RTI SURGICAL, INC.
Form 10-K
March 02, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2017

or

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

For the transition period from to .

Commission file number: 0-31271

RTI SURGICAL, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**59-3466543**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer 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

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

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 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 No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

Emerging Growth Company
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.):

Yes No

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, 2017), was approximately $347.8 million.

The number of shares of Common Stock outstanding as of February 23, 2018 was 62,757,731.

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 2018 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

RTI Surgical is a global surgical implant company that designs, develops, manufactures and distributes biologic, metal and synthetic implants. Our implants are used in orthopedic, spine, sports medicine, general surgery, trauma and other surgical procedures to repair and promote the natural healing of human bone and other human tissues and improve surgical outcomes. We manufacture metal and synthetic implants and process donated human musculoskeletal and other tissue and bovine and porcine animal tissue in producing allograft and xenograft implants using our proprietary BIOCLEANSE®, TUTOPLAST® and CANCELLE® SP sterilization processes. We process tissue at our facilities in Alachua, Florida and Neunkirchen, Germany and manufacture metal and synthetic implants in Marquette, Michigan and Greenville, North Carolina. We are accredited in the U.S. by the American Association of Tissue Banks and we are a member of AdvaMed. Our implants are distributed directly to hospitals throughout the U.S. and in more than 40 countries worldwide with the support of both our and third-party representatives as well as through larger purchasing companies.

Strategy

We are implementing a focused strategy to expand our spine and Original Equipment Manufacturer (OEM) operations and create long-term, profitable growth for the company. In 2017, we introduced a new management team with extensive experience in an effort to spearhead these efforts. The core components of our strategy are:

Reduce Complexity. We are working to reduce complexity in our organization by divesting non-core assets and investing in core competencies.

Drive Operational Excellence. We are working to optimize material cost and drive operational efficiency to reduce other direct costs by pursuing world class manufacturing.

Accelerate Growth. We are investing in innovative, niche high growth product categories leveraging core competency in the spine market; utilizing core technologies to expand OEM relationships and drive organic growth; and building relevant scale in our spinal portfolio to improve importance to the consolidating healthcare market driven by integrated delivery networks and group purchasing organizations.

We distribute our implants through various distribution channels. We operate in one reportable segment composed of six lines of business. The reporting of our lines of business is composed primarily of six categories: spine; sports medicine and orthopedics; surgical specialties; cardiothoracic; international; and global commercial. Effective October 1, 2017, we renamed our global commercial line of business category to OEM. 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 our total revenues for the years ended December 31, 2017, 2016 and 2015:

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	Year Ended December 31,					
	2017		2016		2015	
	(In thousands)					
Revenues:						
Spine	$ 77,514	27.7%	$ 73,907	27.1%	$ 57,983	20.5%
Sports medicine and orthopedics	50,231	18.0%	50,143	18.4%	50,712	18.0%
Surgical specialties	6,980	2.5%	4,466	1.6%	3,029	1.1%
Cardiothoracic	8,164	2.9%	11,147	4.1%	8,699	3.1%
International	23,240	8.3%	21,185	7.8%	18,338	6.5%
Subtotal direct	166,129	59.4%	160,848	59.0%	138,761	49.2%
OEM	103,011	36.9%	99,127	36.3%	129,930	46.0%
Other revenues	10,423	3.7%	12,890	4.7%	13,602	4.8%
Total revenues	$ 279,563	100.0%	$ 272,865	100.0%	$ 282,293	100.0%
Domestic revenues	$ 253,599	90.7%	$ 247,756	90.8%	$ 260,387	92.2%
International revenues	25,964	9.3%	25,109	9.2%	21,906	7.8%
Total revenues	$ 279,563	100.0%	$ 272,865	100.0%	$ 282,293	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.

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. In August 2017, we completed the sale of substantially all of the assets related to our Cardiothoracic closure business (the CT Business) to A&E Advanced Closure Systems, LLC (a subsidiary of A&E Medical Corporation) (A&E). On January 4, 2018, we acquired Zyga Technology, Inc. (Zyga) through the merger of one of our wholly-owned subsidiaries with and into Zyga. 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 bone and tissue is surgical intervention, primarily through the use of surgical implants. When considering a surgical procedure for bone or 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). A recent trend has emerged for advanced materials in spinal interbodies. RTI Surgical has a leadership position in that space through its Fortilink family of products, which is produced by additive manufacturing (3-D printing) using a proprietary polyetherketoneketone (PEKK) material called TETRAfuse® 3-D. The Company s exclusive supplier of TETRAfuse® 3-D is Oxford Performance Materials, Inc.

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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.

Marketing and Distribution

We market and distribute our implants through direct distribution channels and a combination of both exclusive and non-exclusive OEM distributors depending upon the product category. Our implants are used in the following markets: spine, sports medicine, orthobiologics, trauma, dental, and surgical specialties. Our implants range from metals, synthetics, allografts and xenografts that are precision machined for specific surgical applications, to grafts conventionally processed for general surgical uses.

Direct Channels

Spine

The human spine consists of four regions: cervical (neck region), thoracic (back region attached to the ribs), lumbar (lower back), and sacral (tail bone). We design, manufacture, and distribute surgical implants, instruments, and biologics used in the treatment of conditions affecting the spine caused by degenerative conditions, deformities or traumatic injury. Our principal implant offering includes a wide variety of systems comprised of components such as spine screws and rods, spinal spacers, plates, and various biologics offerings all designed to support, enhance, or promote spinal fusion. Our principal implant offerings by market segment are as follows:

Thoracolumbar: Streamline® TL Spinal Fixation System, Quantum® Spinal Fixation System, Streamline® MIS Spinal Fixation System, MIS Fusion™ Instrumentation, Contact® Anterior Lumbar Plate System

Cervical: Streamline® Posterior Cervical Spinal Fixation System, Slimfuse® Anterior Cervical Plate System, Aspect® Anterior Cervical Plate System

Lateral: Clarity® Retractor System, Lat-Fuse™ Lateral Plate System

Interbody: C Plus™ PEEK IBF System, Bullet™ PEEK IBF System, Cross-Fuse II® PEEK VBR/IBF System

Biologics: map3® cellular allogeneic bone graft and the BioSet® DBM, BioReady® DBM, and BioAdapt® DBM families of paste implants

Synthetics: nanOss® advanced bone graft substitute

Sports medicine and orthopedics

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

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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 than non pre-shaped allografts. We also distribute Matrix HD human dermis implants for wound repair and soft tissue augmentation and map3® cellular allogeneic bone graft for foot and ankle repair.

Surgical Specialties

We market and distribute implants for abdominal wall repair, and plastic and reconstructive surgery. These implants are processed through our validated Tutoplast tissue sterilization process, which has a proven track record of safety and performance. Principal products include Cortiva human dermis, Fortiva porcine dermis and Tutopatch and Tutomesh bovine pericardium.

Cardiothoracic

On August 3, 2017, we completed the sale of substantially all of the assets related to our CT Business to A&E. We now serve as an OEM to A&E, who provides surgeons cardiothoracic cable and plating systems. The Company retained all rights to its Cardiothoracic biologic implant. Cardiothoracic hardware implants offer increased stability and rigidity for sternal closures, ranging from routine closures to complex, high-risk closures. The cardiothoracic biologic implant reinforces soft tissue where weakness exists in general, as well as for repair of pericardial structures.

International

Internationally we market and distribute our implants through a direct distribution organization and a network of independent distributors.

OEM Channels

We also market and distribute our implants through relationships with OEM distributors.

Our spine interbody allograft implants are marketed and distributed domestically through our non-exclusive relationships with Aesculap Implant Systems, Inc. (Aesculap), 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 allograft paste implants are marketed and distributed under Puros® DBM by Zimmer, the Opteform® brand with Exactech, Inc. (Exactech). DBM Boat implants are marketed under BIO DBM by Stryker.

Our surgical specialty implants are marketed and distributed through distributors including: Integra for dural repair applications; Davol, Inc., a subsidiary of C. R. Bard, Inc. (Davol) for hernia repair and breast reconstruction; Katena Products, Inc. (Katena) for ophthalmology and Coloplast A/S of Denmark (Coloplast) for urology.

Our allograft dental implants including cancellous and cortical bone and human and bovine membranes primarily for dental procedures related to augmenting ridge restoration are distributed exclusively by Zimmer.

Our trauma implants are distributed through Zimmer and DePuy Synthes (Synthes), a Johnson & Johnson Inc. subsidiary.

Effective August 3, 2017, our cardiothoracic hardware implants are distributed through A&E.

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.

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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. To our knowledge, no other tissue sterilization process related to human tissue in our industry has been reviewed or approved by the FDA. It should be noted, that the FDA does not have a formal approval process in place for tissue related processing techniques.

Two types of preserved allografts are processed using the BIOCLEANSE® process: soft tissue, consisting of tendons and cartilage; and bone tissue, consisting of various configurations of cancellous and cortical bone material. Tendons and cartilage are used to repair/replace native tissue primarily in sports medicine reconstructive surgeries. Processed cortical and cancellous bone materials are used in a wide variety of applications in spine and orthopedic surgeries.

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.

Two types of preserved allografts are processed using the TUTOPLAST® process: 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 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^{-6}).

Tissue Recovery

Tissue recovery is the actual removal of tissue from a donor after legal authorization has been obtained. Authorization 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 bought and 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 through ongoing contractual relationships with other FDA registered tissue recovery organizations. We believe that our established relationships with our recovery organizations are sufficient to meet our demands for our ongoing operations for the next twelve months. These contracted tissue recovery organizations are responsible for obtaining appropriate authorization and conducting federally-mandated donor screening, such as a medical and social history

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interview with the next of kin with each donor evaluated against current acceptance criteria prior to donor tissue being sent to our processing facility. 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 medical eligibility assessment. With respect to laboratory testing, we perform an extensive panel of serological and microbiological tests using Clinical Laboratory Improvements Amendment (CLIA) approved laboratories and FDA test kits. 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 that our established relationships with our sources of xenograft animal tissues are sufficient to meet our demands for our ongoing operations for the next twelve months. 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, 2017, 2016 and 2015 were $13.4 million, $16.1 million and $15.1 million, respectively. In 2017, 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.

We plan to continue to develop new implants, technologies and surgical techniques 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: TETRAfuse® 3-D, BIOCLEANSE®, TUTOPLAST®, CANCELLE® SP, precision machining, assembled grafts, tissue-mediated osteoinduction and our metal and synthetics design and production expertise. We are working to develop differentiated technologies and investing in generating the necessary clinical data to drive demand and support appropriate reimbursement. 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 2017, we launched 8 new implants and product enhancements in spine, sports, and general orthopedics developed by our research and development teams. On October 25, 2017, we announced the commercial launch of Fortilink-C IBF System with TETRAfuse® 3D Technology. The Fortilink-C system is the first in a family of devices to incorporate our TETRAfuse 3D Technology.

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.

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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. Many of our competitors are substantially larger than we are, with much greater resources.

Our principal competitors in the conventional allograft market include the Musculoskeletal Transplant Foundation (MTF), AlloSource Inc., LifeCell, Inc., a subsidiary of Allergan PLC 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 Medtronic, Stryker, Zimmer Biomet, Depuy Synthes, Globus Medical Group, Inc. (Globus), K2M Group Holdings Inc. (K2), NuVasive, Inc. (NuVasive), Alphatec Holdings Inc. (Alphatec), Xtant Medical Holdings, Inc. (Xtant), SeaSpine Holdings Corporation (SeaSpine), and Orthofix International NV (Orthofix).

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 material compliance with all existing pertinent international and domestic laws and regulations, there can be no assurance that changes in governmental administrations and regulations, or their interpretation or application, 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, most of our allograft implants are regulated by the FDA solely 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 some of our allograft-containing implants 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.

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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 pre-market review 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 cGMPs. 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.

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 distributed 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 premarket notification (510(k)) clearance 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 premarket approval application (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.

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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 as well as 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, or will be able to obtain, all necessary clearances and approvals for the manufacture and sale of our implants and that they are, or will be, 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 an implant is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements may include, as applicable: 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 (including unique device identification (UDI) requirements), 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; 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 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 Union has nationally transposed regulations based on the European Commission (EC) Medical Device Directives for the control of medical devices with which manufacturers must comply. New medical device regulation (MDR) will replace the medical device directives effective May 26, 2020. Under the current directives and upcoming MDR, manufacturing plants must have received Conformitè Europèene (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 directives 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 that we distribute in the European Union.

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 may challenge 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

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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. 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. The Company does not believe it is currently a covered entity as defined by HIPAA, but this could change as the Company s business practices further develop and expand, or if a governmental authority determines otherwise.

On September 30, 2014, we received a letter from the FDA regarding our map3® cellular allogeneic bone graft. The letter addresses some technical aspects of the processing of the map3® allograft, as well as language included on our website. Following the 2014 letter, the FDA conducted an on-site inspection of our Alachua, Florida facility in April 2017 to assess compliance of the manufacturing and quality controls for our map3® allograft products to the 21 CFR Part 211 (GMP) regulations. A form 483 was issued by the FDA outlining 9 instances of observed non-compliance. We have worked diligently to resolve all cited observations in a timely manner, however, on November 9, 2017, the FDA issued a Warning Letter to us related to the map3® allograft. The letter reiterated the FDA s concerns regarding the classification and manufacturing of the map3 allograft. There was no requirement to cease production or to recall distributed allografts from the market. We are working diligently and collaboratively with FDA to resolve any concerns regarding the map3® allografts and we are maintaining ongoing dialogue with the FDA. Comprehensive packages of data have been provided to address the FDA s comments. We have also provided the FDA with clarifying information has been provided 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. Additionally, we have removed certain information from our website. We 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.

Effective May 26, 2020, the European Union s new MDR will replace the current medical device directives. All medical devices currently distributed in the European Union under the medical device directives are likely impacted. The MDER may also include products, such as human tissue, not traditionally considered medical devices in the European Union. Additionally, the MDR, among other things, increases regulatory requirements for several medical device groupings applicable to the Company s implants distributed in the European Union, including strengthening notified body oversight for Class I reusable surgical instruments, and up-classifying spinal devices in contact with the spinal column.

Corporate Compliance

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 substantially 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.

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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.

Oversight of interactions with healthcare professionals to ensure compliance with healthcare fraud & abuse laws, including mandated reporting of transfers of value to healthcare professionals under the Affordable Care Act.

Disciplinary guidelines to enforce compliance and address violations.

Screening of employees and relevant 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 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, 2017, we had a total of 942 employees of which 145 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, 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 applicable foreign equivalents, 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 some cases, a single third-party supplier for key raw materials and component parts, apart from human tissue, used in our tissue processing and 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, PEKK, and animal tissue. We rely from time to time on a number of suppliers and, in some cases, on a single source vendor. Our dependence on single third-party suppliers, or even a limited number of third-party suppliers in certain instances, creates several risks, including limited control over pricing, availability, quality and delivery schedules. In addition, any supply interruption or cancellation in a limited or sole sourced component or raw material 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. In addition, a change in manufactures will require qualification of the new supplier to ensure they comply with or quality standards. Delays in qualifying a new supplier or re-qualifying an existing supplier could 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 initiatives and reforms initiated by legislators, regulators and third-party payers to curb rising healthcare costs, in addition to other economic factors, 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 likely 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 group purchasing organizations (GPOs), independent delivery networks (IDNs), and large

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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, among other potential factors, 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 among our existing and prospective customers, exert further downward pressure on the prices of our implants and may adversely impact our business, financial condition or results of operations.

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®, TUTOPLAST® and CANCELLE® SP 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.

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 and untitled 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 would likely 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. For example, on November 9, 2017, the FDA issued a Warning Letter to us related to our map3® allograft. The letter reiterated the FDA s previously expressed belief that the processing of map3® allograft rendered it more than minimally manipulated and therefore subject to the requirements of a biologics license application and associated manufacturing requirements under GMP regulations, 21 CFR Part 211. There was no requirement to cease production or to recall distributed map3® allografts from the market. Although we continue working diligently and collaboratively with FDA to resolve any concerns regarding the map3® allografts, including providing comprehensive packages of data to address the FDA s comments and we believe that in both developing and processing of map3® we have properly considered the relevant regulatory requirements, we cannot be certain that the FDA will ultimately find our corrective actions, proposed resolutions and studies, or arguments unpersuasive and unsuccessful. Further, we cannot guarantee that the FDA will continue to exercise enforcement discretion with respect to map3® allograft and, if so, for how long, and that they will not require us to remove map3® allograft from the market. We 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.

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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.

Most of our metal, synthetic, and xenograft products, and a few allograft products, fall into an FDA classification that requires the submission of a Premarket Notification (510(k)) to the FDA. This process requires us to demonstrate that the device to be marketed is at least as safe and effective as, that is, substantially equivalent to, a legally marketed device. We must submit information that supports our substantial equivalency claims. Before we can market the new device, we must receive an order from the FDA finding substantial equivalence and clearing the new device for commercial distribution in the U.S.

We are also subject to periodic inspection by the FDA for compliance with its Quality System Regulation (21 CFR Part 820) (QSR), among other FDA requirements, such as restrictions on advertising and promotion. Our manufacturing operations, and those of our third-party manufacturers, are required to comply with the QSR, which addresses a company s responsibility for product design, testing and manufacturing quality assurance and the maintenance of records and documentation. The QSR requires that each manufacturer establish a quality system by which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer s written specifications and procedures relating to the devices. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing products. The FDA makes announced and unannounced periodic and on-going inspections of medical device manufacturers to determine compliance with the QSR. If in connection with these inspections the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures, it may issue inspectional observations on Form 483 that would necessitate prompt corrective action. If FDA inspectional observations are not addressed and/or corrective action is not taken in a timely manner and to the FDA s satisfaction, the FDA may issue a warning letter (which would similarly necessitate prompt corrective action) and/or proceed directly to other forms of enforcement action, including the imposition of operating restrictions, including a ceasing of operations, on one or more facilities, enjoining and restraining certain violations of applicable law pertaining to medical devices and assessing civil or criminal penalties against our officers, employees or us. The FDA could also issue a warning letter or a consent decree. The FDA may also recommend prosecution to the U.S. Department of Justice (DOJ). Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products and could have a material adverse effect on our business, financial condition and results of operations. For information regarding certain warning letters and FDA Form 483 inspectional observations that we are addressing, see Note 22 to the consolidated financial statements.

