2017

ORTHOFIX INTERNATIONAL N.V.

ANNUAL REPORT

ORTHOFIX®

OUR MISSION IS TO IMPROVE PATIENTS' LIVES BY PROVIDING SUPERIOR RECONSTRUCTION AND REGENERATIVE MUSCULOSKELETAL SOLUTIONS TO PHYSICIANS WORLDWIDE

Letter from the CEO

Brad Mason
President and Chief Executive Officer

Dear Shareholder,

We are guided by a unifying mission: **To improve patients' lives by providing superior reconstructive and regenerative musculoskeletal solutions to physicians worldwide.** This mission keeps our team focused on providing life-changing solutions for patients like TJ, a former United States Army medic, who is featured on our cover with his daughter.

TJ severely injured his ankle during a parachute training jump. After multiple unsuccessful surgeries he was facing the potential amputation of his leg. Fortunately for TJ a surgeon was able save his leg using the Trinity ELITE® allogeneic bone graft material. TJ is just one example of the many thousands of patients who have benefited from our biologic solutions, medical devices and services. We are very proud of the contributions of our team members and the role we play in helping surgeons treat patients like TJ.

2017 In Review

Overall, 2017 was a very strong year for Orthofix in many ways. Our strategy going into the year was to invest in accelerating our organic topline growth rate while maintaining adjusted EBITDA margins and positioning the company for continued growth acceleration and a return to margin expansion in 2018. The execution of this strategy resulted in us exceeding many of our expectations for the year. Specifically, we:

- Accelerated our growth rate and overachieved our topline expectations with strong volume growth in each of our strategic business units (SBUs)
- Increased adjusted earnings per share by 11% over 2016
- Launched 20 new products and significant line extensions across multiple SBUs during the year
- Successfully transformed our Spine Fixation SBU, delivering exceptional growth and sales momentum in addition to a robust stream of new products
- Continued to make progress on our BioStim clinical trials to evaluate new applications of our Pulsed Electromagnetic Field (PEMF) technology
- Received the Spine Technology Award for our new Stim OnTrack™ mobile app that launched with our next-generation CervicalStim™ and SpinalStim™ bone growth stimulators
- Launched the JuniOrtho™ pediatric initiative focused on bringing products and resources under one umbrella to give medical professionals and families the best services and solutions before, during and after surgery
- Completed planned restructuring initiatives that included a worldwide workforce reduction of 9%; the closing of a non-core business; moving a manufacturing business from the United Kingdom to our operations in Italy; the transition of our Extremity Fixation direct sales business in Puerto Rico and Brazil to stocking distributors to improve profitability; and numerous cost saving efforts in operations and general and administrative expenses in the U.S.

These highlights tell only part of the story of our outstanding year. We continue to benefit from the steady execution of our long-term strategies, one step at a time.

For the full year 2017, our reported sales were $433.8 million dollars or 5.9% reported growth and 5.5% in constant currency growth over the prior year. In 2017 we had some big wins – most notably:

- Our BioStim SBU net sales grew 5.3% for the full year. This growth was in line with expectations and driven primarily by the market acceptance of our next-generation SpinalStim and CervicalStim spinal fusion therapy devices that were launched at the beginning of the year. In addition to significant upgrades to these products, the devices are accompanied by the award winning STIM onTrack mobile app just mentioned. The STIM onTrack mobile app includes a first-to-market feature that enables physicians to remotely view patient adherence to their prescription. Developed in-house by the Orthofix team, this app demonstrates our commitment to providing patients and surgeons with products and services designed to improve outcomes.
- In our Extremity Fixation SBU, sales increased 3.0% for the full year when normalized for restructuring and the discontinuation of a non-core business. We exited 2017 with good sales momentum and the benefit of nine new products and line extensions launched during the year.
- One of our 2017 goals was to return our Spine Fixation SBU to solid growth. This was achieved by delivering a strong topline performance of double digit constant currency growth for the full year of 12.7%. New products were the primary driver along with a growing and engaged sales force, particularly in the U.S. where we saw over 20% sales growth.
- In our Biologics business we reported growth of 8.3% year-over-year, significantly outpacing the allograft stem cell market growth rate, with Trinity ELITE allograft and an expanding sales force continuing to be the drivers of this performance.

2018 and Beyond

As we look forward, we are focused on continuing our organic growth momentum, expanding margins and actively pursuing value-accretive inorganic opportunities to further accelerate growth and create shareholder value. Our recent announcement of the planned acquisition of Spinal Kinetics is illustrative of this strategy. This acquisition has numerous strategic benefits to Orthofix and will allow us to fill a significant product gap in our current spine portfolio with the M6™ artificial disc, a market leading disc in Europe, which is currently undergoing PMA review by the U.S. Food and Drug Administration.

To maintain our organic sales momentum, we must continue our initiatives to further engage our legacy sales force and add new representation in under-served markets, while remaining committed to investing in R&D and a steady pace of new product and service introductions. Additionally, we must continue to educate physicians and payers through published, peer-reviewed research papers that demonstrate the safety, efficacy and cost-effectiveness of our products.

We also see the opportunity for margin expansion in our organic businesses over the next several years. We believe our biggest opportunity exists in gross margins, particularly around improving inventory and instrument set management in our Spine and Extremity Fixation businesses. We also expect to begin to realize the benefit of our 2017 restructuring initiatives as well as leverage our fixed costs in SG&A.

Orthofix is well positioned to accelerate top-line growth through the acquisition of products, technologies and companies. In addition to our strong balance sheet and free cash flow, we have an experienced and proven management team, a global footprint and a reconstructed infrastructure on which to build. We have been and will remain very active in pursuing opportunities that will drive shareholder value, particularly through topline growth acceleration. However, we will remain disciplined in our investment decisions, focusing on deals that are a good strategic fit with our core businesses, that give us access to higher growth markets and have the likelihood of creating significant shareholder value in the near to mid-term. The Spinal Kinetics acquisition is an excellent example that checks all of the boxes of our inorganic investment strategy.

Clinical Research – Laying the Groundwork for Our Future

With an eye on the future, we are investing strategically in our clinical research programs as a vehicle for growth in the years ahead. We continue to make steady progress in our investigational device exemption clinical trials focused on expanding our PEMF technology into new applications for bone and soft tissue repair.

We currently have studies underway for the treatment of Type II odontoid fractures, osteoarthritis of the knee and as announced earlier this year, the use of PEMF as an adjunctive treatment to surgical repair of full thickness rotator cuff tears. We are very excited to build upon our compelling pre-clinical research in these applications and look forward to keeping you updated in the years ahead.

In addition to the BioStim clinical trials, we have numerous ongoing post-market studies supporting our Biologics and Spine fixation products and therapies. Our investments in these studies demonstrate our belief in the enormous potential for the utilization of our technologies in treating many unmet needs related to musculoskeletal disorders.

Our Commitment to Shareholders

We are proud of all that we have accomplished in 2017. We took another big step in a journey we started more than four years ago to transform the Company. We see many exciting opportunities in the years to come and remain focused on creating value for our shareholders over the long-term.

On a sad note, this past year we lost a leader in the medical device space and a great friend with the passing of Dr. Guy Jordan, a long-term member of our Board of Directors. Guy had an immeasurable impact on Orthofix through his years of service and will be greatly missed.

Lastly, I would like to extend my sincere gratitude to our shareholders for the support and trust you place in us, our Board of Directors for their insight and guidance, our team members for their tireless efforts, and our business partners worldwide who, as an extension of Orthofix, help us each day as we strive to exceed the expectations of all of our stakeholders, while improving the lives of the patients we serve.

Sincerely,

Brad Mason

Brad Mason
President and
Chief Executive Officer
Orthofix International, N.V.

