14, 2013, and as a Director from July 9, 2013 to August 14, 2013. Mr. Gandolfo has 25 years of experience as chief financial officer of rapidly growing private and publicly held companies with a primary focus in the life sciences, healthcare and medical device areas. Mr. Gandolfo has had direct responsibility over capital raising, including four public offerings, financial management, mergers and acquisition transactions and SEC reporting throughout his professional career. Prior to joining us, Mr. Gandolfo served as the Chief Financial Officer for Progenitor Cell Therapy LLC, a leading manufacturer of stem cell therapies. Prior to joining Progenitor, Mr. Gandolfo served as the Chief Financial Officer for Power Medical Interventions, Inc., a publicly held developer and manufacturer of computerized surgical stapling and cutter systems, from January 2007 to January 2009. Prior to joining PMI, Mr. Gandolfo was the Chief Financial Officer of Bioject Medical Technologies, Inc., a publicly held supplier of needle-free drug delivery systems to the pharmaceutical and biotechnology industries, from September 2001 to May 2006, and served on the Bioject's board of directors from September 2006 through May 2007. Prior to joining Bioject, Mr. Gandolfo was the Chief Financial Officer of Capital Access Network, Inc., a privately held specialty finance company, from 2000 through September 2001, and Xceed, Inc., a publicly held Internet consulting firm, from 1999 to 2000. From 1994 to 1999, Mr. Gandolfo was Chief Financial Officer and Chief Operating Officer of Impath, Inc., a publicly held, cancer-focused healthcare information company. From 1987 through 1994, he was Chief Financial Officer of Medical Resources, Inc., a publicly held manager of diagnostic imaging centers throughout the United States. A graduate of Rutgers University, Mr. Gandolfo is a certified public accountant (inactive status) who began his professional career at Price Waterhouse.

Board Composition and Terms of Office

The composition of our board of directors, audit committee, compensation committee, and nominations and governance committee, is subject to the corporate governance provisions of the NYSE MKT, including rules relating to the independence of directors. A majority of our board members and all of our board committee members are independent directors. All directors hold office for staggered three year terms and until the election and qualification of their successors. Officers are elected by, and serve at the discretion of, the board of directors.

Board Committees

We have established an audit committee, compensation committee and nominations and corporate governance committee, in compliance with applicable corporate governance requirements, and the Board also formed a Business Development Committee in 2014. The charters of our audit committee, compensation committee and nominations and corporate governance committee have been posted on our website at www.xtantmedical.com . The contents of our website are not incorporated by reference into this annual report on Form 10-K.

Audit Committee

The purpose of the Audit Committee is to assist the oversight of our Board of Directors with the integrity of our financial statements, our compliance with legal and regulatory matters, our internal audit function, and our independent auditor's qualifications, independence, and performance. The primary responsibilities of the Audit Committee are set forth in its charter and include various matters with respect to the oversight of our accounting and financial reporting process and audits of our financial statements. The Audit Committee also selects the independent auditor, reviews the proposed scope of the audit, reviews our accounting and financial controls with the independent auditor and financial accounting staff, and reviews and approves transactions between us and our directors, officers, and their affiliates.

The Audit Committee currently consists of Messrs. Lopach, Swanson and Wickwire, each an independent director under NYSE MKT listing standards as well as under rules adopted by the SEC pursuant to the Sarbanes-Oxley Act of 2002. Mr. Lopach serves as the Chairman of the Audit Committee. The Board of Directors has determined that Messrs. Lopach and Swanson (whose backgrounds are detailed above) each qualify as an "audit committee financial expert" in accordance with applicable rules and regulations of the SEC.

Compensation Committee

The primary purposes of the Compensation Committee are to determine or recommend the compensation of our CEO and other executive officers, and to oversee our Equity Incentive Plan. Our Compensation Committee currently consists of John Deedrick, Michael Lopach and David Goodman, each of whom is an independent director. Mr. Deedrick serves as the Chairman of the Compensation Committee.