The FDA, in cooperation with U.S. Customs and Border Protection (CBP), administers controls over the import of medical devices into the U.S. The CBP imposes its own regulatory requirements on the import of our products, including inspection and possible sanctions for noncompliance. We are also subject to foreign trade controls administered by certain U.S. government agencies, including the Bureau of Industry and Security within the Commerce Department and he Office of Foreign Assets Control within the Treasury Department (OFAC). There are also requirements of state, local and foreign governments that we must comply with in the manufacture and marketing

of our products. In many of the foreign countries in which we market our products, we are subject to local regulations affecting, among other things, design and product standards, packaging requirements and labeling requirements. Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. The member countries of the European Union have adopted the European Medical Device Directive, which creates a single set of medical device regulations for products marketed in all member countries. Compliance with the Medical Device Directive and certification to a quality system (e.g., ISO 13485 certification) enable the manufacturer to place a CE mark on its products. To obtain authorization to affix the CE mark to a product, a recognized European Notified Body must assess a manufacturer s quality system and the product s conformity to the requirements of the Medical Device Directive. We are subject to inspection by the Notified Bodies for compliance with these requirements. In addition, many countries, such as Germany, have very specific additional regulatory requirements for

quality assurance and manufacturing with which we must comply.

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Effective May 26, 2020, the European Union s new MDR will replace the current medical device directives. All medical devices currently distributed in the European Union under the medical device directives are likely impacted. The MDR may also include products, such as human tissue, not traditionally considered medical devices in the European Union. Additionally, the MDR, among other things, increases regulatory requirements for several medical device groupings applicable to the Company s implants distributed in the European Union, including strengthening notified body oversight for Class I reusable surgical instruments, and up-classifying spinal devices in contact with the spinal column. Additional pre-clinical testing or clinical studies may be required to meet new MDR requirements. As notified bodies are preparing for certification under the MDR, a trend has been observed among industry participants that the notified bodies are becoming more rigorous and conservative in their interpretation and application of currently existing directives, resulting in observations requiring corrective actions, particularly with respect to clinical evaluation reports (CERs), that cause industry members, including the Company, to incur additional costs. Further, with the implementation of the MDR the demand for notified body services is anticipated to increase while the number of eligible entities qualified as notified bodies is anticipated to decrease, thereby creating for the foreseeable future an imbalance in supply and demand that is anticipated to increase the cost of notified body services. Meeting the requirements of the MDR will likely cause us to incur additional costs and/or require us to discontinue distributing certain products in the European Union and other countries outside the European Union that rely on the CE mark for distribution into such countries. If we are unable to timely meet the requirements of the new MDR we may be prohibited from distributing our affected products in the European Union and other countries that rely on the CE mark, which could cause us to lose revenue. Further, notified bodies are subject to new certification. If the Company s notified body is not re-certified, or if they are certified for a narrower range of product types, the Company may have to engage a new or additional notified body which could cause a delay in meeting the new MDR requirements. Individually or cumulatively, these changes associated with the MDR could cause us to incur costs or require us to change our business practices in a manner adverse to our business.

Our business is subject to complex and evolving U.S. and international laws and regulation regarding privacy and data protection. Many of these laws and regulations are subject to change and uncertain interpretation and could result in claims, changes to our business practices, penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

Regulatory authorities around the world are considering a number of legislative and regulatory proposals concerning data protection. The interpretation and application of consumer and data protection laws in the U.S., European Union and elsewhere are often uncertain and subject to change. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices. These legislative and regulatory proposals, if adopted, and such interpretations could, in addition to the possibility of fines, result in an order requiring that we change our data practices, which could have an adverse effect on our business and results of operations. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

Recent legal developments in Europe have created compliance uncertainty regarding certain transfers of personal data from Europe to the United States. For example, the General Data Protection Regulation (GDPR), coming into application in the European Union on May 25, 2018, will apply to our activities conducted from an establishment in the European Union or related to products and services that we offer to European Union customers. The GDPR will create a range of new compliance obligations, which could cause us to change our business practices, and will significantly increase financial penalties for noncompliance.

In addition, the European Commission in July 2016 and the Swiss Government in January 2017 approved the EU-U.S. and the Swiss-U.S. Privacy Shield frameworks, respectively, which are designed to allow U.S. companies that self-certify to the U.S. Department of Commerce and publicly commit to comply with the Privacy Shield requirements

to freely import personal data from the European Union and Switzerland. However, these frameworks face a number of legal challenges and their validity remains subject to legal, regulatory and political developments in both the European Union and the U.S. This has resulted in some uncertainty, and compliance obligations could cause us to incur costs or require us to change our business practices in a manner adverse to our business.

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 administrative headquarters or any of our other processing or manufacturing facilities, our operations may be interrupted and we may be unable to process or manufacture certain products for a substantial amount of time.

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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 also developed an information technology disaster recovery plan. However, any future natural disaster at this or our other locations could cause substantial delays in our operations, damage or destroy our facilities, 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 implants 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 implants and technologies, as well as to market and distribute our existing implants and technologies, to new markets or geographical areas. We may not be able to find additional distributors who will agree to and are able to successfully market and distribute our implants 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 service efforts of our distributors. If our distributors are unsuccessful in adequately servicing 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 impact of this far-reaching legislation, including Medicare provisions purportedly 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. With the arrival of a new presidential administration and control of both the U.S. Senate and House of Representatives, all of which are under control of the same political party, as of yet undetermined aspects of currently enacted legislation may change. The extent of any such changes and the impact on our business is uncertain. We therefore 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. Amendments to, or rescissions of, existing laws and regulations, or the implementation of new ones, could meaningfully change the way healthcare is designed and delivered. Any change that lowers reimbursement for an implant, our services, or our other technologies, or that reduces medical procedure volumes, would likely adversely impact 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.

Implants require careful calibration and precise, high-quality processing and/or manufacturing. Achieving precision and quality control requires skill and diligence by our personnel. If we fail to achieve and maintain these high standards, including avoiding processing and manufacturing 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 and/or manufacturing costs could increase.

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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.

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 the broad commercial success of our implants and technologies. If our implants and technologies are not broadly accepted in the marketplace, we may not

remain competitive in the market.

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.

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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, medical devices, surgical instruments 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.

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

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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, medical devices, surgical instruments 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, manufacture, and distribution of implants, medical devices, surgical instruments, and other technologies for surgical and medical 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 typically 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 the laws of foreign jurisdictions 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.

Our business of designing, manufacturing and marketing metal, synthetic, and xenograft medical devices and surgical instruments exposes us to potential product liability risks that are inherent in such activities. In the ordinary course of business, we are the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

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We currently have $15 million of product and $25 million of 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 implants 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 foreign country where we operate. 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 attacks 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.

In addition to product and professional liability legal proceedings and claims, we are from time to time subject to intellectual property and various commercial legal proceedings and claims that arise in the ordinary course of business.

Given the uncertain nature of legal proceedings generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome. We could in the future incur judgments or enter into settlements of claims that could adversely impact our business, financial condition or results of operations.

Any acquisitions, strategic investments, divestures, mergers or joint ventures 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 intend to 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.

Our long-term strategy may include identifying and acquiring, investing in or merging with suitable candidates on acceptable terms, divesting of certain business lines or activities or entering into joint ventures. In particular, over time, we may acquire, make investments in, or merge with providers of product offerings that complement our business or may terminate such activities. Mergers, acquisitions and divestitures include a number of risks and present financial, managerial and operational challenges, including but not limited to:

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;

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

increased costs to integrate or, in the case of a divestiture or joint venture, separate the technology, personnel, customer base and business practices of the acquired or divested business or assets.

Any one of these risks could prevent an acquisition, strategic investment, divesture, merger or joint venture from being scientifically or commercially successful, which could have a material impact on our results of operations, and financial condition.

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 19% 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 stock). In addition, to the extent dividends are not paid in cash in any quarter for any reason, including any restriction on

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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 from the fourth quarter of 2013 through 2017. Consequently, we have accrued $14.4 million in preferred dividends payable as of December 31, 2017. 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 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 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;

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.

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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. In June 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. In June 2016, we entered into a Fourth 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 $30.0 million to $45.0 million. In November 2016, we entered into a Fifth Amendment to the Second Amended and Restated Loan Agreement with TD Bank, N.A. and Regions Bank, which provided for: (i) a decrease in the maximum revolving credit amount from $45.0 million to $42.5 million; (ii) an increase in our leverage to EBITDA ratio from 2.50 to 1.00 to (A) 3.25 to 1.00 through March 31, 2017 and (B) 3.00 to 1.00 after March 31, 2017 and (iii) certain corresponding amendments. In February 2017, we entered into a Sixth Amendment to the Second Amended and Restated Loan Agreement with TD Bank, N.A. and Regions Bank, which modified the definition of Extraordinary Expenses and to increase to 300 basis points the LIBOR Spread applicable when our financial performance under its Leverage Ratio is greater than 3.0x.

In August 2017, we entered into a Third Amended and Restated Loan Agreement (the 2017 Loan Agreement), among us, TD Bank, N.A. and First Tennessee Bank National Association, as Lenders (together with the various financial institutions as in the future may become parties thereto, the Lenders), and TD Bank, N.A., as administrative agent for the Lenders. The 2017 Loan Agreement represents a modification of the Second Amended and Restated Loan Agreement dated July 16, 2013 between us, TD Bank, N.A. and Regions Bank (as amended, the 2013 Loan Agreement). The 2017 Loan Agreement provides for a revolving credit facility (the Revolving Credit Facility), in the aggregate principal amount of $42.5 million which is unchanged from the final Amendment to the 2013 Loan Agreement. We used $22.0 million of the proceeds from the sale of the CT Business to partially pay down amounts owed under the 2013 Loan Agreement, and $10.0 million to pay down amounts owed under the Revolving Credit Facility. Subsequent to the pay down, the outstanding principal balance on the 2013 Loan Agreement Term Loan amounted to $25.4 million which became the principal amount of the 2017 Loan Agreement (the Term Loan Facility and, together with the Revolving Credit Facility the Facility). The Facility is secured by substantially all the assets of the Company and its domestic subsidiaries and is guaranteed by the Company s domestic subsidiaries, as well as 65% of the stock of the Company s foreign subsidiaries. Borrowings made under the 2017 Loan Agreement initially will bear interest at a rate per annum equal to monthly LIBOR plus a margin of up to 3.50%. Interest is payable quarterly in arrears, and principal on the Term Loan Facility is payable in quarterly payments of $1.1 million, each commencing October 1, 2017. The maturity date of the Facility is September 15, 2019, which represents an extension from the 2013 Loan Agreement maturity date of July 16, 2018. We may make optional prepayments on the Facility without penalty at the end of any LIBOR interest period.

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

Our level of indebtedness, particularly the Revolving Credit Facility discussed in the immediately above risk factor, 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 health insurance and prescription drug coverage, along with our self-insurance reserves, may not cover future claims.

For the health insurance year beginning January 1, 2016, we began to self-insure for our U.S. employees medical and prescription drug insurance coverage. We are responsible for losses up to certain retention limits on both a per-claim and aggregate basis.

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For policies under which we are responsible for losses, we record a liability that represents our estimated cost of claims incurred and unpaid as of the balance sheet date. Our estimated liability is not discounted and is based on a number of assumptions and factors, including historical trends and economic conditions, and is closely monitored and adjusted when warranted by changing circumstances. Fluctuating healthcare costs, severity of claims, increases in the employee population, and deviations from our expectations could affect the accuracy of estimates based on historical experience. If actual claims are greater in number and/or severity compared to what was estimated or medical costs increase beyond what was expected, our accrued liabilities might not be sufficient and we may be required to record additional expense. Unanticipated changes may produce materially different amounts of expense than that reported under these programs, which could adversely impact our operating results.

We may be subject to suit under a state or federal whistleblower statute.

Those who engage in business with the federal government, directly or indirectly, may be sued under a federal whistleblower statute designed to combat fraud and abuse in the healthcare industry. These lawsuits, known as qui tam suits, are authorized under certain circumstances by the False Claims Act and can involve significant monetary damages and award bounties to private plaintiffs who successfully bring these suits. If any of these lawsuits were to be brought against us, such suits combined with increased operating costs and substantial uninsured liabilities could have a material adverse effect on our financial condition and operations.

The Affordable Care Act has sought to link the violations of the Anti-Kickback Statute with violations of the False Claims Act, making it arguably easier for the government or for whistleblowers, acting in the name of the government, to sue medical manufactures under the False Claims Act.

In addition to federal whistleblower laws, various states in which we operate also have separate whistleblower laws to which we may be subject.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Responding to actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees. Such activities could interfere with our ability to execute our strategic plan. In addition, a proxy contest for the election of directors at our annual meeting would likely require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and our board of directors. The perceived uncertainties as to our future direction also could affect the market price and volatility of our securities.

The tax treatment of corporations could be subject to potential legislative, administrative or judicial changes or interpretations.

The present federal income tax treatment of corporations may be modified by legislative, administrative or judicial changes or interpretations at any time. For example, on December 22, 2017, the Tax Cuts and Jobs Act (the Tax Legislation) was enacted. The Tax Legislation significantly revises the U.S. corporate income tax code.

We are unable to predict whether future modifications will be made to the U.S. corporate income tax code. Any such future changes could materially adversely affect us.

We are dependent on our key management and technical personnel for continued success.

Our senior management team is concentrated in a small number of key members, and our future success depends to a meaningful extent on the services of our executive officers and other key team members, including members of our scientific staff. Generally, our executive officers and employees can terminate their employment relationship at any time. The loss of any key employees or our inability to attract or retain other qualified personnel could materially harm our business and prospects.

Effective succession planning is important to our long-term success. In January 2017, we announced the appointment of Camille Farhat as Chief Executive Officer effective March 15, 2017. In September 2017, Robert Jordheim stepped down as Chief Financial Officer and we announced the appointment of Jonathon Singer as Chief Financial and Administrative Officer effective October 2, 2017. Additionally, in 2017 we continued the process of reorganizing our business, as part of our ongoing business transformation, which has resulted in a number of additional leadership changes. Disruptions in the transition or reorganization could have a material adverse effect on our business, results of operations, and financial condition and could adversely affect our ability

to attract and retain other key executives.

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Competition for qualified leadership and scientific personnel in our industry is intense, and we compete for leadership and scientific personnel with other companies that have greater financial and other resources than we do. Our future success will depend in large part on our ability to attract, retain, and motivate highly qualified leadership and scientific personnel, and there can be no assurance that we are able to do so. Any difficulty in hiring or retaining needed personnel, or increased costs related thereto, could have a material adverse effect on our business, results of operations, and financial condition.

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 four buildings on approximately 21 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 an 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 two buildings totaling 71,000 square feet which house our corporate headquarters as well as administrative and distribution and marketing functions.

In Deerfield, Illinois, we lease 6,020 square feet for general and administrative functions.

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

On October 20, 2017, the Company sold a building totaling 15,000 square feet previously used for administrative, distribution and marketing functions in Alachua, Florida.

GERMANY

In Neunkirchen, Germany we own 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.

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.

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BEIJING

Our facility in Beijing 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, 2017 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.

2016	High	Low
First Quarter	$ 4.16	$ 2.81
Second Quarter	$ 4.65	$ 3.50
Third Quarter	$ 3.91	$ 2.98
Fourth Quarter	$ 3.50	$ 2.50

2017	High	Low
First Quarter	$ 4.10	$ 3.01
Second Quarter	$ 5.95	$ 3.80
Third Quarter	$ 6.00	$ 4.25
Fourth Quarter	$ 5.08	$ 3.85

As of February 23, 2018, we had 293 stockholders of record of our common stock. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in street name. The closing sale price of our common stock on February 23, 2018 was $4.50 per share.

The following table presents information with respect to our repurchases of our common stock during the year ended December 31, 2017.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
January 1, 2017 to January 31, 2017	25,834	$ 3.25		
February 1, 2017 to February 29, 2017	15,613	$ 3.65		
March 1, 2017 to March 31, 2017				
April 1, 2017 to April 30, 2017				
May 1, 2017 to May 31, 2017				

June 1, 2017 to June 30, 2017			
July 1, 2017 to July 31, 2017			
August 1, 2017 to August 31, 2017			
September 1, 2017 to September 30, 2017			
October 1, 2017 to October 31, 2017			
November 1, 2017 to November 30, 2017	703,675	$	4.73
December 1, 2017 to December 31, 2017			
Total	745,122	$	4.65

(1) The purchases reflect amounts that are attributable to shares surrendered to us by employees to satisfy, in connection with the vesting of restricted stock awards and the exercise of stock options, their purchase of the stock option and their tax withholdings obligations.

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Stock Performance Graph

The SEC 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, 2012 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.

5-YEAR CUMULATIVE TOTAL RETURNS

Total Return Analysis	2012	2013	2014	2015	2016	2017
RTI Surgical, Inc.	$ 100.00	$ 82.90	$ 121.78	$ 92.97	$ 76.11	$ 96.02
NASDAQ Composite	100.00	140.12	160.78	171.97	187.22	242.71
S&P 500 Health Care Equipment Index	100.00	127.69	161.24	170.88	181.96	238.17

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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, our ability to do so under applicable laws, 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, 2017, 2016 and 2015, and selected balance sheet data as of December 31, 2017 and 2016 have been derived from our audited consolidated financial statements and accompanying notes. The consolidated financial statements as of December 31, 2017 and 2016 and for the three years ended December 31, 2017 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.