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: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Curaçao **(State or other jurisdiction of incorporation or organization)**	**98-1340767** **(I.R.S. Employer Identification No.)**
7 Abraham de Veerstraat **Curaçao** **(Address of principal executive offices)**	**N/A** **(Zip Code)**

599-9-4658525

(Registrant's telephone number, including area code)

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

Common Stock, $0.10 par value	**Nasdaq Global Select Market**
(Title of Class)	**(Name of 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 the 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 (§ 229.405 of this chapter) 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 emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☒	Accelerated filer	☐	Emerging Growth Company	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting 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 Act). Yes ☐ No ☒

The aggregate market value of registrant's common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the fiscal quarter ended June 30, 2017, as reported by the Nasdaq Global Select Market, was approximately $842.2 million.

As of February 23, 2018, 18,405,344 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement to be filed with the Commission in connection with the Orthofix International N.V. 2018 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Annual Report.

Orthofix International N.V.

Form 10-K for the Year Ended December 31, 2017
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Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"), and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A, "Risk Factors". Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to further update any such statement, to reflect new information, the occurrence of future events or circumstances or otherwise.

Trademarks

Solely for convenience, our trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

PART I

Item 1. Business

In this Annual Report, the terms "we," "us," "our," "Orthofix," "the Company" and "our Company" refer to the combined operations of Orthofix International N.V. and its consolidated subsidiaries and affiliates, unless the context requires otherwise.

Company Overview

We are a global medical device company focused on musculoskeletal healing products and value-added services. Headquartered in Lewisville, Texas, we have four strategic business units ("SBUs"): BioStim, Extremity Fixation, Spine Fixation, and Biologics. Our products are widely distributed by our sales representatives, distributors and subsidiaries.

We have administrative and training facilities in the United States ("U.S."), Italy, Brazil, the United Kingdom ("U.K."), France, and Germany, and manufacturing facilities in the U.S. and Italy. We directly distribute products in the U.S., Italy, the U.K., Germany, France, and Brazil. In several of these and other markets, we also distribute our products through independent distributors.

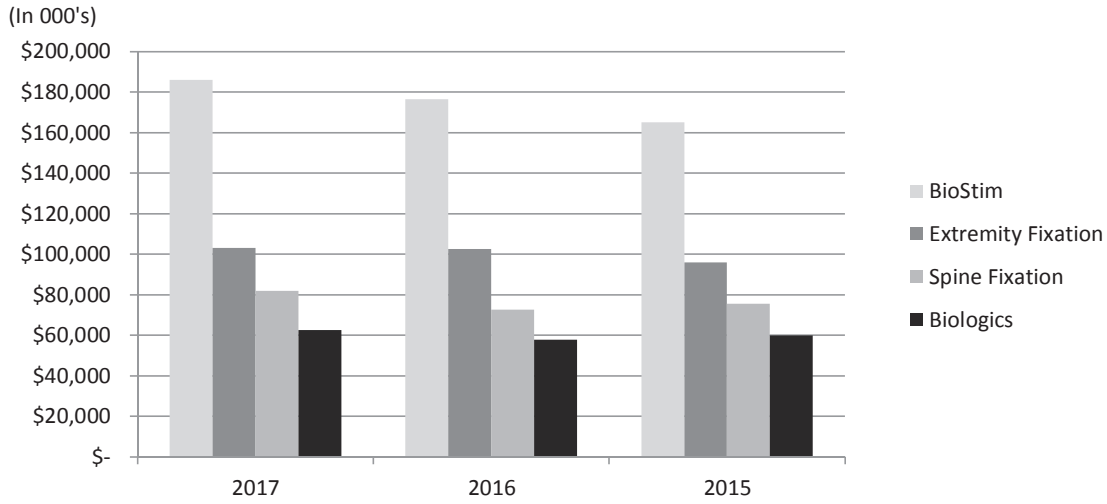
Orthofix International N.V. was formed in 1987 and is a limited liability company operating under the laws of Curaçao. Our executive offices in Curaçao are located at 7 Abraham de Veerstraat, Curaçao.

Available Information and Orthofix Website

Our filings with the Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and Annual Proxy Statement on Schedule 14A and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information on our website or connected to our website is not incorporated by reference into this Annual Report. Our Internet website is located at www.orthofix.com. Our SEC filings are also available on the SEC website at www.sec.gov.

Business Segments

We manage our business by our four SBUs: BioStim, Extremity Fixation, Spine Fixation and Biologics, which accounted for 43%, 24%, 19%, and 14%, respectively, of our total net sales in 2017. The chart below presents net sales, which includes product sales and marketing service fees, by SBU for each of the years ended December 31, 2017, 2016, and 2015.



Financial information regarding our reportable business segments and certain geographic information is included in Part II, Item 7 of this Annual Report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Note 14 to the Consolidated Financial Statements in Item 8 of this Annual Report.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for market-leading bone growth stimulation devices that enhance bone fusion. These class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (nonunions). These devices utilize Orthofix's patented pulsed electromagnetic field ("PEMF") technology, the safety and efficacy of which is supported by basic mechanism of action data in the scientific literature as well as published data from level one randomized controlled clinical trials. The devices are compatible with the STIM onTrack mobile application, which includes a first-to-market feature that enables physicians to remotely view patient adherence to treatment protocols. We currently have research and clinical studies underway to identify potential clinical indications for treating rotator cuff tears, odontoid fractures and osteoarthritis of the knee. This SBU sells almost exclusively in the U.S. using distributors and direct sales representatives to sell and deliver its devices to hospitals, healthcare providers, and patients.

BioStim Strategy

Our strategy for the BioStim SBU is to expand patient access to bone growth therapy devices that deliver noninvasive treatment for promoting healing in fractured bones and spinal fusions. Our key strategies are:

- Promote competitive advantages of our recently launched products and STIM onTrack mobile app
- Support adoption and reimbursement with:
    - North American Spine Society's (NASS) Coverage Policy Recommendation
    - Post-market clinical research
- Continue to invest in expanding our sales force
- Bring to market new PEMF products addressing unmet clinical needs

BioStim Products

The following table and discussion identify our principal BioStim products by trade name and describe their primary applications:

Product	Primary Application
CervicalStim Spinal Fusion Therapy	PEMF non-invasive cervical spinal fusion therapy used to enhance bone growth
SpinalStim Spinal Fusion Therapy	PEMF non-invasive lumbar spinal fusion therapy used to enhance bone growth
PhysioStim Bone Healing Therapy	PEMF non-invasive appendicular skeleton healing therapy used to enhance bone growth in nonunion fractures

Spinal Therapy

Our bone growth therapy devices used in spinal applications are designed to enhance bone growth and the success rate of certain spinal fusions by stimulating the body's own natural healing mechanism post-surgically. These non-invasive portable devices are intended to be used as part of a home treatment program prescribed by a physician.

We offer two spinal fusion therapy devices: the SpinalStim and CervicalStim devices. Our stimulation products use a PEMF technology designed to enhance the growth of bone tissue following surgery and are placed externally over the site to be healed. Research data shows that our PEMF signal induces mineralization and results in a process that stimulates new regeneration at the spinal fusion site. Some spine fusion patients are at greater risk of not achieving a solid fusion of new bone around the fusion site. These patients typically have one or more risk factors such as smoking, obesity or diabetes, or their surgery involves the revision of a failed fusion or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical bone growth therapy has been shown to significantly increase the probability of fusion success.

