RTI SURGICAL, INC.
Form 10-K
March 07, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

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: 0-31271

RTI SURGICAL, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**59-3466543**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**Identification No.)**

11621 Research Circle, Alachua, Florida 32615

(Address of Principal Executive Offices) (Zip Code)

(386) 418-8888

(Registrant s telephone number, including area code)

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

Common Stock, $0.001 par value	**The NASDAQ Stock Market LLC**
(Title of Each Class)	**(Name of Each Exchange on Which Registered)**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that 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 definition of accelerated filer , large accelerated filer and smaller reporting company

in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ¨	Accelerated Filer x
Non-Accelerated Filer ¨	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 of the registrant, based upon the last sale price of the Common Stock reported on the Nasdaq Stock Market as of the last business day of the registrant s most recently completed second fiscal quarter (June 30, 2015), was approximately $372.2 million.

The number of shares of Common Stock outstanding as of February 26, 2016 was 57,803,111.

DOCUMENTS INCORPORATED BY REFERENCE

As stated in Part III of this Annual Report on Form 10-K, portions of the registrant s definitive proxy statement for the registrant s 2016 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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RTI SURGICAL, INC.

FORM 10-K Annual Report

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PART I

This Annual Report on Form 10-K and the documents incorporated by reference contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations, estimates and projections about our industry, our management s beliefs and certain assumptions made by our management. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, requires , hopes, may, will, assumes, variations of such words and similar expressions are intended to identify such forward-looking statements. Do not unduly rely on forward-looking statements. These statements give our expectations about future performance, but are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Some of the matters described below in the Risk Factors section constitute cautionary statements which identify factors regarding these forward-looking statements, including certain risks and uncertainties that could cause actual results to vary materially from the future results indicated in these forward-looking statements. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements. Forward-looking statements speak only as of the date they are made, and unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. BUSINESS.

Company Overview

We are a leader in the use of natural tissues, metals and synthetics to produce orthopedic and other surgical implants that repair and promote the natural healing of human bone and other human tissues and improve surgical outcomes. We process donated human musculoskeletal and other tissue, including bone, cartilage, tendon, ligament, fascia lata, pericardium, sclera and dermal tissue, and bovine and porcine animal tissue in producing allograft and xenograft implants utilizing proprietary BIOCLEANSE®, TUTOPLAST® and CANCELLE® SP sterilization processes and manufacture metal and synthetic implants for distribution to hospitals and surgeons. We process tissue at two facilities in Alachua, Florida and one facility in Neunkirchen, Germany, and manufacture metal and synthetic implants in Marquette, Michigan and Greenville, North Carolina. We distribute our implants and services in all 50 states and in over 45 countries worldwide.

We distribute human tissue, bovine and porcine animal tissue and metal and synthetic implants through various distribution channels. Our lines of business are composed primarily of six categories: spine, ortho fixation, sports medicine, bone graft substitutes and general orthopedic (BGS and general orthopedic), dental and surgical specialties. The following table presents revenues from these six categories and other revenues and their respective percentages of our total revenues for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,					
	2015		2014		2013	
	(In thousands)					
Revenues:						
Spine	$ 76,968	27.3%	$ 82,663	31.5%	$ 57,334	28.9%
Ortho fixation	55,585	19.7%	37,133	14.1%	14,525	7.3%

Sports medicine	46,735	16.5%	46,758	17.8%	42,594	21.5%
BGS and general orthopedic	42,283	15.0%	36,747	14.0%	27,864	14.1%
Dental	23,621	8.4%	20,810	7.9%	19,779	10.0%
Surgical specialties	23,499	8.3%	26,999	10.3%	27,666	14.0%
Other revenues	13,602	4.8%	11,700	4.5%	8,217	4.2%
Total revenues	$ 282,293	100.0%	$ 262,810	100.0%	$ 197,979	100.0%
Domestic revenues	$ 260,387	92.2%	$ 238,936	90.9%	$ 177,207	89.5%
International revenues	21,906	7.8%	23,874	9.1%	20,772	10.5%
Total revenues	$ 282,293	100.0%	$ 262,810	100.0%	$ 197,979	100.0%

For additional financial information concerning our operating performance, please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of this report and our Consolidated Financial Statements in Part II, Item 8 of this report.

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Corporate Information

We were incorporated in 1997 in Florida as a wholly-owned subsidiary of the University of Florida Tissue Bank, (UFTB). We began operations on February 12, 1998 when UFTB contributed to us its allograft processing operations, related equipment and technologies, distribution arrangements, research and development activities and certain other assets. At the time of our initial public offering in August 2000, we reincorporated in the State of Delaware. In July 2013, we completed our acquisition of Pioneer Surgical Technology, Inc. (Pioneer) and, in connection with the acquisition, changed our name from RTI Biologics, Inc. to RTI Surgical, Inc. The results of Pioneer s operations have been included in our consolidated financial statements since the date of acquisition. Our principal offices are located at 11621 Research Circle, Alachua, Florida, and our phone number is (386) 418-8888.

Industry Overview

Defects in bone and other human tissue can be caused by a variety of sources including trauma, congenital defects, aging, revision of joint replacements, infectious disease, cancer and other similar conditions. The predominant method used to repair injured or defective tissue is surgical intervention, primarily through the use of surgical implants. When considering a surgical procedure for tissue repair, surgeons and patients have a number of treatment options including:

metals and synthetics;

xenograft tissue from an animal source;

autograft tissue from the patient; and

allograft tissue from another human donor.

Depending on the specific surgery, surgeons may elect to use any number of these treatment options. We offer a broad line of metal, synthetic, xenograft and allograft solutions to meet their needs.

Metals and Synthetics

The medical community has used metal and synthetic materials for implant procedures for many years. Metal and synthetic technologies are used to create both surgical implants as well as instruments used in surgical procedures. These implants are used in a variety of procedures in spine, cardiothoracic, trauma and other areas. Typical metals used include surgical stainless steel and titanium. These materials are chosen for their strength and durability. Synthetic implants provide alternative implant options for surgeons and also increase availability due to the variable supply of xenograft, autograft and allograft. One common example of a synthetic material is polyetheretherketone (PEEK).

Xenograft Tissue

Xenograft tissue-based implants are common in many areas of medicine including cardiac and vascular procedures, soft tissue repair and wound care. Xenograft based implants are also used in the repair of bone defects in orthopedic surgery as carriers for demineralized bone matrix and bone morphogenic protein products. The production of

xenograft implants involves recovering animal tissue, typically from cattle (bovine) or pigs (porcine), processing and sterilization, and then transplanting the xenograft implant into a human patient.

Autograft and Allograft Tissue

Many surgeons use autograft and allograft tissue in their surgical procedures to take advantage of their natural characteristics. Autograft procedures involve a surgeon harvesting tissue from one part of a patient s body for transplant to another part of the body. Allograft tissues are recovered from cadaveric donors, processed for certain intended uses and then transplanted by a surgeon into the patient s body to make the needed repair.

Autograft and allograft bone implants are not only osteoconductive, meaning they provide a scaffold for new bone to attach itself to, but can be osteoinductive as well, meaning they stimulate the growth of new tissue.

A significant drawback to autograft procedures is that they require an additional surgery to recover the tissue from a second site in the patient s body. Often in autograft procedures, the site where the patient s tissue is harvested becomes painful and uncomfortable, and can take longer to heal than the primary surgical site. Additional complications can involve infection, nerve and arterial injury and joint instability. Moreover, a patient may not have sufficient quantities of quality autograft tissue for transplant procedures.

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Marketing and Distribution

Our implants are used primarily in the following markets: spine, ortho fixation, sports medicine, BGS and general orthopedic, dental and surgical specialties. Our current implants range from allografts, xenografts, synthetics and metals that are precision machined for specific surgical applications to grafts conventionally processed for general surgical uses.

Spine

We design, manufacture, and distribute surgical implants and instruments used in the treatment of conditions affecting the spine and musculoskeletal system caused by degenerative conditions, deformities or traumatic injury of the spine. Our surgical implants include allograft and synthetic interbodies, bone graft substitutes, rods, pedicle screws and plates.

Our spine allografts are marketed domestically through our non-exclusive relationships with Aesculap Implant Systems, Inc. (Aesculap), Alphatec Spine, Inc. (Alphatec), Integra Life Sciences Corporation (Integra), Medtronic, PLC (Medtronic), Orthofix International NV (Orthofix), Stryker Spine, a division of Stryker Corporation (Stryker), and Zimmer Biomet Holdings, Inc. (Zimmer). Our spine metals and synthetics are marketed through a network of independent distributors and our direct distribution force.

Ortho fixation

Ortho fixation includes instruments and implants for trauma and cardio thoracic markets. Our trauma implants include devices used to stabilize damaged or broken bones. Our cardio thoracic implants include cable and plating systems used to close median sternotomies.

Our trauma implants are distributed through Zimmer and DePuy Synthes (Synthes), a Johnson & Johnson Inc. subsidiary. Our cardio thoracic implants are distributed through a direct distribution organization and a network of independent distributors.

Sports Medicine

Many repetitive use and sports-related injuries can be addressed with allograft implants. The most prevalent surgeries in the knee include repairs to the anterior cruciate ligament (ACL), articular cartilage repair, and meniscus transplantation. The most prevalent surgeries in the shoulder include rotator cuff repair and articular cartilage repair. Our principal sports medicine allografts are tendons for ligament reconstruction, fresh osteochondral grafts for cartilage repair, and our meniscal allografts for advanced meniscus injuries. Many of our sports medicine tendon allografts utilize our patented pre-shaped technology, which greatly reduces preparation time in the operating room and are generally easier to implant as compared to non pre-shaped allografts. We also distribute Matrix HD human dermis implants for wound repair and soft tissue augmentation.

Our sports medicine implants such as our BioCleanse Meniscus, BioCleanse full tendon portfolio, fresh-stored osteochondral (OC) allograft portfolio, and our Matrix HD are marketed domestically through our direct biologics representatives and through our network of independent distributors and internationally through a network of independent distributors.

BGS and general orthopedic

map3®. Our map3® cellular allogeneic bone graft is a natural and safe alternative to autograft that supports the body s innate healing mechanisms and provides the scaffold and signals to support the bone healing process. The implant contains three essential elements of bone formation, namely osteogenesis, osteoinduction and osteoconduction.

nanOss®. Our nanOss® advanced bone graft substitute is composed of nano-structured hydroxyapatite granules suspended in a porous gelatin-based foam matrix.

Allograft Paste. Surgeons principally use our allograft paste implants, which are composed of demineralized bone matrix (DBM) and in some cases a biologic gel carrier, in fracture treatment, bone and joint reconstruction and periodontal applications, such as ridge augmentation for dental implants.

Our allograft paste implants are marketed under Osteofil® by Medtronic, Puros® DBM by Zimmer and the Optefil , Opteform®, Regenafil® and Regenaform® brands with Exactech, Inc. (Exactech) and we distribute directly the BioSet® DBM, BioReady DBM and BioAdapt® DBM families of paste implants through our direct representatives, a network of independent distributors and our international distribution network. Our DBM Boat implants are marketed under BIO DBM by Stryker.

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Milled Allograft and Xenograft. Our bone graft substitutes business also includes certain types of blended and milled bone allografts and xenografts, such as our demineralized bone matrix, cortical cancellous chips and ground cancellous chips, used in total hip and knee replacements and for various traumatic injuries.

Conventional Allografts. Our conventional allograft business includes a wide variety of allograft categories including our intercalary grafts, such as our large structural grafts, which are used for cancer treatment procedures and hip and knee reconstruction. We also produce various types of fashioned bone, such as strips and shafts used for various orthopedic procedures.

Dental

We currently provide various implants including cancellous and cortical bone and human and bovine membranes primarily for dental procedures related to augmenting ridge restoration.

We distribute our dental implants exclusively through Zimmer.

Surgical Specialties

We process and distribute implants for surgical specialties, which include abdominal wall repair, plastic and reconstructive surgery, ophthalmology and urology.

The company distributes the following xenograft and allograft implants through our direct distribution organization: Fortiva porcine dermis, Tutopatch and Tutomesh bovine pericardium, and Cortiva human dermis. These implants are all processed through our validated Tutoplast tissue sterilization process, which has a proven track record of safety and performance. These implants are marketed to surgeons in various surgical specialties, including general, colon and rectal, trauma, bariatric, and plastic reconstructive surgery. We also distribute implants through distributors including: Integra for dural repair applications; Davol, Inc., a subsidiary of C. R. Bard, Inc. (Davol) for hernia repair and breast reconstruction; IOP, Inc. (IOP) for ophthalmology and Coloplast A/S of Denmark (Coloplast) for urology.

The BioCleanse® Tissue Sterilization Process

We have developed and utilized in the United States the patented BioCleanse® tissue sterilization process, which is an automated, pharmaceutical grade chemical sterilization process for musculoskeletal bone and certain soft tissue. This process is fully validated to kill or inactivate all classes of conventional pathogens, viruses, microbes, bacteria and fungi. Our BioCleanse® process is able to remove greater than 99% of the blood, fats, lipids and other unwanted materials from the tissue we process. An important element of the BioCleanse® process is that while it removes unwanted materials embedded within the tissue, it maintains the tissue s structural integrity and compression strength. Studies have shown that bone tissue sterilized with the BioCleanse® process maintains the same compression strength as untreated tissue.

The BioCleanse® process has been reviewed by the U.S. Food and Drug Administration (FDA) which concluded that BioCleanse® was a validated tissue sterilization process demonstrated to prevent contamination of tissue grafts. The significance of the review is that we are not aware of any other tissue sterilization process related to human tissue in our industry that has been reviewed or approved by the FDA. The FDA does not have a formal approval process in place for tissue related processing techniques.

The TUTOPLAST® Tissue Sterilization Process

The TUTOPLAST® tissue sterilization process utilizes solvent dehydration and chemical inactivation to remove blood, lipids and extraneous materials, and inactivate viruses and break down RNA and DNA into fragments not capable of replication and disease transmission while preserving the biological and mechanical properties.

We apply the TUTOPLAST® process to two types of preserved allografts: soft tissue, consisting of fascia lata, pericardium, dermis, sclera and cornea; and bone tissue, consisting of various configurations of cancellous and cortical bone material. Processed pericardium, fascia lata and dermis are collagenous tissue used to repair, replace or line native connective tissue primarily in dental, ophthalmology, urology, plastic and reconstructive surgeries. Dermis is also used in hernia repair and pelvic floor reconstruction. Sclera and cornea are used in ophthalmology procedures such as anterior and

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posterior segment patch grafting applications for glaucoma, retina and trauma surgery and oculoplastics, as well as contour wrapping of an orbital implant. Processed cortical and cancellous bone material is used in a wide variety of applications in spine, orthopedic and dental surgeries.

The CANCELLE® SP DBM Sterilization Process

DBM-based pastes and putties are sterilized through the CANCELLE® SP process, which is designed to preserve protein activity. In their final form, the DBM implants serve as bone void fillers in many applications, including spinal, general orthopedic, joint reconstruction and dental surgeries.

CANCELLE® SP is a proprietary process that sterilizes DBM pastes and putties while simultaneously allowing them to maintain their osteoinductive (OI) potential, which is verified by 100 percent lot testing after sterilization. The determination of OI potential is made by lot release animal studies or testing for certain protein markers. These tests are not necessarily predictive of human clinical results. Through a combination of oxidative treatments and acid or alcohol washes, debris is removed and pathogens are inactivated. Cleansing rinses remove residual chemicals, maintaining biocompatibility and preserving the utility of the graft. The CANCELLE® SP irradiation dose is delivered terminally for most pastes and putties to achieve device-level sterility (SAL 10).

Tissue Recovery

Tissue recovery is the actual removal of tissue from a donor after receiving appropriate consent. Consent is obtained by the tissue recovery group. We operate certain tissue recovery groups directly, and contract with other independent FDA registered tissue recovery groups which specialize in this activity. Tissue recovery personnel aseptically recover musculoskeletal tissue within 24 hours following a donor s death, using surgical instruments and sterile techniques similar to those used in hospitals for routine surgery. Recovered tissue is placed on wet or dry ice and then transported by the donor recovery agency to the tissue processor or possibly a research institution.

Under U.S. law, human tissue cannot be sold. However, the law permits the recovery of reasonable payments for the provision of certain services, such as those involved in recovering, processing and storing tissue and related to the advancement of tissue processing technologies, all types of activities in which we are involved.

Donor recovery groups recover a variety of tissue types from donors including the fibula, femur, tibia, humerus, ilium, pericardium, fascia lata, dermis, bone marrow, sclera, tendons and ligaments. In addition to tissue received from recovery groups we control, we also receive donated tissue from independently registered tissue recovery organizations. To make an initial determination as to whether tissues may be appropriately recovered, these independent tissue recovery organizations are responsible for obtaining appropriate consents and conducting federally-mandated donor screening, such as a medical and social history interview with the next of kin. Upon receipt of the tissue, we conduct pre-processing donor screening to determine its medical suitability for transplantation. Pre-processing screening performed by us includes laboratory testing and a donor eligibility assessment. With respect to laboratory testing, we perform an extensive panel of serological and microbiological tests. These results are subject to stringent criteria in order to release the donor tissue to the processing stage.

We have relationships with tissue donor recovery agencies across the United States. We also have relationships outside the United States. We believe additional recovery group relationships would be available if needed and consequently that the loss of any one of our sources of donor tissue would not have a material impact on our operating results.

We continue to develop new xenograft tissue implants. Implants processed from xenograft tissue are regulated by the FDA as devices and require approval or licenses from the FDA prior to marketing in the United States. The sources of our bovine animal tissues are regulated closed herds. We believe the continued development of our xenograft implants will help us meet unmet demand for certain allografts and also allow us to develop new biological implants that cannot currently be made due to structural limitations of human tissue.

Research and Development

Our research and development (R&D) costs for the years ended December 31, 2015, 2014 and 2013 were $15.1 million, $15.5 million and $15.2 million, respectively. In 2015, we continued to invest in our R&D efforts by funding new projects including research and development projects at our facilities in our US locations and in Neunkirchen, Germany.

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We plan to continue to develop new implants and technologies within our current markets, and to develop additional technologies for other markets to address unmet clinical needs. We plan to do this by building on our core technology platforms: BIOCLEANSE®, TUTOPLAST®, CANCELLE® SP, precision machining, assembled grafts, tissue-mediated osteoinduction and our metal and synthetics design and production expertise. We operate a dedicated research team working on advanced technologies, and have embedded development/technical teams who work with the business/marketing teams focused on expanding the scope and scale of existing competencies such as tissue machining and sterilization, and metal and synthetics manufacturing to meet specific surgical needs. This approach has resulted in the development of core science platforms, a pipeline of concepts for development and marketing, and focused projects to meet immediate needs.

In 2015, we launched 16 new implants and product enhancements in spine, ortho fixation, sports medicine, and BGS and general orthopedics developed by our research and development teams.

Intellectual Property

Our business depends upon the significant know-how and proprietary technology we have developed. To protect this know-how and proprietary technology, we rely on a combination of trade secret laws, patents, licenses, trademarks and confidentiality agreements. The effect of these intellectual property rights is to define zones of exclusive use of the covered intellectual property. The duration of patent rights generally is 20 years from the date of filing of priority application, while trademarks, once registered, are essentially perpetual. Our trademarks and service marks provide us and our implants with a certain amount of brand recognition in our markets. However, we do not consider any single patent, trademark or service mark material to our business strategy, financial condition or results of operations. We have also entered into exclusive and non-exclusive licenses relating to a wide array of third-party technologies. In addition, we rely on our substantial body of know-how, including proprietary tissue recovery techniques and processes, research and development, tissue processing and quality assurance.

Our proprietary BIOCLEANSE®, TUTOPLAST® and CANCELLE® SP sterilization processes are covered by one or more U.S. and/or foreign patents, patent applications or trade secrets. Other U.S. and foreign holdings include, without limitation, patents, patent applications or trade secrets relating to or covering certain precision machined allograft intervertebral spacers and other spinal implants; matrix compositions including various bone graft substitutes; membrane tissue implants; and ligament, tendon or meniscus reconstruction and repair with certain precision shaped and/or assembled bone and soft tissue implants, synthetic bone graft substitutes; interbody fusion and motion implants; spinal and orthopedic plates; spinal rods, cables and screws and spinal fixation systems and related instrumentation.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. As the number of entrants into our market increases, the risk of an infringement claim against us, as well as the risk of a third party infringing on our patents, grows. While we attempt to ensure that our implants and methods do not infringe other parties patents and proprietary rights, our competitors may assert that our implants, and the methods we employ, are covered by patents held by them. In addition, our competitors may assert that future implants and methods we may employ infringe their patents. If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected implant. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We have in the past been, and may in the future be, involved in litigation relating to our intellectual property.

Competition

Competition in the medical implant industry is intense and subject to rapid technological change and evolving industry requirements and standards. Companies within the industry compete on the basis of design of related instrumentation, efficacy of implants, relationships with the surgical community, depth of range of implants, scientific and clinical results and pricing.

Our principal competitors in the conventional allograft market include the Musculoskeletal Transplant Foundation (MTF), AlloSource Inc., LifeCell, Inc., a subsidiary of Acelity L.P. Inc. and LifeNet Health, Inc. (LifeNet). Among our competitors in precision machined allograft are MTF, LifeNet and AlloSource. Other companies who process and distribute allograft pastes include Medtronic, AlloSource, Integra LifeSciences Holdings Corp. (Integra), Wright Medical Inc. and MTF. Companies who process and distribute xenograft tissue include Baxter, Inc., LifeCell, Cook Surgical and Medtronic.

We consider our principal competitors in the metal and synthetic markets to include Alphatec, Globus Medical Group, Inc. (Globus), NuVasive, Inc. (NuVasive) and Orthofix International NV (Orthofix).

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Government Regulation and Corporate Compliance

Government Regulation

Government regulation plays a significant role in the processing/manufacturing and distribution of allograft tissue implants and medical devices. We procure, where applicable, process/manufacture, and market our allograft tissue implants and medical devices worldwide. Although some standards of harmonization exist, each country in which we do business has its own specific regulatory requirements. These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. While we believe that we are in compliance with all existing pertinent international and domestic laws and regulations, there can be no assurance that changes in governmental administrations and regulations will not adversely affect our operations. Failure to comply with applicable requirements could result in fines, injunctions, civil penalties, recall or seizure of products, suspension of production, inability to market current products, criminal prosecution, and/or refusal of the government to authorize the marketing of new products.

In the United States, our allograft implants are regulated by the FDA under Title 21 of the Code of Federal Regulations (CFR), Parts 1270 and 1271, Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products (cGTPs). Xenograft tissues and allograft bone paste are regulated as medical devices and subject to FDA 21 CFR, Part 820 Current Good Manufacturing Practices (GMPs) for Medical Devices and related statutes from the FDA. In addition, our U.S. operation is subject to certain state and local regulations, as well as compliance to the standards of the tissue bank industry s accrediting organization, the American Association of Tissue Banks (AATB).

In Germany, allografts are classified as drugs and the German government regulates such implants in accordance with German Drug Law. On April 7, 2004, the European Commission issued a human tissue directive to regulate allografts within the European Union (EU). Our Neunkirchen facility is presently licensed by the German Health Authorities and in compliance with applicable international laws and regulations, allowing us to market our human and animal tissue implants globally.

The FDA and international regulatory bodies conduct periodic compliance inspections of both our U.S. and our German processing facilities. All operations are registered with the U.S. FDA Center for Devices and Radiological Health (CDRH) for device manufacturing locations and Center for Biologics Evaluation and Research (CBER) for human tissue recovery, processing and distribution locations and are certified to ISO 13485:2003. The Alachua facility is also accredited by the AATB and is licensed in the states of Florida, New York, California, Maryland, Delaware and Illinois. The Neunkirchen facility is registered with the German Health Authority (BfArM) as a pharmaceutical and medical device manufacturer and is subject to German drug law. We believe that worldwide regulation of allografts and xenografts is likely to intensify as the international regulatory community focuses on the growing demand for these implants and the attendant safety and efficacy issues of citizen recipients.