The statement of operations data set forth below for the years ended December 31, 2014 and 2013, and the balance sheet data set forth as of December 31, 2015, 2014 and 2013 have been derived from our audited consolidated financial statements and accompanying notes which are not included elsewhere in this Form 10-K.

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	Year Ended December 31,				
	2017	2016	2015	2014	2013
	(In thousands, except share and per share data)				
Statements of Operations Data:					
Revenues	$ 279,563	$ 272,865	$ 282,293	$ 262,810	$ 197,979
Costs of processing and distribution	137,042	140,516	132,551	129,013	117,874
Gross profit	142,521	132,349	149,742	133,797	80,105
Expenses:					
Marketing, general and administrative	115,103	116,125	107,439	107,653	81,635
Research and development	13,375	16,090	15,065	15,536	15,241
Severance and restructuring costs	12,173	2,146	995	4,798	2,881
Strategic review costs		1,150			
Executive transition costs	2,781	4,404			
Contested proxy expenses		2,680			
Asset impairment and abandonments	3,739	5,435	814		
Litigation settlement and settlement charges			804	185	3,000
Acquisition expenses	630				6,004
Gain on cardiothoracic closure business divestiture	(34,090)				
Total operating expenses	113,711	148,030	125,117	128,172	108,761
Operating income (loss)	28,810	(15,681)	24,625	5,625	(28,656)
Other (expense) income:					
Interest expense	(3,180)	(1,655)	(1,492)	(1,357)	(542)
Interest income	8	8	3	9	23
Foreign exchange gain (loss)	87	(132)	78	(88)	251
Total other expense - net	(3,085)	(1,779)	(1,411)	(1,436)	(268)
Income (loss) before income tax (provision) benefit	25,725	(17,460)	23,214	4,189	(28,924)
Income tax (provision) benefit	(19,453)	3,061	(8,299)	(1,493)	11,110
Net income (loss)	6,272	(14,399)	14,915	2,696	(17,814)
Convertible preferred dividend	(3,723)	(3,508)	(3,305)	(3,113)	(1,375)
	$ 2,549	$ (17,907)	$ 11,610	$ (417)	$ (19,189)

Net income (loss) applicable to common shares					
Net income (loss) per common share - basic	$ 0.04	$ (0.31)	$ 0.20	$ (0.01)	$ (0.34)
Net income (loss) per common share - diluted	$ 0.04	$ (0.31)	$ 0.20	$ (0.01)	$ (0.34)
Weighted average shares outstanding - basic	59,684,289	58,236,745	57,611,231	56,735,924	56,258,624
Weighted average shares outstanding - diluted	60,599,952	58,236,745	58,590,494	56,735,924	56,258,624

	As of December 31,				
	2017	**2016**	**2015**	**2014**	**2013**
Balance Sheet Data:					
Cash and cash equivalents	$ 22,381	$ 13,849	$ 12,614	$ 15,703	$ 18,721
Working capital	132,676	121,329	131,941	133,510	134,302
Total assets	345,906	368,031	380,662	378,135	369,854
Long-term obligations - less current portion	42,076	77,267	73,384	69,413	67,706
Redeemable preferred stock	63,923	60,016	56,323	52,834	49,537
Total stockholders equity	181,737	164,916	181,356	167,835	168,053

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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.

Management Overview:

RTI Surgical is a global surgical implant company that designs, develops, manufactures and distributes biologic, metal and synthetic implants. Our implants are used in orthopedic, spine, sports medicine, general surgery, trauma and other surgical procedures to repair and promote the natural healing of human bone and other human tissues and improve surgical outcomes. We manufacture metal and synthetic implants and process donated human musculoskeletal and other tissue and bovine and porcine animal tissue in producing allograft and xenograft implants using our proprietary BIOCLEANSE®, TUTOPLAST® and CANCELLE® SP sterilization processes. We process tissue at our facilities in Alachua, Florida and Neunkirchen, Germany and manufacture metal and synthetic implants in Marquette, Michigan and Greenville, North Carolina. We are accredited in the U.S. by the American Association of Tissue Banks and we are a member of AdvaMed. Our implants are distributed directly to hospitals throughout the U.S. and in more than 40 countries worldwide with the support of both our and third-party representatives as well as through larger purchasing companies. We were founded in 1997 and are headquartered in Alachua, Florida.

Domestic distributions and services accounted for 91% of total revenues in 2017. Most of our implants are distributed directly to healthcare providers, hospitals and other healthcare facilities through a direct distribution force and through various OEM relationships.

International distributions and services accounted for 9% of total revenues in 2017. Our implants are distributed in over 40 countries through a direct distribution force in Germany and through stocking distributors in the rest of the world outside of Germany and the U.S.

Our business is generally not seasonal in nature; however, the number of orthopedic implant surgeries and elective procedures generally declines during the summer months. During the third quarter of 2017, our operations in Florida experienced losses related to a hurricane. Based on our assessment, the negative impact to revenue and net income for the year ended December 31, 2017, was $1.2 million and $0.5 million, respectively.

We are implementing a focused strategy to expand our spine and OEM operations and create long-term, profitable growth for the company. In 2017, we introduced a new management team with extensive experience in an effort to spearhead these efforts. The core components of our strategy are:

Reduce Complexity. We are working to reduce complexity in our organization by divesting non-core assets and investing in core competencies.

Drive Operational Excellence. We are working to optimize material cost and drive operational efficiency to reduce other direct costs by pursuing world class manufacturing.

Accelerate Growth. We are investing in innovative, niche high growth product categories leveraging core competency in the spine market; utilizing core technologies to expand OEM relationships and drive organic growth; and building relevant scale in our spinal portfolio to improve importance to the consolidating healthcare market driven by integrated delivery networks and group purchasing organizations.

In line with our strategy, we completed the sale of substantially all of the assets related to our CT Business to A&E pursuant to an Asset Purchase Agreement between us and A&E, dated August 3, 2017 (the Asset Purchase Agreement). The total consideration received by us under the Asset Purchase Agreement was composed of $54 million in cash consideration, $3 million of which is being held in escrow for up to twelve months to satisfy possible indemnification obligations, if any (the Escrow Amount), plus an additional $5 million in contingent cash consideration if A&E reaches certain revenue milestones (the Contingent Consideration). We are also entitled to an additional $1 million in consideration if we successfully obtain a certain FDA regulatory clearance. As a part of the transaction, we also entered into a multi-year Contract Manufacturing Agreement with A&E (the Contract Manufacturing Agreement). Under the Contract Manufacturing Agreement, we agreed to

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continue to support the CT Business by manufacturing existing products and engineering, developing, and manufacturing potential future products for A&E. We believe this is a significant step toward focusing our business and advancing our efforts to generate predictable and sustainable operating results through disciplined execution and building scale to extend distribution of our products in those areas that offer the greatest opportunities to benefit our patients and shareholders.

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, as well as strategic dispositions from time to time in response to market trends or industry developments.

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.

During the fourth quarter of 2017, we ceased certain long-term projects resulting in asset abandonments of long-term assets at our US facility of $3.5 million. During the fourth quarter of 2016, we concluded a strategic review of our business lines and operations, and updated our financial projections. As a result, our financial projections related to our hernia business line were adjusted downward. This business line is a significant driver of revenue for the Tutogen Germany asset group. As a result, during the fourth quarter of 2016, we completed an asset group impairment test and determined the carrying value was

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not recoverable as of December 31, 2016. We used a market approach to determine the fair value of the Tutogen Germany asset group s long lived assets and recognized impairment charges related to identified intangibles and property and equipment of $5.4 million. During 2015 we incurred asset abandonments of certain long-term assets at our German facility of $0.8 million.

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, procurement contracts, customer lists, distribution agreements and acquired exclusivity rights. Patents 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 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.

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., (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.

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Revenue Recognition. We recognize revenue upon shipping, or receipt by our customers of our products and implants, 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). 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, 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). We value restricted stock awards using the intrinsic value method, which is based on the fair market value price on the grant date. We use a Monte Carlo simulation model to estimate the fair value of restricted stock awards that contain a market condition.

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. On December 22, 2017, the Tax Cuts and Jobs Act (the Tax Legislation) was enacted. The Tax Legislation significantly revises the U.S. corporate income tax code by, among other things, lowering corporate income tax rates and imposing a transition tax on deemed repatriated earnings of foreign subsidiaries. The SEC staff issued SAB 118, which provides guidance on accounting for the tax effects of the Tax Legislation. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Legislation enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, we must reflect the income tax effects of those aspects of the Tax Legislation for which the accounting under ASC 740 is complete. To the extent that our accounting for certain income tax effects of the Tax Legislation is incomplete, but for which we are able to determine a reasonable estimate, we must record a provisional estimate in the consolidated financial statements. If we cannot determine a provisional estimate, we should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Legislation.

Off Balance-Sheet Arrangements

As of December 31, 2017, we had no off-balance-sheet arrangements, as defined in Item 303(a) (4) (ii) of Regulation S-K.

Regulatory Approvals in 2017

AMERICAS

US 510(k) Clearance of the Interbody Fusion (IBF) / Vertebral Body Replacement (VBR) System

US 510(k) Clearance of Fortilink -C with TETRAfuse 3D Technology

US 510(k) Clearance of Fortilink® IBF System with TETRAfuse® 3D Technology

US 510(k) Clearance of Unison-C Anterior Cervical Fixation System

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

Mexico Approval of the Sternal Cable System

Mexico Approval of the Tritium Sternal Cable Plate System

Mexico Approval of the IBF / VBR System

Mexico Approval of the SlimFuse Anterior Cervical Plate System

Mexico Approval of the Streamline TL Spinal Fixation System

Costa Rica Import Permits for various allograft products

Nicaragua Clearance for a commercial partner product

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EUROPE, MIDDLE EAST, AFRICA

Germany Approval of Puros Blend

Germany Approval of 12 Tutoplast Spongiosa product variants

European Union (EU) Approval of Fortiva Porcine Dermis 1 mm and Fortiva Porcine Dermis 1.5 mm perforated

Israel Import Permit for a commercial partner s products

ASIA-PACIFIC

Australia Registration of Fortiva Porcine Dermis 1.5 mm

Vietnam Import Licensure of Bullet-Tip PEEK VBR / IBF System

Vietnam Import Licensure of Streamline TL Spinal Fixation System

China Registration of IBF / VBR System Instruments

China Registration of the Clarity Retractor System

Malaysia Import Permit for various allograft products

Singapore Import Permit for various allograft products

Malaysia Import Permit for commercial partner s products

Hong Kong Licensure for 3 commercial partner products

Certifications, Accreditations and Inspections in 2017

AMERICAS

U.S. Food and Drug Administration (FDA) routine inspections of the RTI Surgical facilities located in Marquette, MI and Greenville, NC

FDA directed inspection of the RTI Surgical Alachua, FL facility

BSI ISO 13485:2003 surveillance audit of the Alachua, FL facility

BSI ISO 13485:2016 certification surveillance audit of the Marquette, Michigan; and Greenville, North Carolina facilities.

Australia authority of Therapeutic Goods Administration (TGA) inspection performed of the Greenville, NC facility

German Authorities (PEI & ROF) inspection performed of the RTI Surgical Alachua, FL Facility

Korean authority of Ministry of Food and Drug Safety (MFDS) inspection performed of the RTI Surgical Alachua, FL facility

EUROPE

German authority (ROF) recertification inspection of RTI Surgical facility located in Neunkirchen, Germany

BSI ISO 13485:2003 unannounced audit of the RTI Surgical facility located in Neunkirchen, Germany

FDA routine inspection of RTI Surgical facility located in Neunkirchen, Germany

Korean authority of MFDS inspection performed of the RTI Surgical facility located in Neunkirchen, Germany

ASIA

SOCOTEC (Singapore) GDPMDS audit of the RTI Surgical Singapore Distribution facility

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

Implant and Product Recalls in 2017

In 2017, there was one voluntary recall with the Center for Devices and Radiological Health (CDRH) of the FDA.

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January 2017 One recall related to incorrect Package Insert for 24 units of BioSet® DBM allograft. All activities were completed and request for official closure with FDA has been made. This recall is still open, with the last correspondence with FDA on March 31, 2017.

In 2017, there were two voluntary recalls with the Center for Biologics Evaluation and Research (CBER) of the FDA.

February 2017 One recall was filed involving release of a single lot of maps® Cellular Allogeneic Bone Graft Strips allograft with a positive final product sterility culture. All activities were completed and verification of closure received from FDA on March 28, 2017.

September 2017 One recall was filed involving release of a single BioCleanse® Tendon allograft with a positive final product sterility culture. All activities were completed and notification of closure received from FDA on October 3, 2017.

In 2017 there was one reportable recall in the rest of the world. This recall was reported to TGA in Australia:

August 2017 (RC-2017-RN-1005-1) One Field Corrective Action was filed involving one lot of nanOss Bioactive Advanced Bone Graft Substitute, 10cc. This lot of implants was shipped to Australia at the incorrect product revision, with the shipped product including a hydration syringe, labeling, and branding not approved by TGA. This field action remains open as of January 30, 2018.

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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,					
	2017		2016		2015	
	(Dollars in thousands)					
Statement of Operations Data:						
Revenues	$ 279,563	100.0%	$ 272,865	100.0%	$ 282,293	100.0%
Costs of processing and distribution	137,042	49.0	140,516	51.5	132,551	47.0
Gross profit	142,521	51.0	132,349	48.5	149,742	53.0
Expenses:						
Marketing, general and administrative	115,103	41.2	116,125	42.6	107,439	38.1
Research and development	13,375	4.8	16,090	5.9	15,065	5.3
Severance and restructuring costs	12,173	4.4	2,146	0.8	995	0.4
Strategic review costs			1,150	0.4		
Executive transition costs	2,781	1.0	4,404	1.6		
Contested proxy expenses			2,680	1.0		
Asset impairment and abandonments	3,739	1.3	5,435	2.0	814	0.3
Litigation settlement and settlement charges					804	0.3
Acquisition expenses	630	0.2				
Gain on cardiothoracic closure business divestiture	(34,090)	(12.2)				
Total operating expenses	113,711	40.7	148,030	54.3	125,117	44.3
Operating income (loss)	28,810	10.3	(15,681)	(5.8)	24,625	8.7
Other (expense) income:						
Interest expense	(3,180)	(1.1)	(1,655)	(0.7)	(1,492)	(0.5)
Interest income	8	0.0	8	0.0	3	0.0
Foreign exchange gain (loss)	87	0.0	(132)	(0.0)	78	0.0
Total other expense - net	(3,085)	(1.1)	(1,779)	(0.7)	(1,411)	(0.5)
Income (loss) before income tax (provision) benefit	25,725	9.2	(17,460)	(6.5)	23,214	8.2
Income tax (provision) benefit	(19,453)	(7.0)	3,061	1.1	(8,299)	(2.9)
Net income (loss)	6,272	2.2	(14,399)	(5.4)	14,915	5.3
Convertible preferred dividend	(3,723)	(1.3)	(3,508)	(1.3)	(3,305)	(1.2)

Net income (loss) applicable to common shares	$ 2,549	0.9%	$ (17,907)	(6.7%)	$ 11,610	4.1%

	Year Ended December 31,			Percent Change	
	2017	2016	2015	2017/2016	2016/2015
Revenues:					
Spine	$ 77,514	$ 73,907	$ 57,983	4.9%	27.5%
Sports medicine and orthopedics	50,231	50,143	50,712	0.2%	-1.1%
Surgical specialties	6,980	4,466	3,029	56.3%	47.4%
Cardiothoracic	8,164	11,147	8,699	-26.8%	28.1%
International	23,240	21,185	18,338	9.7%	15.5%
Subtotal direct	166,129	160,848	138,761	3.3%	15.9%
OEM	103,011	99,127	129,930	3.9%	-23.7%
Other revenues	10,423	12,890	13,602	-19.1%	-5.2%
Total revenues	$ 279,563	$ 272,865	$ 282,293	2.5%	-3.3%
Domestic revenues	$ 253,599	$ 247,756	$ 260,387	2.4%	-4.9%
International revenues	25,964	25,109	21,906	3.4%	14.6%
Total revenues	$ 279,563	$ 272,865	$ 282,293	2.5%	-3.3%

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2017 Compared to 2016

Total Revenues

Our total revenues increased $6.7 million, or 2.5%, to $279.6 million for the year ended December 31, 2017 compared to $272.9 million for the year ended December 31, 2016. Our direct revenues increased by $5.3 million, or 3.3%, to $166.1 million and our OEM revenues increased by $3.9 million, or 3.9%, to $103.0 million.

Direct Revenues

Spine - Revenues from spinal implants increased $3.6 million, or 4.9%, to $77.5 million for the year ended December 31, 2017 compared to $73.9 million for the year ended December 31, 2016. Spine revenues increased primarily as a result of increased distributions of our map3® implant.

Sports Medicine and Orthopedics - Revenues from sports medicine and orthopedics allografts of $50.2 million for the year ended December 31, 2017 were comparable to the year ended December 31, 2016.

Surgical Specialties - Revenues from surgical specialty allografts increased $2.5 million, or 56.3%, to $7.0 million for the year ended December 31, 2017 compared to $4.5 million for the year ended December 31, 2016. Surgical Specialties revenues increased primarily as a result of new customers and increased distributions of our Cortiva™ implants.