Nominations and Corporate Governance Committee

The purposes of the Nominations and Corporate Governance Committee include the selection or recommendation to our Board of Directors of nominees to stand for election as directors, the oversight of the selection and composition of the committees of our Board of Directors, the oversight of the evaluations of our Board of Directors and management, and the development and recommendation to our Board of Directors of a set of corporate governance principles applicable to our company. The Nominations and Corporate Governance Committee currently consists of Messrs. Wickwire, Deedrick and Goodman, each of whom is an independent director of our company under NYSE MKT listing standards as well as under rules adopted by the SEC pursuant to Sarbanes-Oxley. Mr. Wickwire serves as the Chairman of the Nominations and Corporate Governance Committee.

Business Development Committee

In September 2014, the Board formed a Business Development Committee to advise the Board on strategic direction and growth strategies. The Business Development Committee currently consists of Messrs. Deedrick (Chair), Swanson and Goodman..

Nominations to the Board of Directors

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

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

Family Relationships

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

Compliance with Section 16(a) of the Exchange Act

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

To the Company’s knowledge, based solely on our review of the Section 16 reports furnished to us with respect to 2015, we believe all reports required pursuant to Section 16(a) were filed on a timely basis.

Code of Ethics

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

Procedures for Shareholder Recommendation of Nominees to the Board of Directors

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

Item 11. Executive Compensation

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

Name and Principal Position	Year	Salary	Bonus	Stock Awards[1]	Option Awards[1]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Daniel Goldberger	2015	404,000	245,000	-	-	-	-	-	649,000
Chief Executive Officer	2014	400,000	100,154	-	-	-	-	143,422[2]	643,576
David Kirschman	2015	209,615	62,500	-	76,868	-	-	-	348,983
Executive Vice President and Chief Scientific Officer From July 31,2015 to present									
John Gandolfo	2015	330,000	153,000	-	-	-	-	-	483,000
Chief Financial Officer	2014	330,000	20,000	-	90,841	-	-	-	440,841
Robert Di Silvio	2015	325,000	-	-	-	-	-	-	325,000
President	2014	153,750	-	-	150,990	-	-	129,300[3]	433,140

From July 1, 2014 to January 8, 2016. See Note 18, “Subsequent Events” above.

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

(2) Relocation reimbursement.

(3) Consulting fees paid to Mr. Di Silvio for services provided prior to his employment.

Employment Agreements

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

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

Amended and Restated Xtant Medical Equity Incentive Plan and Inducement Grants

The following is a summary of the material terms of the Amended and Restated Xtant Medical Equity Incentive Plan (the “Plan”):

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

There are 1,400,000 shares of our common stock authorized to be issued under the Plan. As of December 31, 2015, we had outstanding options to purchase 381,988 shares and 157,330 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 470,000 shares available for issuance thereunder.

We also granted stock options to our Chief Executive Officer and former President outside of our Plan as inducements material to entering into employment with the company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grants to our Chief Executive Officer and former President were approved by the Compensation Committee of our Board of Directors. The inducement grant to our Chief Executive Officer consists of a stock option to purchase up to 200,000 shares of our common stock, with a per share exercise price of $6.00, which was the adjusted closing price of the Company's common stock on the August 14, 2013 grant date. Our Chief Executive Officer's inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 3,333 underlying shares, beginning September 15, 2014, and one final installment as to 3,330 underlying shares. The inducement grant to our former President consists of a stock option to purchase up to 55,000 shares of our common stock, with a per share exercise price of $6.80, which was the adjusted closing price of our common stock on the July 1, 2014 grant date. Our former President's inducement grant stock option vested over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 917 underlying shares, beginning on August 1, 2015, and one final installment as to 901 underlying shares. Per the terms of his stock option agreement, Mr. Di Silvio has ninety days from January 8, 2016 to exercise his vested stock options.