The SpinalStim device is a non-invasive spinal fusion stimulator system that has been commercially available in the U.S. since 1990. It is designed for the treatment of the lumbar region of the spine. The device uses proprietary technology and a wavelength to generate a PEMF signal. The U.S. Food and Drug Administration (the "FDA") has approved the SpinalStim system as a spinal fusion adjunct to increase the probability of fusion success and as a non-operative treatment for salvage of failed spinal fusion at least nine months post-operatively.

Our CervicalStim product remains the only FDA-approved bone growth stimulator on the market indicated for use as an adjunct to cervical spine fusion surgery in patients at high-risk for non-fusion. The FDA approved this device in 2004, and it has been commercially available in the U.S. since 2005.

In late 2016, the North American Spine Society ("NASS") issued first-of-its-kind coverage recommendations for electrical bone growth stimulators. These evidence-based coverage policy recommendations support the use of PEMF devices as an adjunct to spinal fusion surgery. The NASS coverage policy recommends the use of electrical stimulation for spinal fusion healing in all regions of the spine, including cervical and lumbar regions. Currently, Orthofix is the only company with a bone growth stimulator approved by the FDA as a noninvasive, adjunctive treatment option for cervical fusion. The validation of PEMF electrical stimulation from this leading surgical society has and is expected to continue to further support our efforts to expand the availability and use of the therapy to the many patients who can benefit from it.

In January 2017, we announced the FDA and European Commission CE mark approval for our next-generation SpinalStim and CervicalStim bone growth stimulators. The CervicalStim and SpinalStim systems available in the U.S. are accompanied by a new application for mobile devices called STIM onTrack. The mobile app includes a first-to-market feature that enables physicians to receive real-time data on how their patients are adhering to prescribed treatment protocols. Designed for use with smartphones and other mobile devices, the STIM onTrack tool helps patients follow their prescription with daily treatment reminders and a device usage calendar. The app is free and available through the iTunes App Store. In addition to the app, the next-generation bone growth stimulators include patient enhancements aimed at improving fit, comfort and ease of use.

Orthopedic Therapy

Our PhysioStim bone healing therapy products use PEMF technology similar to that used in our spine stimulators. The primary difference is that the PhysioStim devices are designed for use on the appendicular skeleton.

A bone's regenerative power results in most fractures healing naturally within a few months. In the presence of certain risk factors, however, some fractures do not heal or heal slowly, resulting in "nonunions." Traditionally, orthopedists have treated such fracture conditions surgically, often by means of a bone graft with fracture fixation devices, such as bone plates, screws or intramedullary rods. These are examples of "invasive" treatments. Our patented PhysioStim bone healing therapy products are designed to use a low level of PEMF signals to noninvasively activate the body's natural healing process. The devices are anatomically designed, allowing ease of placement, patient mobility, and the ability to cover a large treatment area.

Future Applications

We have sponsored research at Cleveland Clinic, New York University and University of Medicine and Dentistry of New Jersey, where scientists conducted animal and cellular studies to identify the mechanisms of action of our PEMF signals on bone and efficacy of healing. From this effort, a total of six studies have been published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength as well as proliferation and differentiation of cells involved in regeneration and healing. Furthermore, we believe that the research work with Cleveland Clinic, allowing for characterization and visualization of the Orthofix PEMF waveform, is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data, along with additional clinical data, could represent new clinical indication opportunities for our regenerative stimulation solutions.

Extremity Fixation

The Extremity Fixation SBU offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This SBU specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures. Extremity Fixation distributes its products through a global network of distributors and sales representatives to sell its orthopedic products to hospitals and healthcare providers.

Extremity Fixation Strategy

Our strategy for the Extremity Fixation SBU is to continue to provide highly valued external and internal temporary to definitive fixation devices used in fracture repair, deformity correction and bone reconstruction. Our key strategies are:

- Geographic market & product focus on:
    - Pediatrics & deformity correction worldwide
    - Foot & ankle in the U.S.
    - Trauma in selected geographies
- Promote the advantages of our JuniOrtho pediatric portfolio and support tools
- Leverage the market acceptance of TL-Hex
- Continue the strong pace of new product launches
- Acquire or license products, technologies and companies to support these market opportunities.

Extremity Fixation Products

The following table and discussion identify our principal Extremity Fixation products by trade name and describe their primary applications:

Product	Primary Application
External Fixator	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus, XCaliber and Gotfried P.C.C.P
Eight-Plate + Guided Growth System	The 2nd generation plate for treatment for bowed legs or knock knees of children
LRS Advanced Limb Reconstruction System	External fixation for limb lengthening and corrections of deformity
TrueLok	Ring fixation system for trauma, limb lengthening, and deformity correction
TL-HEX TrueLok Hexapod System (“TL-HEX”)	Hexapod external fixation system for trauma and deformity correction with associated software
HEX RAY	An innovative software to manage pre-operation and post-operation planning in connection with the TL-HEX system
Galaxy Fixation System	External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps
VeroNail Trochanteric Nailing System	Trochanteric titanium nailing system for hip fractures
Centronail Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail
Ankle Hind Foot Nailing System (“AHN”)	An extension of the Centronail range of intramedullary nails
Chimaera Hip Fracture System	A strong, versatile hip nail that allows fixation to be adapted to the type of fracture being treated
Agile Nail	A small rigid intramedullary nail to treat adolescent patients
MJ FLEX	An innovative elastic nail with a unique design to be used in pediatric patients
OSCAR	Ultrasonic bone cement removal
Ankle Hindfoot Nail (“AHN”)	A differentiated solution for hindfoot fusions
Contours Lapidus Plating System (“LPS”)	A plate design contoured specifically for a tarsometatarsal (“TMT”) fusion
Contours VPS Volar Plating System III	The 3rd generation of plates to treat distal radius fractures

We provide internal and external fixation solutions for extremity repair and deformity correction, both for adults and children. Our fracture repair products consist of fixation devices designed to stabilize a broken bone until it can heal. With these devices, we can treat simple and complex fracture patterns along with achieving deformity corrections.

External Fixation

External fixation devices are used to stabilize fractures and offer an ideal treatment for complex fractures, fractures near the joints and in patients with known risk factors or co-morbidities. The treatment method entails the use of bone screws and/or wires which are inserted percutaneously into the bone and stabilized with an external device. The treatment is minimally invasive and allows external manipulation of the bone to obtain and maintain final bone alignment (reduction). The bone is fixed in this way until healing. External fixation devices may also be used temporarily in complex trauma cases to stabilize the fracture prior to treating it definitively. In these situations, the device offers rapid fracture stabilization, which is important in life saving as well as limb salvage procedures.

The Galaxy Fixation System is a modular external fixation system indicated for fracture treatment in the upper and lower limbs. The system incorporates a streamlined combination of clamps, with both pin-to-bar and bar-to-bar coupling capabilities, offering a complete range of applications, including specific anatomic units for the elbow, shoulder and wrist. It is designed both for temporary as well as definitive fracture fixation. It is also available in sterile kits for convenience and ease of use.

The XCaliber external fixator, made of lightweight radiolucent material, offers improved X-ray visualization of the fracture and alignment. It is available in three configurations for the treatment of long bone fractures, fractures near joints, and ankle fractures. XCaliber fixators are supplied pre-assembled, ready to use, in sterile kits to decrease time in the operating room.

The LRS Advanced Limb Reconstruction System uses callus distraction to lengthen bone in a variety of procedures, including monofocal lengthening and corrections of deformity. Its multifocal procedures include bone transport, simultaneous compression and distraction at different sites, bifocal lengthening, and correction of deformities with shortening.