Cardiothoracic - Revenues from cardiothoracic implants decreased $3.0 million, or 26.8%, to $8.2 million for the year ended December 31, 2017 compared to $11.1 million for the year ended December 31, 2016. The decrease was primarily the result of the August 3, 2017, sale of substantially all of the assets of the CT Business to A&E, which was partially offset by the increased distribution of sternal cables and sternal closure plates prior to the sale of the CT Business due to expanded investment in distribution channels. In addition, we have entered into a multi-year Contract Manufacturing Agreement with A&E whereby we will continue to support the CT Business under A&E s ownership through the manufacturing of existing products, which will generate revenue for our OEM business.

International Revenues - International revenues include distributions from our foreign affiliates as well as domestic export revenues. International revenues increased $2.1 million, or 9.7%, to $23.2 million for the year ended December 31, 2017 compared to $21.2 million for the year ended December 31, 2016. International revenues increased primarily as a result of higher distributions in Europe and Asia Pacific due to expanded distribution channels.

OEM

Revenues from OEM increased $3.9 million, or 3.9%, to $103.0 million for the year ended December 31, 2017 compared to $99.1 million for the year ended December 31, 2016. OEM revenues increased primarily as a result of higher orders from certain OEM distributors, primarily in the dental and trauma markets. Effective August 3, 2017, our cardiothoracic hardware implants are distributed through A&E.

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, decreased $2.5 million, or 19.1%, to $10.4 million for the

year ended December 31, 2017 compared to $12.9 million for the year ended December 31, 2016. The decrease was primarily due to lower tissue recovery offset by an increase in service processing fees.

Costs of Processing and Distribution. Costs of processing and distribution decreased $3.5 million, or 2.5%, to $137.0 million for the year ended December 31, 2017 from $140.5 million for the year ended December 31, 2016. Costs of processing and distribution decreased as a percentage of revenues from 51.5% for the year ended December 31, 2016 to 49.0% for the year ended December 31, 2017. The decrease was primarily due to a $9.6 million inventory charge for the year ended December 31, 2016 as a result of writing-off certain excess quantities primarily of hernia and sports medicine inventory, offset by changes in distribution mix for the year ended December 31, 2017.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses decreased $1.0 million, or 0.9%, to $115.1 million for the year ended December 31, 2017 compared to $116.1 million for the year ended December 31, 2016. Marketing, general and administrative expenses decreased as a percentage of revenues from 42.6% for the year ended December 31, 2016 to 41.2% for the year ended December 31, 2017 primarily due to the sale of the CT Business and the reduction of our organizational structure, as a result of improvements in organizational efficiencies.

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Research and Development Expenses. Research and development expenses decreased $2.7 million, or 16.9%, to $13.4 million for the year ended December 31, 2017 compared to $16.1 million for the year ended December 31, 2016. As a percentage of revenues, research and development expenses decreased from 5.9% for the year ended December 31, 2016 to 4.8% for the year ended December 31, 2017. The decrease was primarily due to the reduction of our organizational structure, as a result of improvements in organizational efficiencies.

Severance and Restructuring Costs. Severance and restructuring costs related to the reduction of our organizational structure resulted in $12.2 million of expenses for the year ended December 31, 2017 compared to $2.1 million for the year ended December 31, 2016.

Executive Transition Costs. Executive transition costs related to hiring a new Chief Executive Officer and Chief Financial and Administrative Officer resulted in $2.8 million of an inducement award and stock-based compensation expenses for the year ended December 31, 2017. This compares to executive transition costs related to the retirement of our former Chief Executive Officer which resulted in $4.4 million of severance, stock-based compensation and other retirement related expenses for the year ended December 31, 2016.

Asset Impairment and Abandonments. Asset impairment and abandonments related to asset abandonments of certain long-term assets of $3.7 million primary at our U.S. facility for the year ended December 31, 2017 compared to a $5.4 million asset impairment at our German facility for the year ended December 31, 2016.

Acquisition Expenses. Acquisition expenses related to the purchase of Zyga Technology, Inc. resulted in $0.6 million of expenses for the year ended December 31, 2017. There were no acquisition expenses for the year ended December 31, 2016.

Total Other Expense-Net. Total other expense net was $3.1 million for the year ended December 31, 2017 compared to $1.8 million for the year ended December 31, 2016. The increase in total other expense-net is primarily attributable to higher interest expense of $3.2 million in 2017 compared to $1.7 million in 2016 as a result of higher interest rate and average debt balance as compared to the year ended December 31, 2016, offset by a foreign currency exchange gain of $87,000 for the year ended December 31, 2017, compared to a foreign currency exchange loss of $132,000 for the year ended December 31, 2016, 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, 2017 was $19.5 million compared to an income tax benefit of $3.1 million for the year ended December 31, 2016. Our effective tax rate for the year ended December 31, 2017 and 2016 was 75.6% and 17.5% respectively. Our effective tax rate increased as a result of disposing of non-deductible goodwill relating to the sale of substantially all of the assets of the CT business to A&E, and recording non-deductible executive compensation. In addition, on December 22, 2017, the Tax Cuts and Jobs Act (the Tax Legislation) was enacted. The Tax Legislation significantly revises the U.S. corporate income tax code by, among other things, lowering corporate income tax rates and imposing a transition tax on deemed repatriated earnings of foreign subsidiaries. As a result of the Tax Legislation and in accordance with SAB 118, we recorded a provisional tax expense of $2.2 million, which increased our effective tax rate.

Convertible Preferred Dividend. As a result of the acquisition of Pioneer and pursuant to the terms of the investment agreement with Water Street, we accrued a convertible preferred dividend of $3.7 million for the year ended December 31, 2017 compared to $3.5 million for the year ended December 31, 2016.

2016 Compared to 2015

Total Revenues

Effective January 1, 2016, we revised the reporting of our lines of business, which is now composed primarily of six categories: spine; sports medicine and orthopedics; surgical specialties; cardiothoracic; international; and OEM. Our previous lines of business were composed of: spine; ortho fixation; sports medicine; bone graft substitutes and general orthopedic; dental; and surgical specialties. The prior year comparable revenue information has been restated to conform to the current year presentation. We believe that the change in the reporting of our lines of business will facilitate a better understanding of our lines of business and align more closely with the end markets in which we compete.

Our total revenues decreased $9.4 million, or 3.3%, to $272.9 million for the year ended December 31, 2016 compared to $282.3 million for the year ended December 31, 2015. Our direct revenues increased by $22.1 million, or 15.9%, to $160.8 million, offset by our OEM revenues which decreased by $30.8 million, or 23.7%, to $99.1 million. The

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causes of the increase in our direct revenues are discussed below. Our OEM revenue comparisons were impacted due to a significant amount of our revenue being derived from large OEM 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 year over year comparisons. In addition, OEM revenues decreased primarily as a result of lower orders from certain OEM distributors, primarily in the spinal, dental and trauma markets.

Direct Revenues

Spine - Revenues from spinal implants increased $15.9 million, or 27.5%, to $73.9 million for the year ended December 31, 2016 compared to $58.0 million for the year ended December 31, 2015. Spine revenues increased primarily as a result of new surgeon customers and increased distributions of our map3® and nanOss® implants.

Sports Medicine and Orthopedics - Revenues from sports medicine and orthopedics allografts decreased $569,000, or 1.1%, to $50.1 million for the year ended December 31, 2016 compared to $50.7 million for the year ended December 31, 2015. Sports medicine and orthopedics revenues decreased primarily as a result of lower unit volumes and a procedural shift to autograft in the marketplace.

Surgical Specialties - Revenues from surgical specialty allografts increased $1.4 million, or 47.4%, to $4.5 million for the year ended December 31, 2016 compared to $3.0 million for the year ended December 31, 2015. Surgical Specialties revenues increased primarily as a result of new customers.

Cardiothoracic - Revenues from cardiothoracic implants increased $2.4 million, or 28.1%, to $11.1 million for the year ended December 31, 2016 compared to $8.7 million for the year ended December 31, 2015. Cardiothoracic revenues increased primarily as a result of increased sales of sternal cables and sternal closure plates resulting from expanded investment in distribution channels.

International Revenues - International revenues include distributions from our foreign affiliates as well as domestic export revenues. International revenues increased $2.8 million, or 15.5%, to $21.2 million for the year ended December 31, 2016 compared to $18.3 million for the year ended December 31, 2015. International revenues increased primarily as a result of higher distributions in Europe and Asia Pacific due to expanded distribution channels.

OEM

Revenues from OEM decreased $30.8 million, or 23.7%, to $99.1 million for the year ended December 31, 2016 compared to $129.9 million for the year ended December 31, 2015. OEM revenues decreased primarily as a result of significantly high orders in 2015 which did not repeat in 2016, primarily in the spinal, dental and trauma markets.

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, decreased $712,000, or 5.2%, to $12.9 million for the year ended December 31, 2016 compared to $13.6 million for the year ended December 31, 2015. The decrease was primarily due to the acceleration of deferred revenue recognition of $1.5 million relating to Davol relinquishing its exclusive distribution rights in the breast reconstruction market for the year ended December 31, 2015, partially offset by increased service processing fees.

Costs of Processing and Distribution. Costs of processing and distribution increased $8.0 million, or 6.0%, to $140.5 million for the year ended December 31, 2016 from $132.6 million for the year ended December 31, 2015. Costs of processing and distribution increased as a percentage of revenues from 47.0% for the year ended December 31, 2015 to 51.5% for the year ended December 31, 2016. Costs of processing and distribution as a percentage was negatively impacted by a decrease in manufacturing processing levels as a result of lower OEM revenue distributions and an inventory charge of $9.6 million as a result of writing-off certain excess quantities primarily of hernia and sports medicine inventory.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses increased $8.7 million, or 8.1%, to $116.1 million for the year ended December 31, 2016 compared to $107.4 million for the year ended December 31, 2015. Marketing, general and administrative expenses increased as a percentage of revenues from 38.1% for the year ended December 31, 2015 to 42.6% for the year ended December 31, 2016 due to higher variable compensation and distributor commission expenses on increasing direct revenue distributions.

Research and Development Expenses. Research and development expenses increased $1.0 million, or 6.8%, to $16.1 million for the year ended December 31, 2016 compared to $15.1 million for the year ended December 31, 2015. As a percentage of revenues, research and development expenses increased from 5.3% for the year ended December 31, 2015 to 5.9% for the year ended December 31, 2016. The increase was primarily due to higher research study related expenses.

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Severance and Restructuring Costs. Severance and restructuring costs related to the reduction of our organizational structure resulted in $2.1 million of expenses for the year ended December 31, 2016 compared to $1.0 million for the year ended December 31, 2015.

Strategic Review Costs. Strategic review costs related to the comprehensive strategic review of the Company s business lines and operations to leverage the Company s expertise, technology and products and identify opportunities to increase stockholder values, resulted in $1.2 million of expenses for the year ended December 31, 2016. There were no strategic review costs in the year ended December 31, 2015.

Executive Transition Costs. Executive transition costs related to the retirement of our former Chief Executive Officer pursuant to the Executive Transition Agreement dated August 29, 2012 (as amended and extended to date), and Executive Separation Agreement dated August 15, 2016, resulted in $4.4 million of severance, stock-based compensation and other retirement related expenses for the year ended December 31, 2016. There were no Chief Executive Officer retirement and transition costs in the year ended December 31, 2015.

Contested Proxy Expenses. The Company incurred contested proxy expenses of $2.7 million for the year ended December 31, 2016. There were no contested proxy expenses for the year ended December 31, 2015.

Asset Impairment and Abandonments. Asset impairment and abandonments related to an asset impairment at our German facility of $5.4 million for the year ended December 31, 2016 compared to $814,000 asset abandonments of certain long-term assets at our German facility for the year ended December 31, 2015.

Total Other Expense-Net. Total other expense net was $1.8 million for the year ended December 31, 2016 compared to $1.4 million for the year ended December 31, 2015. The increase in total other expense-net is primarily attributable to higher interest expense of $163,000 as a result of higher average debt balance as compared to the year ended December 31, 2015 and due to a foreign currency exchange transaction loss of $132,000 for the year ended December 31, 2016, compared to a foreign currency exchange transaction gain of $78,000 for the year ended December 31, 2015, 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 Benefit (Provision). Income tax benefit for the year ended December 31, 2016 was $3.1 million compared to an income tax provision of $8.3 million for the year ended December 31, 2015. Our effective tax rate for the year ended December 31, 2016 and 2015 was 17.5% and 35.7% respectively. During the year ending December 31, 2016, the Company s German operations entered into a cumulative net loss position. As a result, the Company recorded a full valuation allowance on its German subsidiary s deferred tax assets. For the year ended December 31, 2016, our income tax rate was impacted due to the full valuation allowance recorded.

Convertible Preferred Dividend. As a result of the acquisition of Pioneer and pursuant to the terms of the investment agreement with Water Street, we accrued a convertible preferred dividend of $3.5 million for the year ended December 31, 2016 compared to $3.3 million for the year ended December 31, 2015.

Non-GAAP Financial Measures

We utilize certain financial measures that are not calculated based on Generally Accepted Accounting Principles (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 provide 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 income applicable to common shares, adjusted. The calculation of the tax effect on the adjustments between GAAP net income (loss) applicable to common shares and

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non-GAAP net income applicable to common shares is based upon our estimated annual GAAP tax rate, adjusted to account for items excluded from GAAP net income (loss) applicable to common shares in calculating non-GAAP net income applicable to common shares. Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP measures are included in the reconciliation below:

	Year Ended December 31,		
	2017	2016	2015
	(In thousands)		
Net income (loss) applicable to common shares, as reported	$ 2,549	$ (17,907)	$ 11,610
Severance and restructuring costs	12,173	2,146	995
Strategic review costs		1,150	
Executive transition costs	2,781	4,404	
Contested proxy expenses		2,680	
Asset impairment and abandonments	3,739	5,435	814
Litigation and settlement charges			804
Excess inventory charge		9,556	
Acquisition expenses	630		
Gain on cardiothoracic closure business divestiture	(34,090)		
Foreign net operating loss valuation reserve		1,224	
Tax effect on new tax legislation	2,187		
Tax effect on other adjustments	13,162	(6,602)	(871)
Non-GAAP net income applicable to common shares, adjusted	$ 3,131	$ 2,086	$ 13,352

The following are explanations of the adjustments that management excluded as part of the non-GAAP measures for the years ended December 31, 2017, 2016 and 2015 as well as the reasons for excluding the individual items:

2017, 2016 and 2015 Severance and restructuring costs This adjustment represents costs relating to the reduction of our organizational structure. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2016 Strategic review costs This adjustment represents charges relating to a comprehensive strategic review of the Company s business lines and operations to leverage the Company s expertise, technology and products and identify opportunities to increase stockholder value. Management removes the amount of these expenses from our operating results to supplement a comparison to our past operating performance.

2017 and 2016 Executive transition costs This adjustment represents charges relating to hiring a new Chief Executive Officer and Chief Financial and Administrative Officer and the retirement of our former Chief Executive Officer. Management removes the amount of these expenses from our operating results to supplement a comparison to our past operating performance.

2016 Contested proxy expenses This adjustment represents charges relating to contested proxy expenses. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2017, 2016 and 2015 Asset impairment and abandonments This adjustment represents an asset impairment and abandonment of certain long-term assets at our U.S. and German facilities. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2015 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.

2016 Excess inventory charge This adjustment represents an inventory charge as a result of writing-off certain excess quantities primarily of hernia and sports medicine inventory. Management removes the amount of these expenses from our operating results to supplement a comparison to our past operating performance.

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2017 Acquisition expenses This adjustment represents charges relating to acquisition expenses. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2017 Gain on cardiothoracic closure business divestiture This adjustment represents the gain relating to the sale of substantially all of the assets of our CT Business to A&E. Management removes the amount of this gain from our operating results to supplement a comparison to our past operating performance.

2016 Foreign net operating loss valuation reserve This adjustment represents charges relating to a foreign net operating loss valuation reserve. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

2017 Tax effect on new tax legislation This adjustment represents charges relating to the Tax Cuts and Jobs Act tax legislation which was enacted on December 22, 2017. Management removes the amount of these costs from our operating results to supplement a comparison to our past operating performance.

Liquidity and Capital Resources

2017 Compared to 2016

Our working capital at December 31, 2017 increased $11.3 million to $132.7 million from $121.3 million at December 31, 2016, primarily as a result of the sale of the CT business and its associated working capital. We used $32 million of the proceeds from the sale of the CT Business to partially pay down our long-term obligations and $12 million of the proceeds to pay estimated income taxes associated with the aforementioned sale.

At December 31, 2017, we had 46 days of revenues outstanding in trade accounts receivable, a decrease of 9 days compared to December 31, 2016. The decrease was due to higher cash receipts from customers than shipments and corresponding billings to customers during 2017.

At December 31, 2017, we had 298 days of inventory on hand, a decrease of 14 days compared to December 31, 2016. The decrease was primarily due to higher distributions during the year ended December 31, 2017. We believe that our inventory levels will be adequate to support our on-going operations for the next twelve months.

We had $22.4 million of cash and cash equivalents at December 31, 2017. At December 31, 2017, our foreign subsidiaries held $2.3 million in cash. The Tax Legislation imposes a transition tax on certain deemed repatriated earnings of foreign subsidiaries. In accordance with SAB 118, we have recorded a provisional tax expense of $0.8 million related to the transition tax, which we have elected to pay over eight years. We intend to indefinitely reinvest the earnings of our foreign subsidiaries. We do not believe that this policy of indefinitely reinvesting the earnings of our foreign subsidiaries will have a material adverse effect on the business as a whole.

Our short and long-term obligations at December 31, 2017, decreased $37.0 million to $46.3 million from $83.3 million at December 31, 2016. The decrease in short and long-term obligations was primarily due to principal payments on long-term obligations.