Except for the Amended and Restated Xtant Medical Equity Incentive Plan and the inducement grants to our Chief Executive Officer and former President discussed above, we do not have any other stock option plans or other similar incentive compensation plans for officers, directors and employees.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2015)

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	Number of shares or units of stock that have not vested	Market value of shares or units of stock that have not vested
Daniel Goldberger	93,328	106,653	$ 6.00	8/14/23	-	-
John Gandolfo	7,500	22,500	5.01	9/4/24	-	-
	7,000	-	6.80	5/24/23	-	-
Robert Di Silvio	15,585	39,415	6.80	7/1/24	-	-

Potential Payments Upon Termination or Change-in-Control

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

Under Mr. Goldberger's employment agreement, Mr. Goldberger currently receives an annual base salary of $520,000, which is subject to annual increases based on periodic reviews, along with other incentive compensation as determined by the Board of Directors, with a bonus target of 50% of Mr. Goldberger's annual base salary. Mr. Goldberger's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for six (6) months severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control.

Dr. David L. Kirschman's employment agreement provides for an annual base salary of $500,000, along with other incentive compensation as determined by the Board of Directors, with a bonus target of 50% of his annual base salary. Dr. Kirschman also received a restricted stock grant of 40,000 shares of our common stock in 2015, vesting over four years. Dr. Kirschman's employment agreement contains customary proprietary information provisions and restrictive covenants, including non-solicitation and non-competition covenants, and his agreement provides for 12 months' severance for termination in connection with a change of control.

Mr. Gandolfo's employment agreement provides for an annual base salary of $360,000, along with other incentive compensation as determined by the Compensation Committee of the Board of Directors, with a bonus target of 50% of Mr. Gandolfo's annual base salary. Mr. Gandolfo's employment agreement contains customary intellectual property provisions and restrictive covenants and provides for twelve (12) months severance for termination without cause, resignation with good reason, or termination in connection with a change in control.

Mr. Di Silvio's employment agreement provided for an annual base salary of $325,000, along with other incentive compensation as determined by the Compensation Committee of the Board of Directors, with a bonus target of 50% of Mr. Di Silvio's annual base salary. Mr. Di Silvio's employment agreement contained customary intellectual property provisions and restrictive covenants and provides for six (6) months severance for termination without cause or resignation with good reason and twelve (12) months of severance for termination in connection with a change in control. We are currently paying severance to Mr. Di Silvio pursuant to the term of his agreement (See Note 18, "Subsequent Events" above).

Retirement Plans

Xtant currently has two 401(k) retirement plans for its employees. Under both plans, the employee becomes qualified after six months of employment. The Company is in the process of integrating the two plans. Terms for the two plans are as follows:

	Bacterin	X-Spine
Matching	2%	None
Contribution Limit	$18,000 or the statutorily prescribed limit	$18,000 or $24,000 if over the age of 50
Enrollment Period	Twice a year	Four times a year

Director Compensation

Name	Fees Earned or Paid in Cash (1)	Stock Awards (2)	Option Awards (2)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Kent Swanson	$ 97,500	$ 40,000	$ -	$ -	$ -	$ -	$137,500
Michael Lopach	$ 56.500	$ 40,000	$ -	$ -	$ -	$ -	$96,500
Jon Wickwire	$ 55,000	$ 40,000	$ -	$ -	$ -	$ -	$95,000
John Deedrick	$ 150,250	$ 40,000	$ -	$ -	$ -	$ -	$190,250
David Goodman	$ 51,750	$ 40,000	$ -	$ -	$ -	$ -	$91,750

(1) Effective September 4, 2014, compensation for our independent Board members was revised as follows: independent directors receive an annual retainer of $40,000 per year, the independent Chairman of our Board receives an additional $20,000 per year, the Audit Committee Chair receives $12,500 per year, other Committee Chairs receive $10,000 per year, Audit Committee members receive $5,000 per year, other Committee members receive $4,000 per year and all independent directors receive an annual equity grant valued at $40,000. In addition, the Chair of our Business Development Committee earned $90,000 for the first six months of 2015, the other member of the Business Development Committee earned $30,000 for the first six months of 2015, and thereafter, beginning July 1, 2015, the annual compensation for the Business Development Committee was set at $12,500 per year for the Committee Chair and $5,000 per year for the other members.