The TrueLok Ring Fixation System is a surgeon-designed, lightweight external fixation system for limb lengthening and deformity correction. In essence, a ring fixation construct consists of circular rings and semi-circular external supports centered on the patient's limb and secured to the bone by crossed, tensioned wires and half pins. The rings are connected externally to provide stable bone fixation. The main external connecting elements are threaded rods, linear distractors, or hinges and angular distractors, which allow the surgeon to adjust the relative position of rings to each other. The ring positions are manipulated either acutely or gradually in precise increments to perform the correction of the deformity, limb lengthening, or bone segment transportation as required by the surgeon. Created with pre-assembled function blocks, the TrueLok products are a simple, stable, versatile ring fixation system.

Building on the TrueLok brand, the TL-HEX TrueLok Hexapod System was released in 2012 in international markets and in 2015 in the U.S. TL-HEX is a hexapod-based system designed at Texas Scottish Rite Hospital for Children as a three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. The system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings' position is adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space. All the basic components from the TrueLok Ring Fixation System (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) can be utilized with the TL-HEX system; therefore, external supports from both systems can be connected to each other when building fixation blocks.

The new addition of HEX-Ray software to the TL-HEX platform allows a unique and realistic representation of the case using real x-rays and providing more accurate and user-friendly management of the surgery. The software is intended to help the surgeon save time by avoiding undesired corrections and mistakes related to software management.

Linked to the TL and TL-HEX line, the Company has also developed a patient app to support the patient in the TL-HEX fixator daily management. The patient is an active part in the healing process and the app is designed to improve the communication and connection with the hospital staff by saving time, optimizing the number of visits to the clinic, and supporting the patient with motivational messages and an online tutorial to sort out the most common issues. Also related to the TL and TL-HEX line, but specifically developed for younger patients, the Company created the Edugame, an online app to help patient learn by playing a virtual game. It has been developed with psychologist involvement in order to deliver useful information in an effective way.

Our proprietary XCaliber bone screws are designed to be compatible with our external fixators and reduce inventory for our customers. Some of these screws are covered with hydroxyapatite, a mineral component of bone that reduces superficial inflammation of soft tissue and improves bone grip. Other screws in this proprietary line do not include the hydroxyapatite coating, but offer different advantages such as patented thread designs for better adherence in hard or poor quality bone. Adding to the XCaliber bone screw product line are our cylindrical screws, which are geared towards the trauma applications of the Galaxy Fixation System. We believe we have a full line of bone screws to meet the demands of the market.

In 2017, Orthofix introduced JuniOrtho, a new brand identity for extremity fixation pediatric products. JuniOrtho is a range of products and resources, dedicated to pediatrics and young adults with bone fractures and deformities. With a long history of developing innovative and leading-edge solutions, Orthofix has brought all of its pediatric expertise and products under the JuniOrtho banner.

Internal Fixation

Internal fixation devices come in various sizes, depending on the bone that requires treatment, and consist of either long rods, commonly referred to as nails, or plates that are attached with the use of screws. A nail is inserted into the medullary canal of a fractured long bone of the human arm or leg (e.g., humerus, femur or tibia). Alternatively, a plate is attached by screws to an area such as a broken wrist, hip or foot. Examples of our internal fixation devices include:

- The Chimaera Hip Nailing System indicated for the treatment of hip fractures. The Chimaera hip nail is designed to offer improvements over currently available nails by taking advantage of decades of knowledge in hip nailing. The result is a strong, versatile nail that allows fixation to be adapted to the type of fracture being treated. An all-in-one dedicated instrument tray contains a color-coded instrument set designed for increased precision during the surgical steps as well as intuitive instrument selection.
- The VeroNail is indicated for the treatment of hip fractures. The nail design is minimally-invasive to reduce surgical trauma and allow patients to begin walking again shortly after the operation. It uses a dual screw configuration that we believe provides more stability than previous single screw designs.
- The Centronail Titanium Nailing System comprises a range of titanium nails to stabilize fractures in the femur, tibia and humerus. The system offers improved mechanical distal targeting and minimal instrumentation to optimize inventory.
- The Ankle Hindfoot Nail, which is an arthrodesis nailing system designed to improve upon the stability, simplicity, and flexibility of current hindfoot nails.
- The Agile Nail, which is designed to treat femoral fractures in patients where a small rigid nail is needed. Its unique design requires less inventory, and the Agile nail is the smallest titanium nail currently available in the market. This provides further benefits such as reduced invasiveness and lightness.
- The MJ Flex is an elastic nail system that innovates a technique considered to be the gold standard in the treatment of pediatric fractures. The unique shape of the nail offers improved strength, better visibility, more rigidity, and potentially a reduced usage of x-rays. The system is available in different sizes, both in titanium and stainless steel.

In addition to treating bone fractures, we also design, manufacture and distribute devices intended to treat congenital bone conditions, such as angular deformities (e.g., bowed legs in children), or degenerative diseases, as well as conditions resulting from a previous trauma. An example of a product offered in this area is the Eight-Plate Guided Growth System.

Spine Fixation

The Spine Fixation SBU designs, develops and markets a portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products globally through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.

Spine Fixation Strategy

Our vision for the Spine Fixation SBU is to become the clear first choice for our distributors and surgeons by demonstrating strength in partnership. Our key strategies are:

- Continue to engage and expand global sales force
- Cultivate independent sales force vs. direct reps in U.S.
- Continue the strong pace of new product launches
- Provide exceptional training and education programs for reps and surgeons
- Acquire or license products, technologies and companies to increase the scale of this business.

Spine Fixation Products

The following table and discussion identify our key Spine Fixation products by trade name and describe their primary applications:

Product	Primary Application
FORZA XP Expandable Spacer System	A titanium expandable spacer system for Posterior Lumbar Interbody Fusion ("PLIF") and Transforaminal Lumbar Interbody Fusion ("TLIF") procedures featuring a large graft window with the ability to pack post expansion in situ
CETRA Anterior Cervical Plate System	An anterior cervical plate system offering a low profile plate with an intuitive locking mechanism, large graft windows, a high degree of screw angulation and simplified instrumentation
CONSTRUX Mini PEEK / Titanium Composite ("PTC") Spacer System	A cervical interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a Polyetheretherketones ("PEEK") core to maintain imaging characteristics
FORZA PTC Spacer System	A posterior lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
PILLAR SA PTC PEEK Spacer System	A standalone Anterior Lumbar Interbody Fusion ("ALIF") lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
FIREBIRD / FIREBIRD NXG Spinal Fixation System	A system of rods, crossbars and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure
JANUS Midline Fixation Screw	An addition to the Firebird Spinal Fixation System designed to achieve more cortical bone purchase in the medial to lateral trajectory when compared to traditional pedicle screws and provides surgeons with the option of a midline approach
Connector System for revisions	A comprehensive system to reduce the complexity of revising and extending existing spinal constructs; this eliminates the need to remove existing hardware while providing stability at adjacent levels
CENTURION Posterior Occipital Cervico-Thoracic ("POCT") System	A multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome that allow the surgeon to build a spinal implant construct
SAMBA-SCREW System	A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients
FIREBIRD Deformity Correction System	An extension to the Firebird Spinal Fixation System that provides additional instrument and implant options for complex thoracolumbar spine procedures

Product	Primary Application
PHOENIX Minimally Invasive Spinal Fixation System	A multi-axial extended reduction screw body used with the Firebird Spinal Fixation System designed to be implanted during a posterior thoracolumbar spine fusion procedure
LONESTAR Cervical Stand Alone ("CSA")	A stand-alone spacer system designed to provide the biomechanical strength to a traditional or minimal invasive Anterior Cervical Discectomy and Fusion ("ACDF") procedure with less disruption of patient anatomy and to preserve the anatomical profile
SKYHAWK Lateral Interbody Fusion System & Lateral Plate System	Provides a complete solution for the surgeon to perform a Lateral Lumbar Interbody Fusion, an approach to spinal fusion in which the surgeon accesses the intervertebral disc space using a surgical approach from the patient's side that disturbs fewer structures and tissues
FORZA Spacer System	PEEK interbody devices for PLIF and TLIF procedures
PILLAR PL & TL PEEK Vertebral Body Replacement ("VBR") System	PEEK interbody devices for PLIF and TLIF procedures