We completed the sale of substantially all of the assets related to our CT Business to A&E pursuant to an Asset Purchase Agreement between us and A&E, dated August 3, 2017. The total consideration received by us under the Asset Purchase Agreement was composed of $54.0 million in cash consideration, $3.0 million of which is being held in escrow for up to twelve months to satisfy possible indemnification obligations, if any, plus an additional $5.0 million in contingent cash consideration if A&E reaches certain revenue milestones. We are also entitled to an

additional $1.0 million in consideration if we successfully obtain a certain FDA regulatory clearance.

Concurrent with the divestiture, we entered into a Third Amended and Restated Loan Agreement, dated as of August 3, 2017 (the 2017 Loan Agreement), among the Company, TD Bank, N.A. and First Tennessee Bank National Association, as Lenders (together with the various financial institutions as in the future may become parties thereto, the Lenders), and TD Bank, N.A., as administrative agent for the Lenders. The 2017 Loan Agreement represents a restructuring of our former loan agreement with TD Bank, N.A. and another lender under the Second Amended and Restated Loan Agreement dated July 16, 2013 between the Company, TD Bank, N.A. and Regions Bank (as amended, the 2013 Loan Agreement).

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The 2017 Loan Agreement provides for a revolving credit facility (the Revolving Credit Facility), in the aggregate principal amount of $42.5 million. As of December 31, 2017, there was $22.5 million outstanding on the Revolving Credit Facility. The 2017 Loan Agreement also contains a term loan facility in the aggregate principal amount of $25.4 million (the Term Loan Facility and, together with the Revolving Credit Facility. We used $32.0 million of the proceeds from the sale of the CT Business to partially pay down $22.0 million of amounts owed under the 2013 Loan Agreement and $10.0 million of amounts owed under the Revolving Credit Facility. The Revolving Credit Facility is secured by substantially all of our assets and the assets of our domestic subsidiaries and is guaranteed by our domestic subsidiaries, as well as 65% of the stock of the Company s foreign subsidiaries.

Borrowings made under the 2017 Loan Agreement initially will bear interest at a rate per annum equal to monthly LIBOR plus a margin of up to 3.50%. As of December 31, 2017, the interest rate for the Term Loan Facility and the Revolving Credit Facility is 4.86%. Interest is payable quarterly in arrears, and principal on the Term Loan Facility is payable in quarterly payments of $1.1 million, each commencing October 1, 2017. The maturity date of the Facility is September 15, 2019.

As of December 31, 2017, we believe that our working capital, together with our borrowing ability under our revolving credit facility, will be adequate to fund our ongoing operations for the next twelve months.

Certain Commitments.

On August 3, 2017, we completed the sale of substantially all of the assets related to our CT Business to A&E pursuant to the Asset Purchase Agreement between us and A&E. The total consideration received by us under the Asset Purchase Agreement was composed of $54.0 million in cash consideration, $3.0 million of which is being held in escrow for up to twelve months to satisfy possible indemnification obligations, if any (the Escrow Amount), plus an additional $5.0 million in contingent cash consideration if A&E reaches certain revenue milestones (the Contingent Consideration). We also are entitled to an additional $1.0 million in consideration if we successfully obtain a certain FDA regulatory clearance. As a part of the transaction, we also entered into a multi-year Contract Manufacturing Agreement with A&E (the Contract Manufacturing Agreement). Under the Contract Manufacturing Agreement, we agreed to continue to support the CT Business by manufacturing existing products and engineering, developing, and manufacturing potential future products for A&E. We elected to account for the Contingent Consideration arrangement including the Escrow Amount, as a gain contingency in accordance with ASC 450 Contingencies. As such, the Contingent Consideration and Escrow Amount were excluded in measuring the fair value of the consideration to be received in connection with the transaction.

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 expired on December 31, 2017. The term automatically renewed for a successive five-year period beginning January 1, 2018. The term automatically renews 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. Because neither party provided notice of non-renewal on or before December 31, 2016, the five-year automatic renewal period was triggered. The distribution agreement will therefore continue at least through December 31, 2022.

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 2017, we achieved and paid the first cumulative revenue milestone of $1.0 million. 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.

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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 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 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, we 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, 2017 are as follows:

	Outstanding Balance	Available Credit
	(In thousands)	
Term loan	$ 23,844	$
Credit facility	22,500	20,000

Total	$ 46,344	$ 20,000

We entered into the 2017 Loan Agreement, among us, TD Bank, N.A. and First Tennessee Bank National Association, as Lenders, and TD Bank, N.A., as administrative agent for the Lenders. The 2017 Loan Agreement represents a modification of the Second Amended and Restated Loan Agreement dated July 16, 2013 between us, TD Bank, N.A. and Regions Bank (as amended, the 2013 Loan Agreement).

The 2017 Loan Agreement provides for a Revolving Credit Facility, in the aggregate principal amount of $42.5 million which is unchanged from the final Amendment to the 2013 Loan Agreement. We used $22.0 million of the proceeds from the sale of the CT Business to partially pay down amounts owed under the 2013 Loan Agreement, and $10.0 million to pay down amounts owed under the Revolving Credit Facility. Subsequent to the pay down, the outstanding principal balance on the 2013 Loan Agreement Term Loan amounted to $25.4 million which became the principal amount of the 2017 Loan Agreement (the Term Loan Facility and, together with the Revolving Credit Facility the Facility). The Facility is secured by substantially all the assets of the Company and its domestic subsidiaries and is guaranteed by the Company s domestic subsidiaries, as well as 65% of the stock of the Company s foreign subsidiaries.

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Borrowings made under the 2017 Loan Agreement initially will bear interest at a rate per annum equal to monthly LIBOR plus a margin of up to 3.50%. Interest is payable quarterly in arrears, and principal on the Term Loan Facility is payable in quarterly payments of $1.1 million, each commencing October 1, 2017. The maturity date of the Facility is September 15, 2019, which represents an extension from the 2013 Loan Agreement maturity date of July 16, 2018. We may make optional prepayments on the Facility without penalty at the end of any LIBOR interest period.

At December 31, 2017, the interest rate for the Term Loan and Revolving Credit Facility is 4.86%. As of December 31, 2017, there was $22.5 million outstanding on the revolving credit facility. The term loan facility requires aggregate principal payments of $6.8 million from January 1, 2018 through June 30, 2019, with a final balloon principal payment of $17.5 million on September 15, 2019. 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.

The total available credit on our revolving credit facility at December 31, 2017 was $20.0 million. Our ability to access our revolving credit facility is subject to and can be limited by our compliance with our financial and other covenants. We were in compliance with the financial covenants related to our revolving credit facility as of December 31, 2017.

The following table provides a summary of our long-term debt obligations, operating lease obligations and other significant obligations as of December 31, 2017.

	Contractual Obligations Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
	(In thousands)				
Long-term debt obligations	$ 46,344	$ 4,268	$ 42,076	$	$
Operating lease obligations	3,189	1,574	1,615		
Purchase obligations (1)	13,106	13,106			
Income taxes payable	710		124	124	462
Total	$ 63,349	$ 18,948	$ 43,815	$ 124	$ 462

(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 are exposed to interest rate risk in the United States and Germany. 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 facility expose us to market risk related to changes in interest rates. As of December 31, 2017, our outstanding floating rate indebtedness totaled $46.3 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 $0.3 million. Other outstanding debt consists of fixed rate instruments. We do not expect changes in interest rates to have a material adverse effect on our income or our cash flows in 2018. However, we can give no assurance that interest rates will not significantly change in the future.

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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. Our international operations currently transact 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, 2017 outstanding intercompany balances, a 1% change in currency rates would have had a de-minimis impact on our results of operations.

We do not expect changes in exchange rates to have a material adverse effect on our income or our cash flows in 2018. However, we can give no assurance that exchange rates will not significantly change in the future.

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.

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

There have been no changes in our internal control over financial reporting during our last fiscal quarter that materially affected, or are reasonably likely to materially affect our 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, 2017. 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, 2017, 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 54.

Item 9B. OTHER INFORMATION.

Not applicable

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by Item 10 relating to our directors, executive officers and corporate governance is incorporated by reference to our definitive proxy statement for 2018 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2017.

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 required by Item 11 relating to executive compensation is incorporated by reference to our definitive proxy statement for our 2018 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2017.

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

The information required by Item 12 relating to security ownership of certain beneficial owners and management, securities authorized for issuance under equity compensation plans and related shareholders matters is incorporated by reference to our definitive proxy statement for our 2018 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2017.

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

The information required by Item 13 relating to certain relationships and related transactions, and director independence is incorporated by reference to our definitive proxy statement for our 2018 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2017.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by Item 14 relating to principal accounting fees and services is incorporated by reference to our definitive proxy statement for our 2018 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2017.

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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 53, the Independent Registered Public Accounting Firm s Report on page 54 and the Consolidated Financial Statements on pages 56 to 59, 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, 2017, 2016 and 2015 is included in the Consolidated Financial Statements of RTI Surgical, Inc. on page 84. 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*:

Exhibit No.	Description	Incorporated by Reference		
		Form	File No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation of RTI Surgical, Inc.	10-K (2015)	000-31271	3/7/2016
3.2	Amended and Restated Bylaws of RTI Surgical, Inc.	8-K	000-31271	7/11/2016
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/A	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	8/6/2004
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	RTI Surgical, Inc. 2015 Incentive Compensation Plan.	S-8	333-203861	5/5/2015
10.8	Form of Incentive Stock Option Agreement (under 2015 Plan).	S-8	333-203861	5/5/2015

10.9	Form of Nonqualified Stock Option Agreement (under 2015 Plan).	S-8	333-203861	5/5/2015
10.10	Form of Restricted Stock Agreement (under 2015 Plan).	S-8	333-203861	5/5/2015
10.11	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
10.12	RTI Biologics, Inc. Executive Nonqualified Excess Plan.	10-K (2011)	000-31271	2/15/2012
10.13	Form of Executive Transition Agreement.	8-K	000-31271	9/4/2012
10.14	Executive Transition Agreement with Brian K. Hutchison, dated August 29, 2012.	8-K	000-31271	9/4/2012
10.15	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
10.16	Executive Separation Agreement, effective August 15, 2016, by and between Brian K. Hutchison and RTI Surgical, Inc.	8-K	000-31271	8/16/2016

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Exhibit No.	Description	Incorporated by Reference Form	File No.	Date Filed
10.17	Release Agreement, effective December 31, 2016, by and between Brian K. Hutchison and RTI Surgical, Inc.	8-K	000-31271	12/19/2016
10.18	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
10.19	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
10.20	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
10.21	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
10.22	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
10.23	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
10.24	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
10.25	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
10.26	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
10.27	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
10.28	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
10.29		8-K	000-31271	7/19/2013

	Investor Rights Agreement dated as of July 16, 2013 by and between RTI Surgical, Inc. and WSHP Biologics Holdings, LLC.			
10.30	Form of Water Street Director Indemnification Agreement.	8-K	000-31271	7/19/2013
10.31	Form of Director Indemnification Agreement.	8-K	000-31271	7/19/2013
10.32	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
10.33	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
10.34	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
10.35	Form of Executive Indemnification Agreement.	10-Q (Q1 2016)	000-31271	5/4/2016
10.36	Fourth Amendment to the Second Amended and Restated Loan Agreement dated June 29, 2016 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	7/5/2016
10.37	Fifth Amendment to the Second Amended and Restated Loan Agreement dated November 7, 2016 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	11/8/2016

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Exhibit No.	Description	Incorporated by Reference Form	File No.	Date Filed
10.38	Sixth Amendment to the Second Amended and Restated Loan Agreement dated February 28, 2017 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 (2017)	000-31271	3/13/2017
10.39	Consultant Agreement, effective February 1, 2017, by and between Caroline A. Hartill and RTI Surgical, Inc.	10-K (2017)	000-31271	3/13/2017
10.40	Executive Separation Agreement, effective January 31, 2017, by and between Caroline A. Hartill and RTI Surgical, Inc.	10-K (2017)	000-31271	3/13/2017
10.41	Release Agreement, effective February 1, 2017, by and between Caroline A. Hartill and RTI Surgical, Inc.	10-K (2017)	000-31271	3/13/2017
10.42	Settlement Agreement, effective March 14, 2017, by and among the Company and Krensavage Partners, LP and certain entities and persons associated with Krensavage Partners, LP.	8-K	000-31271	3/15/2017
10.43	Employment Agreement, dated January 26, 2017, by and between Camille Farhat and RTI Surgical, Inc.	10-Q (Q1 2017)	000-31271	5/3/2017
10.44	Stand Alone Restricted Stock Award Agreement #1, dated January 26, 2017, by and between Camille Farhat and RTI Surgical, Inc.	10-Q (Q1 2017)	000-31271	5/3/2017
10.45	Stand Alone Restricted Stock Award Agreement #2, dated January 26, 2017, by and between Camille Farhat and RTI Surgical, Inc.	10-Q (Q1 2017)	000-31271	5/3/2017
10.46	Stand Alone Stock Option Agreement, dated January 26, 2017, by and between Camille Farhat and RTI Surgical, Inc.	10-Q (Q1 2017)	000-31271	5/3/2017
10.47	Asset Purchase Agreement dated as of August 3, 2017 by and between RTI Surgical, Inc. and A&E Advanced Closure Systems, LLC.	10-Q (Q3 2017)	000-31271	11/3/2017
10.48	Contract Manufacturing Agreement dated as of August 3, 2017 by and between RTI Surgical, Inc. and A&E Advanced Closure Systems, LLC.	10-Q (Q3 2017)	000-31271	11/3/2017
10.49	Third Amended and Restated Loan Agreement, dated as of August 3, 2017 by and among RTI Surgical, Inc., TD Bank, N.A. and First Tennessee Bank National Association, as Lenders (together with the various financial institutions as in the future may become parties thereto, the Lenders), and TD Bank, N.A., as administrative agent for the Lenders.	10-Q (Q3 2017)	000-31271	11/3/2017

10.50	Employment Agreement, dated September 18, 2017, by and between Jonathon M. Singer and RTI Surgical, Inc.	10-Q (Q3 2017)	000-31271	11/3/2017
10.51	Restricted Stock Award Agreement, dated September 18, 2017, by and between Jonathon M. Singer and RTI Surgical, Inc.	10-Q (Q3 2017)	000-31271	11/3/2017
10.52	Stock Option Agreement, dated September 18, 2017, by and between Jonathon M. Singer and RTI Surgical, Inc.	10-Q (Q3 2017)	000-31271	11/3/2017
10.53*	First Amendment to the Stand Alone Restricted Stock Award Agreement #1, dated December 4, 2017, by and between Camille Farhat and RTI Surgical, Inc.			
21.1*	Subsidiaries of the Registrant			
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			

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Exhibit No.	Description	Incorporated by Reference Form	File No.	Date Filed
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.

Item 16. FORM 10-K SUMMARY

Not applicable.

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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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of RTI Surgical, Inc. and subsidiaries (the Company) as of December 31, 2017 and 2016, 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, 2017, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the financial statements). We also have audited the Company s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control Integrated Framework (2013) issued by COSO.

Basis for Opinions

The Company s management is responsible for these financial statements, 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 an opinion on the Company s internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

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

Definition and Limitations of Internal Control over Financial Reporting

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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 its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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/s/ DELOITTE & TOUCHE LLP

Certified Public Accountants

Tampa, Florida

March 2, 2018

We have served as the Company s auditor since 1998.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share data)

	December 31, 2017	2016
Assets		
Current Assets:		
Cash and cash equivalents	$ 22,381	$ 13,849
Accounts receivable less allowances of $1,471 at December 31, 2017 and $1,728 at December 31, 2016	35,081	41,488
Inventories net	111,927	119,743
Prepaid and other current assets	16,285	5,213
Total current assets	185,674	180,293
Property, plant and equipment net	79,564	83,298
Deferred tax assets net	9,575	24,968
Goodwill	46,242	54,887
Other intangible assets net	23,070	23,994
Other assets net	1,781	591
Total assets	$ 345,906	$ 368,031
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 18,252	$ 26,112
Accrued expenses	25,610	22,030
Current portion of deferred revenue	4,868	4,742
Current portion of short and long-term obligations	4,268	6,080
Total current liabilities	52,998	58,964
Long-term obligations less current portion	42,076	77,267
Other long-term liabilities	1,431	256
Deferred revenue	3,741	6,612
Total liabilities	100,246	143,099
Preferred stock Series A, $.001 par value: 5,000,000 shares authorized; 50,000 shares issued and outstanding	63,923	60,016
Stockholders equity:		
Common stock, $.001 par value: 150,000,000 shares authorized; 62,694,441 and 58,433,397 shares issued and outstanding, respectively	63	58
Additional paid-in capital	429,459	417,428
Accumulated other comprehensive loss	(6,329)	(8,316)
Accumulated deficit	(237,066)	(243,338)

Less treasury stock, 1,114,071 and 368,949 shares, respectively, at cost	(4,390)	(916)
Total stockholders equity	181,737	164,916
Total liabilities and stockholders equity	$ 345,906	$ 368,031

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,		
	2017	**2016**	**2015**
Revenues	$ 279,563	$ 272,865	$ 282,293
Costs of processing and distribution	137,042	140,516	132,551
Gross profit	142,521	132,349	149,742
Expenses:			
Marketing, general and administrative	115,103	116,125	107,439
Research and development	13,375	16,090	15,065
Severance and restructuring costs	12,173	2,146	995
Strategic review costs		1,150	
Executive transition costs	2,781	4,404	
Contested proxy expenses		2,680	
Asset impairment and abandonments	3,739	5,435	814
Litigation settlement and settlement charges			804
Acquisition expenses	630		
Gain on cardiothoracic closure business divestiture	(34,090)		
Total operating expenses	113,711	148,030	125,117
Operating income (loss)	28,810	(15,681)	24,625
Other (expense) income:			
Interest expense	(3,180)	(1,655)	(1,492)
Interest income	8	8	3
Foreign exchange gain (loss)	87	(132)	78
Total other expense net	(3,085)	(1,779)	(1,411)
Income (loss) before income tax (provision) benefit	25,725	(17,460)	23,214
Income tax (provision) benefit	(19,453)	3,061	(8,299)
Net income (loss)	6,272	(14,399)	14,915
Convertible preferred dividend	(3,723)	(3,508)	(3,305)
Net income (loss) applicable to common shares	$ 2,549	$ (17,907)	$ 11,610
Other comprehensive income (loss):			