We currently market and distribute allografts that are subject to the FDA s Human Tissue Intended for Transplantation and Human Cells, Tissues, and Cellular and Tissue-Based Products regulations. Under these regulations, we are required to perform donor screening and infectious disease testing and to document this screening and testing for each donor from whom we process tissue, and to process tissues in compliance with cGTP. The FDA has authority under the rules to inspect human tissue processing facilities, and to detain, recall, or destroy tissues for which appropriate documentation and evidence of compliance is not available. We are not required to obtain pre-market approval or clearance from the FDA for allografts that meet the regulation s definition of human tissue.

The FDA may regulate certain allografts as medical devices, drugs, or biologics, which would require that we obtain approval or product licensure from the FDA. This would occur in those cases where the allograft is deemed to have been more than minimally manipulated or indicated for non-homologous use. In general, homologous use occurs when tissue is used for the same basic function that it fulfilled in the donor. The definitional criteria for making these determinations appear in the FDA s rules. If the FDA decides that certain of our current or future allografts are more than minimally manipulated or indicated for non-homologous use, it would require licensure, approval or clearances of those allografts. Allografts requiring such approval are subject to pervasive and continuing regulation by the FDA. We would be required to list these allografts as a drug, as a medical device, or as a biologic, and to manufacture them in specifically registered or licensed facilities in accordance with FDA regulation Current Good Manufacturing Practices. We would also be subject to post-marketing surveillance and reporting requirements. In addition, our manufacturing facilities and processes would be subject to periodic inspection to assess compliance with Current GMPs. Our labeling and promotional activities would be subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of drugs, devices and biologics is also subject to more intensive regulation than is the case for human tissue implants.

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Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our implants sold in the United States are subject to the federal Food, Drug, and Cosmetic Act and the Public Health Services Act as implemented and enforced by the FDA. The regulations that cover our implants and facilities vary widely based on implant type and classification both in the United States, and from country to country. The amount of time required to obtain approvals or clearances from regulatory authorities also differs from country to country.

Unless an exemption applies, each medical device that we wish to commercially distribute in the United States will be covered by either premarket notification (510(k)) clearance or approval of a premarket approval application (PMA) from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring approval through the lengthy PMA process. Manufacturers of most class II medical devices are required to obtain 510(k) clearance prior to marketing their devices. To obtain 510(k) clearance, a company must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in technological and performance characteristics to another legally marketed 510(k)-cleared predicate device. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval.

Class III medical devices are required to undergo the PMA approval process in which the manufacturer must establish the safety and effectiveness of the device to the FDA s satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will typically conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. FDA reviews of PMA applications, generally can take between one and three years, or longer.

The medical devices that we develop, manufacture, distribute and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining FDA clearance and other regulatory approvals to develop and market a medical device, particularly from the FDA, can be costly and time-consuming, and there can be no assurance that such approvals will be granted on a timely basis, if at all. While we believe that we have obtained all necessary clearances and approvals for the manufacture and sale of our implants and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance. After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include: product listing and establishment registration; Quality System Regulation (QSR) which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications; clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices; approval of product modifications that affect the safety or effectiveness of one of our PMA approved devices; Medical

Device Reporting regulations, which require that manufacturers report to FDA if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; the FDA s recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; regulations pertaining to voluntary recalls; and notices of corrections or removals.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA s QSR and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our

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officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. Moreover, governmental authorities outside the United States have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. The European Commission (EC) has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received CE certification from a notified body in order to be able to sell products within the member states of the European Union. Certification allows manufacturers to stamp the products of certified plants with a CE mark. Products covered by the EC regulations that do not bear the CE mark cannot be sold or distributed within the European Union. We have received certification for all currently existing manufacturing facilities and products.

Our products may be reimbursed by third-party payers, such as government programs, including Medicare, Medicaid, and Tricare or private insurance plans and healthcare networks. Third-party payers may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the policy holder s healthcare insurance benefits are limited. Also, third-party payers are increasingly challenging the medical necessity and prices paid for our products and services.

Civil False Claims Act and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as numerous state laws, regulate healthcare and insurance. These laws are enforced by the Office of Inspector General within the U.S. Department of Health and Human Services, the U.S. Department of Justice, and other federal, state and local agencies. Among other things, these laws and others generally: (1) prohibit the provision of anything of value in exchange for the referral of patients for, or the purchase, order, or recommendation of, any item or service reimbursed by a federal healthcare program, (including Medicare and Medicaid); (2) require that claims for payment submitted to federal healthcare programs be truthful; (3) prohibit the transmission of protected healthcare information to persons not authorized to receive that information; and (4) require the maintenance of certain government licenses and permits.

In addition, U.S. federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information such as medical records and restrict the use and disclosure of that protected information. At the federal level, the Department of Health and Human Services promulgated health information privacy and security rules under HIPAA. These rules protect health information by regulating its use and disclosure, including for research and other purposes. Failure of a HIPAA covered entity to comply with HIPAA regarding such protected health information could constitute a violation of federal law, subject to civil and criminal penalties. Covered entities include healthcare providers (including those that sell devices or equipment) that engage in particular electronic transactions, including the transmission of claims to health plans. Consequently, health information that we access, collect, analyze, and otherwise use and/or disclose includes protected health information that is subject to HIPAA. As noted above, many state laws also pertain to the confidentiality of health information. Such laws are not necessarily preempted by HIPAA, in particular those state laws that afford greater privacy protection to the individual than HIPAA. These state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

On September 30, 2014, we received a letter from the FDA regarding our map3® cellular allogeneic bone graft. The letter addressed some technical aspects of the processing of the map3® allograft, as well as language included on our website. We have removed the relevant information from the website and submitted responses to the FDA letter

including a comprehensive package of data to address the FDA s comments and clarifying information regarding the technical components of the implant processing. We believe that in both developing and processing of map3®, we have properly considered the relevant regulatory requirements. We have worked with FDA throughout 2015 as it pertains to our map3® cellular allogeneic bone graft and are committed to resolving the concerns raised by the FDA. However, it is not possible to predict the specific outcome or timing of a resolution at this time.

Corporate Compliance

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) published a final rule which requires making information publicly available about payments or other transfers of value from certain manufacturers of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid, and the Children s Health Insurance Program (CHIP), defined as applicable manufacturers, to physicians and teaching hospitals, which are defined as covered recipients. Called the National Physician Payment Transparency Program: Open Payments, this is one of many steps in the Affordable Care Act (ACA) designed to create greater transparency in health care markets.

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The ACA specified that applicable manufacturers must report annually to the Secretary of Health and Human Services all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) from applicable manufacturers to covered recipients. In addition to reporting on payments, applicable manufacturers, as well as applicable group purchasing organizations (GPOs), must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities. The ACA requires CMS to provide applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors at least 45 days to review, dispute and correct their reported information before posting it on a publicly available website.

We have a comprehensive compliance program. It is a fundamental policy of our company to conduct business in accordance with the highest ethical and legal standards. Our corporate compliance and ethics program is designed to promote legal compliance and ethical business practices throughout our domestic and international businesses.

Our compliance program is designed to meet U.S. Sentencing Commission Guidelines for effective organizational compliance and ethics programs and to prevent and detect violations of applicable federal, state and local laws.

Key elements of our compliance program include:

- Organizational oversight by senior-level personnel responsible for the compliance functions within our company.
- Written standards and procedures, including a Code of Business Conduct.
- Methods for communicating compliance concerns, including anonymous reporting mechanisms.
- Investigation and remediation measures to ensure prompt response to reported matters and timely corrective action.
- Compliance education and training for employees and contracted business associates such as distributors.
- Auditing and monitoring controls to promote compliance with applicable laws and assess program effectiveness.
- Disciplinary guidelines to enforce compliance and address violations.
- Screening of employees and contracted business associates.
- Risk assessments to identify areas of regulatory compliance risk.

Environmental

Our allografts and xenografts, as well as the chemicals used in processing natural tissues and also in the manufacturing of metal and synthetic implants, are handled and disposed of in accordance with country-specific, federal, provincial, regional, state and/or local regulations, as applicable. We contract with independent, third parties to perform all gamma irradiation-terminal sterilization of our surgical implants. In view of the engagement of a third party to perform irradiation services, the requirements for compliance with radiation hazardous waste do not apply, and therefore we do not anticipate that having any material adverse effect upon our capital expenditures, results of operations or financial condition. However, we are responsible for assuring that the service is being performed in accordance with applicable regulations.

Employees

As of December 31, 2015, we had a total of 1,169 employees of which 195 were employed outside of the United States. Management believes its relations with its employees are good.

Available Information

Our Internet address is www.rtix.com. Information included on our website is not incorporated by reference in our Form 10-K. We make available, free of charge, on or through the investor relations portion of our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), as soon as reasonably practicable after we file such material with, or furnish it to the Securities and Exchange Commission (SEC). These filings are also available on the SEC s website at www.sec.gov. Also available on our website is our Corporate Governance Guidelines, our Code of Conduct, our Code of Ethics for Senior Financial Professionals, our California Compliance Program Declaration and the charters for our Audit Committee, Compensation Committee, Nominating and Governance Committee and Science and Technology Committee. Within the time period required by the SEC and Nasdaq, we will post any amendment to our Code of Ethics for our senior financial professionals and any waiver of our Code of Conduct applicable to our senior financial professionals, executive officers and directors.

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Item 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should consider each of the risks and uncertainties described in this section and all of the other information in this document before deciding to invest in our common stock. Any of the risk factors we describe below could severely harm our business, financial condition and results of operations. The market price of our common stock could decline if any of these risks or uncertainties develops into actual events and you may lose all or part of your investment.

We depend heavily upon sources of human tissue, and any failure to obtain tissue from these sources in a timely manner will interfere with our ability to process and distribute allografts.

The supply of human tissue has at times limited our growth, and may not be sufficient to meet our future needs. In addition, due to seasonal changes in mortality rates, some scarce tissues that we currently use for allografts are at times in particularly short supply. Other factors, some of which are unpredictable, such as negative publicity and regulatory actions in the industry in which we operate (and which may not involve us) also could unexpectedly reduce the available supply of tissue.

We rely on donor recovery groups for their human tissue supplies and we have relationships with tissue donor recovery groups across the country. We also have relationships outside the United States. Donor recovery groups are part of relatively complex relationships. They provide support to donor families, are regulated by the FDA, and are often affiliated with hospitals, universities or organ procurement organizations. Our relationships with donor recovery groups, which are critical to our supply of tissue, could be affected by relationships recovery groups have with other organizations. Any negative impact arising from potential regulatory and disease transmission issues facing the industry, as well as the negative publicity that these issues could create, could adversely affect our ability to negotiate contracts with recovery groups.

We cannot be sure that the supply of human tissue will continue to be available at current levels or will be sufficient to meet our needs. If we are not able to obtain tissue from current sources sufficient to meet our needs, we may not be able to locate additional replacement sources of tissue on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of tissue could significantly impact our revenues. We expect that our revenues from allografts would decline in proportion to any decline in tissue supply.

We depend on various third-party suppliers, and in one case a single third-party supplier, for key raw materials used in our manufacturing processes and the loss of any of these third-party suppliers, or their inability to supply us with adequate raw materials, could harm our business.

We use a number of raw materials in addition to human tissue, including titanium, titanium alloys, stainless steel, PEEK, and animal tissue. We rely from time to time on a number of suppliers and, in the case of PEEK, on a single source vendor, Invibio, Inc. (Invibio). Invibio is one of a limited number of companies that is currently approved in the U.S. to distribute PEEK for use in implantable devices. Our dependence on a single third-party PEEK supplier creates several risks, including limited control over pricing, availability, quality and delivery schedules. In addition, any supply interruption in a limited or sole sourced component or raw material, such as PEEK, could materially harm our ability to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have an adverse effect on our business, financial condition and results of operations.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Numerous intitiatives and reforms initiated by legislators, regulators and third-party payers to curb rising healthcare costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become, and will continue to become, more intense. This in turn has resulted, and will likely continue to result in, greater pricing pressures and the exclusion of certain suppliers from various market segments as GPOs, independent delivery networks (IDNs), and large single accounts continue to use their market power to consolidate purchasing decisions for some of our existing and prospective customers. We expect the market demand, government regulation, and third-party reimbursement policies will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and prospective customers, which may reduce competition, exert further downward pressure on the prices of our implants and may adversely impact our business, financial condition or results of operations.

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Our administrative headquarters and a majority of all of our allograft processing facilities are currently conducted in locations that may be at risk of damage from hurricanes, fire, or other natural disasters. If a natural disaster strikes, our operations may be interrupted and we may be unable to manufacture certain products for a substantial amount of time.

Our administrative headquarters and a majority of all of our allograft processing facilities are located in Alachua, Florida, in an area with historical occurrences of hurricane damage and wild fires. We have taken precautions to safeguard our facilities, including obtaining property, casualty and business interruption insurance. We have developed an information technology disaster recovery plan. However, any future natural disaster could cause substantial delays in our operations, damage or destroy our equipment or inventory and cause us to incur additional expenses. A disaster could seriously harm our business, financial condition and results of operations. Our facilities would be difficult to replace and would require substantial lead time to repair or replace. The insurance we maintain may not be adequate to cover our losses in any particular case and may not continue to be available to us on acceptable terms, or at all.

If we fail to maintain existing strategic relationships or are unable to identify distributors of our implants, revenues may decrease.

We currently derive a significant amount of our revenues through distributors such as Zimmer, Medtronic and Davol. In addition, our spine distributors provide nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for the lines of spinal allografts that we produce and they distribute.

Variations in the timing and volume of orders by our distributors, particularly those who distribute a significant amount of our implants, may have a material effect upon our revenues. If our relationships with our distributors are terminated or reduced for any reason and we are unable to replace these relationships with other means of distribution, we could suffer a material decrease in revenues.

We may need, or decide it is otherwise advantageous to us, to obtain the assistance of additional distributors to market and distribute our new allografts and technologies, as well as to market and distribute our existing allografts and technologies, to new markets or geographical areas. We may not be able to find additional distributors who could successfully market and distribute our allografts and technologies on commercially reasonable terms, if at all. If we are unable to establish additional distribution relationships on favorable terms, our revenues may decline.

Also, our financial results are dependent upon the sales and marketing efforts of our distributors. If our distributors are unsuccessful in adequately promoting, marketing and selling our products, our sales could significantly decrease.

If third-party payers fail to provide appropriate levels of reimbursement for the use of our implants, revenues could be adversely affected.

The impact of United States healthcare reform legislation on our business remains uncertain. In 2010 federal legislation to reform the United States healthcare system was enacted into law. The legislation is far-reaching and is intended to expand access to health insurance coverage, improve the quality and reduce the costs of healthcare over time. Its provisions have become effective at various dates, and will continue to do so, and there are many programs and requirements for which the details have not been determined. We expect the law will have a significant impact upon various aspects of our business operations. Provisions of this legislation, 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 designed and delivered. Further, we cannot predict what other healthcare programs and regulations will be ultimately

implemented at the federal or state level or the effect of any future legislation or regulation in the United States. However, any change that lowers reimbursements for our implants or reduces medical procedure volumes could adversely affect our business and results of operations.

If we fail to maintain the high processing standards that implants require or if we are unable to develop processing capacity as required, our commercial opportunity will be reduced or eliminated.

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Implants require careful calibration and precise, high-quality processing. Achieving precision and quality control requires skill and diligence by our personnel. If we fail to achieve and maintain these high processing standards, including avoiding processing errors, and, depending on the nature of the complaint, design defects or component failures; we could be forced to recall, withdraw or suspend distribution of our implants; our implants and technologies could fail quality assurance and performance tests; production and deliveries of our implants could be delayed or cancelled and our processing costs could increase.

Further, to be successful, we will need to manage our human tissue processing capacity related to tissue recovery and demand for our allografts. It may be difficult for us to match our processing capacity to demand due to problems related to the amount of suitable tissue, quality control and assurance, tissue availability, adequacy of control policies and procedures and lack of skilled personnel. If we are unable to process and produce our implants on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if we experience unanticipated technological problems or delays in processing, it may reduce revenues, increase our cost per allograft processed or both.

We operate in a highly regulated industry. An inability to meet current or future regulatory requirements in the U.S. or foreign jurisdictions, or any deficiencies with our manufacturing or quality systems and processes identified by regulatory agencies, could disrupt our business, subject us to regulatory action and costly litigation, damage our reputation for high quality production, cause a loss of confidence in the company and our implants and negatively impact our financial position and operating results.

The FDA and several states have statutory authority to regulate allograft processing, including our BioCleanse® and TUTOPLAST® processes, and allograft-based materials. We must register our facilities, whether located in the United States or elsewhere, with the FDA as well as regulators outside the U.S., and our implants must be made in a manner consistent with current good tissue practices (cGTP) or similar standards in each jurisdiction in which we manufacture. In addition, the FDA and other agencies perform periodic audits to ensure that our facilities remain in compliance with all appropriate regulations, including primarily the quality system regulations and medical device reporting regulations. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGTP or other regulations (such as a FDA report on Form 483, Notice of Observations), or a warning letter for violations of regulatory significance that may result in enforcement action if not promptly and adequately corrected. For example, in Summer 2012, the FDA performed a cGTP inspection not related to a specific implant of our processing facility in Alachua, Florida to audit our compliance with cGTP requirements. At the conclusion of the audit, the FDA inspectors issued a Form FD483, primarily related to environmental monitoring activities in certain areas of our Alachua facility, for which we have subsequently received a final close out letter from the FDA to formally resolve its concerns. The FDA could identify other deficiencies in future inspections of our facilities or those of our suppliers.

Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, including medical device companies, by hiring new investigators and stepping up inspections of manufacturing facilities. In recent years, the FDA has also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our implants are ineffective or pose an unreasonable health risk, the FDA could ban such implants, detain or seize adulterated or misbranded implants, order a recall, repair, replacement, or refund of such implants, refuse to grant pending premarket approval applications or require certificates of foreign governments for exports and/or require us to notify health professionals and others that the implants present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our implants. Any inability to meet current or future regulatory

requirements in the United States or foreign jurisdictions, or any deficiencies with our manufacturing or quality systems and processes identified by regulatory agencies could disrupt our business, subject us to regulatory action and costly litigation, damage our reputation for high quality production, cause a loss of confidence in the company and our implants and negatively impact our financial position and operating results.

If any of our allografts fall under the FDA s definitions of more than minimally manipulated or indicated for non-homologous use, we would be required to obtain medical device approval or clearance or biologics licenses, which could require clinical testing and could result in disapproval of our license applications and restricted distribution of any of our allografts which may become subject to pre-market approval. The FDA could require post-market testing and surveillance to monitor the effects of such allografts, could restrict the commercial applications of these allografts, and could conduct periodic inspections of our facilities and our suppliers. Delays encountered during the FDA approval process could shorten the patent protection period during which we have the exclusive right to commercialize such technologies or could allow others to come to market before us with similar technologies.

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cGTP covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. In addition, these regulations have a significant effect upon recovery agencies which supply us with tissue and have increased the cost of recovery activities. These increases have translated into increased costs for us, because we are expected to reimburse the recovery agencies based on their cost of recovery.

In addition to the FDA, several state agencies regulate tissue banking. Regulations issued by Florida, New York, California and Maryland are particularly relevant to our business. Most states do not currently have tissue banking regulations, but it is possible that others may make allegations against us or against donor recovery groups or tissue banks, including those with which we have relationships, about non-compliance with applicable FDA regulations or other relevant statutes and 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.

Some of our implants contain tissue derived from animals, commonly referred to as xenografts. Xenograft implants are medical devices that are subject to pre-market approval or clearance by the FDA. We have received FDA clearance on several xenograft implants. However, we may not receive FDA approval or clearance to market new implants as we attempt to expand the quantity of xenograft implants available for distribution.

The allograft industry is subject to additional local, state, federal and international government regulations and any increased regulations of our activities could significantly increase the cost of doing business, thereby reducing profitability.

Some aspects of our business are subject to additional local, state, federal or international regulation. Changes in the laws or new interpretations of existing laws could negatively affect our business, revenues or prospects, and increase the costs associated with conducting our business. In particular, the procurement and transplantation of allograft tissue is subject to federal regulation under the National Organ Transplant Act (NOTA), a criminal statute that prohibits the purchase and sale of human organs, including bone and other tissue. NOTA permits the payment of reasonable fees associated with the transportation, processing, preservation, quality control and storage of human tissue. If NOTA were amended or interpreted in a way that made us unable to include some of these costs in the amounts we charge our customers, it could reduce our revenues and therefore negatively impact our business. It is possible that more restrictive interpretations or expansions of NOTA could be adopted which could require us to change one or more aspects of our business, at a substantial cost, in order to continue to comply with this statute.

A variety of additional local, state, federal and international government laws and regulations govern our business, including those relating to the storage, handling, generation, manufacture and disposal of medical wastes from the processing of tissue and collaborations with health care professionals. If we fail to conduct our business in compliance with these laws and regulations, we could be subject to significant liabilities for which our insurance may not be adequate. Moreover, such insurance may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which would harm our financial condition and liquidity.

Our success depends on the continued acceptance of our surgical implants and technologies by the medical community.

New allograft, xenograft, metal or synthetic implants, technologies or enhancements to our existing implants may never achieve broad market acceptance, which can be affected by numerous factors, including lack of clinical acceptance of implants and technologies; introduction of competitive treatment options which render implants and technologies too expensive or obsolete; lack of availability of third-party reimbursement; and difficulty training surgeons in the use of tissue implants and technologies.

Market acceptance will also depend on our ability to demonstrate that our existing and new implants and technologies are an attractive alternative to existing treatment options. Our ability to do so will depend on surgeons evaluations of the clinical safety, efficacy, ease of use, reliability and cost-effectiveness of these treatment options and technologies. For example, we believe that some in the medical community have lingering concerns over the risk of disease transmission through the use of allografts.

Furthermore, we believe that even if the medical community generally accepts our implants and technologies, acceptance and recommendations by influential surgeons will be important to their broad commercial success. If our implants and technologies are not broadly accepted in the marketplace, we may not remain competitive in the market.

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Rapid technological changes could result in reduced demand for our implants and products.

Technologies change rapidly in the industry in which we operate. For example, steady improvements have been made in synthetic human tissue substitutes which compete with our tissue implants. Unlike allografts, synthetic tissue technologies are not dependent on the availability of tissue. If one of our competitors successfully introduces synthetic technologies using recombinant technologies, which stimulate the growth of tissue surrounding an implant, it could result in a decline in demand for tissue implants. We may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new technologies or enhancements to existing implants in a timely and cost-effective manner, if at all. If we are unable to achieve the improvements in our implants necessary for their successful commercialization, the demand for our implants will suffer.

We face intense competition, which could result in reduced acceptance and demand for our implants and technologies.

The medical technology/biotechnology industry is intensely competitive. We compete with companies in the United States and internationally that engage in the development and production of medical technologies and processes including biotechnology, orthopedic, pharmaceutical, biomaterial and other companies; academic and scientific institutions; and public and private research organizations.

Many of our competitors have much greater financial, technical, research, marketing, distribution, service and other resources than we do. Moreover, our competitors may offer a broader array of tissue repair treatment products and technologies or may have greater name recognition in the marketplace. We compete with a number of companies with significantly greater resources and brand recognition than ours. Our competitors, including several development stage companies, may develop or market technologies that are more effective or commercially attractive than our technologies, or that may render our technologies obsolete. For example, the development of a synthetic tissue implant that permits remodeling of bones could reduce the demand for allograft and xenograft-based implants and technologies.

If we do not manage the medical release of donor tissue into processing in an effective and efficient manner, it could adversely affect profitability.

Many factors affect the level and timing of donor medical releases, including the effectiveness of donor screening performed by donor recovery groups, the timely receipt, recording and review of required medical documentation, and employee loss and turnover in our medical records department. We can provide no assurance that releases will occur at levels which maximize our processing efficiency and minimize our cost per allograft processed.

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 methods of tissue recovery from donors and actual or potential disease transmission from donated tissue may limit widespread acceptance of our allografts, whether directed to allografts generally or our allografts specifically. Unfavorable reports of improper or illegal tissue recovery practices by any participant in the industry, 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.

If our patents and the other means we use to protect our intellectual property prove to be inadequate, our competitors could exploit our intellectual property to compete more effectively against us.