Spinal Repair Solutions

We provide a wide array of implants designed for use primarily in cervical, thoracic and lumbar fusion surgeries. These implants are made of either metal or a thermoplastic compound called PEEK. The majority of the implants that we offer are made of titanium metal. This includes the Cetra, 3°, Reliant and Hallmark cervical plates. Additionally, the Spinal Fixation System, the Firebird Spinal Fixation System, the Phoenix Minimally Invasive Spinal Fixation System, the Ascent, Ascent LE, and the Centurion POCT Systems are sets of rods, cross connectors and screws that are implanted during posterior fusion procedures. The Firebird Modular and pre-assembled Spinal Fixation Systems are designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our product ProView MAP System. To complement our plates, rods and screw fixation options we offer an entire portfolio of cervical and thoracolumbar PEEK interbody devices within our Pillar and Forza product lines. This interbody portfolio includes two stand-alone devices, Lonestar and Pillar SA, as well as the Construx Mini PTC system, a novel titanium composite spacer which offers a superior alternative to other plasma spray coated options currently available on the market. We also offer specialty plates and screws that are used in less common procedures, and as such, are not manufactured by many device makers. These specialty implants include the New Bridge Laminoplasty Fixation System that is designed to expand the cervical vertebrae and relieve pressure on the spinal canal, the Samba-Screw System used in sacroiliac joint fixation, as well as the Unity plate which is used in anterior lumbar fusion procedures.

Biologics

The Biologics SBU provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This SBU specializes in the marketing of regeneration tissue forms and distributes MTF Biologics ("MTF") tissues to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives. Our partnership with MTF allows us to exclusively market the Trinity Evolution and Trinity ELITE tissue forms for musculoskeletal defects to enhance bony fusion.

Biologics Strategy

In order to drive further adoption and use of our products, our strategy for the Biologics SBU is to educate physicians, both directly and through our sales force, of the surgical and patient benefits of using our portfolio of regenerative tissues and products to augment their surgical procedures and results. Our key strategies are:

- Increase sales force coverage in the spine market and continue to expand into other orthopedic procedures
- Cultivate independent sales force vs. direct reps in the U.S.
- Continue to leverage the surgeon-preferred Trinity ELITE characteristics and clinical evidence
- Accelerate new tissue development projects with MTF Biologics.

Biologics Products

The following table and discussion identify our principal Biologics products by trade name and describe their primary applications:

Product	Primary Application
AlloQuent Structural Allografts	Interbody devices made of cortical bone (or cortical-cancellous grafts) that are designed to restore the space that has been lost between two or more vertebrae due to a degenerated disc during a spinal fusion procedure
Trinity ELITE	A fully moldable allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion or bone fusion procedure
Trinity Evolution	An allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion or bone fusion procedure
VersaShield	A thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands
Collage Synthetic Osteoconductive Scaffold	A synthetic bone void filler

The regenerative solutions offered as part of the Biologics SBU's portfolio include solutions for a variety of musculoskeletal defects used in spinal and extremity orthopedic procedures.

Regenerative Solutions

The premier biologics tissues we market include the Trinity ELITE and Trinity Evolution tissue forms, which are cortical cancellous allografts that contain viable cells and are used during surgery in the treatment of musculoskeletal defects for bone reconstruction and repair. These allografts are intended to offer a viable alternative to an autograft procedure as harvesting autograft has been shown to add risk of an additional surgical procedure and related patient discomfort in conjunction with a repair surgery.

To provide structural support and facilitate bone growth in spine fusion procedures, we offer a full line of AlloQuent allograft structural spacers derived from human cadaveric bone. These spacers are used to restore the height lost between vertebral bodies when discs are removed in fusion procedures and to facilitate spine fusion.

We offer the Collage product as an osteoconductive scaffold and a bone graft substitute product. The product is a combination synthetic bone graft substitute comprised of beta tri-calcium phosphate and type 1 bovine collagen.

We also market the VersaShield tissue form, a thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands. Amniotic tissue forms derived from donated human placenta are used in a wide variety of applications and are valued for their healing properties, scar reduction and anti-adhesion characteristics. The VersaShield tissue is derived from the human placental layers amnion and chorion; these thin elastic membranes allow the tissue to conform to the surface of the surgical site.

We receive marketing fees through our collaboration with MTF for the Trinity Evolution, Trinity ELITE, and VersaShield tissues. MTF processes the tissues, maintains inventory, and invoices hospitals and surgery centers and other points of care for service fees, which are submitted by customers via purchase orders. We have exclusive worldwide rights to market the Trinity Evolution and Trinity ELITE tissue forms. We market the VersaShield tissue under a private label brand via a non-exclusive marketing agreement for the tissue form.

To date, our Biologics products are offered primarily in the U.S. market due in part to restrictions on providing U.S. human donor tissue in other countries.

Product Development

Our research and development departments are responsible for new product development. Our primary research and development facilities are located in Verona, Italy and Lewisville, Texas. We work with leading hospital research institutions as well as with physicians and other consultants on the long-term scientific planning and evolution of our products and therapies.

We maintain interactive relationships with spine and orthopedic centers in the U.S. and Europe, including research and clinical organizations such as Sinai Hospital of Baltimore, Cleveland Clinic, Texas Scottish Rite Hospital for Children, and MTF. Several of the products that we market have been developed through these collaborations. In addition, we periodically receive suggestions for new products and product enhancements from the scientific and medical community, some of which result in Orthofix entering into assignment or license agreements with physicians and third parties. We also receive occasional requests for the production of customized instruments, some of which have resulted in new products.

In 2017, 2016 and 2015 we incurred $29.7 million, $28.8 million and $26.4 million, respectively, of research and development expense.

Patents, Trade Secrets, Assignments and Licenses

We rely on a combination of patents, trade secrets, assignment and license agreements, and non-disclosure agreements to protect our proprietary intellectual property. We own numerous U.S. and foreign patents, have numerous pending patent applications and have license rights under patents held by third parties. Our primary products are patented in the major markets in which they are sold. No assurance can be given that pending patent applications will result in issued patents, that patents issued or assigned to or licensed by us will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with any competitive advantage or protection. Third parties might also obtain patents that would require assignments to or licensing by us to conduct our business. We rely on confidentiality and non-disclosure agreements with key employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology.

We obtain assignments or licenses of varying durations for certain of our products from third parties. We typically acquire rights under such assignments or licenses in exchange for lump-sum payments or arrangements under which we pay a percentage of sales to the licensor. However, while assignments or licenses to us generally are irrevocable, no assurance can be given that these arrangements will continue to be made available to us on terms that are acceptable to us, or at all. The terms of our license and assignment agreements vary in length from a specified number of years to the life of product patents or the economic life of the product. These agreements generally provide for royalty payments and termination rights in the event of a material breach.