Unrealized foreign currency translation gain (loss)	1,987	(1,274)	(3,161)
Comprehensive income (loss)	$ 4,536	$ (19,181)	$ 8,449
Net income (loss) per common share basic	$ 0.04	$ (0.31)	$ 0.20
Net income (loss) per common share diluted	$ 0.04	$ (0.31)	$ 0.20
Weighted average shares outstanding basic	59,684,289	58,236,745	57,611,231
Weighted average shares outstanding diluted	60,599,952	58,236,745	58,590,494

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, 2015	$ 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)
Amortization of preferred stock Series A issuance costs		(186)				(186)
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
Net loss				(14,399)		(14,399)
Foreign currency translation adjustment			(1,274)			(1,274)
Exercise of common stock options		57				57
Stock-based compensation		3,590				3,590
Purchase of treasury stock					(470)	(470)
Amortization of preferred stock Series A issuance costs		(185)				(185)
Preferred stock Series A dividend		(3,508)				(3,508)
Change in income tax benefit from stock-based compensation		(251)				(251)
Balance, December 31, 2016	58	417,428	(8,316)	(243,338)	(916)	164,916
Net income				6,272		6,272
Foreign currency translation adjustment			1,987			1,987
Exercise of common stock options	5	9,176				9,181
Stock-based compensation		6,762				6,762
Purchase of treasury stock					(3,474)	(3,474)
		(184)				(184)

Amortization of preferred stock Series A issuance costs						
Preferred stock Series A dividend		(3,723)				(3,723)
Balance, December 31, 2017	$ 63	$ 429,459	$ (6,329)	$ (237,066)	$ (4,390)	$ 181,737

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,		
	2017	**2016**	**2015**
Cash flows from operating activities:			
Net income (loss)	$ 6,272	$ (14,399)	$ 14,915
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization expense	14,226	16,510	16,522
Provision for bad debts and product returns	946	895	1,568
Provision for inventory write-downs	5,066	13,880	5,390
Amortization of deferred revenue	(4,744)	(4,867)	(6,225)
Deferred income tax provision	13,329	(3,395)	5,543
Stock-based compensation	6,660	3,590	2,548
Asset impairment and abandonments	3,739	5,435	
Gain on cardiothoracic closure business divestiture	(34,090)		
Other	2,392	603	2,280
Change in assets and liabilities:			
Accounts receivable	5,784	4,756	(10,435)
Inventories	1,375	(15,369)	(11,990)
Accounts payable	(12,899)	4,583	(12,660)
Accrued expenses	2,599	(6,536)	5,532
Deferred revenue	2,000	2,000	2,000
Other operating assets and liabilities	(10,200)	7,637	(5,992)
Net cash provided by operating activities	2,455	15,323	8,996
Cash flows from investing activities:			
Purchases of property, plant and equipment	(12,301)	(15,337)	(17,740)
Patent and acquired intangible asset costs	(2,266)	(2,615)	(498)
Proceeds from sale of building	1,818		
Cardiothoracic closure business divestiture	51,000		
Net cash provided by (used in) investing activities	38,251	(17,952)	(18,238)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	5,060	57	2,505
Proceeds from long-term obligations	6,000	17,000	8,750
Net (payments) proceeds from short-term obligations		(1,511)	422
Payments on long-term obligations	(43,000)	(11,424)	(5,294)
Other financing activities	(458)	(458)	(109)

Net cash (used in) provided by financing activities	(32,398)	3,664	6,274
Effect of exchange rate changes on cash and cash equivalents	224	200	(121)
Net increase (decrease) in cash and cash equivalents	8,532	1,235	(3,089)
Cash and cash equivalents, beginning of period	13,849	12,614	15,703
Cash and cash equivalents, end of period	$ 22,381	$ 13,849	$ 12,614
Supplemental cash flow disclosure:			
Cash paid for interest	$ 3,023	$ 1,224	$ 1,425
Cash paid for income taxes, net of refunds	12,142	(238)	3,667
Non-cash acquisition of property, plant and equipment	593	952	3,795
Stock-based compensation related to severance			310
Receivable for executive stock option exercise	1,234		
Stock-based compensation related to sale of CT business	102		
Change in accrual for dividend payable	3,723	3,508	3,305

See notes to consolidated financial statements.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Years Ended December 31, 2017, 2016 and 2015

(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), while our manufacturing facilities produce metal and synthetic implants. 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 Surgical, Inc. Cardiovascular (inactive), Biological Recovery Group Inc. (inactive), and RTI Services, Inc. (inactive). 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 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 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, 2017 and 2016, 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 write-downs 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 write-downs 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 write-down 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, 2017, 2016 and 2015.

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 to 5 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 related to a recognized debt liability are presented in the balance sheet as a direct deduction from the carrying amount of that debt liability.

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. During the fourth quarter of 2017, the Company ceased certain long-term projects resulting in asset abandonments of long-term assets at its US

facility of $3,539. During the fourth quarter of 2016, the Company concluded a strategic review of its business lines and operations, and updated its financial projections. As a result, the Company s financial projections related to its hernia business line were adjusted downward. This business line is a significant driver of revenue for the Tutogen Germany asset group. As a result, during the fourth quarter of 2016, the Company completed an asset group impairment test and determined the carrying value was not recoverable as of December 31, 2016. The Company used a market approach to determine the fair value of the Tutogen Germany asset group s long-lived assets and recognized impairment charges related to identified intangibles and property and equipment of $5,435. During 2015 the Company incurred asset abandonments of certain long-term assets at our German facility of $814.

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Goodwill Financial Accounting Standards Board (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, 2017 and 2016.

Goodwill is tested for impairment annually by comparing the fair value of the reporting unit to its carrying amount, including goodwill. We evaluate our goodwill for impairment by utilizing an income approach and a market approach. 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, distribution agreements, and procurement contracts. Patents 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, distribution agreements, and procurement contracts are amortized over estimated useful lives of between 5 to 25 years.

Other intangible assets are tested for impairment whenever events or circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. 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 consist 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 which is included in revenues.

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). 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, 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. The Company uses a Monte Carlo simulation model to estimate the fair value of restricted stock awards that contain a market condition.

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. On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Legislation). The Tax Legislation makes broad and complex changes to the U.S. tax code. The SEC staff issued SAB 118, which provides guidance on accounting for the tax effects of the Tax Legislation. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Legislation enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, the Company must reflect the income tax effects of those aspects of the Tax Legislation for which the accounting under ASC 740 is complete. To the extent that the Company s accounting for certain income tax effects of the Tax Legislation is incomplete, but the Company is able to determine a reasonable estimate, it must record a provisional estimate in the

consolidated financial statements. If the Company cannot determine a provisional estimate, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Legislation.

Treasury Stock The Company may periodically repurchase shares of its common stock from employees for the satisfaction of their individual payroll tax withholding upon vesting of restricted stock awards in connection with the Company s incentive plans. The Company s repurchases of common stock are recorded at the stock price on the vesting date of the common stock. The Company repurchased 745,122, 138,597, and 49,454 shares of its common stock for $3.5 million, $0.4 million, and $0.3 million for the years ended December 31, 2017, 2016, and 2015, respectively.

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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,		
	2017	2016	2015
Weighted average basic shares	59,684,289	58,236,745	57,611,231
Effect of dilutive securities:			
Stock options	915,663		979,263
Weighted average diluted shares	60,599,952	58,236,745	58,590,494

Options to purchase 4,692,037 shares of common stock at prices ranging from $2.69 to $8.20 per share which were outstanding as of December 31, 2017, 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 5,764,607 shares of common stock at prices ranging from $2.69 to $9.57 per share which were outstanding as of December 31, 2016, 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.

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.

For the years ended December 31, 2017, 2016 and 2015, 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.

Income Statement Reporting Comprehensive Income In November 2017, the FASB issued ASU 2017-14, *Income Statement Reporting Comprehensive Income* (Topic 220), Revenue Recognition (Topic 605), and Revenue from Contracts with Customers (Topic 606). These amendments provide additional clarification and implementation guidance on the previously issued ASU 2014-09. The Company is evaluating the impact of adopting this new accounting guidance on its consolidated financial statements.

Earnings Per Share In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share* (Topic 260), *Distinguishing Liabilities from Equity* (Topic 480), and *Derivative and Hedging* (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down- round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down-round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the

existence of a down-round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down-round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down-round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Accounting Standards Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments in Part I of this Update should be applied either retrospectively to outstanding financial instruments with a down-round feature by means of a cumulative-effect adjustment to the statement of financial position as of the beginning of the first fiscal year and interim period(s) in which the pending content that links to this paragraph is effective or retrospectively to outstanding financial instruments with a down-round feature for each prior reporting period presented in accordance with the guidance on accounting changes in paragraphs 250-10-45-5 through 45-10. The amendments in Part II of this Update do not require any transition guidance because those amendments do not have an accounting effect. The Company is evaluating the impact of adopting this new accounting guidance on its consolidated financial statements, however, does not expect the adoption of this standard to have a significant impact on its EPS calculations, as it does not have any free-standing equity based financial instruments with down-round provisions.

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Compensation Stock Compensation In May 2017, the FASB issued ASU 2017-09, *Compensation Stock Compensation* (Topic 718): Scope of Modification Accounting. The requirement provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. For public business entities, this ASU should be effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2017. The Company adopted ASU 2017-09 on January 1, 2018 and it did not have an impact on its consolidated financial statements.

Other Income Gains and Losses from the Derecognition of Nonfinancial Assets In February 2017, the FASB issued ASU 2017-05, *Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets* (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets. This ASU requires all entities to derecognize a business or nonprofit activity in accordance with Topic 810, and also requires that all entities derecognize an equity method investment in accordance with Topic 860. The amendments in this ASU eliminate the scope exceptions, and simplifies GAAP. This ASU is effective for fiscal years beginning after December 15, 2017, including interim reporting periods within that reporting period. Public entities may apply the guidance earlier but only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company adopted ASU 2017-05 on January 1, 2018 and it did not have an impact on its consolidated financial statements.

Simplifying the Test for Goodwill Impairment In January 2017, the FASB issued ASU No. 2017-04, Simplifying the Test for Goodwill Impairment (Topic 350) (ASU No. 2017-04). The amendments in ASU No. 2017-04 are intended to reduce the cost and complexity of the goodwill impairment test by eliminating Step 2 from the impairment test. The amendments modify the concept of impairment from the condition that exists when the carrying amount of goodwill exceeds its implied fair value to the condition that exists when the carrying amount of a reporting unit exceeds its fair value. Under the amendments in ASU No. 2017-04, an entity will perform its annual, or interim, goodwill impairment test by comparing the fair value of the reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The amendments in ASU No. 2017-04 are effective for the Company s annual or any interim goodwill impairment test in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted ASU No. 2017-04 on January 1, 2017, and it did not have a material impact on the Company s results of operations, financial position and disclosures.

Business Combinations Clarifying the Definition of a Business In January 2017, FASB issued ASU No. 2017-01, *Business Combinations Clarifying the Definition of a Business* (Topic 805) (ASU No. 2017-01). ASU 2017-01 provides a framework to use in determining when a set of assets and activities is a business. ASU 2017-01 provides more consistency in applying the business combination guidance, reduces the costs of application, and makes the definition of a business more operable. ASU 2017-01 is effective for interim and annual periods within those annual periods beginning after December 15, 2017. The Company is currently evaluating the impact ASU 2017-01 will have on the Company s results of operations, financial position and disclosures, but it is not expected to have a material impact.

Compensation Stock Compensation In March 2016, the FASB issued ASU No. 2016-09, *Compensation Stock Compensation* (Topic 718) (ASU 2016-09). ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows.

ASU 2016-09 requires recognition through opening retained earnings of any pre-adoption date net operating loss carryforwards from share-based payments, as well as recognition of all income tax effects from share based-payments in income tax expense. In addition, under ASU 2016-09 excess tax benefits no longer represent financing activities, but instead represent operating activities in the statement of cash flow. ASU 2016-09 allows companies to recognize excess tax benefits as an operating activity on a prospective or retrospective basis. The Company adopted ASU 2016-09 on January 1, 2017. The Company has decided to recognize this requirement on a prospective basis and has not adjusted prior periods. For the year ended December 31, 2017, there was no material impact on the Company s consolidated financial statements, apart from income tax expense of $1,591 recorded relating to tax deficiencies from share-based payment transactions.

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Leases In February 2016, the FASB issued 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.

Simplifying the Measurement of Inventory In July 2015, the FASB issued ASU No. 2015-11, *Inventory Simplifying the Measurement of Inventory* (Topic 330). 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 adopted ASU 2015-11 effective January 1, 2017. Adoption of ASU 2015-11 had no material impact on the Company s consolidated financial statements.

Revenue from Contracts with Customers In May 2014, the FASB, issued a new revenue recognition standard which amends revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The new standard provides a five-step framework whereby revenue is recognized when control of promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In August 2015, the FASB deferred the effective date of the new revenue standard from January 1, 2017 to January 1, 2018. In March 2016, the FASB issued amendments to clarify the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued amendments to clarify the guidance on accounting for licenses of intellectual property and identifying performance obligations. In May 2016, the FASB issued amendments related to collectability, non-cash consideration, the presentation of sales and other similar taxes collected from customers and transition. The standard allows for adoption using a full retrospective method or a modified retrospective method. On January 1, 2018, the Company adopted this standard using the modified retrospective method. The Company s implementation approach included performing a detailed review of its agreements. The Company has reviewed all types of customer contracts and has gone through the five step process outlined in the new revenue recognition standard for each type of contract. The new five step process required by the new revenue recognition standard provides results substantially consistent with the Company s current revenue recognition policies. In addition, the Company designed internal controls to enable the preparation of financial information. The Company is in the process of finalizing its conclusions on key accounting assessments related to the new standard, including its assessment that the impact of accounting for costs incurred to obtain a contract.

The Company identified two contracts which previously resulted in revenue recognition occurring at the time of shipment; however, under the new revenue recognition standard, the Company is required to recognize revenue over time. The Company currently estimates the impact of adopting the new revenue standard on the two contracts will result in a $1,800 to $2,200 reduction in accumulated deficit, the cumulative effect adjustment under the modified retrospective approach, a $2,500 to $3,000 increase in accounts receivable, and a $700 to $800 decrease in deferred tax assets. The Company also identified a contract that contains significant upfront payments; however, the Company has not yet finalized its assessment of the contract. Except for the three contracts discussed above, the Company does not anticipate the finalization of this assessment will result in a material impact to the Company s financial position, results of operations, and disclosures.

4. Cardiothoracic Closure Business Divestiture

The Company completed the sale of substantially all of the assets related to its Cardiothoracic closure business (the CT Business) to A&E Advanced Closure Systems, LLC (a subsidiary of A&E Medical Corporation) (A&E) pursuant to an Asset Purchase Agreement between the Company and A&E, dated August 3, 2017 (the Asset Purchase Agreement). The total consideration received by the Company under the Asset Purchase Agreement was composed of $54,000 in cash consideration, $3,000 of which is being held in escrow for up to twelve months to satisfy possible indemnification obligations, if any (the Escrow Amount), plus an additional $5,000 in contingent cash consideration if A&E reaches certain revenue milestones (the Contingent Consideration). The Company is also entitled to an additional $1,000 in consideration if the Company successfully obtains a certain FDA regulatory clearance. As a part of the transaction, the Company also entered into a multi-year Contract Manufacturing Agreement with A&E (the Contract Manufacturing Agreement). Under the Contract Manufacturing Agreement, the Company agreed to continue to support the CT Business by manufacturing existing products and engineering, developing, and manufacturing potential future products for A&E. The Company elected to account for the Contingent Consideration arrangement including the Escrow Amount, as a gain contingency in accordance with ASC 450 Contingencies. As such, the Contingent Consideration and Escrow Amount were excluded in measuring the fair value of the consideration to be received in connection with the transaction.

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The calculation of the gain on the CT Business divestiture is as follows:

Proceeds from cardiothoracic closure business divestiture	$ 51,000
Inventories net	(2,893)
Property, plant and equipment net	(1,299)
Goodwill	(8,645)
Other intangible assets net	(280)
Cardiothoracic closure business divestiture expenses	(3,793)
Gain on cardiothoracic closure business divestiture	$ 34,090

5. Stock-Based Compensation

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 five to 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.

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

	Year Ended December 31,		
	2017	2016	2015
Expected term (years)	6.50	6.50	6.50
Risk free interest rate	2.26%	1.85%	1.67%
Volatility factor	47.39%	45.57%	46.29%
Dividend yield			

Stock Options

Stock options outstanding, exercisable and available for grant at December 31, 2017, are summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value

				(Years)	
Outstanding at January 1, 2017	5,764,607	$	4.28		
Granted	2,875,438		3.64		
Exercised	(2,572,859)		3.57		
Forfeited or expired	(1,375,149)		5.69		
Outstanding at December 31, 2017	4,692,037	$	3.86	5.86	$ 2,554
Vested or expected to vest at December 31, 2017	4,247,224	$	3.87	5.69	$ 2,301
Exercisable at December 31, 2017	1,422,953	$	4.28	3.65	$ 530
Available for grant at December 31, 2017	1,949,068				

The aggregate intrinsic value in the table 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.