The law of patents and trade secrets is constantly evolving and often involves complex legal and factual questions. The U.S. government may deny or significantly reduce the coverage we seek for our patent applications before or after a patent is issued. We cannot be sure that any particular patent for which we apply will be issued, that the scope of the patent protection will be comprehensive enough to provide adequate protection from competing technologies, that interference, derivation, reexamination, post-grant review or inter parties review proceedings regarding any of our patent applications will not be filed, or that we will achieve any other competitive advantage from a patent. In addition, it is possible that one or more of our patents will be held invalid or reduced in scope of claims if challenged or that others will claim rights in or ownership of our patents and other proprietary rights. If any of these events occur, our competitors may be able to use our intellectual property to compete more effectively against us.

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Because patent applications remain secret until published (typically 18 months after first filing) and the publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that our patent application was the first application filed disclosing or potentially covering a particular invention. If another party s rights to an invention are superior to ours, we may not be able to obtain a license to use that party s invention on commercially reasonable terms, if at all. In addition, our competitors, many of which have greater resources than ours, could obtain patents that will prevent, limit or interfere with our ability to make use of our inventions either in the United States or in international markets. Further, the laws of some foreign countries do not always protect our intellectual property rights to the same extent as the laws of the United States. Litigation or regulatory proceedings in the United States or foreign countries also may be necessary to enforce our patent or other intellectual property rights or to determine the scope and validity of the proprietary rights of our competitors. These proceedings may prove unsuccessful and may also be costly, result in development delays, and divert the attention of our management.

We rely upon unpatented proprietary techniques and processes in tissue recovery, research and development, tissue processing, manufacturing and quality assurance. It is possible that others will independently develop technology similar to our technology or otherwise gain access to or disclose our proprietary technologies. We may not be able to meaningfully protect our rights in these proprietary technologies, which would reduce our ability to compete.

Our success depends in part on our ability to operate without infringing on or misappropriating the proprietary rights of others, and if we are unable to do so we may be liable for damages.

We cannot be certain that U.S. or foreign patents or patent applications of other companies do not exist or will not be issued that would prevent us from commercializing our allografts, xenografts, surgical implants and other technologies. Third parties may sue us for infringing or misappropriating their patent or other intellectual property rights. Intellectual property litigation is costly. If we do not prevail in litigation, in addition to any damages we might have to pay, we could be required to cease the infringing activity or obtain a license requiring us to make royalty payments. It is possible that a required license may not be available to us on commercially acceptable terms, if at all. In addition, a required license may be non-exclusive, and therefore our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around another company s patent, we may be unable to make use of some of the affected technologies or distribute the affected allografts, xenografts or surgical implants, which would reduce our revenues.

The defense costs and settlements for patent infringement lawsuits are not covered by insurance. Patent infringement lawsuits can take years to settle. If we are not successful in our defenses or are not successful in obtaining dismissals of any such lawsuit, legal fees or settlement costs could have a material adverse effect on our results of operations and financial position.

We or our competitors may be exposed to product or professional liability claims which could cause us to be liable for damages or cause investors to think we will be liable for similar claims in the future.

The development of allografts and technologies for human tissue repair and treatment entails an inherent risk of product or professional liability claims, and substantial product or professional liability claims may be asserted against us. We are party to a number of legal proceedings relating to professional liability. The prevailing view among the states throughout the United States is that providing allografts is a service and not the sale of a product. As such, allografts are not subject to product liability causes of action. However, the law of a particular state could change in response to legislative changes or by judicial interpretation in a state where such issue has either not been previously addressed or prior precedent is overturned or subject to different interpretations by a court of higher precedential authority. In addition, due to the international scope of our activities we are subject to international laws which may treat allografts as products in those jurisdictions.

The implantation of donated human tissue implants creates the potential for transmission of communicable diseases. Although we comply with federal, state and foreign regulations and guidelines intended to prevent communicable disease transmission, and our tissue suppliers are also required to comply with such regulations, there can be no assurances that: (i) our tissue suppliers will comply with such regulations intended to prevent communicable disease transmissions; (ii) even if such compliance is achieved, that our implants have not been or will not be associated with transmission of disease; or (iii) a patient otherwise infected with disease would not erroneously assert a claim that the use of our implants resulted in disease transmission.

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We currently have $20 million of product and professional liability insurance to cover claims. This amount of insurance may not be adequate for potential claims if we are not successful in our defenses. Moreover, insurance covering our business may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which would harm our financial condition and liquidity. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain surgeon acceptance of our allografts or to expand our business.

We are subject to federal, state and foreign laws and regulations, including fraud and abuse laws, as well as anti-bribery laws, and could face substantial penalties if we fail to fully comply with such regulations and laws.

Our relationship with foreign and domestic government entities and healthcare professionals, such as physicians, hospitals and those to whom and through whom we may market our implants and technologies, are subject to scrutiny under various federal, state and territorial laws in the United States and other jurisdictions in which we conduct business. These include, for example, anti-kickback laws, physician self-referral laws, false claims laws, criminal health care fraud laws, and anti-bribery laws (e.g., the United States Foreign Corrupt Practices Act). Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, and their respective counterparts in the applicable foreign jurisdictions in which we conduct business. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years.

If we are not successful in expanding our distribution activities into international markets, we will not be able to pursue one of our strategies for increasing revenues.

Our international distribution strategies vary by market, as well as within each country in which we operate. For example, we distribute only a portion of our line of allograft and xenograft implants within each country. Our international operations will be subject to a number of risks which may vary from the risks we face in the United States, including the need to obtain regulatory approvals in additional foreign countries before we can offer our implants and technologies for use; the potential burdens of complying with a variety of foreign laws; longer distribution-to-collection cycles, as well as difficulty in collecting accounts receivable; dependence on local distributors; limited protection of intellectual property rights; fluctuations in the values of foreign currencies; and political and economic instability.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site and off-site systems. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attaches by hackers; viruses, breaches or interruptions due to employee error or malfeasance, terrorist attacks, hurricanes, fire, flood, other natural disasters, power loss, computer systems failure, data network failure, internet failure, or lapses in compliance with privacy and security mandates. Any such virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also interrupt our operations, including our ability to receive and ship orders from customers, bill our customers, provide customer support services, conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

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The outcome of litigation or arbitration in which we are involved is unpredictable and an adverse decision in any such matter could adversely impact our business, financial condition or results of operations.

We are from time to time subject to legal proceedings and claims that arise in the ordinary course of business. For example, we were named as a party, along with a number of other recovery and processor defendants, in lawsuits relating to the tissue recovery practices of Biomedical Tissue Service, Ltd. (BTS), an unaffiliated recovery agency. We settled the BTS cases in 2012 and 2013 for payments totaling $2.4 million and $3.0 million, respectively. Accordingly, we recorded a litigation settlement charge of $3.0 million in the second quarter of 2013.

As an additional example, Lanx, Inc., a subsidiary of Zimmer Biomet Holdings, Inc. (Lanx), filed suit in the second quarter of 2013 against Pioneer in the U.S. District Court, District of Colorado, alleging that one of our medical devices infringed certain of Lanx s U.S. intellectual property rights, and sought monetary damages and threatened injunctive relief. In the second quarter of 2014, the parties resolved the claim with no material financial impact to us or our operations. As part of the resolution of the claim, a settlement payment of $325,000 was made to Lanx from the indemnification escrow account in connection with the Pioneer transaction.

An adverse resolution of lawsuits or arbitrations could adversely impact our business, financial condition or results of operations.

Any acquisitions we make may require the issuance of a significant amount of equity or debt securities and may not be scientifically or commercially successful.

As part of our business strategy, we may make certain acquisitions to obtain additional businesses, product and/or process technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes securities, we may be required to issue a substantial amount of equity, debt, warrants, convertible instruments or other similar securities. Such an issuance could dilute your investment in our common stock or increase our interest expense and other expenses.

Further, acquisitions involve a number of operational risks, such as:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company s relationship with customers and key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to the acquisition;
- the potential need to implement financial and other systems and add management resources;

the potential for internal control deficiencies in the internal controls of the acquired operations;

potential inexperience in a business area that is either new to us or more significant to us than prior to the acquisition;

the diversion of our management s attention from our core business; and

the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

Any one of these risks could prevent an acquisition from being scientifically or commercially successful, which could have a material impact on our results of operations not only with respect to the operations of the acquired company but with respect to us on a consolidated basis.

Water Street may exercise significant influence over us, including through its ability to elect up to two members of our Board of Directors.

We issued 50,000 shares of Series A convertible preferred stock (Preferred Stock) to WSHP Biologics Holdings, LLC, an affiliate of Water Street Healthcare Partners, a leading healthcare-focused private equity firm (Water Street), in connection with the closing of the Pioneer acquisition. As holders of this Preferred Stock, Water Street is entitled to vote on an as-converted basis upon all matters upon which holders of our common stock have the right to vote. The shares of Preferred Stock owned by Water Street currently represent approximately 18% of the voting rights in respect of our share capital on an as-converted basis; accordingly, Water Street has the ability to significantly influence the outcome of any matter submitted for the vote of our stockholders (also, Water Street is not prohibited from buying shares of our common

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stock). In addition, to the extent dividends are not paid in cash in any quarter for any reason, including any restriction on making such distributions under the terms of our credit agreement with TD Bank (as discussed below), the dividends which have accrued on each outstanding share of Preferred Stock during such three-month period are accumulated and are added to the liquidation value with respect to such share of Preferred Stock. We did not pay dividends on the Preferred Stock in the fourth quarter of 2013 and throughout 2014 and 2015. Consequently we have accrued $7.2 million in preferred dividends payable as of December 31, 2015. To the extent dividends continue to accrue on the Preferred Stock, Water Street s voting rights in respect of our share capital on an as-converted basis will continue to increase.

Water Street may have interests that diverge from, or even conflict with, those of our other stockholders. In addition, our Amended and Restated Certificate of Incorporation and Investor Rights Agreement with Water Street provide that Water Street s consent is required before we may take certain actions for so long as Water Street and its permitted transferees beneficially own in the aggregate at least 10% of our issued share capital.

In addition, our Amended and Restated Certificate of Incorporation and our Investor Rights Agreement with Water Street provide that Water Street has the right to designate and nominate, respectively, directors to our Board of Directors such that the percentage of our board members so designated or nominated is approximately equal to Water Street s percentage equity ownership interest in the company. The maximum number of directors that Water Street is able to designate or nominate is two, with at least one of such directors to serve on each of our Board committees. If Water Street s ownership of our share capital on an as-converted basis falls below 5% (calculated on a fully diluted basis, assuming conversion of the Preferred Stock at the then-existing conversion price), Water Street would have no further director designation or nomination rights under our Amended and Restated Certificate of Incorporation or the investor rights agreement.

In addition, the ownership position and the governance rights of Water Street could discourage a third party from proposing a change of control or other strategic transaction with us.

Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations.

In connection with the closing of the acquisition of Pioneer, we obtained from our lenders a 5-year, $80 million senior secured facility, which includes a $60 million term loan and a $20 million revolving credit facility (which was increased to $30 million in June 2015). Our level of indebtedness may limit our ability to react to changes in the economy or our industry and prevent us from meeting our obligations under the agreements relating to our indebtedness.

Our ability to pay dividends and to make distributions may be limited or prohibited by the terms of our indebtedness or Preferred Stock.

We are, and may in the future become, party to agreements and instruments that restrict or prevent the payment of dividends on our capital stock. Under the terms of our credit agreement with TD Bank, we are restricted from paying dividends on our common stock without the prior written consent of the administrative agent. We are also restricted from paying dividends or making distributions on our common stock without the prior written consent of the holders of a majority of the Preferred Stock pursuant to the terms of the Certificate of Designation of Series A Convertible Preferred Stock, so long as any shares of the Preferred Stock remain outstanding. In addition, under the terms of our credit agreement with TD Bank, distributions to holders of our Preferred Stock are permitted only to the extent that we can satisfy certain financial covenant tests (based on the ratio of our total indebtedness to consolidated EBITDA) and meet other requirements. In the event that we fail to pay the accrued dividends payable on our Preferred Stock for any reason, including any restriction on making such distributions under the terms of our credit agreement with TD Bank,

dividends payable will continue to accrue on such Preferred Stock.

Our credit agreement contains financial and operating restrictions that may limit our access to credit. If we fail to comply with financial or other covenants in our credit agreement, we may be required to repay indebtedness to our existing lenders, which may harm our liquidity.

Provisions in our credit agreement impose restrictions on our ability to, among other things:

merge or consolidate;

make strategic acquisitions;

make dispositions of property;

create liens;

enter into transactions with affiliates;

become a guarantor;

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pay dividends and make distributions;

incur more debt; and

make investments.

Our credit agreement also contains financial covenants that require us to maintain compliance with specified financial ratios and maintain a specified amount of cash on hand.

We may not be able to comply with the financial covenants in the future. In the absence of a waiver from our lenders, any failure by us to comply with these covenants in the future may result in the declaration of an event of default, which could prevent us from borrowing under our credit agreement. In addition to preventing additional borrowings under our credit agreement, an event of default, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding, if any, under the agreement, which would require us to pay all amounts outstanding. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we then may not have sufficient funds available for repayment or the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. For example, in December 2013, we entered into an amendment to the credit agreement which, in part, modified certain financial covenants so that we could maintain compliance with the financial ratios. In October 2014, we entered into a second amendment to the second amended and restated loan agreement with TD Bank, N.A. and Regions Bank, which amended the loan agreement to remove certain financial covenants.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 2. PROPERTIES.

UNITED STATES

Our headquarters and U.S natural tissue processing facilities are located in Alachua, Florida, near metropolitan Gainesville, including five buildings on approximately 23 acres of property that we own.

Processing, Manufacturing and Laboratory Facilities

In Alachua, Florida, we own a 65,500 square foot processing facility and lease a 8,000 square foot facility for the processing of natural tissues utilizing our BioCleanse® and TUTOPLAST® and CANCELLE® SP sterilization processes. In addition, we also own a 42,000 square foot logistics and technology center.

In Marquette, Michigan, we own a 106,000 square foot facility for manufacturing metal and synthetic implants and instruments that also houses laboratory facilities.

In Greenville, North Carolina, we lease a 15,500 square foot facility for manufacturing synthetic implants.

Our processing and manufacturing facilities meet the FDA s Current Good Manufacturing Practices requirements and allows us to meet the requirements of an FDA approved medical device manufacturer.

Administrative and Distribution and Marketing Offices

In Alachua, Florida, we own three buildings totaling 86,000 square feet which house our corporate headquarters as well as administrative and distribution and marketing functions.

In Jacksonville, Florida, we lease 5,300 square feet for distribution and marketing functions.

In Austin, Texas, we lease 10,600 square feet for distribution, marketing and research and development functions.

GERMANY

Our facility in Neunkirchen consists of six buildings totaling approximately 60,000 square feet on approximately two acres of land, including 11,000 square feet of area for processing natural tissues utilizing the TUTOPLAST sterilization process.

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FRANCE

Our facility in Metz consists of a small leased distribution and tissue procurement office.

THE NETHERLANDS

Our facility in Houten consists of approximately 10,000 square feet of a sales and distribution office.

SINGAPORE

Our facility in Singapore consists of a small leased administrative and sales office.

We believe that we have sufficient space and facilities to meet our current and foreseeable future needs.

Item 3. LEGAL PROCEEDINGS.

The Company is, from time to time, involved in litigation relating to claims arising out of its operations in the ordinary course of business. The Company believes that none of these claims that were outstanding as of December 31, 2015 will have a material adverse impact on its financial position or results of operations. Please see Note 22, Legal and Regulatory Actions, to the consolidated financial statements contained in Part II, Item 8 of this report for additional information.

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

Item 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is quoted on the Nasdaq Stock Market under the symbol RTIX. The following table sets forth the range of high and low sales prices for our common stock for each quarterly period in the last two fiscal years.

2014	High	Low
First Quarter	$ 4.46	$ 3.00
Second Quarter	$ 5.00	$ 3.61
Third Quarter	$ 5.58	$ 4.09
Fourth Quarter	$ 5.67	$ 3.50

2015	High	Low
First Quarter	$ 5.74	$ 4.36
Second Quarter	$ 7.11	$ 4.90
Third Quarter	$ 7.48	$ 5.30
Fourth Quarter	$ 5.74	$ 3.56

As of February 29, 2016, we had 318 stockholders of record of our common stock. The closing sale price of our common stock on February 29, 2016 was $3.50 per share.

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Stock Performance Graph

The Securities and Exchange Commission requires us to present a chart comparing the cumulative total stockholder return on our common stock with the cumulative total stockholder return of: (1) a broad equity market index and (2) a published industry or line-of-business index. We selected the Standard & Poor s 500 Health Care Equipment Index based on our good faith determination that this index fairly represents the companies which compete in the same industry or line-of-business as we do. The chart below compares our common stock with the Nasdaq Composite Index and the Standard & Poor s 500 Health Care Equipment Index and assumes an investment of $100.00 on December 31, 2010 in each of the common stock, the stocks comprising the Nasdaq Composite Index and the stocks comprising the Standard & Poor s 500 Health Care Equipment Index.

Total Return Analysis	12/10	12/11	12/12	12/13	12/14	12/15
RTI Surgical, Inc.	$ 100.00	$ 166.29	$ 159.93	$ 132.58	$ 194.76	$ 148.69
NASDAQ Composite	100.00	99.17	116.48	163.21	187.27	200.31
S&P 500 Health Care Equipment Index	100.00	99.20	116.33	148.54	187.58	198.78

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Dividend Policy

We have never paid cash dividends to holders of our common stock. We do not expect to declare or pay any dividends on our common stock in the foreseeable future. Other than the possibility that we may pay dividends on our preferred stock, we intend to retain all earnings, if any, to invest in our operations. The payment of future dividends, if any, will depend upon our future earnings, if any, our capital requirements, financial condition, debt covenant terms, and other relevant factors. Under our current credit agreement with TD Bank, we are restricted from paying dividends on our common stock without the prior written consent of the administrative agent. In addition, pursuant to the terms of the Certificate of Designation of Series A Convertible Preferred Stock, so long as any shares of the Preferred Stock remain outstanding, we may not pay any dividend or make any distribution upon any junior securities (including the common stock) without the prior written consent of the holders of a majority of the Preferred Stock.

Item 6. SELECTED FINANCIAL DATA.

The statement of operations data set forth below for the years ended December 31, 2015, 2014 and 2013, and selected balance sheet data as of December 31, 2015 and 2014 have been derived from our audited consolidated financial statements and accompanying notes. The consolidated financial statements as of December 31, 2015 and 2014 and for the three years ended December 31, 2015 are included elsewhere in this Form 10-K. The selected consolidated financial data set forth below should be read along with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations, and our consolidated financial statements and accompanying notes included elsewhere in this document.

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The statement of operations data set forth below for the years ended December 31, 2012 and 2011, and the balance sheet data set forth as of December 31, 2013, 2012 and 2011 have been derived from our audited consolidated financial statements and accompanying notes which are not included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(In thousands, except share and per share data)				
Statements of Operations Data:					
Revenues	$ 282,293	$ 262,810	$ 197,979	$ 178,113	$ 169,316
Costs of processing and distribution	132,551	129,013	117,874	92,896	92,102
Gross profit	149,742	133,797	80,105	85,217	77,214
Expenses:					
Marketing, general and administrative	107,439	107,653	81,635	58,376	55,576
Research and development	15,065	15,536	15,241	12,231	9,806
Asset abandonments	814			20	61
Litigation and settlement charges	804	185	3,000	2,350	
Restructuring charges			2,881		
Acquisition expenses			6,004		
Severance charges	995	4,798			
Total operating expenses	125,117	128,172	108,761	72,977	65,443
Operating income (loss)	24,625	5,625	(28,656)	12,240	11,771
Other (expense) income:					
Interest expense	(1,492)	(1,357)	(542)		(201)
Interest income	3	9	23	185	193
Foreign exchange gain (loss)	78	(88)	251	19	(159)
Total other (expense) income - net	(1,411)	(1,436)	(268)	204	(167)
Income (loss) before income tax (provision) benefit	23,214	4,189	(28,924)	12,444	11,604
Income tax (provision) benefit	(8,299)	(1,493)	11,110	(4,042)	(3,226)
Net income (loss)	14,915	2,696	(17,814)	8,402	8,378
Convertible preferred dividend	(3,305)	(3,113)	(1,375)		
Net income (loss) applicable to common shares	$ 11,610	$ (417)	$ (19,189)	$ 8,402	$ 8,378
Net income (loss) per common share - basic	$ 0.20	$ (0.01)	$ (0.34)	$ 0.15	$ 0.15

Net income (loss) per common share - diluted	$ 0.20	$ (0.01)	$ (0.34)	$ 0.15	$ 0.15
Weighted average shares outstanding - basic	57,611,231	56,735,924	56,258,624	55,861,957	55,150,886
Weighted average shares outstanding - diluted	58,590,494	56,735,924	56,258,624	56,068,795	55,354,675

	As of December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Balance Sheet Data:					
Cash and cash equivalents	$ 12,614	$ 15,703	$ 18,721	$ 49,696	$ 46,178
Working capital	131,785	133,510	134,302	129,110	124,064
Total assets	381,065	378,135	369,854	241,409	230,027
Long-term obligations - less current portion	73,631	69,413	67,706	4	143
Redeemable preferred stock	56,323	52,834	49,537		
Total stockholders equity	181,356	167,835	168,053	183,992	172,419

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Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion of our financial condition and results of operations together with those financial statements and the notes to those statements included elsewhere in this filing. This discussion contains forward looking statements based on our current expectations, assumptions, estimates and projections about us and our industry. Our actual results could differ materially from those anticipated in these forward looking statements. We undertake no obligation to update publicly any forward looking statements for any reason, even if new information becomes available or other events occur in the future.

Executive Level Overview:

RTI Surgical, Inc. together with its subsidiaries, designs, develops, manufactures and distributes surgical implants for use in a variety of surgical procedures. We are a leader in providing natural tissue implants as well as metal and synthetic implants for the benefit of surgeons and patients worldwide. We process donated human musculoskeletal and other tissues including bone, cartilage, tendons, ligaments, fascia lata, pericardium, sclera, cornea and dermal tissues, as well as bovine and porcine animal tissues to produce allograft and xenograft implants. We process the majority of our natural tissue implants using our proprietary BIOCLEANSE®, TUTOPLAST® and CANCELLE® SP sterilization processes. In addition, we manufacture, market and distribute metal and synthetic implants for treatment of spinal and other orthopedic disorders. Our implants are used in the fields of spine, ortho fixation, sports medicine, bone graft substitutes and general orthopedic, dental and surgical specialties. We distribute our implants to hospitals and surgeons in the United States and internationally through a direct distribution organization, as well as through a network of independent distributors. We were founded in 1997 and are headquartered in Alachua, Florida.

Domestic distributions and services accounted for 92% of total revenues in 2015. Most of our implants are distributed directly to doctors, hospitals and other healthcare facilities through a direct distribution force and through various strategic relationships.

International distributions and services accounted for 8% of total revenues in 2015. Our implants are distributed in over 45 countries through a direct distribution force in Germany and through stocking distributors in the rest of the world outside of Germany and the United States.

Our business is generally not seasonal in nature; however, the number of orthopedic implant surgeries and elective procedures generally declines during the summer months.

Our principal goals are to honor the gift of donated tissue, donor families and patients while building our competitive strength in the marketplace to increase revenues, profitability and cash flow as we focus on improved operational efficiency, productivity and asset management. We are making investments in new implant and product development and our U.S. direct distribution network to promote growth in 2016 and beyond.

We continue to maintain our commitment to research and development and the introduction of new strategically targeted allograft, xenograft, metal and synthetic implants as well as focused clinical efforts to support their acceptance in the marketplace. In addition, we consider strategic acquisitions from time to time for new implants and technologies intended to augment our existing implant offerings.

Mergers and Acquisitions

On July 16, 2013, we completed our acquisition of Pioneer. Under the terms of the merger agreement dated June 12, 2013, we acquired Pioneer for $126.3 million in cash. The transaction was funded through a combination of cash on

hand, a new credit facility and a concurrent private placement of convertible preferred equity. We obtained from Toronto-Dominion Bank, N.A., TD Securities USA LLC (TD Bank) and Regions Bank, a 5-year, $80.0 million senior secured facility, which includes a $60.0 million term loan and a $20.0 million revolving credit facility, that matures on July 16, 2018 with a variable interest rate between 100 and 300 basis points in excess of the one month LIBOR rate. The $20.0 million revolving credit facility was increased to $30.0 million on June 29, 2015. Additionally, we received $50.0 million in gross proceeds from a private placement of convertible preferred equity to Water Street Healthcare Partners, a leading healthcare-focused private equity firm. The convertible preferred stock is convertible into shares of our common stock. The convertible preferred stock also accrues dividends at a rate of 6% per year.