Compliance and Ethics Program

It is fundamental policy of our Company to conduct business in accordance with the highest ethical and legal standards. We have a comprehensive compliance and ethics program, which is overseen by our Chief Ethics and Compliance Officer who reports directly to our Chief Executive Officer and the Compliance Committee of the Board of Directors. The program is intended to promote legal compliance and ethical business practices throughout our domestic and international businesses. It is designed to meet the standards set forth in guidance issued by the U.S. Department of Justice (“Evaluation of Corporate Compliance Programs” (February 2017)), the Office of Inspector General (HCCA-OIG “Measuring Compliance Program Effectiveness: A Resource Guide” (March 2017)) and by the U.S. Sentencing Commission (“Effective Compliance and Ethics Programs (November 2014)) and to prevent and detect violations of applicable federal, state and local laws. Key elements of the program include:

- Organizational oversight by senior-level personnel responsible for the compliance function within our Company;
- Written standards and procedures, including a Corporate Code of Conduct;
- Methods for communicating compliance concerns, including anonymous reporting mechanisms;
- Investigation and remediation measures to ensure prompt response to reported matters and timely corrective action;
- Compliance education and training for employees and contracted business associates;
- Auditing and monitoring controls to promote compliance with applicable laws and assess program effectiveness;
- Disciplinary guidelines to enforce compliance and address violations;
- Due diligence reviews of high risk intermediaries and exclusion lists screening of employees and contracted business associates; and
- Risk assessments to identify areas of compliance risk.

Government Regulation

Classification and Approval of Products by the FDA and other Regulatory Authorities

Our research, development and clinical programs, and our manufacturing and marketing operations, are subject to extensive regulation in the U.S. and other countries. Most notably, all of our products sold in the U.S. 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 products and facilities vary widely 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 we commercially distribute in the U.S. is covered by either premarket notification ("510(k)") clearance, letter to file, approval of a premarket approval application ("PMA"), or some other approval from the FDA. The FDA classifies medical devices into one of three classes, which generally determine the type of FDA approval required. Devices deemed to pose low risk are placed in class I, while devices that are considered to pose moderate risk are placed in class II, and devices deemed to pose the greatest risks requiring more regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, or devices deemed not substantially equivalent to a device that previously received 510(k) clearance (as described below), are placed in class III. Our Spine Fixation and Extremity Fixation products are, for the most part, class II devices and the instruments used in conjunction with these products are generally class I. Our BioStim bone growth therapy products are classified as class III by the FDA, and have been approved for commercial distribution in the U.S. through the PMA process.

The medical devices 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 such approvals will be granted on a timely basis, if at all. While we believe we have obtained all necessary clearances and approvals for the manufacture and sale of our products and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance.

To market our devices within the member states of the European Union, we are required to comply with the European Medical Device Directives. Under the European Medical Device Directives, all medical devices must bear the CE mark. To obtain authorization to affix the CE mark to our products, a recognized European Notified Body must assess our quality systems and the product's conformity to the requirements of the European Medical Device Directives. We are subject to an annual inspection by a Notified Body for compliance with these requirements.

Our Biologics SBU markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE, our allogeneic bone matrices comprised of cancellous bone containing viable stem cells and a demineralized cortical bone component. These allografts are regulated under the FDA's Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device, biologic or a drug. The Biologics SBU also distributes certain surgical implant products known as "allograft" products that are derived from human tissues and which are used for bone reconstruction or repair and are surgically implanted into the human body. These tissues are regulated by the FDA as minimally-manipulated tissue and covered by FDA's "Good Tissues Practices" regulations, which cover all stages of allograft processing. There can be no assurance our suppliers of the Trinity Evolution, Trinity ELITE and allograft products will continue to meet applicable regulatory requirements or that those requirements will not be changed in ways that could adversely affect our business. Further, there can be no assurance these products will continue to be made available to us or that applicable regulatory standards will be met or remain unchanged. Moreover, products derived from human tissue or bones are from time to time subject to recall for certain administrative or safety reasons and we may be affected by one or more such recalls. For a description of these risks, see Item 1A Risk Factors.

Certain Other Product and Manufacturing Regulations

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include: product listing and establishment registration; Quality System Regulation ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; labeling regulations and governmental prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications; clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices; approval of product modifications that affect the safety or effectiveness of one of our PMA approved devices; Medical Device Adverse Event Reporting regulations, which require that manufacturers report to the FDA and other foreign governmental agencies 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 and European Notified Bodies to determine our compliance with the FDA's QSR and other international 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. In addition to FDA inspections, all manufacturing facilities of the Company are subject to annual Notified Body inspections.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices. 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. For a description of these risks, see Item 1A Risk Factors.

Accreditation Requirements

In addition, our subsidiary Orthofix Inc. has been accredited by the Accreditation Commission for Health Care, Inc. ("ACHC") for medical supply provider services with respect to durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). ACHC, a private, not-for-profit corporation, which is certified to ISO 9001:2000 standards, was developed by home care and community-based providers to help companies improve business operations and quality of patient care. Although accreditation is generally a voluntary activity where healthcare organizations submit to peer review their internal policies, processes and patient care delivery against national standards, the Centers for Medicare and Medicaid Services ("CMS") required DMEPOS suppliers to become accredited. We believe that by attaining accreditation, Orthofix Inc. has demonstrated its commitment to maintain a higher level of competency and strive for excellence in its products, services, and customer satisfaction.

Third-Party Payor Requirements

Our products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid, and Tricare or private insurance plans and healthcare networks. Third-party payors 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 policyholder's healthcare insurance benefits are limited. Also, non-government third-party payors are increasingly challenging the medical necessity and prices paid for our products and services. The Medicare program is expected to continue to implement a new payment mechanism for certain DMEPOS items via the implementation of its competitive bidding program. Bone growth stimulation products are currently exempt from this competitive bidding process.

Laws Regulating Healthcare Fraud and Abuse; State Healthcare Laws

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

Laws Protecting the Confidentiality of Health Information

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 promulgates 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 certain of those that sell devices or equipment) that engage in particular electronic transactions, including, as we do, the transmission of claims to health plans. Consequently, health information that we access, collect, analyze, and otherwise use and/or disclose includes protected health information that is subject to HIPAA. As noted above, many state laws also pertain to the confidentiality of health information. Such laws are not necessarily preempted by HIPAA, in particular those state laws that afford greater privacy protection to the individual than HIPAA. These state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

In Europe, the Data Protection Directive requires us to manage individually identifiable information in the EU and, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data.

Physician Payments Sunshine Provision of the Affordable Care Act

The Physician Payments Sunshine Provision of the Affordable Care Act (Section 6002), which was enacted in 2010 and became subject to final CMS rules in 2013, requires public disclosure to the United States government of payments to physicians and teaching hospitals, including in-kind transfers of value such as gifts or meals. The Act also provides penalties for non-compliance. The Act requires that we file an annual report on March 31st of a calendar year for the transfers of value incurred for the prior calendar year. Non-compliance is subject to civil monetary penalties.