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

Compensation Committee Interlocks and Insider Participation

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

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

The following table sets forth information regarding the beneficial ownership of our common stock as of December 31, 2015 by (a) each of our directors and named executive officers, (b) all of our current directors and executive officers as a group, and (c) each person who is known by us to beneficially own more than 5% of our common stock.

Name and Address of Beneficial Owner	**Number of Shares Beneficially Owned[2]**		**Percentage of Shares Beneficially Owned[3]**	
Directors and Named Executive Officers[1]:				
Daniel Goldberger	197,026	(4)	1.7	%
Kent Swanson	120,828	(5)	1.0	%
Michael Lopach	43,812	(6)	*	
Jon Wickwire	74,509	(7)	*	
John Deedrick	26,621	(8)	*	
David Goodman, M.D.	5,000	(9)	*	
David L. Kirschman, M.D.	1,701,063	(10)	14.3	%
John P. Gandolfo	23,287	(11)	*	
Robert Di Silvio	18,617	(12)	*	
All executive officers and directors as a group (10 persons)	2,221,478		18.7	%
Five Percent Stockholders:				
OrbiMed Advisors LLC 601 Lexington Ave., 54th Floor New York, NY 10022	1,187,421	(13)	10.0	%
Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998 9485 Gulfshore Drive, B-201 Naples, FL 34108	1,272,796	(14)	10.7	%

Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998 P.O. Box 421 15643 Captive Drive Captiva, FL 33924	1,272,796	(15)	10.7 %

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

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

(2) Unless otherwise indicated, includes shares owned by a spouse, minor children and relatives sharing the same home, as well as entities owned or controlled by the named person. Also includes shares that the named person has the right to acquire within 60 days after December 31, 2015, by the exercise or conversion of any warrant, stock option or convertible preferred stock. Unless otherwise noted, shares are owned of record and beneficially by the named person and the persons named in the table have sole voting and investment power with respect to the shares beneficially owned by them as set forth opposite their respective names.

The calculation in this column is based on 11,897,601 shares of common stock outstanding on December 31, 2015.

(3) The shares of common stock underlying warrants and stock options are deemed outstanding for purposes of computing the percentage of the person holding them, but are not deemed outstanding for the purpose of computing the percentage of any other person.

(4) Consists of (a) 15,510 shares of our common stock held directly, (b) 81,522 shares of our common stock held by an IRA, and (c) options to purchase 99,994 shares of our common stock.

(5) Consists of (a) 84,828 shares of our common stock held directly, (b) 20,000 shares held by a family limited partnership, (c) warrants to purchase 5,000 shares of our common stock, and (d) options to purchase 11,000 shares of our common stock.

(6) Consists of (a) 11,522 shares of our common stock held directly, (b) 14,258 shares held by a 401(k) plan, (c) warrants to purchase 2,032 shares of our common stock, and (d) options to purchase 16,000 shares of our common stock.

(7) Consists of (a) 31,247 shares of our common stock held directly, (b) 25,762 shares of common stock held by trusts, (c) warrants to purchase 1,500 shares of our common stock, and (d) options to purchase 16,000 shares of our common stock.

(8) Consists of (a) 16,621 shares of our common stock, and (b) options to purchase 10,000 shares of our common stock.

(9) Consists of an option to purchase 5,000 shares of our common stock not yet exercised.

(10) Consists of (a) 4,000 shares of our common stock held directly, and (b) 1,697,063 shares of our common stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement and escrow agreement.

(11) Consists of (a) 6,396 shares of our common stock held directly, (b) 994 shares of our common stock held by an IRA, (c) warrants to purchase 397 shares of our common stock, and (d) options to purchase 15,500 shares of our common stock.

(12) Consists of (a) 1,198 shares of our common stock, and (b) options to purchase 17,419 shares of our common stock.