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Critical Accounting Policies

The preparation of our financial statements in accordance with accounting principles generally accepted in the United States (U.S. GAAP) often requires us to make estimates and judgments that affect reported amounts. These estimates and judgments are based on historical experience and assumptions that we believe to be reasonable under the circumstances. Assumptions and judgments based on historical experience may provide reported results which differ from actual results; however, these assumptions and judgments historically have not varied significantly from actual experience and we therefore do not expect them to vary significantly in the future.

The accounting policies which we believe are critical, or require the most use of estimates and judgment, relate to the following items presented in our financial statements: 1) Tissue Inventory Valuation; 2) Accounts Receivable Allowances; 3) Long-Lived Assets; 4) Intangible Assets and Goodwill; 5) Revenue Recognition; 6) Stock-Based Compensation Plans; and 7) Income Taxes.

Tissue Inventory Valuation. U.S. GAAP requires that inventory be stated at the lower of cost or market value. Due to various reasons, some tissue within our inventory will never become available for distribution. Therefore, we must make estimates of future distribution from existing inventory in order to write-off inventory which will not be distributed and which therefore has reduced or no market value.

Our management reviews available information regarding processing costs, inventory distribution rates, industry supply and demand, medical releases and processed tissue rejections, in order to determine write-offs of cost above market value. For a variety of reasons, we may from time to time be required to adjust our assumptions as processes change and as we gain better information. Although we continue to refine the information on which we base our estimates, we cannot be sure that our estimates are accurate indicators of future events. Accordingly, future adjustments may result from refining these estimates. Such adjustments may be significant.

Accounts Receivable Allowances. We maintain allowances for doubtful accounts based on our review and assessment of payment history and our estimate of the ability of each customer to make payments on amounts invoiced. If the financial condition of any of our customers were to deteriorate, additional allowances might be required. From time to time we must adjust our estimates. Changes in estimates of the collection risk related to accounts receivable can result in decreases and increases to current period net income.

Long-Lived Assets. We periodically evaluate the period of depreciation or amortization for long-lived assets to determine whether current circumstances warrant revised estimates of useful lives. We review our property, plant and equipment for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to the net undiscounted cash flows expected to be generated by the asset. An impairment loss would be recorded for the excess of net carrying value over the fair value of the asset impaired. The fair value is estimated based on expected discounted future cash flows. The results of impairment tests are subject to management s estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and the likelihood of materially different reported results. Past estimates by management of the fair values and useful lives of long-lived assets and investments have periodically been impacted by one-time events.

Intangible Assets and Goodwill. Financial Accounting Standards Board (FASB) ASC 350, *Goodwill and Other Intangible Assets*, requires companies to test goodwill for impairment on an annual basis at the reporting unit level (or an interim basis if an event occurs that might reduce the fair value of a reporting unit below its carrying value). We have one reporting unit and the annual impairment test is performed at each year-end unless indicators of impairment are present and require more frequent testing. FASB ASC 350 also requires that the carrying value of an identifiable

intangible asset that has an indefinite life be determined by using a fair value based approach.

Intangible assets generally consist of patents, trademarks, procurement contracts, customer lists, non-compete agreements, distribution agreements and acquired exclusivity rights. Patents and trademarks are amortized on the straight-line method over the shorter of the remaining protection period or estimated useful lives of between 8 and 16 years. Procurement contracts, customer lists, acquired exclusivity rights, non-compete agreements and distribution agreements are amortized over estimated useful lives of between 5 to 25 years.

Goodwill is tested for impairment by comparing the fair value of the reporting unit to its carrying amount, including goodwill. In concluding as to fair value of the reporting unit for purposes of testing goodwill, an income approach and a market approach are utilized. The conclusion from these two approaches are weighted equally and then adjusted to incorporate a control premium or acquisition premium that reflects the additional amount a buyer is willing to pay for elements of control and for a premium that reflects the buyer s perception of its ability to add value through synergies.

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In general, the income approach employs a discounted cash flow model that considers: 1) assumptions that marketplace participants would use in their estimates of fair value, including the cash flow period, terminal values based on a terminal growth rate and the discount rate; 2) current period actual results, and 3) projected results for future periods that have been prepared and approved by our senior management. The forecasted cash flows do not include synergies that a marketplace participant would be expecting to achieve.

The market approach employs market multiples from guideline public companies operating in our industry. Estimates of fair value are derived by applying multiples based on revenue and earnings before interest, taxes, depreciation and amortization (EBITDA) adjusted for size and performance metrics relative to peer companies. A control premium was included in determining the fair value under this approach.

If the carrying amount of the reporting unit exceeds its calculated fair value, the second step of the goodwill impairment test is performed in accordance with FASB ASC 805 to measure the amount of the impairment loss, if any.

Both approaches used in the analysis have a degree of uncertainty. Potential events or changes in circumstances which could impact the key assumptions used in our goodwill impairment evaluation are as follows:

Change in peer group or performance of peer group companies

Change in the company s markets and estimates of future operating performance

Change in the company s estimated market cost of capital

Change in implied control premiums related to acquisitions in the medical device industry.

The valuation of goodwill and intangible assets with indefinite useful lives requires management to use significant judgments and estimates including, but not limited to, projected future revenue and cash flows. Changes in assumptions or market conditions could result in a change in estimated future cash flows and the likelihood of materially different reported results.

If we overestimate the useful life of an asset, or overestimate the fair value of an asset, and at some time in the future we dispose of that asset for a lower amount than its carrying value, our historically reported total assets and net income would have been higher than they would have been during periods prior to our recognition of the loss on disposal of assets, and lower during the period when we recognize the loss.

The fair value of these long-term investments is dependent on their performance, as well as volatility inherent in the external markets for these investments. These determinations require complex calculations based on estimated future benefit and fair value. We have often made investments for which the expected future benefit has not been easily estimated. Examples of such investments include, but are not limited to, our acquisition of Pioneer and our acquisition of Tutogen Medical, Inc., a Delaware corporation (TMI), our investment in equipment; and our investment in obtaining patents. In assessing potential impairment for these investments, we consider these factors as well as forecasted financial performance. If forecasts are not met, impairment charges may be required.

Revenue Recognition. We recognize revenue upon shipping, or receipt by our customers of the processed tissue for implantation, depending on our distribution agreements with our customers or distributors. We recognize our other revenues when all appropriate contractual obligations have been satisfied.

We permit returns of tissue in accordance with the terms of contractual agreements with customers if the tissue is returned in a timely manner, in unopened packaging and from the normal channels of distribution. We provide allowances for returns based upon analysis of our historical patterns of returns, matched against the fees from which they originated. Historical returns have been within the amounts we reserved.

Stock-Based Compensation Plans. We account for our stock-based compensation plans in accordance with FASB ASC 718, Accounting for Stock Compensation. FASB ASC 718 requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and restricted stock. Under the provisions of FASB ASC 718, and U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 107, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight-line basis over the requisite service period of the entire award (generally the vesting period of the award).

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Income Taxes. We use the asset and liability method of accounting for income taxes. Deferred income taxes are recorded to reflect the tax consequences on future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts which are more likely than not to be realized.

Off Balance-Sheet Arrangements

As of December 31, 2015, we had no off-balance-sheet arrangements, as defined in Item 303(a) (4) (ii) of Regulation S-K.

Regulatory Approvals in 2015

AMERICAS

US 510(k) Clearance of Tritium SCP System (extension)

US 510(k) Clearance of C-Plus IBF (extension)

US 510(k) Clearance of Nerve Monitoring Cable System and Disposable Dilators

US 510(k) Clearance of Streamline OCT Occipito-Cervico-Thoracic System (extension)

Panama Approval of BioSet

EUROPE

Portugal Registration of Sternal Cable System

Portugal Registration of Tutobone, Tutomesh Bovine Pericardium, and Tutopatch Bovine Pericardium

Portugal Registration of Fortiva Porcine Dermis

ASIA-PACIFIC / MIDDLE EAST

Australia Spine Implant Registrations of:

Streamline TL

Streamline MIS

Quantum Rods

C-Plus

T-Plus

Bullet-Tip

Rotate

CrossFuse II

PAC Plate

NuNec

Australia Registrations of fifteen spine instrument types

China Approval for Streamline TL System expansion

Egypt Registration of Tutobone, Tutomesh Bovine Pericardium, and Tutopatch Bovine Pericardium

Korea Registration of Allograft Tendons

New Zealand Listing of Matrix HD

New Zealand Listing of Fortiva Porcine Dermis

New Zealand Listing of Allograft Bone

Singapore Licenses for Allograft Tendons,Bone, Meniscus, Fascia Lata, and Dermis

Singapore Licenses for BioSet, BioReady, and BioAdapt

Singapore Licenses for Tutoplast Allografts (Tutoplast Fascia lata, T. Fascia temp., T. Pericardium, T. Dermis, T. Cancellous, T. Illiac Crest, T. shaft bones, T. ATT, T. cartilage)

Singapore License for Fortiva Porcine Dermis

Singapore License for Tutopatch Bovine Pericardium

Singapore Approval on six products for a commercial partner

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Certifications, Accreditations and Inspections in 2015

AMERICAS

- SGS ISO 13485 surveillance audit at the Alachua, Florida and Allendale, New Jersey facilities
- American Association of Tissue Banks reaccreditation inspections at the Alachua, Florida facility for RTI Surgical and RTI Donor Services
- BSI ISO 13485 surveillance audit at the Marquette, Michigan; Austin, Texas; and Greenville, North Carolina facilities
- State of New York inspection of the Alachua, Florida facility

EUROPE

- German authorities (PEI & ROF) inspections of Tutogen Medical facility located in Neunkirchen, Germany
- U.S. Food and Drug Administration (FDA) inspection of Tutogen Medical facility located in Neunkirchen, Germany
- Houten Netherlands facility received their BSI ISO 13485 certification in 06/2015

All registrations, licensures, certifications and accreditations were renewed or continued for all locations.

Implant and Product Recalls

In 2015, there were two voluntary recalls with the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA).

- May 2015 One recall was filed with CDRH involving three lots of Bullet Tip and T-Plus VBR devices. These device lots were recalled due to incorrect color ID labels. This recall has been considered closed by RTI Surgical and the FDA since November 4, 2015.
- June 2015 One recall was filed with CDRH involving one lot of DePuy Songer Cable System Stainless Steel Cable. This device lot was recalled due to the label incorrectly stating that the devices were made from Titanium when they were made from Stainless Steel. This recall has been considered closed by RTI Surgical since November 17, 2015. The closure letter is still pending from the FDA.

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Results of Operations

The following tables set forth, in both dollars and as a percentage of revenues, the results of our operations for the years indicated:

	Year Ended December 31,					
	2015		2014		2013	
	(Dollars in thousands)					
Statement of Operations Data:						
Revenues	$ 282,293	100.0%	$ 262,810	100.0%	$ 197,979	100.0%
Costs of processing and distribution	132,551	47.0	129,013	49.1	117,874	59.5
Gross profit	149,742	53.0	133,797	50.9	80,105	40.5
Expenses:						
Marketing, general and administrative	107,439	38.1	107,653	41.0	81,635	41.2
Research and development	15,065	5.3	15,536	5.9	15,241	7.7
Asset abandonments	814	0.3				
Litigation settlement charges	804	0.3	185	0.1	3,000	1.5
Restructuring charges					2,881	1.5
Acquisition expenses					6,004	3.0
Severance charges	995	0.4	4,798	1.8		
Total operating expenses	125,117	44.3	128,172	48.8	108,761	54.9
Operating income (loss)	24,625	8.7	5,625	2.1	(28,656)	(14.4)
Other (expense) income:						
Interest expense	(1,492)	(0.5)	(1,357)	(0.5)	(542)	(0.3)
Interest income	3	0.0	9	0.0	23	0.0
Foreign exchange gain (loss)	78	0.0	(88)	(0.0)	251	0.1
Total other expense - net	(1,411)	(0.5)	(1,436)	(0.5)	(268)	(0.2)
Income (loss) before income tax (provision) benefit	23,214	8.2	4,189	1.6	(28,924)	(14.6)
Income tax (provision) benefit	(8,299)	(2.9)	(1,493)	(0.6)	11,110	5.6
Net income (loss)	14,915	5.3	2,696	1.0	(17,814)	(9.0)
Convertible preferred dividend	(3,305)	(1.2)	(3,113)	(1.2)	(1,375)	(0.7)
Net income (loss) applicable to common shares	$ 11,610	4.1%	$ (417)	(0.2%)	$ (19,189)	(9.7%)

	Year Ended December 31,			Percent Change	
	2015	2014	2013	2015/2014	2014/2013
Revenues:					
Spine	$ 76,968	$ 82,663	$ 57,334	-6.9%	44.2%
Ortho fixation	55,585	37,133	14,525	49.7%	155.6%
Sports medicine	46,735	46,758	42,594	0.0%	9.8%
BGS and general orthopedic	42,283	36,747	27,864	15.1%	31.9%
Dental	23,621	20,810	19,779	13.5%	5.2%
Surgical specialties	23,499	26,999	27,666	-13.0%	-2.4%
Other revenues	13,602	11,700	8,217	16.3%	42.4%
Total revenues	$ 282,293	$ 262,810	$ 197,979	7.4%	32.7%
Domestic revenues	$ 260,387	$ 238,936	$ 177,207	9.0%	34.8%
International revenues	21,906	23,874	20,772	-8.2%	14.9%
Total revenues	$ 282,293	$ 262,810	$ 197,979	7.4%	32.7%

2015 Compared to 2014

Revenues. Our total revenues increased $19.5 million, or 7.4%, to $282.3 million for the year ended December 31, 2015 compared to $262.8 million for the year ended December 31, 2014. Our year over year revenue comparisons were impacted due to a significant amount of our revenue being derived from large commercial stocking distributors, whose timing of orders can vary from year to year. These ordering patterns can result in significant unit volume variations, which can result in significant variation in period over period comparisons.

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Spine - Revenues from spinal implants decreased $5.7 million, or 6.9%, to $77.0 million for the year ended December 31, 2015 compared to $82.7 million for the year ended December 31, 2014. Spine revenues decreased primarily as a result of lower unit volumes of 2.3% and lower average revenue per unit of 4.8% due to timing of stocking orders and unfavorable changes in distribution mix from our commercial stocking distributors.

Ortho Fixation Revenues from ortho fixation increased $18.5 million, or 49.7%, to $55.6 million for the year ended December 31, 2015 compared to $37.1 million for the year ended December 31, 2014. Ortho fixation revenues increased primarily as a result of higher unit volumes of 39.0% and higher average revenue per unit of 7.7%. The higher unit volumes were primarily due to the timing of orders from our commercial stocking distributors and the higher average revenue per unit was primarily due to favorable changes in distribution mix.

Sports Medicine - Revenues from sports medicine allografts of $46.7 million for the year ended December 31, 2015 were comparable to the year ended December 31, 2014. Sports medicine revenues were comparable year over year as a result of higher unit volumes of 5.1%, partially offset by lower average revenue per unit of 4.9%. The lower average revenue per unit was primarily due to unfavorable changes in distribution mix and increased price pressures in the marketplace.

Bone Graft Substitutes (BGS) and General Orthopedic - Revenues from BGS and general orthopedic allografts increased $5.5 million, or 15.1%, to $42.3 million for the year ended December 31, 2015 compared to $36.7 million for the year ended December 31, 2014. BGS and general orthopedic revenues increased primarily as a result of higher unit volumes of 9.4% and higher average revenue per unit of 5.3%. This increase in average revenue per unit was primarily due to significant changes in distribution mix toward units with higher revenue per unit and new product launches, generally with higher revenue per unit.

Dental Revenues from dental allografts increased $2.8 million, or 13.5%, to $23.6 million for the year ended December 31, 2015 compared to $20.8 million for the year ended December 31, 2014. Dental revenues increased primarily as a result of higher unit volumes of 18.3%, partially offset by lower average revenue per unit of 4.0%. The lower average revenue per unit was primarily due to unfavorable changes in distribution mix.

Surgical Specialties Revenues from surgical specialty allografts decreased $3.5 million, or 13.0%, to $23.5 million for the year ended December 31, 2015 compared to $27.0 million for the year ended December 31, 2014. Surgical Specialties revenues decreased primarily as a result of lower unit volumes of 3.3% and lower average revenue per unit of 10.0%. The lower average revenue per unit was primarily due to unfavorable changes in distribution mix from our commercial stocking distributors.

Other Revenues - Revenues from other sources consisting of service processing, tissue recovery fees, biomedical laboratory fees, recognition of previously deferred revenues, shipping fees, distribution of reproductions of our allografts to distributors for demonstration purposes and restocking fees, increased $1.9 million, or 16.3%, to $13.6 million for the year ended December 31, 2015 compared to $11.7 million for the year ended December 31, 2014. The increase was primarily due to increased service processing fees and the acceleration of deferred revenue recognition of $1.5 million relating to Davol relinquishing its exclusive distribution rights in the breast market.

International Revenues International revenues include distributions from our foreign affiliates as well as domestic export revenues. International revenues decreased $2.0 million, or 8.2% to $21.9 million for the year ended December 31, 2015 compared to $23.9 million for the year ended December 31, 2014. On a constant currency basis, international revenues increased $1.0 million, or 4.4% due to increased distributions in Europe.

Costs of Processing and Distribution. Costs of processing and distribution increased by $3.5 million, or 2.7%, to $132.6 million for the year ended December 31, 2015 from $129.0 million for the year ended December 31, 2014. The increase was primarily due to higher costs of processing and distribution arising from higher revenue levels. Costs of processing and distribution decreased as a percentage of revenues from 49.1% for the year ended December 31, 2014 to 47.0% for the year ended December 31, 2015. The decrease was primarily due to changes in distribution mix.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses of $107.4 million for the year ended December 31, 2015 were comparable to the year ended December 31, 2014. Marketing, general and administrative expenses decreased as a percentage of revenues from 41.0% for the year ended December 31, 2014 to 38.1% for the year ended December 31, 2015 due to lower compensation expenses as a result of us flattening our organizational structure in 2014.

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Research and Development Expenses. Research and development expenses decreased by $471,000, or 3.0%, to $15.1 million for the year ended December 31, 2015 compared to $15.5 million for the year ended December 31, 2014. As a percentage of revenues, research and development expenses decreased from 5.9% for the year ended December 31, 2014 to 5.3% for the year ended December 31, 2015. The decrease was primarily due to lower research study related expenses.

Asset Abandonments. Asset abandonments related to abandonment of certain long-term assets at our German facility was $814,000 for the year ended December 31, 2015. There were no asset abandonments in the year ended December 31, 2014.

Litigation and Settlement Charges. Litigation and settlement charges relating to the settlement of domestic and international distributor disputes resulted in $804,000 of expenses for the year ended December 31, 2015 compared to $185,000 for the year ended December 31, 2014.

Severance Charges. Severance charges related to the termination of former employees as a result of us reorganizing our distribution force resulted in $995,000 of expenses for the year ended December 31, 2015 compared to $4.8 million for the year ended December 31, 2014 as a result of us flattening our organizational structure.

Net Other (Expense) Income. Net other expense was $1.4 million for both the year ended December 31, 2015 and the year ended December 31, 2014.

Income Tax Provision. Income tax provision for the year ended December 31, 2015 was $8.3 million compared to $1.5 million for the year ended December 31, 2014. Our effective tax rate for the year ended December 31, 2015 and 2014 was 35.7% and 35.6% respectively.

Convertible Preferred Dividend. As a result of the acquisition of Pioneer and pursuant to the terms of the investment agreement with Water Street, we recorded a convertible preferred dividend of $3.3 million for the year ended December 31, 2015 compared to $3.1 million for the year ended December 31, 2014.

2014 Compared to 2013

Revenues. Our total revenues increased $64.8 million, or 32.7%, to $262.8 million for the year ended December 31, 2014 compared to $198.0 million for the year ended December 31, 2013. Our year over year revenue comparisons are impacted as a result of the acquisition of Pioneer. Our prior year revenues include Pioneer related revenues for the stub period of July 16, 2013 to December 31, 2013, whereas our current year period includes a full year of Pioneer related revenues. In addition, a significant amount of our revenue is derived from large commercial stocking distributors, whose timing of orders can vary from year to year. These ordering patterns can result in significant unit volume variations year over year, which can result in significant variation in period over period comparisons.

Spine - Revenues from spinal implants increased $25.3 million, or 44.2%, to $82.7 million for the year ended December 31, 2014 compared to $57.3 million for the year ended December 31, 2013. Spine revenues increased primarily as a result of higher unit volumes of 59.9%, partially offset by lower average revenue per unit of 9.8%. The increase was primarily due to the recognition of a full year of current period Pioneer spine revenues as compared to the prior stub period.

Ortho Fixation Revenues from ortho fixation increased $22.6 million, or 155.6%, to $37.1 million for the year ended December 31, 2014 compared to $14.5 million for the year ended December 31, 2013. We did not offer ortho fixation implants prior to July 16, 2013.

Sports Medicine - Revenues from sports medicine allografts increased $4.2 million, or 9.8%, to $46.8 million for the year ended December 31, 2014 compared to $42.6 million for the year ended December 31, 2013. Sports medicine revenues increased primarily as a result of higher unit volumes of 9.9% and slightly lower average revenue per unit of 0.1%, primarily due to changes in distribution mix.

Bone Graft Substitutes (BGS) and General Orthopedic - Revenues from BGS and general orthopedic allografts increased $8.9 million, or 31.9%, to $36.7 million for the year ended December 31, 2014 compared to $27.9 million for the year ended December 31, 2013. BGS and general orthopedic revenues increased primarily as a result of higher average revenue per unit of 35.7%, partially offset by lower unit volumes of 3.0%. This increase was primarily due to significant changes in distribution mix toward units with higher revenue per unit and new product launches, generally with higher revenue per unit.

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Dental Revenues from dental allografts increased $1.0 million, or 5.2%, to $20.8 million for the year ended December 31, 2014 compared to $19.8 million for the year ended December 31, 2013. Dental revenues increased primarily as a result of higher unit volumes of 4.9% and higher average revenue per unit of 0.3%, primarily due to changes in distribution mix.

Surgical Specialties Revenues from surgical specialty allografts decreased $667,000, or 2.4%, to $27.0 million for the year ended December 31, 2014 compared to $27.7 million for the year ended December 31, 2013. Surgical specialties revenues decreased primarily as a result of lower average revenue per unit of 4.5%, primarily due to changes in distribution mix, partially offset by higher unit volumes of 2.1%.

Other Revenues - Revenues from other sources consisting of service processing, tissue recovery fees, biomedical laboratory fees, recognition of previously deferred revenues, shipping fees, distribution of reproductions of our allografts to distributors for demonstration purposes and restocking fees, increased $3.5 million, or 42.4%, to $11.7 million for the year ended December 31, 2014 compared to $8.2 million for the year ended December 31, 2013. The increase was primarily due to increased service processing fees and tissue recovery fees, offset by the acceleration of deferred revenue recognition of $1.7 million relating to Davol relinquishing their exclusive distribution rights in the hernia market in the first quarter of 2013.

International Revenues International revenues include distributions from our foreign affiliates as well as domestic export revenues. International revenues increased $3.1 million, or 14.9% to $23.9 million for the year ended December 31, 2014 compared to $20.8 million for the year ended December 31, 2013. On a constant currency basis, international revenues were comparable to the prior year.

Costs of Processing and Distribution. Costs of processing and distribution increased by $11.1 million, or 9.4%, to $129.0 million for the year ended December 31, 2014 from $117.9 million for the year ended December 31, 2013. This increase was primarily due to higher costs of processing and distribution arising from higher revenue levels as a result of the Pioneer acquisition.