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For the years ended December 31, 2017, 2016 and 2015, the Company recognized stock-based compensation as follows:

	Year Ended December 31,		
	2017	2016	2015
Stock-based compensation:			
Costs of processing and distribution	$ 132	$ 140	$ 132
Marketing, general and administrative	6,586	3,406	2,356
Research and development	44	44	60
Total	$ 6,762	$ 3,590	$ 2,548

As of December 31, 2017, there was $3,344 of total unrecognized stock-based compensation related to nonvested stock options. That expense is expected to be recognized over a weighted-average period of 1.96 years.

Other information concerning stock options are as follows:

	Year Ended December 31,		
	2017	2016	2015
Weighted average fair value of stock options granted	$ 1.66	$ 1.55	$ 2.50
Aggregate intrinsic value of stock options exercised	2,786	12	1,584

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

Restricted Stock Awards

The value of restricted stock awards is determined by the market value of the Company s common stock at the date of grant. In 2017, restricted stock awards in the amount of 1,546,890 shares and 154,687 shares was granted to employees and non-employee directors, respectively. As of December 31, 2017, there was $3,684 of total unrecognized stock-based compensation related to unvested restricted stock awards. That expense is expected to be recognized on a straight-line basis over a weighted-average period of 1.76 years. The following table summarizes information about unvested restricted stock awards as of December 31, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2017	530,988	$ 3.64
Granted	1,701,577	4.05
Vested	(960,652)	3.77

Forfeited	(138,389)		3.56
Unvested at December 31, 2017	1,133,524	$	4.15

Inducement Grant

President and Chief Executive Officer

On January 26, 2017 (the Grant Date), the Company issued an inducement grant to its President and Chief Executive Officer, Mr. Camille Farhat. This grant was in the form of: (1) a restricted stock award agreement (the Restricted Stock Agreement #1); (2) another restricted stock award agreement (the Restricted Stock Agreement #2); and (3) a stock option agreement (the Option Agreement).

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Under the Restricted Stock Agreement #1, the Company granted Mr. Farhat 850,000 shares of restricted common stock. On the first anniversary of the Grant Date, 170,000 shares will vest. The remaining shares will vest on the last day of each calendar quarter at a rate of 42,500 shares per calendar quarter commencing after the first anniversary of the Grant Date and continuing for four years after. Vesting of these shares may accelerate upon the occurrence of either of two performance conditions.

On December 4, 2017, the Company and Mr. Farhat entered into the First Amendment to the Restricted Stock Agreement #1 (the Amendment). The Amendment revised the vesting conditions for the Company s common stock, par value $0.001 per share (the Common Stock), granted under the Restricted Stock Agreement #1. Pursuant to the Amendment, certain acceleration conditions contained in the Restricted Stock Agreement #1 were deleted and 425,000 shares of restricted Common Stock vested on December 4, 2017 (the Vested Grant). If Mr. Farhat voluntarily leaves the employment of the Company (other than for Good Reason) or is terminated for Cause (as those terms are defined in the Employment Agreement between the Company and Mr. Farhat, dated January 26, 2017) on or before March 31, 2019, then Mr. Farhat will forfeit all of the shares of the Vested Grant that would not have otherwise vested under vesting schedule contained in the Restricted Stock Agreement #1 at the time of termination. For example, if Mr. Farhat leaves the employment of the Company without Good Reason on June 1, 2018, he will forfeit 425,000 of the 637,500 vested restricted shares of Common Stock granted under the Restricted Stock Agreement #1. Pursuant to the Amendment, Mr. Farhat will also be required to hold the shares of the Vested Grant until March 31, 2019, except to the extent those shares would have vested under the vesting schedule contained in the Restricted Stock Agreement #1 at the time of a proposed transfer by Mr. Farhat.

The unaccelerated shares of restricted Common Stock granted under the Restricted Stock Agreement #1 will vest under vesting schedule contained in the Restricted Stock Agreement #1. Pursuant to the Restricted Stock Agreement #1 vesting schedule, 170,000 of the unaccelerated restricted shares will vest on January 26, 2018, and the remaining unaccelerated restricted shares will vest in 42,500 share increments on the last day of each calendar quarter commencing on March 31, 2018, continuing until all unaccelerated restricted shares have vested. Under the terms of the Amendment, the final tranche of shares of restricted Common Stock granted under the Restricted Stock Agreement #1 will vest as of June 30, 2019, instead of on December 31, 2021, which would have been the case if no acceleration occurred.

Under the Restricted Stock Agreement #2, the Company granted Mr. Farhat 150,000 shares of restricted common stock. These 150,000 restricted shares will become fully vested on the latest date (the Purchase Date) on which the fair market value of the cumulative amount of shares that Mr. Farhat purchases on the open market equals $500, so long as the Purchase Date is on or before March 15, 2018. After vesting, the shares will be non-transferable for a period of one year following the Purchase Date. During the second quarter of 2017, Mr. Farhat purchased $572 worth of the Company s shares on the open market. Accordingly, the 150,000 restricted shares of common stock granted to Mr. Farhat pursuant to the Restricted Stock Award #2 became fully vested, effective May 18, 2017.

Under the Option Agreement, the Company granted Mr. Farhat the option to purchase 1,950,000 shares of common stock (the Stock Options). The exercise price for the Stock Options is $3.20. The Stock Options will expire on January 26, 2022. The Stock Options will vest based on the Company s attainment of three average stock price benchmarks. The first 650,000 shares will vest if the Company s average publicly traded stock price is over $6.00 for a sixty-consecutive calendar day period. The next 650,000 shares will vest if the Company s average publicly traded stock price is over $7.00 for a sixty-consecutive calendar day period. The final 650,000 shares will vest if the Company s average publicly traded stock price is over $8.00 for a sixty-consecutive calendar day period. The vesting of the Stock Options is cumulative.

Chief Financial and Administrative Officer

On September 18, 2017 (the Grant Date), the Company issued an inducement grant to its Chief Financial and Administrative Officer, Mr. Jonathon Singer. This grant was in the form of: (1) a restricted stock award agreement (the Restricted Stock Agreement); and (2) a stock option agreement (the Option Agreement). This inducement grant was made under the RTI Surgical, Inc. 2015 Incentive Compensation Plan, which was filed with the SEC on May 5, 2015.

Under the Restricted Stock Agreement, the Company granted Mr. Singer 109,890 shares of restricted Common Stock. The shares will vest over a three-year period. On the first anniversary of the Grant Date, 36,630 shares will vest. On the second anniversary of the Grant Date, an additional 36,630 shares will vest. On the third anniversary of the Grant Date, the final 36,630 shares will vest.

Under the Option Agreement, the Company granted Mr. Singer the option to purchase 306,900 shares of Common Stock (the Stock Options), as of the Grant Date. The exercise price for the Stock Options is $4.55 per share. The Stock Options will expire on September 18, 2027. The Stock Options will vest based the Company s attainment of three average stock price benchmarks. The first 102,300 shares will vest if the Company s average publicly traded stock price is over

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$7.00 per share for a sixty-consecutive calendar day period. The next 102,300 shares will vest if the Company s average publicly traded stock price is over $8.00 per share for a sixty-consecutive calendar day period. The final 102,300 shares will vest if the Company s average publicly traded stock price is over $9.00 per share for a sixty-consecutive calendar day period. The vesting of the Stock Options is cumulative.

6. Inventories

Inventories by stage of completion are as follows:

	December 31,	
	2017	**2016**
Unprocessed tissue, raw materials and supplies	$ 22,071	$ 31,745
Tissue and work in process	40,481	38,552
Implantable tissue and finished goods	49,375	49,446
	$ 111,927	$ 119,743

For the years ended December 31, 2017, 2016, and 2015, the Company had inventory write-downs of $5,066, $13,880 and $5,390, respectively, relating primarily to excess quantities and obsolescence of inventories.

7. Prepaid and Other Current Assets

Prepaid and Other Current Assets are as follows:

	December 31,	
	2017	**2016**
Income tax receivable	$ 9,825	$ 1,041
Receivable for executive stock option exercise	1,234	
Other	5,226	4,172
	$ 16,285	$ 5,213

8. Property, Plant and Equipment

Property, plant and equipment are as follows:

	December 31,	
	2017	**2016**
Land	$ 2,020	$ 2,324
Buildings and improvements	57,954	59,187
Processing equipment	44,137	38,387
Surgical instruments	21,256	18,394

Office equipment, furniture and fixtures	1,352	1,701
Computer equipment and software	19,332	11,852
Construction in process	5,980	17,554
	152,031	149,399
Less accumulated depreciation	(72,467)	(66,101)
	$ 79,564	$ 83,298

For the years ended December 31, 2017, 2016, and 2015, the Company had depreciation expense in connection with property, plant and equipment of $10,513, $12,835, and $12,240, respectively. In addition, on October 20, 2017, the Company sold an owned property previously used for administrative, distribution and marketing functions for $1,818 net of selling costs.

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9. Goodwill

The change in the carrying amount of goodwill for the year ended December 31, 2017 is as follows:

	Year Ended December 31,	
	2017	2016
Balance at January 1	$ 54,887	$ 54,887
Goodwill disposed of related to sale of CT business	8,645	
Balance at December 31	$ 46,242	$ 54,887

On August 3, 2017, the Company completed the sale of substantially all of the assets related to its CT Business to A&E, which resulted in the disposal of goodwill. In connection with the sale of the Company s CT Business, we also performed the goodwill impairment test on an interim basis as of August 3, 2017, and concluded that there was no impairment to goodwill. The Company performed its annual goodwill impairment test as of December 31, 2017, and concluded that there was no impairment of goodwill.

10. Other Intangible Assets

Other intangible assets are as follows:

	December 31, 2017		December 31, 2016	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	$ 11,373	$ 4,890	$ 11,559	$ 4,159
Acquired licensing rights	14,747	9,097	12,204	8,302
Marketing and procurement intangible assets	20,603	9,666	20,694	8,002
Total	$ 46,723	$ 23,653	$ 44,457	$ 20,463

For the years ended December 31, 2017, 2016, and 2015, the Company had amortization expense of other

intangible assets of $3,713, $3,675, and $4,282, respectively. At December 31, 2017, management s estimates of future amortization expense for the next five years are as follows:

	Amortization Expense
2018	$ 3,800
2019	3,800
2020	3,700
2021	3,700

2022	3,500

11. Fair Value Information

Long-lived assets, including property and equipment and intangible assets subject to amortization were impaired and written down to their estimated fair values during the fourth quarter of 2016. Fair value is measured as of the impairment date using Level 3 inputs. Level 3 is defined as unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions. The long-lived asset level 3 fair value was determined using a market approach, which used inputs that included replacement costs (unobservable), physical deterioration estimates (unobservable), economic obsolescence (unobservable), and market sales data for comparable assets.

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The following table summarizes impairments of long-lived assets and the related post impairment fair values of the corresponding assets for the year ended December 31, 2016:

	Year Ended December 31, 2016	
	Impairment	Fair Value
Property, plant and equipment net	$ 4,717	$ 4,708
Other intangible assets net	718	150
	$ 5,435	$ 4,858

No impairments on long-lived assets were recorded for the year ended December 31, 2017.

12. Accrued Expenses

Accrued expenses are as follows:

	December 31,	
	2017	2016
Accrued compensation	$ 8,257	$ 4,904
Accrued severance and restructuring charges	3,279	505
Accrued executive transition costs	2,300	2,406
Accrued distributor commissions	3,889	4,422
Accrued donor recovery fees	4,144	6,350
Other	3,741	3,443
	$ 25,610	$ 22,030

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

13. Short and Long-Term Obligations

Short and long-term obligations are as follows:

	December 31,	
	2017	2016
Term loan	$ 24,250	$ 50,750
Revolving Credit facility	22,500	33,000
Less unamortized debt issuance costs	(406)	(403)
Total	46,344	83,347
Less current portion	(4,268)	(6,080)

Long-term portion	$ 42,076	$ 77,267

The Company entered into a Third Amended and Restated Loan Agreement, dated as of August 3, 2017 (the 2017 Loan Agreement), among the Company, TD Bank, N.A. and First Tennessee Bank National Association, as Lenders (together with the various financial institutions as in the future may become parties thereto, the Lenders), and TD Bank, N.A., as administrative agent for the Lenders. The 2017 Loan Agreement represents a modification of the Second Amended and Restated Loan Agreement dated July 16, 2013 between the Company, TD Bank, N.A. and Regions Bank (as amended, the 2013 Loan Agreement).

The 2017 Loan Agreement provides for a revolving credit facility (the Revolving Credit Facility), in the aggregate principal amount of $42,500 which is unchanged from the final Amendment to the 2013 Loan Agreement. The Company used $22,000 of the proceeds from the sale of the CT Business to partially pay down amounts owed under the 2013 Loan Agreement, and $10,000 to pay down amounts owed under the Revolving Credit Facility. Subsequent to the pay down, the outstanding principal balance on the 2013 Loan Agreement Term Loan amounted to $25,375 which became the principal amount of the 2017 Loan Agreement (the Term Loan Facility and, together with the Revolving Credit Facility the Facility). The Facility is secured by substantially all the assets of the Company and its domestic subsidiaries and is guaranteed by the Company s domestic subsidiaries, as well as 65% of the stock of the Company s foreign subsidiaries.

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Borrowings made under the 2017 Loan Agreement initially will bear interest at a rate per annum equal to monthly LIBOR plus a margin of up to 3.50%. Interest is payable quarterly in arrears, and principal on the Term Loan Facility is payable in quarterly payments of $1,125, each commencing October 1, 2017. The maturity date of the Facility is September 15, 2019, which represents an extension from the 2013 Loan Agreement maturity date of July 16, 2018. The Company may make optional prepayments on the Facility without penalty at the end of any LIBOR interest period.

At December 31, 2017, the interest rate for the Term Loan and Revolving Credit Facility is 4.86%. As of December 31, 2017, there was $22,500 outstanding on the revolving credit facility. The term loan facility requires aggregate principal payments of $6,750 from January 1, 2018 through June 30, 2019, with a final balloon principal payment of $17,500 on September 15, 2019. 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 total available credit on the Company s revolving credit facility at December 31, 2017 was $20,000. The Company s ability to access its Revolving Credit Facility is subject to and can be limited by the Company s compliance with the Company s financial and other covenants. The Company was in compliance with the financial covenants related to its revolving credit facility as of December 31, 2017.

Interest expense associated with the amortization of debt issuance costs for the years ended December 31, 2017, 2016 and 2015 was $409, $202 and $148, respectively.

As of December 31, 2017, contractual maturities of the Term Loan net of debt issuance costs, and the Revolving Credit Facility are as follows:

	Term Loan	Revolving Credit Facility	Total
2018	$ 4,268	$	$ 4,268
2019	19,576	22,500	42,076
	$ 23,844	$ 22,500	$ 46,344

14. Income Taxes

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

	Year Ended December 31,		
	2017	2016	2015
Current:			
Federal	$ (3,176)	$ (150)	$ (988)
State	(915)	(92)	(159)
International		456	(544)
Total current	(4,091)	214	(1,691)

Deferred:			
Federal	(14,340)	2,477	(5,695)
State	(1,022)	562	68
International		(192)	(981)
Total deferred	(15,362)	2,847	(6,608)
Total income tax (provision) benefit	$ (19,453)	$ 3,061	$ (8,299)

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

	December 31, 2017 Deferred Income Tax		December 31, 2016 Deferred Income Tax	
	Assets	Liabilities	Assets	Liabilities
Allowance for bad debts	$ 186	$	$ 485	$
Deferred compensation	1,783		4,675	
Inventory	5,905		12,811	
Fixed assets and intangibles		(7,370)		(5,690)
Investments			2,133	
Net operating losses	8,106		4,547	
Tax credits	4,387		5,235	
Deferred revenue	1,874		3,804	
Accrued liabilities	2,072		2,004	
Other		(110)		(120)
Valuation allowance	(7,258)		(4,916)	
Total	$ 17,055	$ (7,480)	$ 30,778	$ (5,810)

The Company expects its deferred tax assets of $9,575, net of the valuation allowance at December 31, 2017 of $7,258, to be realized through the generation of future taxable income and the reversal of existing taxable temporary differences.

On December 22, 2017, the US government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Legislation). The Tax Legislation makes broad and complex changes to the U.S. tax code including, but not limited to the following:

Reduction of the U.S. federal corporate tax rate from 35% to 21%

Requiring a transition tax on certain unrepatriated earnings of foreign subsidiaries

Bonus depreciation that will allow for full expensing of qualified property

Elimination of the corporate alternative minimum tax

The repeal of the domestic production activity deduction

Limitations on the deductibility of certain executive compensation

Limitations on net operating losses generated after December 31, 2017

In addition, beginning in 2018, the Tax Legislation includes a global intangible low-taxed income (GILTI) provision, which as currently interpreted by the Company, requires a tax on foreign earnings in excess of a deemed return on tangible assets of foreign subsidiaries. The Company has elected an accounting policy to account for GILTI as a period cost if incurred, rather than recognizing deferred taxes for temporary basis differences expected to reverse as a result of GILTI. Other provisions of the Tax Legislation that impact future tax years continue to be assessed.