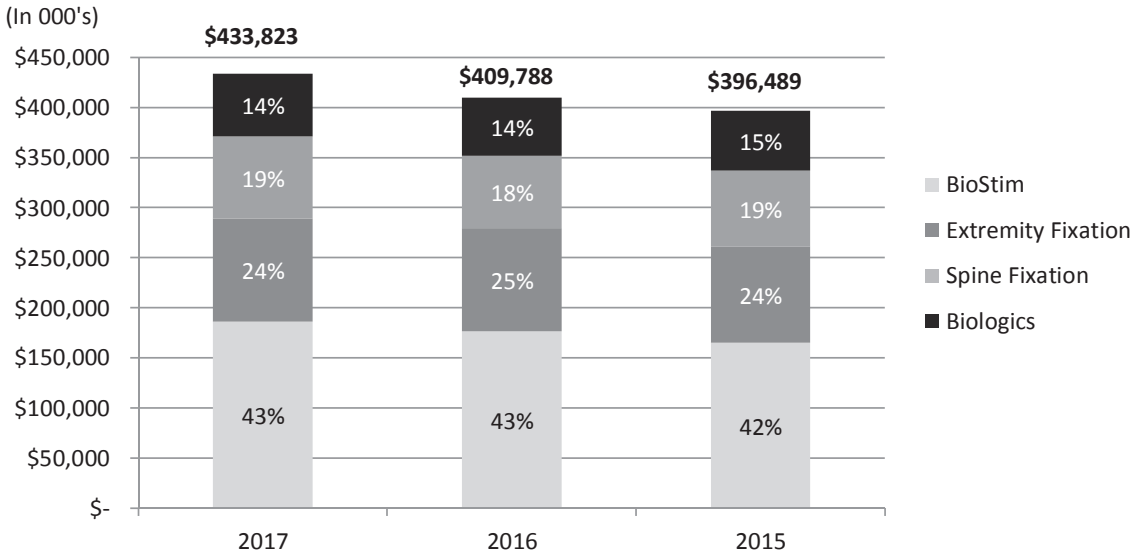
Sales, Marketing and Distribution

General Trends

We believe that demographic trends, principally in the form of a better informed, more active and aging population in the major healthcare markets of the U.S., Western Europe and Japan, together with opportunities in emerging markets such as the Asia-Pacific Region and Latin America, as well as our focus on innovative products, will continue to have a positive effect on the demand for our products.

Strategic Business Units

Our revenues are generated from the sales of products in our four SBUs: BioStim, Extremity Fixation, Spine Fixation and Biologics. See the chart below for the distribution of sales between each of our SBUs for each of the years ended December 31, 2017, 2016, and 2015.



Sales Network

We have a broad sales network comprised of direct sales representatives and distributors. This established sales network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products worldwide in over 60 countries.

In our largest market, the U.S., our sales network is generally comprised of four sales forces, each addressing one of our business units, however some independent distributors sell products for more than one of our businesses. A hybrid distribution network of direct sales representatives and independent distributors sells products in our BioStim SBU, while primarily independent distributors sell products in our Extremity Fixation, Spine Fixation, and Biologics SBUs.

Outside the U.S., we employ direct sales representatives and contract with independent distributors. In order to provide support to our independent sales network, we have sales and marketing specialists who regularly visit independent distributors to provide training and product support.

Marketing and Product Education

We market and sell our products principally to physicians, hospitals, ambulatory surgery centers, integrated health delivery systems and other purchasing organizations.

We support our sales force through specialized training workshops in which physicians and sales specialists participate. We also produce marketing and training materials, including materials outlining surgical procedures, for our customers, sales force and distributors in a variety of languages using printed, video and multimedia formats. We also require all of our sales force, direct and independent, to undergo extensive product, policy, and compliance training to ensure adherence to our standards, policies, and applicable law.

To provide additional advanced training for physicians, consistent with the AdvaMed Code of Ethics (“AdvaMed Code”) and the MedTech Europe Code of Ethical Business Practice (“MedTech Code”), we organize regular multilingual teaching seminars in multiple locations. Those places include our facility in Verona, Italy, various locations in Latin America and in Lewisville, Texas. In recent years, thousands of surgeons from around the world attended these product education seminars, which included a variety of lectures from specialists, as well as demonstrations and hands-on workshops.

Competition

Our bone growth therapy products, which are part of our BioStim and Biologics SBUs, compete principally with similar products marketed by Zimmer Biomet, Inc.; DJO Global; and Bioventus. The Biologics HCT/P and Spine Fixation products we market compete with products marketed by Medtronic, Inc.; DePuy Synthes, a division of Johnson and Johnson; Stryker Corp.; Zimmer Biomet, Inc.; NuVasive, Inc.; Globus Medical Inc.; and various smaller public and private companies. For Extremity Fixation devices, our principal competitors include DePuy Synthes; Zimmer Biomet, Inc.; Stryker Corp.; and Smith & Nephew plc.

We believe we enhance our competitive position by focusing on product features such as ease of use, versatility, cost and patient acceptability, together with value-added services, such as Stim on Track and our JuniOrtho educational products and services. We attempt to avoid competing based solely on price. Overall cost and medical effectiveness, innovation, reliability, value-added service, and training are the most prevalent methods of competition in the markets for our products, and we believe we compete effectively.

Manufacturing and Sources of Supply

We generally design, develop, assemble, test and package our stimulation, orthopedic, and spinal implant products, and subcontract the manufacture of a substantial portion of the component parts and instruments. We design and develop our AlloQuent Allograft HCT/Ps and subcontract its manufacturing. Through subcontracting a portion of our manufacturing, we attempt to maintain operating flexibility in meeting demand while focusing our resources on product development, education and marketing as well as quality assurance standards. Although certain of our key raw materials are obtained from a single source, we believe alternate sources for these materials are available. Further, we believe an adequate inventory supply is maintained to avoid product flow interruptions. Historically, we have not experienced difficulty in obtaining the materials necessary to meet our production schedules.

The Trinity Evolution and Trinity ELITE HCT/Ps, for which we have exclusive marketing rights, are allograft tissue forms that are supplied to customers by MTF in accordance with orders received directly from us. MTF sources, processes and packages the tissue forms and is the sole supplier of the Trinity Evolution and Trinity ELITE HCT/Ps to our customers.

Our products are currently manufactured and assembled in the U.S. and Italy. We believe our plants comply in all material respects with the requirements of the FDA and all relevant regulatory authorities outside the U.S. For a description of the laws to which we are subject, see Item 1, “Business”, under the subheadings “Corporate Compliance and Ethics Program” and “Government Regulation.” We actively monitor each of our subcontractors in order to maintain manufacturing and quality standards and product specification conformity. In addition, we do not consider the backlog of firm orders to be material.

Employees

At December 31, 2017, we had 858 employees worldwide. Of these, 594 were employed in the U.S. and 264 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 184 at December 31, 2017, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. We are not a party to any other collective bargaining agreement. We believe we have good relations with our employees.

eNeura Debt Security

On March 4, 2015, we entered into an Option Agreement (the “Option Agreement”) with eNeura, Inc. (“eNeura”), a privately held medical technology company that is developing devices for the treatment of migraines. The Option Agreement provided us with an exclusive option to acquire eNeura (the “Option”) during the 18-month period following the grant of the Option, which expired in September 2016 without us exercising the Option. In consideration for the Option, (i) we paid a non-refundable $0.3 million fee to eNeura, and (ii) we loaned eNeura $15 million pursuant to a convertible, secured Promissory Note (the “eNeura Note”) that was issued to us. The principal amount of the eNeura Note is $15.0 million and interest accrues at 8.0%. The eNeura Note will mature on March 4, 2019 and interest is due when the eNeura Note matures, provided that if a change in control of eNeura (generally defined as a third-party acquisition of fifty percent or more of eNeura’s voting equity or all or substantially all of eNeura’s assets) occurs prior to the maturity date, the eNeura Note will automatically convert into preferred stock of eNeura, and the value of such preferred stock could be less than the principal amount of the note. The investment is recorded in other long-term assets as an available for sale debt security and any interest recognized is recorded in interest income. For additional discussion see Note 6 to the Consolidated Financial Statements in Item 8 of this Annual Report.

Item 1A. Risk Factors

In addition to the other information contained in this Annual Report and the exhibits hereto, you should carefully consider the risks described below. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this Annual Report.

Risks Related to our Legal and Regulatory Environment

If we fail to maintain an effective system of internal controls or discover material weaknesses in our internal control over financial reporting, we may not be able to report our financial results accurately or detect fraud, which could harm our business and the trading price of our Common Stock.