(13) Based on Schedule 13G/A filed with the SEC on February 17, 2015, as well as our knowledge regarding recent purchases of the Notes by affiliates of OrbiMed. Includes 475,438 shares of our common stock and warrants to purchase 87,719 shares of our common stock held by Royalty Opportunities S.àr.l., an entity managed by OrbiMed. Affiliates of OrbiMed also purchased $52.0 million aggregate principal amount of the Notes, which are convertible into shares of our common stock. However, the indenture prevents note holders from converting their Notes to the extent that such conversion would result in beneficial ownership by the note holder or any of its affiliates in excess of 9.99% of the then-outstanding shares of our common stock. OrbiMed, an investment advisor, and Samuel D. Isaly, its managing member and a control person, each have shared voting and dispositive power with respect to shares of our common stock and notes held by Royalty Opportunities S.àr.l. and Royalty Opportunities II, LP.

(14) Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 1,272,796 shares of our common stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement and escrow agreement. Kenneth J. Hemmelgarn, Jr. is a beneficiary of and the sole trustee of the Kenneth J. Hemmelgarn, Jr. Revocable Living Trust dated February 9, 1998, which may be revoked by Kenneth J. Hemmelgarn, Jr. Kenneth J. Hemmelgarn, Jr. and Brian J. Hemmelgarn are brothers and may be deemed to be members of a “group” for purposes of Section 13(d)(3) of the Exchange Act, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

(15) Based on Schedule 13D filed with the SEC on August 10, 2015. Consists of 1,272,796 shares of our common stock acquired in connection with our acquisition of X-spine, which are subject to a lock-up agreement and escrow agreement. Brian J. Hemmelgarn is a beneficiary of and the sole trustee of the Brian J. Hemmelgarn Revocable Living Trust dated February 9, 1998, which may be revoked by Brian J. Hemmelgarn. Kenneth J. Hemmelgarn, Jr. and Brian J. Hemmelgarn are brothers and may be deemed to be members of a “group” for purposes of Section 13(d)(3) of the Exchange Act, though they have disclaimed any express agreement to act as a group, other than as described in their jointly filed Schedule 13D.

Because the table above is limited to shares that are owned or which the person has the right to acquire within 60 days, it does not present a complete view of the economic exposure our directors and executive officers have to our common stock. Excluded from the table above are unvested stock options, unvested restricted stock units and unvested warrants which will become vested more than 60 days from December 31, 2015.

Securities authorized for issuance under equity compensation plans

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	409,081	$ 12.90	400,000	(1)
Equity compensation plans not approved by security holders[(2)]	255,000	$ 6.17	N/A	
Total	664,081	$ 10.64	400,000	

(1) In addition to options outstanding, the Company also has 58,820 shares of restricted stock outstanding that have been issued under the Plan.

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

Amended and Restated Xtant Medical Equity Incentive Plan and Inducement Grants

We have granted stock options, shares of common stock and restricted stock units under our Amended and Restated Xtant Medical Equity Incentive Plan (the “Plan”), as well as inducement grants consisting of (i) an option to purchase 200,000 shares of our common stock to our Chief Executive Officer, and (ii) an option to purchase 55,000 shares of our common stock to our former President, both granted outside of our Plan. The following is a summary of the material terms of our Plan and the inducement grants.

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

There are 1,400,000 shares of our common stock authorized to be issued under the Plan. As of December 31, 2015, we had outstanding options to purchase 664,081 shares and 157,330 shares of restricted stock issued, to directors, executives, employees and consultants, leaving approximately 470,000 shares available for issuance thereunder.

The inducement grants to our Chief Executive Officer and former President were approved by the Compensation Committee of our Board of Directors and granted outside of the Plan as an inducement material to entering into employment with the Company pursuant to Section 711(a) of the NYSE MKT Company Guide. The inducement grant to our Chief Executive Officer consists of a stock option to purchase up to 200,000 shares of our common stock, with a per share exercise price of $6.00, which was the adjusted closing price of our common stock on the August 14, 2013 grant date. Our Chief Executive Officer’s inducement grant stock option vests over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 3,333 underlying shares, beginning September 15, 2014, and one final installment as to 3,330 underlying shares. The inducement grant to our former President consists of a stock option to purchase up to 55,000 shares of our common stock, with a per share exercise price of $6.80, which was the adjusted closing price of our common stock on the July 1, 2014 grant date. Our former President’s inducement grant stock option vested over five years, with 20% of the underlying shares vesting after one year and the remaining 80% vesting in forty-seven (47) equal monthly installments as to 917 underlying shares, beginning on August 1, 2015, and one final installment as to 901 underlying shares. Our former President has ninety days from January 8, 2016 to exercise his vested stock options.