Costs of processing and distribution decreased as a percentage of revenues from 59.5% for the year ended December 31, 2013 to 49.1% for the year ended December 31, 2014. The decrease was primarily due to purchase accounting step up adjustments to inventory of $16.4 million that were charged to costs of processing and distribution as inventory was sold during the year ended December 31, 2013 compared to $5.7 million for the year ended December 31, 2014. Excluding the purchase accounting step up, costs of processing and distribution decreased as a percentage of revenues due to improvement in product distribution mix. This decrease was partially offset primarily by the higher costs relating to the Pioneer acquisition and referenced in the above paragraph.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses increased by $26.0 million, or 31.9%, to $107.7 million for the year ended December 31, 2014 compared to $81.6 million for the year ended December 31, 2013. Marketing, general and administrative expenses decreased as a percentage of revenues from 41.2% for the year ended December 31, 2013 to 41.0% for the year ended December 31, 2014. The increase in expenses was primarily due to higher variable distribution costs and variable compensation. Our prior year marketing, general and administrative expenses include marketing related costs for new products acquired and general and administrative expenses in the Pioneer acquisition for the stub period of July 16, 2013 to December 31, 2013, whereas our current year period includes a full year of marketing related costs for new products acquired and general and administrative expenses in the Pioneer acquisition.

Research and Development Expenses. Research and development expenses increased by $295,000, or 1.9%, to $15.5 million for the year ended December 31, 2014 compared to $15.2 million for the year ended December 31, 2013. As a

percentage of revenues, research and development expenses decreased from 7.7% for the year ended December 31, 2013 to 5.9% for the year ended December 31, 2014. The decrease was primarily due to cost reductions arising from the restructuring that followed the acquisition of Pioneer in the prior year.

Litigation Settlement. Litigation settlement related to the settlement of an international distributor dispute, which resulted in $185,000 of expenses for the year ended December 31, 2014 compared to $3.0 million for the year ended December 31, 2013.

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Severance Charges. Severance charges related to the termination of former employees as a result of us flattening our organizational structure, which resulted in $4.8 million of expenses for the year ended December 31, 2014.

Net Other (Expense) Income. Net other expense was $1.4 million for the year ended December 31, 2014 compared to $268,000 for the year ended December 31, 2013. The increase in net other expense is primarily attributable to interest expense incurred on debt primarily due to the recognition of a full year of interest expense as compared to the prior year stub period and due to a change from a $251,000 foreign currency exchange transaction gain for the year ended December 31, 2013 compared to an $88,000 foreign currency exchange transaction loss for the year ended December 31, 2014 resulting from changes in the value of the U.S. dollar versus the Euro and the timing of payments on foreign currency liabilities.

Income Tax (Provision) Benefit. Income tax provision for the year ended December 31, 2014 was $1.5 million compared to an income tax benefit of $11.1 million for the year ended December 31, 2013. Our effective tax rate for the year ended December 31, 2014 and 2013 was 35.6% expense and 38.4% benefit respectively. For the year ended December 31, 2014, our comparative income tax rate was favorably impacted due to the inclusion of the 2014 research tax credit. The favorable impact from the research tax credit was partially offset by a valuation allowance charge recorded on a portion of foreign losses incurred during 2014.

Convertible Preferred Dividend. As a result of the acquisition of Pioneer and pursuant to the terms of the investment agreement with Water Street, we recorded a convertible preferred dividend of $3.1 million for the year ended December 31, 2014 compared to $1.4 million for the year ended December 31, 2013.

Non-GAAP Financial Measures

We utilize certain financial measures that are not calculated based on Generally Accepted Accounting Principles, or GAAP. Certain of these financial measures are considered non-GAAP financial measures within the meaning of Item 10 of Regulation S-K promulgated by the SEC. We believe that non-GAAP financial measures reflect an additional way of viewing aspects of our operations that, when viewed with the GAAP results, provide a more complete understanding of our results of operations and the factors and trends affecting our business. These non-GAAP financial measures are also used by our management to evaluate financial results and to plan and forecast future periods. However, non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. Non-GAAP financial measures used by us may differ from the non-GAAP measures used by other companies, including our competitors.

To supplement our consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures that exclude certain amounts, including non-GAAP net (loss) income applicable to common shares. These non-GAAP financial measures are not in accordance with, or an alternative for, generally accepted accounting principles in the United States. Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP measures are included in the reconciliation below:

	Year Ended December 31,		
	2015	2014	2013
	(In thousands)		
Net income (loss) applicable to common shares, as reported	$ 11,610	$ (417)	$ (19,189)
Asset abandonments, net of tax effect	584		

Litigation and settlement charges, net of tax effect	543	133	1,822
Severance charges, net of tax effect	615	3,007	
Inventory purchase price adjustment, net of tax effect		3,467	9,949
Restructuring charges, net of tax effect			1,750
Acquisition expenses, net of tax effect			4,923
Integration expenses, net of tax effect			671
Non-GAAP net income (loss) applicable to common shares, adjusted	$ 13,352	$ 6,190	$ (74)

The following are explanations of the adjustments that management excluded as part of the non-GAAP measures for the years ended December 31, 2015 and 2014 as well as the reasons for excluding the individual item:

2015 Asset abandonments This adjustment represents an abandonment of certain long-term assets at our German facility. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

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2015 and 2014 Litigation and settlement charges This adjustment represents charges relating to settlements of domestic and international distributor disputes. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2015 and 2014 Severance charges This adjustment represents charges relating to the termination of former employees. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2014 Inventory purchase price adjustment This adjustment represents the purchase price effects of acquired Pioneer inventory that was sold in 2014 and which has been included in costs of processing and distribution. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

Liquidity and Capital Resources

Our working capital at December 31, 2015 decreased $1.7 million to $131.8 million from $133.5 million at December 31, 2014 primarily as a result of a change in the classification of deferred tax assets from current to long-term primarily offset by increases in accounts receivable and inventory.

At December 31, 2015, we had 61 days of revenues outstanding in trade accounts receivable, an increase of 7 days compared to December 31, 2014. The increase was due to lower cash receipts from customers than shipments and corresponding billings to customers during 2015.

At December 31, 2015, we had 320 days of inventory on hand, a decrease of 9 days compared to December 31, 2014. The decrease was primarily due to higher product distributions in the fourth quarter of 2015. We believe that our inventory levels will be adequate to support our on-going operations for the next twelve months.

We had $12.6 million of cash and cash equivalents at December 31, 2015. At December 31, 2015, our foreign subsidiaries held $888,000 in cash which is not available for use in the U.S. without incurring U.S. taxes. U.S. income taxes have not been paid or accrued for on the undistributed earnings of our foreign subsidiaries. We intend to indefinitely reinvest the earnings of our foreign subsidiaries. We do not believe that our policy of indefinitely reinvesting the earnings of our foreign subsidiaries will have a material adverse effect on the business as a whole.

Our short-term and long-term obligations at December 31, 2015 increased $3.7 million to $79.6 million from $75.9 million at December 31, 2014. The increase in short- and long-term obligations was primarily due to planned additional borrowings to reduce current liabilities partially offset by principal payments on long-term obligations. On June 29, 2015, we entered into a third amendment to the second amended and restated loan agreement with TD Bank, N.A. and Regions Bank, which increased the maximum revolving credit amount from $20 million to $30 million. At December 31, 2015, we have $6.4 million of borrowing capacity available under our revolving credit facilities.

As of December 31, 2015, we believe that our working capital, together with our borrowing ability under our revolving credit facilities, will be adequate to fund our ongoing operations for the next twelve months.

On July 16, 2013, we completed our acquisition of Pioneer. Under the terms of the merger agreement dated June 12, 2013, we acquired Pioneer for $126.3 million in cash. The transaction was funded through a combination of cash on hand, a new credit facility and a concurrent private placement of convertible preferred equity as summarized below:

		(In thousands)
Cash proceeds from term loan	$	60,000
Net cash proceeds from preferred share issuance		48,710
Cash from RTI Surgical		17,597
Total purchase price	$	126,307

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The Preferred Stock accrues dividends at a rate of 6% per annum or $3.0 million payable in cash on a quarterly basis for each outstanding share of Preferred Stock. The payments of the dividends are subject to certain bank covenant restrictions. To the extent dividends are not paid in cash in any quarter, the dividends which have accrued on each outstanding share of Preferred Stock during such three-month period are accumulated and remain accumulated dividends with respect to such share of Preferred Stock until paid in cash or converted to common stock. We accrued $3.3 million, $3.1 million and $1.4 million in preferred dividends payable for the years ended December 31, 2015, 2014 and 2013, respectively, and paid the third quarter 2013 dividend of $625,000 in October 2013.

Certain Commitments.

On October 12, 2013, we entered into a distribution agreement with Medtronic, pursuant to which Medtronic will distribute certain allograft implants for use in spinal, general orthopedic and trauma surgery. Under the terms of this distribution agreement, Medtronic will be a non-exclusive distributor except for certain specified implants for which Medtronic will be the exclusive distributor. Medtronic will maintain its exclusivity with respect to these specified implants unless the cumulative fees received by us from Medtronic in respect of these specified implants decline by a certain amount during any trailing 12-month period. The initial term of this distribution agreement will continue through December 31, 2017, unless earlier terminated in accordance with the agreement. This initial term will automatically renew for successive five-year periods, unless either party provides written notice of its intent not to renew at least one year prior to the expiration of the initial term or the applicable renewal period. This distribution agreement superseded and replaced our prior distribution agreement with Medtronic which would have expired in accordance with its terms in June 2014.

On September 10, 2010, we entered into an Exclusive License Agreement with Athersys, Inc. (Athersys), pursuant to which Athersys will provide us access to its Multipotent Adult Progenitor Cell (MAPC) technologies to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications. In consideration for the Exclusive License, we agreed to pay Athersys the following: 1) a non-refundable $3.0 million license fee, payable in three time-based $1.0 million installments, the last of which was paid in the first quarter of 2011; 2) payment of $2.0 million contingent upon successful achievement of certain development milestones which we paid in 2012; and 3) up to $32.5 million contingent upon achievement of certain cumulative revenue milestones in future years. In addition, we pay Athersys royalties from the distribution of implants under a tiered royalty structure based on achievement of certain cumulative revenue milestones. The term of this license agreement is the longer of five years, or the remaining life of any patent or trade secret. These acquired licensing rights are being amortized to expense on a straight-line basis over the expected life of the asset.

On September 3, 2010, we entered into an exclusive distribution agreement with Zimmer Dental Inc. (Zimmer Dental), a subsidiary of Zimmer, with an effective date of September 30, 2010. The Agreement has an initial term of ten years. Under the terms of this distribution agreement, we agreed to supply sterilized allograft and xenograft implants at an agreed upon transfer price, and Zimmer Dental has agreed to be the exclusive distributor of the implants for dental and oral applications worldwide (except the Ukraine), subject to certain Company obligations under an existing distribution agreement with a third party with respect to certain implants for the dental market. In consideration for Zimmer Dental s exclusive distribution rights, Zimmer Dental agreed to the following: 1) payment to us of $13.0 million within ten days of the effective date (the Upfront Payment); 2) annual exclusivity fees (Annual Exclusivity Fees) paid annually for the term of the contract to be paid at the beginning of each calendar year; and, 3) escalating annual purchase minimums to maintain exclusivity. Upon occurrence of an event that materially and adversely affects Zimmer Dental s ability to distribute the implants, Zimmer Dental may be entitled to certain refund rights with respect to the Upfront Payment and the then current Annual Exclusivity Fee, where such refund would be in an amount limited by a formula specified in this agreement that is based substantially on the number of days from the occurrence of such event to the date that it is cured by us to the satisfaction of Zimmer Dental. The Upfront

Payment, the Annual Exclusivity Fees and the fees associated with distributions of processed tissue are considered to be a single unit of accounting. Accordingly, the Upfront Payment and the Annual Exclusivity Fees are deferred as received and are being recognized as other revenues over the term of this distribution agreement based on the expected contractual escalating annual purchase minimums relative to the total contractual minimum purchase requirements in this distribution agreement. Additionally, we considered the potential impact of this distribution agreement s contractual refund provisions and do not expect these provisions to impact future expected revenue related to this distribution agreement.

On July 13, 2009, we and Davol amended their previous distribution agreement with TMI for human dermis implants. Under the amended agreement: 1) Davol paid us $8.0 million in non-refundable fees for exclusive distribution rights for the distribution to the breast reconstruction market until July 13, 2019; 2) the exclusive worldwide distribution agreement related to the hernia market was extended to July 13, 2019; and 3) Davol agreed to pay us certain additional exclusive distribution rights fees contingent upon the achievement of certain revenue milestones by Davol during the duration of the contract. In the fourth quarter of 2010, Davol paid the first revenue milestone payment of $3.5 million. The non-refundable fees and the fees associated with distributions of processed tissue are considered to be a single unit of

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accounting. Accordingly, the $8.0 million and $3.5 million exclusivity payments were deferred and were being recognized as other revenues on a straight-line basis over the initial term of the amended contract of ten years, and the remaining term of the amended contract, respectively. Davol did not achieve certain revenue growth milestones which resulted in Davol relinquishing its exclusive distribution rights in the hernia market effective January 1, 2013 and in the breast reconstruction market effective January 1, 2015. As a result, the Company recognized additional deferred revenue as other revenues during the three months ended March 31, 2013 and 2015, of $1.7 million and $1.5 million, respectively, due to the acceleration of deferred revenue recognition relating to Davol relinquishing its exclusive distribution rights in the hernia and the breast reconstruction markets. The remaining balance is being recognized as other revenues on a straight-line basis over the remaining term of the amended contract.

Our debt obligations and availability of credit as of December 31, 2015 are as follows:

	Outstanding Balance	Available Credit
	(In thousands)	
Term loan	$ 54,125	$
Credit facilities	25,477	6,377
Capital leases	38	
Total	$ 79,640	$ 6,377

We obtained from TD Bank and Regions Bank, a 5-year, $80.0 million senior secured facility, which includes a $60.0 million term loan and a $20.0 million revolving credit facility that matures on July 16, 2018, with a variable interest rate between 100 and 175 basis points in excess of the one month LIBOR rate. On October 15, 2014, we entered into a second amendment to the second amended and restated loan agreement with TD Bank, N.A. and Regions Bank, which amended the loan agreement to remove certain financial covenants. On June 29, 2015, we entered into a third amendment to the second amended and restated loan agreement with TD Bank, N.A. and Regions Bank, which increased the maximum revolving credit amount from $20.0 million to $30.0 million. At December 31, 2015, the interest rate for the term loan and revolving credit facility is 1.86%. The facility is secured by substantially all the assets of the Company and its subsidiaries and guaranteed by the Company s domestic subsidiaries, other than RTIDS. As of December 31, 2015, there was $24.0 million outstanding on the revolving credit facility. The term loan facility requires aggregate principal payments of $12.8 million from March 31, 2016 through June 30, 2018, with a final balloon principal payment of $41.4 million on July 2, 2018. The credit agreement also contains various restrictive covenants which limit, among other things, indebtedness and liens, as well as payment of dividends, while requiring a minimum cash balance on hand of $10.0 million and certain financial covenant ratios. We were in compliance with all financial covenants related to our senior secured credit facility as of December 31, 2015.

In addition to the credit facility with TD Bank and Regions Bank, we have through our German subsidiary, three credit facilities with three German banks as of December 31, 2015. Under the terms of the revolving credit facilities, we may borrow up to 1.7 million Euro, or approximately $1.9 million, for working capital needs. The 1.0 million Euro revolving credit facility is secured by a mortgage on the Company s German facility. The 500,000 Euro revolving credit facility is secured by accounts receivable of the Company s German subsidiary. The 200,000 Euro revolving credit facility is unsecured. The current interest rates for these lines of credit vary from 2.55% to 8.50%. As of December 31, 2015, there was $1.5 million outstanding on revolving credit facilities with German banks.

The total available credit on our four revolving credit facilities at December 31, 2015 was $6.4 million. We were in compliance with all financial covenants related to our revolving credit facilities as of December 31, 2015.

We have capital leases with interest rates ranging from 1.49% to 2.85% and maturity dates through 2017.

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The following table provides a summary of our debt obligations, operating lease obligations and other significant obligations as of December 31, 2015.

	Contractual Obligations Due by Period					
	Total	2016	2017	2018	2019	2020 and Beyond
			(In thousands)			
Short and long-term debt obligations	$ 79,640	$ 6,009	$ 5,256	$ 68,375	$	$
Operating lease obligations	4,018	1,874	1,121	560	319	144
Purchase obligations (1)	5,301	5,301				
Unrecognized tax benefits	110			110		
Total	$ 89,069	$ 13,184	$ 6,377	$ 69,045	$ 319	$ 144

(1) These amounts consist of contractual obligations for capital expenditures and open purchase orders.

Impact of Inflation

Inflation generally affects us by increasing our cost of labor, equipment and processing tools and supplies. We do not believe that the relatively low rates of inflation experienced in the United States since the time we began operations have had any material effect on our business.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are subject to market risk from exposure to changes in interest rates based upon our financing, investing and cash management activities. We do not expect changes in interest rates to have a material adverse effect on our income or our cash flows in 2016. However, we cannot assure that interest rates will not significantly change in the future.

In the United States and Germany, we are exposed to interest rate risk. Changes in interest rates affect interest income earned on cash and cash equivalents and interest expense on revolving credit arrangements. We have not entered into derivative transactions related to cash and cash equivalents or debt. Our borrowings under our term loan and credit facilities expose us to market risk related to changes in interest rates. As of December 31, 2015, our outstanding floating rate indebtedness totaled $79.6 million. The primary base interest rate is LIBOR. Assuming the outstanding balance on our floating rate indebtedness remains constant over a year, a 100 basis point increase in the interest rate would decrease net income and cash flow by approximately $0.5 million. Other outstanding debt consists of fixed rate instruments, including capital leases. Accordingly, we are subject to changes in interest rates. Based on December 31, 2015 outstanding intercompany balances, a 1% change in interest rates would have had a de-minimis impact on our results of operations.

The value of the U.S. dollar compared to the Euro affects our financial results. Changes in exchange rates may positively or negatively affect revenues, gross margins, operating expenses and net income. The international operation currently transacts business primarily in the Euro. Assets and liabilities of foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the period. Intercompany transactions are translated from the Euro to the U.S. dollar. Based on December 31, 2015 outstanding

intercompany balances, a 1% change in currency rates would have had a de-minimis impact on our results of operations.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and supplementary data required in this item are set forth at the pages indicated in Item 15(a)(1).

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

Item 9A. CONTROLS AND PROCEDURES.

Attached as exhibits to this Form 10-K are certifications of our Chief Executive Officer and Chief Financial Officer, which are required in accordance with Rule 13a-15 of the Exchange Act. This Controls and Procedures section includes information concerning the controls and controls evaluation referred to in the certifications.

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As of the end of the period covered by this report, an evaluation was performed on the effectiveness of the design and operation of our disclosure controls and procedures under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures include controls and other procedures that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission s rules and forms, and accumulated and communicated to the Company s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective as of the end of the period covered by this report.

Changes in Internal Controls

The Company is in the process of expanding the use of the enterprise resource system, SAP. On July 1, 2015, the Company completed a phase of its implementation of SAP. The Company continues to evaluate the impact to its internal control over financial reporting due to the continuing implementation of SAP. There have been no changes in the Company s internal control over financial reporting during the Company s last fiscal quarter that materially affected, or are reasonably likely to materially affect the Company s internal control over financial reporting.

Management s Report on Effectiveness of Internal Controls

The management of RTI Surgical, Inc. and subsidiaries (the Company) is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Securities Exchange Act Rules 13a-15(f) and 15d-15(f)). The Company s internal control system was designed to provide reasonable assurance to the Company s management and board of directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company s management assessed the effectiveness of the Company s internal control over financial reporting as of December 31, 2015. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework (2013)*. Based on this assessment, management believes that, as of December 31, 2015, the Company s internal control over financial reporting is effective based on those criteria.

The Company s independent registered public accounting firm has issued a report on the Company s internal control over financial reporting. This report appears on page 44.

Item 9B. OTHER INFORMATION.

On March 7, 2016, the Company s board of directors, approved, effective immediately, the Amended and Restated Bylaws attached as Exhibit 3.2 to this Annual Report on Form 10-K. The only change made in these Amended and Restated Bylaws was to update the Company s name in the title from RTI Biologics, Inc. (the Company s prior name) to RTI Surgical, Inc.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information set forth under the caption Directors and Executive Officers in our definitive proxy statement for 2016 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2015 is incorporated by reference. Information relating to our Code of Ethics that applies to our senior financial professionals is available on our website http://www.rtix.com/investors/corporate-governance. Any amendments to, or waiver of, any provision of the Code of Ethics will be posted on our website.

Item 11. EXECUTIVE COMPENSATION.

The information set forth under the caption Executive Compensation in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2015 is incorporated by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information set forth under the captions Beneficial Ownership of Common Stock by Certain Stockholders and Management and Securities Authorized For Issuance Under Equity Compensation Plans in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2015 is incorporated by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information set forth under the caption Certain Relationships and Related Transactions, and Director Independence in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2015 is incorporated by reference.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information set forth under the caption Audit Matters in our definitive proxy statement for our 2016 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2015 is incorporated by reference.

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PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) (1) *Financial Statements*:

See Index to Consolidated Financial Statements and Financial Statement Schedule on page 43, the Independent Registered Public Accounting Firm s Report on page 44 and the Consolidated Financial Statements on pages 46 to 49, all of which are incorporated herein by reference.

(2) *Financial Statement Schedule*:

The following Financial Statement Schedule is filed as part of this Report:

Schedule II, Valuation and Qualifying Accounts for the years ended December 31, 2015, 2014 and 2013 is included in the Consolidated Financial Statements of RTI Surgical, Inc. on page 71. All other financial statement schedules are omitted because they are inapplicable, not required or the information is indicated elsewhere in the consolidated financial statements or the notes thereto.

(3) *Exhibits*:

The information required by this item is set forth on the exhibit index that follows the signature page of this report.

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

AND FINANCIAL STATEMENT SCHEDULE

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

RTI Surgical, Inc.

Alachua, Florida

We have audited the accompanying consolidated balance sheets of RTI Surgical, Inc. and subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of comprehensive income (loss), stockholders equity, and cash flows for each of the three years in the period ended December 31, 2015. Our audits also included the financial statement schedule listed in Item 15(a)(2). We also have audited the Company s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for these financial statements and the financial statement schedule, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Effectiveness of Internal Controls. Our responsibility is to express an opinion on these financial statements and the financial statement schedule and an opinion on the Company s internal control over financial reporting 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over

financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of RTI Surgical, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

As described in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for income taxes effective December 31, 2015 due to the early adoption of Accounting Standards Update No. 2015-17, *Balance Sheet Classification of Deferred Taxes* on a prospective basis.