The SEC staff issued SAB 118, which provides guidance on accounting for the tax effects of the Tax Legislation. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Legislation enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, the Company must reflect the income tax effects of those aspects of the Tax Legislation for which the accounting under ASC 740 is complete. To the extent that the Company s accounting for certain income tax effects of the Tax Legislation is incomplete, but the Company is able to determine a reasonable estimate, it must record a provisional estimate in the consolidated financial statements. If the Company cannot determine a provisional estimate, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Legislation

In connection with our initial analysis of the impact of the Tax Legislation, the Company has recorded provisional tax expense of $2,187 in the period ending December 31, 2017. This provisional tax expense consists of $1,436 to revalue the Company s deferred tax assets using the reduced corporate tax rate and $751 related to the transition tax. Given the complexity of the Tax Legislation and anticipated guidance from the U.S. Treasury about implementing the Tax Legislation, the Company s analysis and accounting for the income tax effects of the Tax Legislation is preliminary. The amounts recorded by the Company to revalue its deferred tax assets and impact of the transition tax are provisional estimates. The Company has not fully completed its analysis of certain aspects of

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the Tax Legislation that could result in adjustments to the revaluation of the Company s deferred tax assets, and its analysis and calculation of foreign earnings subject to the transition tax. Upon completion of the Company s analysis, these estimates may be adjusted through income tax expense in the consolidated financial statement.

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 $7,258 and $4,916 have been established at December 31, 2017 and December 31, 2016, respectively, against a portion of the deferred tax assets.

As of December 31, 2017, the Company has U.S. federal net operating loss carryforwards of $1,635 that will expire in the years 2026 and 2027. As of December 31, 2017, the Company has U.S. state net operating loss carryforwards of $42,420 that will expire in the years 2018 through 2037. As of December 31, 2017, the Company has foreign net operating loss carryforwards of $20,551 that will carryfoward indefinitely.

As of December 31, 2017, the Company has research tax credit carryforwards of $4,403 that will expire in years 2030 through 2037. As of December 31, 2017, the Company has foreign tax credit carryforwards of $751 that will expire in 2037.

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.

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 consolidated U.S. operations are in a cumulative income position. However, one U.S. entity (Entity) is in a three-year cumulative loss position. Future taxable income exclusive of reversing temporary differences and carryforwards is one source of taxable income available that can be used to realize tax benefits. During 2017, the Company has undertaken various cost reduction activities to reduce complexity and increase operational excellence within the organization. The Entity anticipates generating significant cost savings from the various cost reduction activities. After adjusting the Entity s cumulative losses to include the projected costs savings, the Entity s operations project future profits sufficient to utilize the Entity s separate state deferred tax assets before expiration. The Company considers this objectively verifiable evidence that all its U.S. deferred tax assets are more likely than not realizable.

The Company s foreign operations are in three-year cumulative loss position. As a result, the Company has recorded a full valuation allowance on its foreign subsidiary s deferred tax assets.

As such, valuation allowances of $7,258 and $4,916 have been established at December 31, 2017 and December 31, 2016, respectively, against a portion of the deferred tax assets.

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, 2017, the Company has $1,591 of unrecognized tax benefits, which was recorded net against deferred tax assets in the accompanying consolidated balance sheet.

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The Company s unrecognized tax benefits are summarized as follows:

	Year Ended December 31,		
	2017	2016	2015
Opening balance	$ 1,591	$ 1,986	$ 1,787
Reductions based on tax positions related to the current year			
Additions for tax positions of prior years			199
Reductions for tax positions of prior years		(60)	
Reductions for expiration of statute of limitations		(335)	
	$ 1,591	$ 1,591	$ 1,986

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

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 2017, 2016 and 2015 and no interest and penalties accrued at December 31, 2017 and 2016.

The Company s 2015 U.S. federal income tax return is under examination by the Internal Revenue Service (IRS). Currently, the Company has not recorded any material adjustments related to the IRS examination.

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

	Year Ended December 31,		
	2017	2016	2015
Statutory federal rate	35.00%	35.00%	35.00%
State income taxes net of federal tax benefit	2.43%	1.73%	0.25%
Foreign rate differential	2.85%	(3.29%)	(2.18%)
Tax legislation transition tax	2.92%		
Tax legislation revaluation of deferred tax assets	5.58%		
Other permanent items	1.63%	(3.15%)	0.56%
Tax credits	(4.62%)	7.02%	(0.28%)
Domestic production activities deduction	0.00%	1.38%	
Goodwill disposal	11.76%		
Officer compensation	4.26%		
Stock-based compensation	6.18%		
Valuation allowance	5.94%	(21.71%)	0.85%
Other reconciling items, net	1.69%	0.55%	1.55%
Effective tax rate	75.62%	17.53%	35.75%

For the years ended December 31, 2017, 2016 and 2015, the Company had no individually significant other reconciling items.

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15. Preferred Stock

Preferred stock is as follows:

	Preferred Stock Liquidation Value	Preferred Stock Issuance Costs	Net Total
Balance at January 1, 2015	$ 53,863	$ (1,029)	$ 52,834
Accrued dividend	3,305		3,305
Amortization of preferred stock issuance costs		184	184
Balance at December 31, 2015	57,168	(845)	56,323
Accrued dividend	3,508		3,508
Amortization of preferred stock issuance costs		185	185
Balance at December 31, 2016	60,676	(660)	60,016
Accrued dividend	3,723		3,723
Amortization of preferred stock issuance costs		184	184
Balance at December 31, 2017	$ 64,399	$ (476)	$ 63,923

On June 12, 2013, the Company and WSHP Biologics Holdings, LLC, an affiliate of Water Street Healthcare Partners, a leading healthcare-focused private equity firm (Water Street), entered into an investment agreement. Pursuant to the terms of the investment agreement, the Company issued $50,000 of convertible preferred equity to Water Street in a private placement which closed on July 16, 2013, with preferred stock issuance costs of $1,290. 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. Our credit agreement with TD Bank and First Tennessee Bank contains various covenants of financial conditions which, if not met, would restrict the Company from paying dividends.

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. Executive Transition Costs

The Company recorded Chief Executive Officer retirement and transition costs related to the retirement of our former Chief Executive Officer pursuant to the Executive Transition Agreement dated August 29, 2012 (as amended and extended to date), which resulted in $4,404 of expenses for the year ended December 31, 2016. The total Chief Executive Officer retirement and transition costs are expected to be paid in full prior to the first quarter of 2019. In addition, the Company recorded executive transition costs of $2,781 as a result of hiring a new Chief Executive Officer and Chief Financial and Administrative Officer for the year ended December 31, 2017, separately disclosed on the Consolidated Statements of Comprehensive Income (Loss). The total executive transition costs of which $1,169 is cash basis is expected to be paid in full in 2018. The following table includes a rollforward of executive transition costs included in accrued expenses, see Note 12.

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Accrued executive transition costs at January 1, 2016	$
Executive transition costs accrued in 2016	4,404
Stock-based compensation	(1,535)
Cash payments	(463)
Accrued executive transition costs at December 31, 2016	2,406
Executive transition costs accrued in 2017	2,781
Stock-based compensation	(1,612)
Cash payments	(1,275)
Accrued executive transition costs at December 31, 2017	$ 2,300

18. Severance and Restructuring Costs

The Company recorded severance and restructuring costs related to the reduction of our organizational structure which resulted in $995 of expenses for the year ended December 31, 2015. The total severance and restructuring costs were paid in full by December 31, 2016. Severance and restructuring payments were made 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 severance and restructuring costs related to the reduction of our organizational structure which resulted in $2,146 of expenses for the year ended December 31, 2016. The total severance and restructuring costs are expected to be paid in full prior to the first quarter of 2018. Severance and restructuring payments are made over periods ranging from one month to twelve months and are not expected to have a material impact on cash flows of the Company in any quarterly period.

The Company recorded severance and restructuring costs related to the reduction of our organizational structure which resulted in $12,173 of expenses for the year ended December 31, 2017, separately disclosed on the Consolidated Statements of Comprehensive Income (Loss). The total severance and restructuring costs are expected to be paid in full prior to the fourth quarter of 2018. Severance and restructuring payments are made over periods ranging from one month to twelve months and are not expected to have a material impact on cash flows of the Company in any quarterly period. The following table includes a rollforward of severance and restructuring costs included in accrued expenses, see Note 12.

Accrued severance and restructuring charges at January 1, 2015	$ 2,771
Severance and restructuring expenses accrued in 2015	995
Severance and restructuring cash payments	(2,591)
Stock based compensation	(310)
Accrued severance and restructuring charges at December 31, 2015	865
Severance and restructuring expenses accrued in 2016	2,146
Severance and restructuring cash payments	(1,866)
Asset abandonments	(640)

Accrued severance and restructuring charges at December 31, 2016	505
Severance and restructuring expenses accrued in 2017	12,173
Severance and restructuring cash payments	(8,246)
Stock based compensation	(1,153)
Accrued severance and restructuring charges at December 31, 2017	$ 3,279

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, 2017, 2016 and 2015, the amounts expensed under the plan were $3,036, $3,094 and $3,034, respectively.

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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 two of the distribution companies, Zimmer Biomet Holdings Inc. (Zimmer) and Medtronic, PLC (Medtronic). The following table presents percentage of total revenues derived from the Company s largest distributors:

	Year Ended December 31,		
	2017	2016	2015
Percent of revenues derived from:			
Distributor			
Zimmer	17%	16%	24%
Medtronic	9%	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 A&E On August 3, 2017, the Company completed the sale of substantially all of the assets related to its CT Business to A&E pursuant to an Asset Purchase Agreement between the Company and A&E (the Asset Purchase Agreement). The total consideration received by the Company under the Asset Purchase Agreement was composed of $54,000 in cash consideration, $3,000 of which is being held in escrow for up to twelve months to satisfy possible indemnification obligations, if any (the Escrow Amount), plus an additional $5,000 in contingent cash consideration if A&E reaches certain revenue milestones (the Contingent Consideration). The Company is also entitled to an additional $1,000 in consideration if the Company successfully obtains a certain FDA regulatory clearance. As a part of the transaction, the Company also entered into a multi-year Contract Manufacturing Agreement with A&E (the Contract Manufacturing Agreement). Under the Contract Manufacturing Agreement, the Company agreed to continue to support the CT Business by manufacturing existing products and engineering, developing, and manufacturing potential future products for A&E. The Company elected to account for the Contingent Consideration arrangement including the Escrow Amount, as a gain contingency in accordance with ASC 450 Contingencies. As such, the Contingent Consideration and Escrow Amount were excluded in measuring the fair value of the consideration to be received in connection with the transaction.

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 was to have been through December 31, 2017. The term automatically renews 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. Neither party provided notice of non-renewal on or before December 31, 2016, thereby triggering the five-year automatic renewal period upon the expiration of the initial term. The distribution agreement will therefore continue at least through December 31, 2022. 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 2021. 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, 2017, 2016, and 2015 was $1,325, $1,378 and $1,443, 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, 2017 are as follows:

	Operating Leases
2018	$ 1,574
2019	939
2020	559
2021	117
	$ 3,189

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, 2017 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. Consequently, the Company recorded cumulative litigation and settlement charges of $804 pertaining to the aforementioned agreements in the fourth quarter of 2015.

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) (the Tissue Only Claims and the Tissue-Non-Coloplast Claims being collectively referred to as Indemnified Claims). As of December 31, 2017, there are a cumulative total of 1,214 Indemnified 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.

On September 30, 2014, the Company received a letter from the FDA regarding its 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. Following the 2014 letter, the FDA conducted an on-site inspection of the Company s Alachua, Florida facility in April 2017 to assess compliance of the manufacturing and quality controls for its map3® allograft products to the 21 CFR Part 211 (GMP) regulations. A form 483 was issued by the FDA outlining 9 instances of observed non-compliance. The Company has worked diligently to resolve all cited observations in a timely manner, however, on November 9, 2017, the FDA issued a Warning Letter to the Company related to the map3® allograft. The letter reiterated the FDA s concerns regarding the classification and manufacturing of the map3 allograft. There was no requirement to cease production or to recall distributed allografts from the market. The Company is working diligently and collaboratively with FDA to resolve any concerns regarding the map3® allografts and the Company is maintaining ongoing dialogue with the FDA. Comprehensive packages of data have been provided to address the FDA s comments. The Company has also provided the FDA with clarifying information has been provided regarding the technical components of

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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 Company has removed certain information from its website. 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.

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 reporting of the Company s lines of business is composed primarily of six categories: spine; sports medicine and orthopedics; surgical specialties; cardiothoracic; international; and global commercial. Effective October 1, 2017, we renamed our global commercial line of business category to Original Equipment Manufacturer (OEM). 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, 2017, 2016 and 2015:

	Year Ended December 31,					
	2017		2016		2015	
	(In thousands)					
Revenues:						
Spine	$ 77,514	27.7%	$ 73,907	27.1%	$ 57,983	20.5%
Sports medicine and orthopedics	50,231	18.0%	50,143	18.4%	50,712	18.0%
Surgical specialties	6,980	2.5%	4,466	1.6%	3,029	1.1%
Cardiothoracic	8,164	2.9%	11,147	4.1%	8,699	3.1%
International	23,240	8.3%	21,185	7.8%	18,338	6.5%
Subtotal direct	166,129	59.4%	160,848	59.0%	138,761	49.2%
OEM	103,011	36.9%	99,127	36.3%	129,930	46.0%
Other revenues	10,423	3.7%	12,890	4.7%	13,602	4.8%
Total revenues	$ 279,563	100.0%	$ 272,865	100.0%	$ 282,293	100.0%
Domestic revenues	$ 253,599	90.7%	$ 247,756	90.8%	$ 260,387	92.2%
International revenues	25,964	9.3%	25,109	9.2%	21,906	7.8%
Total revenues	$ 279,563	100.0%	$ 272,865	100.0%	$ 282,293	100.0%

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

	December 31,	
	2017	2016
Property, plant and equipment net:		
Domestic	$ 73,363	$ 77,596
International	6,201	5,702

Total	$ 79,564	$ 83,298

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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, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Quarter Ended:				
Revenues	$ 69,939	$ 72,120	$ 66,688	$ 70,816
Gross profit	35,779	36,963	33,511	36,268
Net (loss) income applicable to common shares	(2,782)	(2,613)	16,548	(8,604)
Net (loss) income per common share:				
Basic	$ (0.05)	$ (0.04)	$ 0.28	$ (0.14)
Diluted	(0.05)	(0.04)	$ 0.22	$ (0.14)

In 2017, the Company s net income was negatively impacted by severance and restructuring costs of $12,173, executive transition costs of $2,781, asset impairment and abandonments of $3,739, acquisition expenses of $630, tax effect on new tax legislation of $2,187 offset set by a gain on CT Business divestiture of $34,090.

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

	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Quarter Ended:				
Revenues	$ 67,351	$ 67,620	$ 66,547	$ 71,347
Gross profit	36,025	33,949	34,274	28,101
Net income (loss) applicable to common shares	1,543	(3,162)	(4,489)	(11,799)
Net income (loss) per common share:				
Basic	$ 0.03	$ (0.05)	$ (0.08)	$ (0.20)
Diluted	0.03	(0.05)	$ (0.08)	$ (0.20)

In 2016, the Company s net income was negatively impacted by an excess inventory charge of $9,556, severance and restructuring costs of $2,146, strategic review costs of $1,150, executive transition costs of $4,404, contested proxy expenses of $2,680, and an asset impairment of $5,435.

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, except for on January 4, 2018, the Company acquired Zyga Technology, Inc., a leading spine-focused medical device company that develops and produces innovative minimally invasive devices to treat underserved conditions of the lumbar spine. Zyga Technology s primary product is the SImmetry® Sacroiliac Joint Fusion System. Under the terms of the merger agreement dated January 4, 2018, the Company acquired Zyga Technology for $21,000 in upfront cash, $1,000 contingent upon the successful achievement of a clinical milestone, and a revenue based earnout consideration of up to $35,000. The initial cash payment was funded

through cash on hand. The Company has not completed its preliminary purchase price allocation, and as such cannot disclose the preliminary purchase price allocation.

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RTI SURGICAL, INC. AND SUBSIDIARIES

Schedule II

Valuation and Qualifying Accounts

Years Ended December 31, 2017, 2016 and 2015

(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, 2017:				
Allowance for doubtful accounts	$ 1,728	$ 418	$ 675	$ 1,471
Allowance for product returns	629	528	47	1,110
Allowance for excess and obsolescence	14,798	5,066	11,762	8,102
Deferred tax asset valuation allowance	4,916	1,668	(674)	7,258
For the year ended December 31, 2016:				
Allowance for doubtful accounts	1,454	645	371	1,728
Allowance for product returns	714	250	335	629
Allowance for excess and obsolescence	7,083	13,880	6,165	14,798
Deferred tax asset valuation allowance	1,106	3,833	23	4,916
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 excess and obsolescence	5,112	5,390	3,419	7,083
Deferred tax asset valuation allowance	959	197	50	1,106

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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 2, 2018

RTI SURGICAL, INC.

By: /s/ Camille I. Farhat
Camille I. Farhat
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/ Camille I. Farhat	President and Chief Executive Officer	March 2, 2018
Camille I. Farhat	(Principal Executive Officer) and Director	
/s/ Jonathon M. Singer	Chief Financial and Administrative Officer, Corporate Secretary (Principal Financial and Chief Accounting Officer)	March 2, 2018
Jonathon M. Singer		
/s/ Curt M. Selquist	Chairman	March 2, 2018
Curt M. Selquist		
/s/ Peter F. Gearen	Vice Chairman	March 2, 2018
Peter F. Gearen		
/s/ Thomas A. McEachin	Director	March 2, 2018
Thomas A. McEachin		
/s/ Mark D. Stolper	Director	March 2, 2018
Mark D. Stolper		
/s/ Christopher R. Sweeney	Director	March 2, 2018
Christopher R. Sweeney		
/s/ Paul G. Thomas	Director	March 2, 2018

Paul G. Thomas		
/s/ Nicholas J. Valeriani	Director	March 2, 2018
Nicholas J. Valeriani		
/s/ Shirley A. Weis	Director	March 2, 2018
Shirley A. Weis		