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

Transactions with Related Persons, Promoters and Certain Control Persons

Certain former X-spine shareholders, who now own over 10% of our common stock, own a controlling interest in Norwood Tool Company d/b/a Norwood Medical, X-spine's largest supplier. In 2015, Xtant purchased from Norwood Medical approximately 12% of its operating products.

David Kirschman's sister, Deborah Kirschman Klopsch, serves as Xtant's Corporate Counsel and Director of Corporate Compliance. Compensation paid to Ms. Klopsch since the acquisition date was $50,327 in 2015. Ms. Klopsch also received 1,005 of the restricted stock units at $3.19 a share for a total cost of approximately $3,000 to be expensed ratably over the vesting period as General and administrative expense. See Note 10, "Stock-Based Compensation" above.

Unless delegated to the Compensation Committee by the Board of Directors, the Audit Committee or the disinterested members of the full Board of Directors reviews and approves all related party transactions.

Director Independence

The following board members are independent directors, as defined under the independence standards of the NYSE MKT LLC: Kent Swanson, Michael Lopach, Jon Wickwire, John Deedrick and David Goodman. All of our board committees are comprised solely of independent directors, and the composition of our board committees is described in Item 10 of this Form 10-K.

Item 14. Principal Accountant Fees and Services

EKS&H LLLP ("EKS&H") served as the independent registered public accounting firm to audit our books and accounts for the fiscal years ending December 31, 2015 and December 31, 2014. The following table presents the aggregate fees billed for professional services rendered by EKS&H for the years ended December 31, 2015 and December 31, 2014.

	2015	2014
Audit fees	$226,200	$157,500
Audit-related fees	$63,764	$49,546
Tax fees	$34,800	$-
All other fees	$-	$-

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

Audit Committee's Pre-Approval Policy

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

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

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

SIGNATURES

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

XTANT MEDICAL HOLDINGS, INC .

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial Officer
Date: March 24, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 24, 2016.

Signature	**Title**
/s/ Daniel Goldberger Daniel Goldberger	Chief Executive Officer and Director (Principal Executive Officer)
/s/ John Gandolfo John Gandolfo	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ David Kirschman David Kirschman	Executive Vice President, Director and Chief Scientific Officer
/s/ Kent Swanson Kent Swanson	Director
/s/ Michael Lopach Michael Lopach	Director
/s/ Jon Wickwire Jon Wickwire	Director
/s/ John Deedrick John Deedrick	Director