/s/ DELOITTE & TOUCHE LLP

Certified Public Accountants

Tampa, Florida

March 7, 2016

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RTI SURGICAL, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share data)

	December 31, 2015	2014
Assets		
Current Assets:		
Cash and cash equivalents	$ 12,614	$ 15,703
Accounts receivable - less allowances of $1,454 at December 31, 2015 and $818 at December 31, 2014	47,243	38,833
Inventories - net	118,673	113,464
Prepaid and other current assets	13,184	6,668
Deferred tax assets - net		22,828
Total current assets	191,714	197,496
Property, plant and equipment - net	84,992	77,028
Deferred tax assets - net	22,385	6,193
Goodwill	54,887	54,887
Other intangible assets - net	26,213	30,261
Other assets - net	874	12,270
Total assets	$ 381,065	$ 378,135
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 20,446	$ 26,834
Accrued expenses	28,609	24,689
Current portion of deferred revenue	4,865	5,984
Current portion of short and long-term obligations	6,009	6,479
Total current liabilities	59,929	63,986
Long-term obligations - less current portion	73,631	69,413
Other long-term liabilities	472	11,607
Deferred revenue	9,354	12,460
Total liabilities	143,386	157,466
Preferred stock Series A, $.001 par value: 5,000,000 shares authorized; 50,000 shares issued and outstanding	56,323	52,834
Stockholders equity:		
Common stock, $.001 par value: 150,000,000 shares authorized; 57,803,111 and 56,917,414 shares issued and outstanding, respectively	58	57

Additional paid-in capital	417,725	415,702
Accumulated other comprehensive loss	(7,042)	(3,881)
Accumulated deficit	(228,939)	(243,854)
Less treasury stock, 230,352 and 180,898 shares, respectively, at cost	(446)	(189)
Total stockholders equity	181,356	167,835
Total liabilities and stockholders equity	$ 381,065	$ 378,135

See notes to consolidated financial statements.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)

(In thousands, except share and per share data)

	Year Ended December 31,		
	2015	**2014**	**2013**
Revenues	$ 282,293	$ 262,810	$ 197,979
Costs of processing and distribution	132,551	129,013	117,874
Gross profit	149,742	133,797	80,105
Expenses:			
Marketing, general and administrative	107,439	107,653	81,635
Research and development	15,065	15,536	15,241
Asset abandonments	814		
Litigation and settlement charges	804	185	3,000
Restructuring charges			2,881
Acquisition expenses			6,004
Severance charges	995	4,798	
Total operating expenses	125,117	128,172	108,761
Operating income (loss)	24,625	5,625	(28,656)
Other (expense) income:			
Interest expense	(1,492)	(1,357)	(542)
Interest income	3	9	23
Foreign exchange gain (loss)	78	(88)	251
Total other expense - net	(1,411)	(1,436)	(268)
Income (loss) before income tax (provision) benefit	23,214	4,189	(28,924)
Income tax (provision) benefit	(8,299)	(1,493)	11,110
Net income (loss)	14,915	2,696	(17,814)
Convertible preferred dividend	(3,305)	(3,113)	(1,375)
Net income (loss) applicable to common shares	$ 11,610	$ (417)	$ (19,189)
Other comprehensive (loss) gain:			
Unrealized foreign currency translation (loss) gain	(3,161)	(3,069)	964
Comprehensive income (loss)	$ 8,449	$ (3,486)	$ (18,225)

Net income (loss) per common share - basic	$ 0.20	$ (0.01)	$ (0.34)
Net income (loss) per common share - diluted	$ 0.20	$ (0.01)	$ (0.34)
Weighted average shares outstanding - basic	57,611,231	56,735,924	56,258,624
Weighted average shares outstanding - diluted	58,590,494	56,735,924	56,258,624

See notes to consolidated financial statements.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders Equity

(In thousands)

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock	Total
Balance, January 1, 2013	$ 56	$ 414,482	$ (1,776)	$ (228,736)	$ (34)	$ 183,992
Net loss				(17,814)		(17,814)
Foreign currency translation adjustment			964			964
Exercise of common stock options		332				332
Stock-based compensation		2,220				2,220
Purchase of treasury stock					(33)	(33)
Amortization of preferred stock Series A issuance costs		(77)				(77)
Preferred stock Series A dividend		(1,375)				(1,375)
Change in income tax benefit from stock-based compensation		(156)				(156)
Balance, December 31, 2013	56	415,426	(812)	(246,550)	(67)	168,053
Net income				2,696		2,696
Foreign currency translation adjustment			(3,069)			(3,069)
Exercise of common stock options	1	888				889
Stock-based compensation		3,032				3,032
Purchase of treasury stock					(122)	(122)
Amortization of preferred stock Series A issuance costs		(184)				(184)
Preferred stock Series A dividend		(3,113)				(3,113)
Change in income tax benefit from stock-based compensation		(347)				(347)
Balance, December 31, 2014	57	415,702	(3,881)	(243,854)	(189)	167,835
Net income				14,915		14,915
Foreign currency translation adjustment			(3,161)			(3,161)
Exercise of common stock options	1	2,504				2,505
Stock-based compensation		2,858				2,858
Purchase of treasury stock					(257)	(257)
		(186)				(186)

Amortization of preferred stock Series A issuance costs						
Preferred stock Series A dividend		(3,305)				(3,305)
Change in income tax benefit from stock-based compensation		152				152
Balance, December 31, 2015	$ 58	$ 417,725	$ (7,042)	$ (228,939)	$ (446)	$ 181,356

See notes to consolidated financial statements.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Cash flows from operating activities:			
Net income (loss)	$ 14,915	$ 2,696	$ (17,814)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	16,522	15,395	12,202
Provision for bad debts and product returns	1,568	891	435
Provision for inventory write-downs	5,390	3,763	1,785
Amortization of deferred revenue	(6,225)	(5,420)	(6,451)
Deferred income tax provision (benefit)	5,543	502	(11,544)
Stock-based compensation	2,548	3,032	2,220
Other	2,280	958	227
Change in assets and liabilities:			
Accounts receivable	(10,435)	(8,058)	(50)
Inventories	(11,990)	(11,244)	5,231
Accounts payable	(12,660)	4,087	5,276
Accrued expenses	5,532	1,375	(3,247)
Deferred revenue	2,000		6,000
Other operating assets and liabilities	(5,992)	(1,083)	1,276
Net cash provided by (used in) operating activities	8,996	6,894	(4,454)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(17,740)	(15,577)	(15,011)
Patent and acquired intangible asset costs	(498)	(737)	(915)
Acquisition of Pioneer Surgical Technology			(126,307)
Net cash used in investing activities	(18,238)	(16,314)	(142,233)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	2,505	889	332
Proceeds from long-term obligations	8,750	7,000	68,250
Net proceeds from short-term obligations	422	658	638
Payment of debt issuance costs			(699)
Proceeds from preferred stock issuance			50,000
Payment of preferred stock issuance costs			(1,290)
Payment of preferred stock dividend			(625)
Payments on long-term obligations	(5,294)	(682)	(142)
Other financing activities	(109)	5	(841)

Net cash provided by financing activities	6,274	7,870	115,623
Effect of exchange rate changes on cash and cash equivalents	(121)	(1,468)	89
Net decrease in cash	(3,089)	(3,018)	(30,975)
Cash and cash equivalents, beginning of period	15,703	18,721	49,696
Cash and cash equivalents, end of period	$ 12,614	$ 15,703	$ 18,721
Supplemental cash flow disclosure:			
Cash paid for interest	$ 1,425	$ 1,624	$ 570
Cash paid for income taxes, net of refunds	3,667	578	2,819
Non-cash acquisition of property, plant and equipment	3,795	1,947	1,557
Stock-based compensation related to severance	310		
Change in accrual for dividend payable	3,305	3,113	750

See notes to consolidated financial statements.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Years Ended December 31, 2015, 2014 and 2013

(In thousands, except share and per share data)

1. Business

RTI Surgical, Inc. (the Company), and its subsidiaries recover and process human and animal tissue and manufacture metal and synthetic implants and instruments. The processing transforms the tissue into either conventional or precision machined allograft implants (human) or xenograft implants (animal). The implants are used for orthopedic and other surgical applications to promote the natural healing of human bone and other human tissue. These implants are distributed domestically and internationally, for use in reconstruction and fracture repair.

2. Summary of Significant Accounting Policies

Principles of Consolidation The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Pioneer Surgical Technology, Inc. (Pioneer), Tutogen Medical, Inc. (TMI), RTI Biologics, Inc. Cardiovascular (inactive), Biological Recovery Group (inactive), and RTI Services, Inc. The consolidated financial statements also include the accounts of RTI Donor Services, Inc. (RTIDS), which is a controlled entity. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). All intercompany balances and transactions have been eliminated in consolidation.

RTIDS is a taxable not-for-profit entity organized and controlled by the Company. RTIDS is the corporate entity that is responsible for procuring tissue for the Company. Expenses incurred by RTIDS to procure tissue are passed through to the Company. RTIDS has no significant assets or liabilities except for its intercompany accounts receivable and accounts payable to tissue recovery agencies. The Company pays all expenses of RTIDS.

Use of Estimates The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions relating to inventories, receivables, long-lived assets, investment valuations and litigation are made at the end of each financial reporting period by management. Actual results could differ from those estimates.

Foreign Currency Translation The functional currency of the Company s foreign subsidiaries is the Euro. Assets and liabilities of the foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the period. The resulting translation adjustments, representing unrealized, noncash gains and losses are recorded and presented as a component of comprehensive income (loss). Gains and losses resulting from transactions of the Company and its subsidiaries, which are made in currencies different from their own, are included in income or loss as they occur and are included in other (expense) income in the consolidated statements of comprehensive income (loss).

Fair Value of Financial Instruments The estimated fair value of financial instruments disclosed in the consolidated financial statements has been determined by using available market information and appropriate valuation

methodologies. The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature. The carrying value of the long-term debt obligations approximates fair value. The carrying value of capital lease obligations approximates their fair value, based on current market prices.

Cash and Cash Equivalents The Company considers all funds in banks and short-term highly liquid investments with an original maturity of three months or less to be cash and cash equivalents. Cash equivalents comprise overnight repurchase agreements. Cash balances are held at a few financial institutions and usually exceed insurable amounts. The Company mitigates this risk by depositing its uninsured cash in major well capitalized financial institutions, and by investing excess operating cash in overnight repurchase agreements which are 101% collateralized by U.S. Government backed securities with the Company s bank. At December 31, 2015 and 2014, the Company had no cash equivalents.

Accounts Receivable Allowances The Company maintains allowances for doubtful accounts based on the Company s review and assessment of payment history and its estimate of the ability of each customer to make payments on amounts invoiced. If the financial condition of any of its customers were to deteriorate, additional allowances might be required. From time to time the Company must adjust its estimates. Changes in estimates of the collection risk related to accounts receivable can result in decreases and increases to current period net income.

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Inventories Inventories are stated at the lower of cost or market, with cost determined using the first-in, first-out method. Inventory writedowns for unprocessed donor tissue are recorded based on the estimated amount of inventory that will not pass the quality control process based on historical data, and the amount of inventory that is not readily distributable or is unusable. In addition, provisions for inventory writedowns are estimated for tissue in process inventory that is not readily distributable or is unusable. Any implantable donor tissue deemed to be obsolete is included in the writedown at the time the determination is made. Non-tissue inventory is evaluated for obsolescence and excess quantities by analyzing inventory levels, historical loss trends, expected product lives, product at risk of expiration, sales levels by product and projections of future sales demand.

Implant and Product Recalls The Company accrues the estimated cost of recalls at the date the recall is initiated. The cost of recalls is primarily comprised of implant replacement costs. The Company incurred immaterial costs related to all of the recalls for the years ended December 31, 2015, 2014 and 2013.

Surgical Instruments Surgical instruments which are included in property, plant and equipment are handheld devices used by surgeons during implant procedures. The Company retains title to the surgical instruments. Depreciation for surgical instruments is included in selling and marketing expenses in the accompanying consolidated statements of comprehensive income (loss).

Property, Plant and Equipment Property, plant and equipment are stated at cost less accumulated depreciation. The cost of equipment under capital leases and leasehold improvements is amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset. Depreciation is computed on the straight-line method over the following estimated useful lives of the assets:

Buildings	25 to 40 years
Building improvements and leasehold improvements	8 to 40 years
Processing equipment	7 to 10 years
Office equipment, furniture and fixtures	5 to 7 years
Computer hardware and software	3 to 7 years
Surgical instruments	3 years

Software Costs Included in property, plant and equipment are costs related to purchased software that are capitalized.

Debt Issuance Costs Debt issuance costs include costs incurred to obtain financing and are amortized using the straight-line method, which approximates the effective interest method, over the life of the related debt. Debt issuance costs are included in prepaid and other current assets and other assets - net in the accompanying consolidated balance sheets.

Long-Lived Assets The Company periodically evaluates the period of depreciation or amortization for long-lived assets to determine whether current circumstances warrant revised estimates of useful lives. The Company reviews its property, plant and equipment for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to the net undiscounted cash flows expected to be generated by the asset. An impairment loss would be recorded for the excess of net carrying value over the fair value of the asset impaired. The fair value is estimated based on expected discounted future cash flows. The results of impairment tests are subject to management s estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and the likelihood of materially different reported results. The Company abandoned $814 of certain long-term assets at our German facility for the year ended December 31, 2015.

Goodwill FASB Accounting Standards Codification (ASC) 350, *Goodwill and Other Intangible Assets* (FASB ASC 350), requires companies to test goodwill for impairment on an annual basis at the reporting unit level (or an interim basis if an event occurs that might reduce the fair value of a reporting unit below its carrying value). The Company has one reporting unit and the annual impairment test is performed at each year-end unless indicators of impairment are present and require more frequent testing. The Company did not have any other identifiable intangible assets with indefinite useful lives as of December 31, 2015 and 2014.

Goodwill is tested for impairment annually by comparing the fair value of the reporting unit to its carrying amount, including goodwill. The Company adopted ASU No. 2011-08, *Intangibles Goodwill and Other: Testing*

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Goodwill for Impairment, which permits the consideration of qualitative indicators of the fair value of a reporting unit when it is unlikely that a reporting unit has impaired goodwill. If the Company determines the fair value is more-likely- than-not greater than its carrying amount, no additional testing is considered necessary. However, if the Company determines the fair value is more-likely-than-not below the carrying value of the reporting unit, the Company performs the two step goodwill impairment test. If the two step goodwill impairment test is required, an income approach and a market approach are utilized. The conclusion from these two approaches are generally weighted equally and then adjusted to incorporate a control premium or acquisition premium that reflects the additional amount a buyer is willing to pay for elements of control and for a premium that reflects the buyer s perception of its ability to add value through synergies.

In general, the income approach employs a discounted cash flow model that considers: 1) assumptions that marketplace participants would use in their estimates of fair value, including the cash flow period, terminal values based on a terminal growth rate and the discount rate; 2) current period actual results, and 3) projected results for future periods that have been prepared and approved by senior management of the Company. The forecasted cash flows do not include synergies that a marketplace participant would be expecting to achieve.

The market approach employs market multiples from guideline public companies operating in our industry. Estimates of fair value are derived by applying multiples based on revenue and earnings before interest, taxes, depreciation and amortization (EBITDA) adjusted for size and performance metrics relative to peer companies. A control premium was included in determining the fair value under this approach.

If the carrying amount of the reporting unit exceeds its calculated fair value, the second step of the goodwill impairment test is performed in accordance with FASB ASC 350 to measure the amount of the impairment loss, if any.

Both approaches used in the analysis have a degree of uncertainty. Potential events or changes in circumstances which could impact the key assumptions used in our goodwill impairment evaluation are as follows:

Change in peer group or performance of peer group companies

Change in the Company s markets and estimates of future operating performance

Change in the Company s estimated market cost of capital

Change in implied control premiums related to acquisitions in the medical device industry.

Goodwill represents the excess of purchase price over fair value of tangible net assets of acquired businesses at the acquisition date, after amounts allocated to other identifiable intangible assets. Factors that contribute to the recognition of goodwill include securing synergies that are specific to our business and not available to other market participants and are expected to increase revenues and profits; acquisition of a talented workforce; cost savings opportunities; the strategic benefit of expanding our presence in core and adjacent markets; and diversifying our product portfolio.

Other Intangible Assets Other intangible assets, which constitutes finite lives assets, generally consist of patents, acquired exclusivity rights, licensing rights, trademarks, customer lists, non-compete agreements, distribution agreements, and procurement contracts. Patents and trademarks are amortized on the straight-line method over the shorter of the remaining protection period or estimated useful lives of between 8 and 16 years. The acquired exclusivity rights are being amortized over eight years, the remaining term of the amended distribution agreement. Licensing rights, customer lists, non-compete agreements, distribution agreements, and procurement contracts are amortized over estimated useful lives of between 5 to 25 years.

Other intangible assets are tested for impairment annually (if indefinite lived) or whenever events or circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The Company had one asset group for the year ended December 31, 2014 and 2015. The recoverability test is described in the Company s accounting policy for long-lived assets set forth above.

Revenue Recognition Revenue is recognized upon shipping, or receipt by the Company s customers of the implant, depending on the Company s distribution agreements with the Company s customers or distributors. Other revenues are recognized when all significant contractual obligations have been satisfied.

The Company permits returns of implants in accordance with the terms of contractual agreements with customers if the implant is returned in a timely manner, in unopened packaging, and from the normal channels of distribution. Allowances for returns are provided based upon analysis of the Company s historical patterns of returns matched against the revenues from which they originated.

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The Company records estimated implant returns, discounts, rebates and other distribution incentives as a reduction of revenue in the same period revenue is recognized. Estimates of implant returns are recorded for anticipated implant returns based on historical distributions and returns information. Estimates of discounts, rebates and other distribution incentives are recorded based on contractual terms, historical experience and trend analysis.

Other Revenues Other revenues consists of service processing, tissue recovery fees, biomedical laboratory fees, recognition of previously deferred revenues, shipping fees, distribution of reproductions of our allografts to distributors for demonstration purposes and restocking fees.

Stock-Based Compensation Plans The Company accounts for its stock-based compensation plans in accordance with FASB ASC 718, *Accounting for Stock Compensation*. FASB ASC 718 requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and restricted stock. Under the provisions of FASB ASC 718, and U.S. Securities and Exchange Commission *Staff Accounting Bulletin No. 107*, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight-line basis over the requisite service period of the entire award (generally the vesting period of the award). The Company uses the Black-Scholes model to value its stock option grants under FASB ASC 718 and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of stock options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk free interest rate. The term assumption is primarily based on the contractual vesting term of the option and historic data related to exercise and post-vesting cancellation history experienced by the Company. The Company uses the simplified method for estimating the expected term used to determine the fair value of options under FASB ASC 718. The expected term is determined separately for options issued to the Company s directors and to employees. The Company s anticipated volatility level is primarily based on the historic volatility of the Company s common stock. The Company s model includes a zero dividend yield assumption, as the Company has not historically paid nor does it anticipate paying dividends on its common stock. The risk free interest rate approximates recent U.S. Treasury note auction results with a similar life to that of the option. The Company s model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions. The period expense is then determined based on the valuation of the options, and at that time an estimated forfeiture rate is used to reduce the expense recorded. The Company s estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company, and is adjusted to reflect actual forfeitures as the options vest.

Research and Development Costs Research and development costs, including the cost of research and development conducted for others and the cost of contracted research and development, are expensed as incurred.

Income Taxes The Company uses the asset and liability method of accounting for income taxes. Deferred income taxes are recorded to reflect the tax consequences on future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts which are more likely than not to be realized.

Earnings Per Share Basic earnings per share (EPS) is computed by dividing earnings attributable to common stockholders by the weighted-average number of common shares outstanding for the periods. Diluted EPS reflects the potential dilution of securities that could share in the earnings. A reconciliation of the number of common shares used in the calculation of basic and diluted EPS is presented below:

	Year Ended December 31,		
	2015	2014	2013
Basic shares	57,611,231	56,735,924	56,258,624
Effect of dilutive securities:			
Stock options	979,263		
Diluted shares	58,590,494	56,735,924	56,258,624

Options to purchase 5,661,514 shares of common stock at prices ranging from $2.69 to $9.57 per share which were outstanding as of December 31, 2015, were included in the computation of diluted EPS because dilutive shares are factored into the calculation of EPS when income applicable to common shares is reported.

Options to purchase 5,735,784 shares of common stock at prices ranging from $2.69 to $9.57 per share which were outstanding as of December 31, 2014, were not included in the computation of diluted EPS because dilutive shares are not factored into the calculation of EPS when a loss applicable to common shares is reported as they would be anti-dilutive.

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Options to purchase 5,518,604 shares of common stock at prices ranging from $2.54 to $13.52 per share which were outstanding as of December 31, 2013, were not included in the computation of diluted EPS because dilutive shares are not factored into the calculation of EPS when a loss applicable to common shares is reported as they would be anti-dilutive.

For the years ended December 31, 2015, 2014 and 2013, 50,000 shares of convertible preferred stock and accrued but unpaid dividends were anti-dilutive on an as if-converted basis and were not included in the computation of diluted net income (loss) per common share.

3. Recently Issued Accounting Standards.

Leases In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02 (ASU 2016-02), *Leases (Topic 842)*, which supersedes existing guidance on accounting for leases in *Leases (Topic 840)* and generally requires all leases to be recognized in the statement of financial position. The provisions of ASU 2016-02 are effective for reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of this ASU are to be applied using a modified retrospective approach. The Company is currently evaluating the effect that this ASU will have on its consolidated financial statements.

Income Taxes On November 20, 2015, the FASB issued ASU Update No. 2015-17, *Income Taxes (Topic 740)* . Update No. 2015-17 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years. The Company early adopted ASU 2015-17 effective December 31, 2015 on a prospective basis. Adoption of this ASU resulted in a reclassification of the Company s net current deferred tax assets to net non-current deferred tax assets in its consolidated balance sheet as of December 31, 2015. No prior periods were retrospectively adjusted as allowed by this ASU.

Simplifying the Measurement of Inventory In July 2015, the FASB issued ASU Update No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* . Update No. 2015-11 more closely aligns the measurement of inventory in U.S. GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated distribution prices of the inventory in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Update No. 2015-11 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years. Update No. 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company is evaluating the impact of this ASU on its financial position, results of operations, and cash flows and has not yet determined if it will early adopt the ASU.

Presentation of Financial Statements - Going Concern In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40).* The new guidance addresses management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. Management s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company does not expect to early adopt this guidance and does not believe that the adoption of this guidance will have a material impact on its consolidated financial statements.

Revenue from Contracts with Customers In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* , which supersedes the revenue recognition requirements in Accounting

Standards Codification (ASC) Topic 605, *Revenue Recognition* . This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. As updated in August 2015, the effective date will be annual reporting periods beginning after December 15, 2017, using one of two retrospective application methods. The Company has not yet determined the potential effects, if any, on its financial position, results of operations, and cash flows.

4. Merger with Pioneer Surgical Technology, Inc.

On July 16, 2013, the Company completed its acquisition of Pioneer. Under the terms of the merger agreement dated June 12, 2013, the Company acquired Pioneer for $126,307 in cash. The transaction was funded through a combination of cash on hand, a new credit facility and a concurrent private placement of convertible preferred equity. The Company obtained from Toronto-Dominion Bank, N.A., TD Securities USA LLC (TD Bank) and Regions Bank, a 5-year, $80,000 senior secured facility, which includes a $60,000 term loan and a $20,000 revolving credit facility, that matures on July 16, 2018 with a variable interest rate between 100 and 300 basis points in excess of the one month LIBOR rate. On June 29, 2015, the Company entered into a third amendment to the second amended and restated loan agreement with TD Bank and Regions Bank, which increased the maximum revolving credit amount from $20,000 to $30,000.

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Additionally, the Company received $50,000 in gross proceeds from a private placement of convertible preferred equity to WSHP Biologics Holdings, LLC, (WSHP), a leading healthcare-focused private equity firm. The convertible preferred stock is convertible into shares of the Company s common stock. The convertible preferred stock will also accrue dividends at a rate of 6% per year. In 2013, the Company capitalized $1,989 in financing costs associated with the preferred stock issuance and the debt issuance and expensed $6,004 of acquisition costs. The acquisition costs are reflected separately in the accompanying Consolidated Statements of Comprehensive Income (Loss).

The Company has accounted for the acquisition of Pioneer under ASC 805, *Business Combinations*. Pioneer s results of operations are included in the consolidated financial statements for periods ending after July 16, 2013, the acquisition date.

The purchase price was financed as follows:

		(In thousands)
Cash proceeds from term loan	$	60,000
Net cash proceeds from preferred share issuance		48,710
Cash from RTI Surgical		17,597
Total purchase price	$	126,307

The table below represents an allocation of the total consideration to Pioneer s tangible and intangible assets and liabilities based on management s estimate of their respective fair values as of July 16, 2013.

		(In thousands)
Inventories	$	35,972
Accounts receivable		10,567
Other current assets		6,059
Property, plant and equipment		15,258
Other assets		13,260
Current liabilities		(10,893)
Other long-term liabilities		(19,841)
Net tangible assets acquired		50,382
Other intangible assets		23,100
Goodwill		52,825
Total net assets acquired	$	126,307

Total net assets acquired as of July 16, 2013, are all part of the Company s only operating segment. Fair values are based on management s estimates and assumptions including variations of the income approach, the cost approach and the market approach.

The Company believes that the acquisition of Pioneer has offered and continues to offer the potential for substantial strategic and financial benefits. The transaction will enhance the Company s existing core competency in biologics

processing with the addition of Pioneer s core competency in metals and synthetics. The Company believes the acquisition will enhance stockholder value through, among other things, enabling the Company to capitalize on the following strategic advantages and opportunities:

Diversification of its implant portfolio.

Expansion of its direct distribution and marketing organizations.

Enhancement of its current international business.

Improvement of its margin profile and additional revenue opportunities.