/s/ David Goodman David Goodman	Director

Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of June 30, 2010, by and among K-Kitz, Inc., KB Merger Sub, Inc. and Bacterin International, Inc.(1)
2.2	Common Stock Purchase Agreement dated March 16, 2015 by and between Bacterin and Aspire Capital Fund, LLC(9)
2.3	Amended and Restated Common Stock Purchase Agreement dated April 17, 2015 by and between Bacterin and Aspire Capital Fund, LLC(18)
2.4	Stock Purchase Agreement dated July 27, 2015 by and among Bacterin, X-spine Systems, Inc. and the sellers named therein(19)
3.1	Restated Certificate of Incorporation(2)
3.2	Certificate of Amendment to Restated Certificate of Incorporation(3)
3.3	Certificate of Amendment to Restated Certificate of Incorporation(4)
3.4	Amended and Restated Bylaws(5)
4.1	Form of Warrant to Purchase Common Stock(1)(6)(7)
4.2	Form of Common Stock Certificate(27)
4.3	Registration Rights Agreement dated March 16, 2015 by and between Bacterin and Aspire Capital Fund, LLC(9)
4.4	Registration Rights Agreement dated July 31, 2015 by and among Bacterin, Leerink Partners LLC, OrbiMed Royalty Opportunities II, LP and ROS Acquisition Offshore LP(10)
4.5	Indenture dated July 31, 2015 by and between Bacterin and Wilmington Trust, National Association(11)
4.6	Form of 6.00% Convertible Senior Note due 2021(11)
10.1•	Form of Indemnification Agreement for officers and directors(28)
10.2•	Amended and Restated Xtant Medical Equity Incentive Plan(12)
10.3•	Form of Stock Option Agreement(13)
10.4*•	Form of Amended and Restated Restricted Stock Agreement
10.5•	Daniel Goldberger Employment Agreement(14)
10.6•	Daniel Goldberger Stock Option Agreement(15)
10.7•	Daniel Goldberger Indemnification Agreement(16)
10.8•	John Gandolfo Employment Agreement(17)
10.9•	David Kirschman Employment Agreement (25)
10.10*•	David Kirschman Restricted Stock Agreement
10.11	Amended and Restated Credit Agreement dated July 27, 2015 by and between Bacterin and ROS Acquisition Offshore LP(20)
10.12	Termination of Royalty Agreement dated July 27, 2015 by and between Bacterin and ROS Acquisition Offshore LP(21)
10.13	Securities Purchase Agreement dated July 27, 2015 by and between Bacterin and the investors named therein(22)
10.14	Purchase Agreement dated July 27, 2015 by and between Bacterin and Leerink Partners LLC(23)
10.15	Distribution Agreement dated January 23, 2014 by and between X-spine Systems, Inc. and Zimmer Spine, Inc., as amended(24)
21.1	Subsidiaries of the Registrant(26)
23.1*	Consent of Independent Accounting Firm, EKS&H LLLP

31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1**	Section 1350 Certification of Chief Executive Officer
32.2**	Section 1350 Certification of Chief Financial Officer
101.INS*	XBRL INSTANCE DOCUMENT
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF*	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

- Indicates a management contract or compensatory plan.

* Filed herewith.

** Furnished herewith.

(1) Incorporated herein by reference to the Registrant's Form 8-K filed with the SEC on June 30, 2010.
(2) Incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q filed with the SEC on November 14, 2011.
(3) Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on July 25, 2014.
(4) Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on August 3, 2015.
(5) Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed with the SEC on October 1, 2015.
(6) Incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed with the SEC on July 31, 2014.
(7) Incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K filed with the SEC on June 5, 2013.
(8) Incorporated by reference to the Registrant's Form 10-K filed with the SEC on March 18, 2015.
(9) Incorporated by reference to the Registrant's Form 8-K filed with the SEC on March 17, 2015.
(10) Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on August 3, 2015.
(11) Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on August 3, 2015.
(12) Incorporated by reference to Exhibit 10.8 to the Registrant's Form 10-Q filed with the SEC on November 16, 2015.
(13) Incorporated by reference to Exhibit 10.23 to the Registrant's Form 10-Q filed with the SEC on May 4, 2012.
(14) Incorporated by reference to Exhibit 10.25 to the Registrant's Form 8-K filed with the SEC on August 15, 2013.
(15) Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the SEC on September 19, 2013.
(16) Incorporated by reference to Exhibit 10.26 to the Registrant's Form 10-Q filed with the SEC on November 14, 2013.
(17) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on July 29, 2014.
(18) Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 filed with the SEC on April 17, 2015.
(19) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on July 28, 2015.
(20) Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on July 28, 2015.
(21) Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on July 28, 2015.
(22) Incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed with the SEC on July 28, 2015.
(23) Incorporated by reference to Exhibit 10.5 to the Registrant's Form 8-K filed with the SEC on July 28, 2015.
(24) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on August 3, 2015.
(25) Incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed with the SEC on August 3, 2015.
(26) Incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1/A filed with the SEC on August 25, 2015.
(27) Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 filed with the SEC on December 21, 2015.
(28) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-K filed with the SEC on March 18, 2015.