These potential benefits resulted in the Company paying a premium for Pioneer resulting in the recognition of goodwill. The $52,825 of goodwill was assigned to the Company s only operating segment and reporting unit.

The fair value of receivables acquired is $10,567, with the gross contractual amount being $11,712, of which $1,145 was not expected to be collected.

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The amount of Pioneer s revenues and net income since the July 16, 2013 acquisition date, included in the Company s Consolidated Statement of Comprehensive (Loss) Income for the year ended December 31, 2013, are $35,994 and $894, respectively.

The following unaudited pro forma information shows the results of the Company s operations as though the acquisition had occurred as of the beginning of that period (in thousands, except per share data):

	December 31, 2013
Revenues	$ 243,001
Net loss applicable to common shares	(5,597)
Basic net loss per share	(0.10)
Diluted net loss per share	(0.10)

The unaudited pro forma results have been prepared for comparative purposes only and are not necessarily indicative of the actual results of operations had the merger taken place as of the beginning of the periods presented, or the results that may occur in the future.

These amounts have been calculated to reflect the additional depreciation, amortization, preferred dividend, and interest expense that would have been incurred assuming the fair value of adjustments and borrowings occurred on January 1, 2013, together with the consequential tax effects. In addition, these amounts exclude costs incurred which are directly attributable to the acquisition, and which do not have a continuing impact on the combined companies operating results.

The Company completed its analysis of the purchase price allocation in the third quarter of 2014.

5. Stock-Based Compensation

The Company has six stock-based compensation plans (although it may currently issue awards only under one of such plans). The Company s policy is to grant stock options at an exercise price equal to 100% of the market value of a share of common stock at closing on the date of the grant. The Company s stock options generally have ten-year contractual terms and vest over a one to five year period from the date of grant. The Company s policy is to grant restricted stock awards at a fair value equal to 100% of the market value of a share of common stock at closing on the date of the grant. The Company s restricted stock awards generally vest over one to three year periods.

2015 Incentive Compensation Plan On April 14, 2015, the Company s stockholders approved and adopted the 2015 Incentive Compensation Plan (the 2015 Plan). The 2015 Plan provides for the grant of incentive and nonqualified stock options and restricted stock to key employees, including officers and directors of the Company and consultants and advisors. The 2015 Plan allows for up to 4,656,587 shares of common stock to be issued with respect to awards granted.

1998 Stock Option Plan, 2004 Equity Incentive Plan, 2010 Equity Incentive Plan, TMI 1996 Stock Option Plan and TMI 2006 Incentive and Non-Statutory Stock Option Plan The Company adopted equity incentive plans in 1998 (the 1998 Plan), 2004 (the 2004 Plan) and 2010 (the 2010 Plan) and in connection with the merger with TMI in 2008, the Company assumed the TMI 1996 Stock Option Plan (the 1996 Plan) and the TMI 2006 Incentive and Non-Statutory Stock Option Plan (the 2006 Plan), which provided for the grant of incentive and nonqualified stock options and restricted stock to key employees, including officers and directors of the Company and consultants and

advisors. With the adoption of the 2015 Plan, new stock options and restricted stock may no longer be awarded under the 1998 Plan, 2004 Plan, 2010 Plan, 1996 Plan or the 2006 Plan.

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The following weighted-average assumptions were used to determine the fair value of options under FASB ASC 718:

	Year Ended December 31,		
	2015	2014	2013
Expected term (years)	6.50	6.50	6.50
Risk free interest rate	1.67%	2.29%	1.30%
Volatility factor	46.29%	46.53%	47.50%
Dividend yield			

Stock Options

Stock options outstanding, exercisable and available for grant at December 31, 2015, are summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2015	5,735,784	$ 4.34		
Granted	950,000	5.27		
Exercised	(858,130)	4.30		
Forfeited or expired	(166,140)	4.82		
Outstanding at December 31, 2015	5,661,514	$ 4.49	5.75	$ 1,544
Vested or expected to vest at December 31, 2015	5,394,566	$ 4.48	5.61	$ 1,517
Exercisable at December 31, 2015	3,435,614	$ 4.56	4.21	$ 1,188
Available for grant at December 31, 2015	4,530,421			

The aggregate intrinsic value in the tables above represents the total pre-tax intrinsic value of stock options for which the fair market value of the underlying common stock exceeded the respective stock option exercise price.

For the years ended December 31, 2015, 2014 and 2013, the Company recognized stock-based compensation as follows:

	Year Ended December 31,		
	2015	2014	2013
Stock-based compensation:			
Costs of processing and distribution	$ 132	$ 132	$ 132

Marketing, general and administrative	2,356	2,840	2,028
Research and development	60	60	60
Total	$ 2,548	$ 3,032	$ 2,220

For the years ended December 31, 2015, 2014, and 2013, the Company recognized total income tax benefits from stock-based compensation of $1,022, $1,198, and $883, respectively.

As of December 31, 2015, there was $3,241 of total unrecognized stock-based compensation related to nonvested stock options. That expense is expected to be recognized over a weighted-average period of 3.12 years.

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Other information concerning stock options are as follows:

	Year Ended December 31,		
	2015	2014	2013
Weighted average fair value of stock options granted	$ 2.50	$ 1.87	$ 1.66
Aggregate intrinsic value of stock options exercised	1,584	295	117

The aggregate intrinsic value of stock options exercised in a period represents the pre-tax cumulative difference between the fair market value of the underlying common stock and the stock option exercise prices, of the stock options exercised during the period.

Restricted Stock Awards

During 2015, the Company granted 201,166 shares of restricted stock with a weighted-average grant date fair value of $5.43 per share. As of December 31, 2015, there was $705 of total unrecognized stock-based compensation related to time-based, nonvested restricted stock. That expense is expected to be recognized on a straight-line basis over a weighted-average period of 1.12 years.

6. Inventories

Inventories by stage of completion are as follows:

	December 31,	
	2015	2014
Unprocessed tissue, raw materials and supplies	$ 33,028	$ 31,626
Tissue and work in process	36,614	44,688
Implantable tissue and finished goods	49,031	37,150
	$ 118,673	$ 113,464

For the years ended December 31, 2015, 2014, and 2013, the Company had inventory write-downs of $5,390, $3,763 and $1,785, respectively, relating primarily to product obsolescence.

7. Property, Plant and Equipment

Property, plant and equipment are as follows:

	December 31,	
	2015	2014
Land	$ 2,319	$ 2,474
Buildings and improvements	63,699	49,483
Processing equipment	41,831	45,878
Surgical instruments	15,702	9,428

Office equipment, furniture and fixtures	4,657	3,863
Computer equipment and software	11,804	7,674
Construction in process	10,850	20,957
Office equipment under capital leases	152	152
	151,014	139,909
Less accumulated depreciation	(66,022)	(62,881)
	$ 84,992	$ 77,028

For the years ended December 31, 2015, 2014, and 2013, the Company had depreciation expense in connection with property, plant and equipment of $12,240, $11,010, and $8,267, respectively.

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8. Goodwill

Goodwill for both years ended December 31, 2015 and 2014 was $54,887. The Company performed its annual goodwill impairment test as of December 31, 2015, and concluded that there was no impairment of goodwill.

9. Other Intangible Assets

Other intangible assets are as follows:

	December 31, 2015		December 31, 2014	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	$ 11,532	$ 3,448	$ 11,420	$ 2,727
Acquired licensing rights	10,850	7,691	10,850	6,538
Marketing and procurement intangible assets	22,179	7,209	22,342	5,086
Total	$ 44,561	$ 18,348	$ 44,612	$ 14,351

For the years ended December 31, 2015, 2014, and 2013, the Company had amortization expense of other intangible assets of $4,282, $4,385, and $3,935, respectively. At December 31, 2015, management s estimates of future amortization expense for the next five years are as follows:

	Amortization Expense
2016	$ 3,400
2017	3,300
2018	3,300
2019	3,300
2020	3,300
	$ 16,600

10. Other Assets

Other assets are as follows:

	December 31,	
	2015	2014
Indemnification asset	$	$ 11,394
Other	874	876

	$ 874	$ 12,270

Under the Pioneer acquisition agreement as described in Note 4, Pioneer deposited $13,000 in an escrow account and indemnified the Company for up to $13,000 for various outstanding and potential legal issues. At acquisition, the Company recorded a $13,000 indemnification asset and a corresponding $13,000 indemnification liability. Under the acquisition agreement, the Company submitted claims against the escrow account during the initial escrow period which ended on October 16, 2014. Under certain provisions of the agreement, the claims period for certain claims may be extended to 30 months after the closing date. Claims made against the escrow that remain unresolved at the end of the claims period will be retained in escrow until resolved. During the fourth quarter of 2015, the Company successfully resolved certain claims. The Company expects to resolve the remaining claims within the next 12 months, and as such has reclassified the remaining indemnification asset and liability to prepaid and other current assets and accrued expenses, respectively.

Interest expense associated with the amortization of debt issuance costs for the years ended December 31, 2015, 2014 and 2013 was $148, $142 and $57, respectively. The remaining unamortized debt issuance costs are included in Other in the table above.

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11. Accrued Expenses

Accrued expenses are as follows:

	December 31,	
	2015	2014
Accrued compensation	$ 4,740	$ 6,220
Accrued severance charges	717	2,771
Accrued distributor commissions	3,835	3,159
Accrued donor recovery fees	7,144	3,249
Accrued taxes	514	1,249
Accrued restructuring charges		13
Accrued indemnification liability	6,579	
Other	5,080	8,028
	$ 28,609	$ 24,689

The Company accrues for the estimated donor recovery fees due to third party recovery agencies as tissue is received.

12. Short and Long-Term Obligations

Short and long-term obligations are as follows:

	December 31,	
	2015	2014
Term loan	$ 54,125	$ 59,375
Credit facilities	25,477	16,435
Capital leases	38	82
Total	79,640	75,892
Less current portion	(6,009)	(6,479)
Long-term portion	$ 73,631	$ 69,413

The Company obtained from TD Bank and Regions Bank, a 5-year, $80,000 senior secured facility, which includes a $60,000 term loan and a $20,000 revolving credit facility that matures on July 16, 2018, with a variable interest rate between 100 and 175 basis points in excess of the one month LIBOR rate. On October 15, 2014, the Company entered into a second amendment to the second amended and restated loan agreement with TD Bank, N.A. and Regions Bank, which amended the loan agreement to remove certain financial covenants. On June 29, 2015, the Company entered into a third amendment to the second amended and restated loan agreement with TD Bank, N.A. and Regions Bank, which increased the maximum revolving credit amount from $20,000 to $30,000. At December 31, 2015, the interest rate for the term loan and revolving credit facility is 1.86%. The facility is secured by substantially all the assets of the Company and its subsidiaries and guaranteed by the Company s domestic subsidiaries, other than RTIDS. As of December 31, 2015, there was $24,000 outstanding on the revolving credit facility. The term loan facility requires

aggregate principal payments of $18,000 from January 1, 2015 through June 30, 2018, with a final balloon principal payment at the end of the loan agreement. The credit agreement also contains various restrictive covenants which limit, among other things, indebtedness and liens, as well as payment of dividends, while requiring a minimum cash balance on hand of $10,000 and certain financial covenant ratios. The Company was in compliance with all financial covenants related to its senior secured credit facility as of December 31, 2015.

In addition to the credit facility with TD Bank and Regions Bank, the Company has through its German subsidiary, three credit facilities with three German banks as of December 31, 2015. Under the terms of the revolving credit facilities, the Company may borrow up to 1,700 Euro, or approximately $1,854, for working capital needs. The 1,000 Euro revolving credit facility is secured by a mortgage on the Company s German facility. The 500 Euro revolving credit facility is secured by accounts receivable of the Company s German subsidiary. The 200 Euro revolving credit facility is unsecured. The current interest rates for these lines of credit vary from 2.55% to 8.50%. As of December 31, 2015, there was $1,477 outstanding on revolving credit facilities with German banks.

The total available credit on the Company s four revolving credit facilities at December 31, 2015 was $6,377. The Company was in compliance with all financial covenants related to its revolving credit facilities as of December 31, 2015.

The Company has capital leases with interest rates ranging from 1.49% to 2.85% and maturity dates through 2017. The $38 representing future maturities of capital leases includes immaterial interest at December 31, 2015. The present value of minimum lease payments as of December 31, 2015 was $38.

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As of December 31, 2015, contractual maturities of short and long-term obligations are as follows:

	Term Loan	Credit Facilities	Capital Leases	Total
2016	$ 4,500	$ 1,477	$ 32	$ 6,009
2017	5,250		6	5,256
2018	44,375	24,000		68,375
	$ 54,125	$ 25,477	$ 38	$ 79,640

13. Other Long-Term Liabilities

Other long-term liabilities are as follows:

	December 31, 2015	2014
Indemnification liability	$	$ 11,394
Other	472	213
	$ 472	$ 11,607

As described in Note 10, the Company has reclassified the remaining indemnification liability to accrued expenses.

14. Income Taxes

The Company s income tax (provision) benefit consists of the following components:

	Year Ended December 31, 2015	2014	2013
Current:			
Federal	$ (988)	$ (1,062)	$ 127
State	(159)	(150)	167
International	(544)	(86)	219
Total current	(1,691)	(1,298)	513
Deferred:			
Federal	(5,695)	(1,118)	8,017
State	68	(76)	1,675
International	(981)	999	905
Total deferred	(6,608)	(195)	10,597

Total income tax (provision) benefit	$ (8,299)	$ (1,493)	$ 11,110

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The components of the deferred tax assets and liabilities consisted of the following at:

	December 31, 2015 Deferred Income Tax		December 31, 2014 Deferred Income Tax	
	Assets	Liabilities	Assets	Liabilities
Current:				
Allowance for bad debts	$	$	$ 415	$
Inventory			11,513	
Net operating losses			340	
Tax credits			2,370	
Deferred compensation			3,912	
Deferred revenue			1,969	
Accrued liabilities			2,517	
Other				(208)
Total current			23,036	(208)
Noncurrent:				
Allowance for bad debts	376			
Deferred compensation	4,013			
Inventory	10,604			
Fixed assets and intangibles		(7,667)		(6,485)
Investments	2,133		2,073	
Net operating losses	2,830		3,293	
Tax credits	4,645		2,596	
Deferred revenue	4,968		5,318	
Accrued liabilities	1,847		357	
Other		(258)		
Valuation allowance	(1,106)		(959)	
Total noncurrent	30,310	(7,925)	12,678	(6,485)
Total	$ 30,310	$ (7,925)	$ 35,714	$ (6,693)

The Company expects its deferred tax assets of $22,385, net of the valuation allowance at December 31, 2015 of $1,106, to be realized through the generation of future taxable income and the reversal of existing taxable temporary differences, see Note 3.

Valuation allowances are established when necessary to reduce deferred tax assets to amounts which are more likely than not to be realized. As such, valuation allowances of $1,106 and $959 have been established at December 31, 2015 and December 31, 2014, respectively, against a portion of the deferred tax assets relating to certain net operating loss carryforwards.

The Company recorded a tax benefit from the exercise of stock options in the amount of $1,139, $539, and $315 for the years ended December 31, 2015, 2014 and 2013, respectively.

As of December 31, 2015, the Company has U.S. federal net operating loss carryforwards of $1,978 that will expire in 2027.

As of December 31, 2015, the Company has U.S. state net operating loss carryforwards of $20,766 that will expire in the years 2018 through 2035.

As of December 31, 2015, the Company has foreign net operating loss carryforwards of $4,447 that will carryfoward indefinitely.

As of December 31, 2015, the Company has research tax credit carryforwards of $5,693 that will expire in years 2027 through 2035. As of December 31, 2015, the Company has alternative minimum tax credit carryforwards of $827 that will carryfoward indefinitely.

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On December 18, 2015, the Protecting Americans from Tax Hikes (PATH) Act was signed into law. The PATH retroactively extended the research tax credit to the beginning of 2015. In addition, under PATH the research tax credit is made permanent. Under ASC 740, *Accounting for Income Taxes*, the effects of the tax legislation are recognized upon enactment. Therefore, the Company recognized the tax benefit associated with the 2015 research tax credit in 2015.

U.S. income taxes have not been provided on the undistributed earnings of the Company s foreign subsidiaries. It is not practicable to estimate the amount of tax that might be payable. The Company s intention is to indefinitely reinvest earnings of its foreign subsidiaries outside of the U.S. As of December 31, 2015 and 2014, the amount of undistributed earnings related to the Company s foreign subsidiaries considered to be indefinitely reinvested was $11,227 and $7,238, respectively.

The Company evaluates the need for deferred tax asset valuation allowances based on a more likely than not standard. The ability to realize deferred tax assets depends on the ability to generate sufficient taxable income within the carryback or carryforward periods provided for in the tax law for each applicable tax jurisdiction.

The assessment regarding whether a valuation allowance is required or should be adjusted also considers all available positive and negative evidence. It is difficult to conclude a valuation allowance is not required when there is significant objective and verifiable negative evidence, such as cumulative losses in recent years. The Company utilizes a rolling three years of actual results as the primary measure of cumulative losses in recent years.

On a rolling three years, the Company s U.S. operations are in a cumulative income position. The Company considers this objectively verifiable evidence that its current U.S. operations existing on December 31, 2015, have consistently demonstrated the ability to operate at a profit. The Company has a history of utilizing 100 percent of its U.S. deferred taxes assets before they expire and the forecasts of taxable earnings project a complete realization of all U.S. deferred tax assets before they expire, including under stressed scenarios.

The Company s German and French operations are in a cumulative loss position. However, after adjusting projections of profitability for items not indicative of its ability to generate taxable income in future years its German operations are in a cumulative income position. The Company considers this objectively verifiable evidence that its current German operations existing on December 31, 2015, have consistently demonstrated the ability to operate at a profit. As of December 31, 2015, the Company s German deferred tax assets primarily relate to net operating loss carryforwards. In general, the Company s foreign net operating loss carryforwards can be carried forward indefinitely. As a result, the Company has not recorded an additional valuation allowance charge on its German deferred tax assets. The Company has recorded additional valuation allowances on its French deferred tax assets.

The Company has evaluated all available positive and negative evidence, including the extent to which that evidence was objectively verifiable. The Company has concluded, for those jurisdictions where valuation allowances have not been established, the positive evidence outweighed the negative evidence and the deferred tax assets are more likely than not realizable as of December 31, 2015.

The Company will continue to regularly assess the realizability of our deferred tax assets. Changes in historical earnings performance and future earnings projections, among other factors, may cause the Company to adjust its valuation allowance, which would impact the Company s income tax expense in the period the Company determines that these factors have changed.

As of December 31, 2015, the Company has $1,986 of unrecognized tax benefits, of which $110 were recorded in other liabilities and $1,876 of unrecognized tax benefits were recorded net against deferred tax assets in the

accompanying consolidated balance sheet.

The Company s unrecognized tax benefits are summarized as follows:

	Year Ended December 31,		
	2015	2014	2013
Opening balance	$ 1,787	$ 2,825	$ 1,797
Reductions based on tax positions related to the current year		(136)	(174)
Additions for tax positions of prior years	199		1,337
Reductions for tax positions of prior years		(902)	(135)
	$ 1,986	$ 1,787	$ 2,825

The unrecognized tax benefits if recognized, would favorably impact the Company s effective tax rate.

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The Company s policy is to recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in the provision for income taxes. There were no interest and penalties recorded in 2015, 2014 and 2013 and no interest and penalties accrued at December 31, 2015 and 2014.

One of the Company s foreign subsidiaries is undergoing an examination by the German tax authorities. The German examination covers the foreign subsidiary s 2010 through 2013 tax years.

The effective tax rate differs from the statutory federal income tax rate for the following reasons:

	Year Ended December 31,		
	2015	2014	2013
Statutory federal rate	35.00%	35.00%	35.00%
State income taxes net of federal tax benefit	0.25%	3.51%	4.14%
Foreign rate differential	(2.18%)	4.99%	(0.46%)
Other permanent expenses	0.56%	(1.25%)	(4.27%)
Research tax credits	(0.28%)	(7.52%)	3.56%
Domestic production activities deduction		(4.33%)	
Unrecognized tax benefits			0.86%
Valuation allowance	0.85%	5.26%	
Other reconciling items, net	1.55%	(0.02%)	(0.42%)
Effective tax rate	35.75%	35.64%	38.41%

For the years ended December 31, 2015, 2014 and 2013, the Company had no individually significant other reconciling items.

15. Preferred Stock

Preferred stock is as follows:

	Preferred Stock Liquidation Value	Preferred Stock Issuance Costs	Net Total
Balance at July 16, 2013	$ 50,000	$ (1,290)	$ 48,710
Accrued dividend payable	1,375		1,375
Dividend paid	(625)		(625)
Amortization of preferred stock issuance costs		77	77
Balance at December 31, 2013	50,750	(1,213)	49,537
Accrued dividend payable	3,113		3,113
Amortization of preferred stock issuance costs		184	184

Balance at December 31, 2014		53,863	(1,029)	52,834
Accrued dividend payable		3,305		3,305
Amortization of preferred stock issuance costs			184	184
Balance at December 31, 2015	$	57,168	$ (845)	$ 56,323

On June 12, 2013, the Company and WSHP entered into an investment agreement. Pursuant to the terms of the investment agreement, the Company agreed to a $50,000 private placement of convertible preferred equity with WSHP. In connection with the closing of the transactions contemplated by the investment agreement, the Company and WSHP amended the investment agreement on July 15, 2013, and the Company filed a Certificate of Designation of Series A Convertible Preferred Stock creating the Series A Convertible Preferred Stock, par value $0.001 per share (the Preferred Stock), and establishing the designations, preferences, and other rights of the Preferred Stock. The Preferred Stock accrues dividends at a rate of 6% per annum. To the extent dividends are not paid in cash in any quarter, the dividends which have accrued on each outstanding share of Preferred Stock during such three-month period will accumulate until paid in cash or converted to common stock. The payments of dividends may be restricted by various covenants under our credit agreement with TD Bank and Regions Bank.

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The Preferred Stock will be convertible at the election of the holders into shares of the Company s common stock at an initial conversion price of $4.39 per share which would result in a conversion ratio of approximately 228 shares of common stock for each share of Preferred Stock. The Preferred Stock is convertible at the election of the Company five years after its issuance or at any time if the Company s common stock closes at or above $7.98 per share for at least 20 consecutive trading days.

The Company may, upon 30 days notice, redeem the Preferred Stock, in whole or in part, five years after its issuance at the initial liquidation preference of $1,000 per share of the Preferred Stock plus an amount per share equal to accrued but unpaid dividends (collectively, the Liquidation Value). The holders of the Preferred Stock may require the Company to redeem their Preferred Stock, in whole or in part, at the Liquidation Value seven years after its issuance or upon the occurrence of a change of control.

16. Stockholders Equity

Preferred Stock The Company has 5,000,000 shares of preferred stock authorized under its Certificate of Incorporation of which 50,000 are currently issued and outstanding. These shares may be issued in one or more series having such terms as may be determined by the Company s Board of Directors.

Common Stock The Company has 150,000,000 shares of common stock authorized. The common stock s voting, dividend, and liquidation rights presently are subject to or qualified by the rights of the holders of any outstanding shares of preferred stock. Holders of common stock are entitled to one vote for each share held at all stockholder meetings. Shares of common stock do not have redemption rights.

17. Restructuring Charges

The Company instituted a restructuring plan primarily related to termination of employees and a location closure as a result of the integration activities following the acquisition of Pioneer, which resulted in $2,881 of expenses for the year ended December 31, 2013. The total restructuring charges were paid in full by February 28, 2015. Severance payments were made to terminated employees over periods ranging from one month to twelve months and did not have a material impact on cash flows of the Company in any quarterly period. The following table includes a rollforward of restructuring charges included in accrued expenses, see Note 11.

Accrued restructuring charges at January 1, 2015	$ 13
Cash payments	(13)
Accrued restructuring charges at December 31, 2015	$

18. Severance Charges

The Company recorded severance charges related to the termination of former employees as a result of the Company flattening its organizational structure, which resulted in $4,798 of expenses for the year ended December 31, 2014. The total severance charges were paid in full by December 31, 2015. Severance payments were made to terminated employees over periods ranging from one month to twelve months and did not have a material impact on cash flows of the Company in any quarterly period.

The Company recorded additional severance charges related to the termination of former employees as a result of the Company reorganizing its distribution force, which resulted in $995 of expenses for the year ended December 31, 2015. The total severance charges are expected to be paid in full prior to December 31, 2016. Severance payments are made to terminated employees over periods ranging from one month to twelve months and will not have a material impact on cash flows of the Company in any quarterly period. The following table includes a rollforward of severance charges included in accrued expenses, see Note 11.

Accrued severance charges at January 1, 2015	$ 2,771
Severance cash payments	(2,591)
Stock based compensation	(310)
Employee separation expenses accrued in 2015	995
Accrued severance charges at December 31, 2015	$ 865

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19. Retirement Benefits

The Company has a qualified 401(k) plan available to all U.S. employees who meet certain eligibility requirements. The 401(k) plan allows each employee to contribute up to the annual maximum allowed under the Internal Revenue Code. The Company has the discretion to make matching contributions up to 6% of the employee s earnings. For the years ended December 31, 2015, 2014 and 2013, the amounts expensed under the plan were $3,034, $2,663 and $1,964, respectively.

20. Concentrations of Risk

Distribution The Company s principal concentration of risk is related to its limited distribution channels. The Company s revenues include the distribution efforts of thirteen independent companies with significant revenues coming from three of the distribution companies, Zimmer Biomet Holdings Inc. (Zimmer), Medtronic, PLC (Medtronic) and Davol Inc (Davol). The following table presents percentage of total revenues derived from the Company s largest distributors and international distribution:

	Year Ended December 31,		
	2015	2014	2013
Percent of revenues derived from:			
Distributor			
Zimmer Biomet Holdings, Inc.	24%	18%	17%
Medtronic, PLC	10%	12%	16%
Davol, Inc.	3%	5%	9%
International	8%	9%	10%

The Company s distribution agreements are subject to termination by either party for a variety of causes. No assurance can be given that such distribution agreements will be renewed beyond their expiration dates, continue in their current form or at similar rate structures. Any termination or interruption in the distribution of the Company s implants through one of its major distributors could have a material adverse effect on the Company s operations.

Tissue Supply The Company s operations are dependent on the availability of tissue from human donors. For the majority of the tissue recoveries, the Company relies on the efforts of independent procurement agencies to educate the public and increase the willingness to donate bone tissue. These procurement agencies may not be able to obtain sufficient tissue to meet present or future demands. Any interruption in the supply of tissue from these procurement agencies could have a material adverse effect on the Company s operations.

21. Commitments and Contingencies

Distribution Agreement with Medtronic On October 12, 2013, the Company entered into a replacement distribution agreement with Medtronic, plc. (Medtronic), pursuant to which Medtronic will distribute certain allograft implants for use in spinal, general orthopedic and trauma surgery. Under the terms of this distribution agreement, Medtronic will be a non-exclusive distributor except for certain specified implants for which Medtronic will be the exclusive distributor. Medtronic will maintain its exclusivity with respect to these specified implants unless the cumulative fees received by us from Medtronic for these specified implants decline by a certain amount during any trailing 12-month period. The initial term of this distribution agreement will continue through December 31, 2017, unless earlier terminated in accordance with this distribution agreement. This initial term will automatically renew for successive five-year periods, unless either party provides written notice of its intent not to renew at least one year prior to the

expiration of the initial term or the applicable renewal period. This distribution agreement superseded and replaced our prior distribution agreement with Medtronic which would have expired in accordance with its terms in June 2014.

Exclusive License Agreement with Athersys - On September 10, 2010, the Company entered into an Exclusive License Agreement with Athersys, pursuant to which Athersys will provide the Company access to its MAPC technologies to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications. In consideration for the Exclusive License, the Company agreed to pay Athersys the following: 1) a non-refundable $3,000 license fee, payable in three time-based $1,000 installments, the last of which was paid in the first quarter of 2011, 2) payment of $2,000 contingent upon successful achievement of certain development milestones which the Company paid in 2012, and 3) up to $32,500 contingent upon achievement of certain cumulative revenue milestones in future years. In addition, the Company pays Athersys royalties from the distribution of implants under a tiered royalty structure based on achievement of certain cumulative revenue milestones. The term of this license agreement is the remaining life of any applicable patent or trade secret. These acquired licensing rights are being amortized to expense on a straight-line basis over the expected life of the asset.

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Distribution Agreement with Zimmer Dental Inc. - On September 3, 2010, the Company and Zimmer Dental Inc. (Zimmer Dental), a subsidiary of Zimmer, entered into an exclusive distribution agreement, with an effective date of September 30, 2010. This distribution agreement has an initial term of ten years. Under the terms of this distribution agreement, the Company has agreed to supply sterilized allograft and xenograft implants at an agreed upon transfer price, and Zimmer Dental has agreed to be the exclusive distributor of the implants for dental and oral applications worldwide (except Ukraine), subject to certain Company obligations under an existing distribution agreement with a third party with respect to certain implants for the dental market. In consideration for Zimmer Dental s exclusive distribution rights, Zimmer Dental agreed to the following: 1) payment to the Company of $13,000 within ten days of the effective date (the Upfront Payment); 2) annual exclusivity fees (Annual Exclusivity Fees) paid annually for the term of the contract to be paid at the beginning of each calendar year; and, 3) escalating annual purchase minimums to maintain exclusivity. Upon occurrence of an event that materially and adversely affects Zimmer Dental s ability to distribute the implants, Zimmer Dental may be entitled to certain refund rights with respect to the Upfront Payment and the then current Annual Exclusivity Fee, where such refund would be in an amount limited by a formula specified in this distribution agreement that is based substantially on the number of days from the occurrence of such event to the date that it is cured by the Company to the satisfaction of Zimmer Dental. The Upfront Payment, the Annual Exclusivity Fees and the fees associated with distributions of processed tissue are considered to be a single unit of accounting. Accordingly, the Upfront Payment and the Annual Exclusivity Fees are deferred as received and are being recognized as other revenues over the term of this distribution agreement based on the expected contractual escalating annual purchase minimums relative to the total contractual minimum purchase requirements in this distribution agreement. Additionally, the Company has considered the potential impact of this distribution agreement s contractual refund provisions and does not expect these provisions to impact future expected revenue related to this distribution agreement.

Distribution Agreement with Davol - On July 13, 2009, the Company and Davol amended their previous distribution agreement with TMI for human dermis implants. Under the amended agreement: 1) Davol paid the Company $8,000 in non-refundable fees for exclusive distribution rights for the distribution to the breast reconstruction market until July 13, 2019; 2) the exclusive worldwide distribution agreement related to the hernia market was extended to July 13, 2019; and 3) Davol agreed to pay the Company certain additional exclusive distribution rights fees contingent upon the achievement of certain revenue milestones by Davol during the duration of the contract. In the fourth quarter of 2010, Davol paid the first revenue milestone payment of $3,500. The non-refundable fees and the fees associated with distributions of processed tissue are considered to be a single unit of accounting. Accordingly, the $8,000 and $3,500 exclusivity payments were deferred and were being recognized as other revenues on a straight-line basis over the initial term of the amended contract of ten years, and the remaining term of the amended contract, respectively. Davol did not achieve certain revenue growth milestones which resulted in Davol relinquishing its exclusive distribution rights in the hernia market effective January 1, 2013 and in the breast reconstruction market effective January 1, 2015. As a result, the Company recognized additional deferred revenue as other revenues during the three months ended March 31, 2013 and 2015, of $1,715 and $1,500, respectively, due to the acceleration of deferred revenue recognition relating to Davol relinquishing its exclusive distribution rights in the hernia and the breast reconstruction markets. The remaining balance is being recognized as other revenues on a straight-line basis over the remaining term of the amended contract.

The Company s aforementioned revenue recognition methods related to the Zimmer and Davol distribution agreements do not result in the deferral of revenue less than amounts that would be refundable in the event the agreements were to be terminated in future periods. Additionally, the Company evaluates the appropriateness of the aforementioned revenue recognition methods on an ongoing basis.

Leases The Company leases certain facilities, items of office equipment and vehicles under non-cancelable operating lease arrangements expiring on various dates through 2019. The facility leases generally contain renewal options and

escalation clauses based upon increases in the lessors operating expenses and other charges. The Company anticipates that most of these leases will be renewed or replaced upon expiration. Rent expense for the years ended December 31, 2015, 2014, and 2013 was $1,443, $1,609 and $1,529, respectively, and is included as a component of marketing, general and administrative expenses.

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Future minimum lease commitments under non-cancelable operating leases as of December 31, 2015 are as follows:

	Operating Leases
2016	$ 1,874
2017	1,121
2018	560
2019	319
2020 and beyond	144
	$ 4,018

22. Legal and Regulatory Actions

The Company is, from time to time, involved in litigation relating to claims arising out of its operations in the ordinary course of business. The Company believes that none of these claims that were outstanding as of December 31, 2015 will have a material adverse impact on its financial position or results of operations.

Litigation and Settlement Charges. In the fourth quarter of 2015, the Company reached agreements with three separate entities for the resolution of various claims asserted by these entities for breach of contract. The Company recorded cumulative litigation and settlement charges of $804 pertaining to the aforementioned agreements.

Lanx, Inc. Lanx, a subsidiary of Biomet, Inc. filed suit in the second quarter of 2013 against Pioneer in the U.S. District Court, District of Colorado, alleging that one of the Company s medical devices infringed certain of Lanx s U.S. intellectual property rights, and sought monetary damages and threatened injunctive relief. In the second quarter of 2014, the parties resolved the claim with no material financial impact to the Company or its operations. As part of the resolution of the claim, a settlement payment of $325 was made to Lanx from the indemnification escrow account, see Note 10 Other Assets.

Coloplast The Company is presently named as co-defendant along with other companies in a small percentage of the transvaginal surgical mesh (TSM) mass tort claims being brought in various state and federal courts. The TSM litigation has as its catalyst various Public Health Notifications issued by the U.S. Food and Drug Administration (FDA) with respect to the placement of certain TSM implants that were the subject of 510k regulatory clearance prior to their distribution. The Company does not process or otherwise manufacture for distribution in the U.S. any implants that were the subject of these FDA Public Health Notifications. The Company denies any allegations against it and intends to continue to vigorously defend itself.

In addition to claims made directly against the Company, Coloplast, a distributor of TSM s and certain allografts processed and private labeled for them under a contract with the Company, has also been named as a defendant in individual TSM cases in various federal and state courts. Coloplast requested that the Company indemnify or defend Coloplast in those claims which allege injuries caused by the Company s allograft implants, and on April 24, 2014, Coloplast sued RTI Surgical, Inc. in the Fourth Judicial District of Minnesota for declaratory relief and breach of contract. On December 11, 2014, Coloplast entered into a settlement agreement with RTI Surgical, Inc. and Tutogen Medical, Inc. (the Company Parties) resulting in dismissal of the case. Under the terms of the settlement agreement, the Company Parties are responsible for the defense and indemnification of two categories of present and future claims: (1) tissue only (where Coloplast is solely the distributor of Company processed allograft tissue and no

Coloplast-manufactured or distributed synthetic mesh is identified) (Tissue Only Claims), and (2) tissue plus non-Coloplast synthetic mesh (Tissue-Non-Coloplast Claims). There are presently 435 Tissue Only Claims and 443 Tissue-Non-Coloplast Claims for which the Company Parties are providing defense and indemnification. The defense and indemnification of these cases are covered under the Company s insurance policy subject to a reservation of rights by the insurer.

Based on the current information available to the Company, it is not possible to evaluate and estimate with reasonable certainty the impact that current or any future TSM litigation may have on the Company.

The Company s accounting policy is to accrue for legal costs as they are incurred.

In the quarter ended September 30, 2014, the Company received a letter from the FDA regarding the Company s map3® cellular allogeneic bone graft. The letter addresses some technical aspects of the processing of the map3® allograft, as well as language included on the Company s website. The Company has submitted an initial response to the FDA letter, and is preparing a comprehensive package of data to address the FDA s comments and provide clarifying information regarding the technical components of the implant processing. The Company believes that in both developing and processing of map3®, the Company has properly considered the relevant regulatory requirements. Additionally, the

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Company has removed the relevant information from the website pending thorough review and revisions as needed. The Company is committed to resolving the concerns raised by the FDA. However, it is not possible to predict the specific outcome or timing of a resolution at this time.

In October 2012, the Company received a warning letter from the FDA related to environmental monitoring activities in certain areas of its processing facility in Alachua, Florida. The FDA re-inspected the processing facility in Alachua, Florida in September 2013, and determined that the Company had addressed the FDA s concerns from the previous inspection. In October 2013, the Company received a final close out letter from the FDA to formally resolve their concerns. The warning letter did not restrict the Company s ability to process or distribute implants, nor did it require the withdrawal of any implants from the marketplace.

23. Segment Data

The Company distributes human tissue, bovine and porcine animal tissue, metal and synthetic implants through various distribution channels. The Company operates in one reportable segment composed of six lines of business. The Company s lines of business are composed primarily of six categories: spine, ortho fixation, sports medicine, BGS and general orthopedic, dental and surgical specialties. Discrete financial information is not available for these six lines of business. The following table presents revenues from these six categories and other revenues and their respective percentages of the Company s total revenues for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,					
	2015		2014		2013	
	(In thousands)					
Revenues:						
Spine	$ 76,968	27.3%	$ 82,663	31.5%	$ 57,334	28.9%
Ortho fixation	55,585	19.7%	37,133	14.1%	14,525	7.3%
Sports medicine	46,735	16.5%	46,758	17.8%	42,594	21.5%
BGS and general orthopedic	42,283	15.0%	36,747	14.0%	27,864	14.1%
Dental	23,621	8.4%	20,810	7.9%	19,779	10.0%
Surgical specialties	23,499	8.3%	26,999	10.3%	27,666	14.0%
Other revenues	13,602	4.8%	11,700	4.5%	8,217	4.2%
Total revenues	$ 282,293	100.0%	$ 262,810	100.0%	$ 197,979	100.0%
Domestic revenues	$ 260,387	92.2%	$ 238,936	90.9%	$ 177,207	89.5%
International revenues	21,906	7.8%	23,874	9.1%	20,772	10.5%
Total revenues	$ 282,293	100.0%	$ 262,810	100.0%	$ 197,979	100.0%

The following table presents property, plant and equipment - net by significant geographic location:

	December 31,	
	2015	2014
Property, plant and equipment - net:		

Domestic	$ 72,901	$ 63,009
International	12,091	14,019
Total	$ 84,992	$ 77,028

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24. Quarterly Results of Operations (Unaudited)

The following table sets forth the results of operations for the periods indicated:

	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Quarter Ended:				
Revenues	$ 68,034	$ 71,609	$ 66,529	$ 76,121
Gross profit	36,999	37,203	35,233	40,307
Net income applicable to common shares	2,934	2,685	2,670	3,321
Net income per common share:				
Basic	$ 0.05	$ 0.05	$ 0.05	$ 0.06
Diluted	0.05	0.05	0.05	0.06

The Company s acquisition of Pioneer added diversification of our implant portfolio, expanded our direct distribution and marketing organizations and enhanced our international business. The Company continues to maintain its commitment to research and development and the introduction of new strategically targeted allograft, xenograft, metal and synthetic implants as well as focused clinical efforts to support their acceptance in the marketplace. In the fourth quarter of 2015, the Company s net income was negatively impacted by asset abandonments of $814, litigation and settlement charges of $804 and severance charges of $995.

The following table sets forth the results of operations for the periods indicated:

	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Quarter Ended:				
Revenues	$ 60,745	$ 66,029	$ 65,163	$ 70,873
Gross profit	26,198	35,054	34,693	37,852
Net (loss) income applicable to common shares	(3,060)	1,577	1,202	(136)
Net (loss) income per common share:				
Basic	$ (0.05)	$ 0.03	$ 0.02	$ (0.00)
Diluted	(0.05)	0.03	0.02	(0.00)

The Company s acquisition of Pioneer added diversification to our implant portfolio, expanded our direct distribution and marketing organizations and enhanced our international business. The Company continues to maintain its commitment to research and development and the introduction of new strategically targeted allograft, xenograft, metal and synthetic implants as well as focused clinical efforts to support their acceptance in the marketplace. In 2014, the Company s net income was negatively impacted by an inventory purchase accounting adjustment of $5,708, a severance charge of $4,798 and a litigation settlement charge of $185.

25. Subsequent Events

The Company evaluated subsequent events as of the issuance date of the consolidated financial statements as defined by FASB ASC 855 *Subsequent Events*, and identified no subsequent events that require adjustment to, or disclosure

of, in these consolidated financial statements.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Schedule II

Valuation and Qualifying Accounts

Years Ended December 31, 2015, 2014 and 2013

(Dollars in thousands)

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions-Write-offs, Payments	Balance at End of Period
For the year ended December 31, 2015:				
Allowance for doubtful accounts	$ 818	$ 1,037	$ 401	$ 1,454
Allowance for product returns	525	531	342	714
Allowance for obsolescence	5,112	5,390	3,419	7,083
Deferred tax asset valuation allowance	959	197	50	1,106
For the year ended December 31, 2014:				
Allowance for doubtful accounts	492	709	383	818
Allowance for product returns	343	182		525
Allowance for obsolescence	5,399	3,763	4,050	5,112
Deferred tax asset valuation allowance	469	490		959
For the year ended December 31, 2013:				
Allowance for doubtful accounts	346	180	34	492
Allowance for product returns	283	255	195	343
Allowance for obsolescence	7,735	1,785	4,121	5,399
Deferred tax asset valuation allowance	469			469

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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.

March 7, 2016

RTI SURGICAL, INC.

By: /s/ Brian K. Hutchison
Brian K. Hutchison
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Brian K. Hutchison Brian K. Hutchison	President and Chief Executive Officer (Principal Executive Officer) and Director	March 7, 2016
/s/ Robert P. Jordheim Robert P. Jordheim	Executive Vice President and Chief Financial Officer (Principal Financial and Chief Accounting Officer)	March 7, 2016
/s/ Curt M. Selquist Curt M. Selquist	Chairman	March 7, 2016
/s/ Peter F. Gearen Peter F. Gearen	Vice Chairman	March 7, 2016
/s/ Dean H. Bergy Dean H. Bergy	Director	March 7, 2016
/s/ Philip R. Chapman Philip R. Chapman	Director	March 7, 2016
/s/ Thomas A. McEachin Thomas A. McEachin	Director	March 7, 2016
/s/ Adrian J.R. Smith	Director	March 7, 2016

Adrian J.R. Smith		
/s/ Christopher R. Sweeney	Director	March 7, 2016
Christopher R. Sweeney		
/s/ Shirley A. Weis	Director	March 7, 2016
Shirley A. Weis		

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Form	File No.	Date Filed
3.1*	Amended and Restated Certificate of Incorporation of RTI Surgical, Inc.			
3.2*	Amended and Restated Bylaws of RTI Surgical, Inc..			
3.3	Certificate of Designation of Series A Convertible Preferred Stock of RTI Surgical, Inc., dated July 16, 2013.	8-K	000-31271	7/19/2013
3.4	Certificate of Ownership and Merger dated July 16, 2013.	8-K	000-31271	7/19/2013
4.3	Specimen Stock Certificate.	S-1	333-35756	8/02/2000
10.1	Omnibus Stock Option Plan.	S-1	333-35756	4/27/2000
10.2	Year 2000 Compensation Plan.	S-1	333-35756	4/27/2000
10.3	RTI Regeneration Technologies, Inc. 2004 Equity Incentive Plan.	10-Q	000-31271	6/30/2004
10.4	Form of Nonqualified Stock Option Grant Agreement.	10-K (2004)	000-31271	3/16/2005
10.5	Form of Incentive Stock Option Grant Agreement.	10-K (2004)	000-31271	3/16/2005
10.6	RTI Surgical, Inc. 2010 Equity Incentive Plan.	DEF 14A	000-31271	3/19/2010
10.7	Exclusive Distribution Agreement between RTI Biologics, Inc. and Zimmer Dental Inc., dated as of September 3, 2010 and effective as of September 30, 2010.	10-Q (Q3 2010)	000-31271	11/08/2010
10.8	RTI Biologics, Inc. Executive Nonqualified Excess Plan.	10-K (2011)	000-31271	2/15/2012
10.9	Form of Executive Transition Agreement.	8-K	000-31271	9/4/2012
10.10	Executive Transition Agreement with Brian K. Hutchison, dated August 29, 2012.	8-K	000-31271	9/4/2012
10.11	Extension Letter with Brian K. Hutchison, dated August 28, 2015, extending Executive Transition Agreement through December 31, 2015.	8-K	000-31271	8/31/2015
10.12	Extension Letter with Robert P. Jordheim, dated August 28, 2015, extending Executive Transition Agreement through December 31, 2015.	8-K	000-31271	8/31/2015
10.13	Extension Letter with Roger W. Rose, dated August 28, 2015, extending Executive Transition Agreement through December 31, 2015.	8-K	000-31271	8/31/2015
10.14	Extension Letter with Caroline A. Hartill, dated August 28, 2015, extending Executive Transition Agreement through December 31, 2015.	8-K	000-31271	8/31/2015

10.15	Extension Letter with Brian K. Hutchison, dated December 3, 2015, extending Executive Transition Agreement through December 31, 2018.	8-K	000-31271	12/4/2015
10.16	Extension Letter with Robert P. Jordheim, dated December 3, 2015, extending Executive Transition Agreement through December 31, 2018.	8-K	000-31271	12/4/2015
10.17	Extension Letter with Roger W. Rose, dated December 3, 2015, extending Executive Transition Agreement through December 31, 2018.	8-K	000-31271	12/4/2015
10.18	Extension Letter with Caroline A. Hartill, dated December 3, 2015, extending Executive Transition Agreement through December 31, 2018.	8-K	000-31271	12/4/2015
10.19	Second Amended and Restated Loan Agreement dated July 16, 2013 by and among RTI Surgical, Inc., TD Bank, N.A., a national banking association, as administrative agent for the Lenders and each of the Lenders from time to time a party thereto.	8-K	000-31271	7/19/2013
10.20	First Amendment to the Second Amended and Restated Loan Agreement dated December 30, 2013 by and among RTI Surgical, Inc., TD Bank, N.A., a national banking association, as administrative agent for the Lenders and each of the Lenders from time to time a party thereto.	8-K	000-31271	12/30/2013
10.21	Investment Agreement, dated as of June 12, 2013, by and between RTI Biologics, Inc. and WSHP Biologics Holdings, LLC.	8-K	000-31271	6/13/2013
10.22	Amendment to Investment Agreement, dated as of July 15, 2013 by and among RTI Biologics, Inc. and WSHP Biologics Holdings, LLC.	8-K	000-31271	7/19/2013
10.23	Investor Rights Agreement dated as of July 16, 2013 by and between RTI Surgical, Inc. and WSHP Biologics Holdings, LLC.	8-K	000-31271	7/19/2013

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Exhibit		Incorporated by Reference		
No.	**Description**	**Form**	**File No.**	**Date Filed**
10.24	Form of Water Street Director Indemnification Agreement.	8-K	000-31271	7/19/2013
10.25	Form of Director Indemnification Agreement.	8-K	000-31271	7/19/2013
10.26*	2013 Distribution Agreement, effective as of October 12, 2013, between RTI Surgical, Inc. and Medtronic Sofamor Danek USA, Inc.	10-K (2013)	000-31271	3/10/2014
10.27*	Second Amendment to the Second Amended and Restated Loan Agreement dated October 15, 2014 by and among RTI Surgical, Inc., TD Bank, N.A., a national banking association, as administrative agent for the Lenders and each of the Lenders from time to time a party thereto.	10-K (2014)	000-31271	3/4/2015
10.28	Third Amendment to the Second Amended and Restated Loan Agreement dated June 29, 2015 by and among RTI Surgical, Inc., TD Bank, N.A., a national banking association, as administrative agent for the Lenders and each of the Lenders from time to time a party thereto.	8-K	000-31271	7/2/2015
23.1*	Consent of Independent Registered Public Accounting Firm.			
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a)/15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a)/15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101.INS*	XBRL Instance Document			
101.SCH*	XBRL Taxonomy Extension Schema Document			
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document			
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document			
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document			
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document			

Confidential treatment requested as to certain portions, which portions were omitted and filed separately with the Commission.

Indicates a management contract or any compensatory plan, contract, or arrangement.

* Filed herewith.