Effective internal controls are necessary for us to produce reliable financial reports and are important in our effort to prevent financial fraud. We are required to periodically evaluate the effectiveness of the design and operation of our internal controls. As has occurred in several years prior, including in connection with our prior restatements of financial statements, these evaluations may result in the conclusion that enhancements, modifications or changes to our internal controls are necessary or desirable. While management evaluates the effectiveness of our internal controls on a regular basis, these controls may not always be effective. There are inherent limitations on the effectiveness of internal controls, including collusion, management override, and failure of human judgment. Because of this, control procedures are designed to reduce rather than eliminate business risks. If we fail to maintain an effective system of internal controls or if management or our independent registered public accounting firm were to discover material weaknesses in our internal controls, we may be unable to produce reliable financial reports or prevent fraud, which could harm our financial condition and operating results, and could result in a loss of investor confidence and a decline in our stock price.

We have previously settled violations of the Foreign Corrupt Practices Act and any future violations could further subject us to adverse consequences.

In 2013, we self-reported to the U.S. Department of Justice (the "DOJ") and the SEC an internal investigation of improper payments by our Brazilian subsidiary, Orthofix do Brasil Ltda., regarding non-compliance by such subsidiary with the Foreign Corrupt Practices Act (the "FCPA"). This followed a prior matter that we self-reported to the DOJ and SEC in 2011, and settled in 2012, involving FCPA-related non-compliance by our then Mexican subsidiary, Promeca S.A. de C.V. In January 2017 we consented to a cease-and-desist order with the SEC to settle the Brazil-related violations, pursuant to which we agreed to pay approximately $6.1 million in disgorgement and penalties, and agreed to retain an independent compliance consultant for one year to review and test our FCPA compliance program.

The FCPA and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on U.S. publicly traded entities and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws.

In connection with our self-reported FCPA violations, we instituted extensive remediation measures, including terminating employees, as well as relationships with third-party representatives and distributors, conducting a global review of our anti-corruption and anti-bribery program, implementing regular audits of our third-party distributors and sales agents and developing and implementing new global accounting policies to provide further structure and guidance to foreign subsidiaries, establishing an internal audit function, improving the quality of personnel in our Compliance department, and implementing enhanced anti-corruption compliance training for employees and certain third parties. However, notwithstanding these efforts to make FCPA-related compliance a priority, our compliance policies and procedures may not always protect us from reckless or criminal acts committed by our employees, distributors or agents.

Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities,

disgorgement and other remedial measures, disruptions of our operations, and significant management distraction. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. Any reduction in international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations and financial condition.

We are subject to federal and state healthcare fraud, abuse and anti-self-referral laws, and could face substantial penalties if we are determined not to have fully complied with such laws.

Healthcare fraud and abuse regulations by federal and state governments impact our business. Healthcare fraud and abuse laws potentially applicable to our operations include:

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program (such as the Medicare or Medicaid programs);
- the federal Stark law, which prohibits physician self-referral, specifically a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services if the physician or an immediate family member has a financial relationship with that entity;
- federal false claims laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal government payors that are false or fraudulent; and
- state and non-U.S. laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental or non-U.S. governmental third-party payors, including commercial insurers.

Due to the breadth of some of these laws, there can be no assurance that we will not be found to be in violation of any such laws, and as a result we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations or the exclusion from participation in federal, non-U.S. or state healthcare programs. Any penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Reimbursement policies of third parties, cost containment measures and healthcare reform could adversely affect the demand for our products and limit our ability to sell our products.

Our products are sold either directly by us or by independent sales representatives to customers or to our independent distributors and purchased by hospitals, healthcare providers, and patients. These products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid and Tricare, or private insurance plans and healthcare networks. Major third-party payors for medical services in the U.S. and internationally continue to work to contain health care costs and are increasingly challenging the policies and the prices charged for medical products and services. Any medical policy developments that eliminate, reduce or materially modify coverage of our reimbursement rates for our products could have an impact on our ability to sell our products. In addition, third-party payors may deny reimbursement if they determine that a device or product provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. These policies and criteria may be revised from time-to-time.

Limits put on reimbursement could make it more difficult to buy our products and substantially reduce, or possibly eliminate, patient access to our products. In addition, should governmental authorities continue to enact legislation or adopt regulations that affect third-party coverage and reimbursement, access to our products and coverage by private or public insurers may be reduced with a consequential material adverse effect on our sales and profitability.

The CMS, in its ongoing implementation of the Medicare program, periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that this information could have on Medicare coverage policy for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Globally, our products are sold in many countries, such as the U.K., France, and Italy, which have publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales.

As required by law, the CMS has continued efforts to implement a competitive bidding program for selected durable medical equipment, prosthetic, orthotic supplies ("DMEPOS") items paid for by the Medicare program. In this program, Medicare rates are based on bid amounts for certain products in designated geographic areas, rather than the Medicare fee schedule amount. Bone growth stimulation products are currently exempt from this competitive bidding process. We cannot predict which products from any of our businesses may ultimately be affected or whether or when the competitive bidding process may be extended to our businesses. There can be no assurance that the implementation of the competitive bidding program will not have an adverse impact on the sales of some of our products.

We and certain of our suppliers may be subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products.

The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. These authorities regulate the development, approval, classification, testing, manufacturing, labeling, marketing and sale of medical devices. Likewise, our use and disclosure of certain categories of health information may be subject to federal and state laws, implemented and enforced by governmental authorities that protect health information privacy and security. For a description of these regulations, see Item 1, "Business," under the subheading "Government Regulation."

The approval or clearance by governmental authorities, including the FDA in the U.S., is generally required before any medical devices may be marketed in the U.S. or other countries. We cannot predict whether, in the future, the U.S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition, results of operations or cash flows. The process of obtaining FDA clearance and approvals to develop and market a medical device can be costly, time-consuming and subject to the risk that such clearances or approvals will not be granted on a timely basis, if at all. The regulatory process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices. The FDA has the ability to change the regulatory classification of a cleared or approved device from a higher to a lower regulatory classification, or to reclassify an HCT/P, either of which could materially adversely impact our ability to market or sell our devices. For example, the FDA included Class III bone growth stimulator products in its 2015 strategic priority work plan, as part of a list of 21 product categories it would review for possible down classification. Shortly after the issuance of the work plan, the Company, together with other manufacturers of bone growth stimulator products, submitted a public comment letter opposing the possible down classification. The FDA did not respond to the comment letter and has not taken any action with respect to the bone growth stimulator product category since publication of the 2015 work plan. If a down classification were to occur and new entrants to the market were able to create technology with comparable efficacy to our devices, our BioStim SBU could face additional competition, which could negatively affect its future sales.

In addition, we may be subject to compliance actions, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses, or if the FDA challenges one or more of our determinations that a product modification did not require new approval or clearance by the FDA. Device manufacturers are permitted to promote products solely for the uses and indications set forth in the approved product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses, including actions alleging that federal health care program reimbursement of products promoted for "off-label" uses are false and fraudulent claims to the government. The failure to comply with "off-label" promotion restrictions can result in significant administrative obligations and costs, and potential penalties from, and/or agreements with, the federal government.

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. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of the foregoing actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations or cash flows.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. The European Commission ("EC") has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received a full Quality Assurance Certification from a "Notified Body" in order to be able to sell products within the member states of the European Union. This Certification allows manufacturers to stamp the products of certified plants with a "CE" mark. Products covered by the EC regulations that do not bear the CE mark cannot be sold or distributed within the European Union. We have received certification for all currently existing manufacturing facilities.

The impact of the Affordable Care Act and other United States healthcare reform legislation on us remains uncertain.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. Among other things, the ACA:

- requires certain medical device manufacturers to pay an excise tax equal to 2.3% of the price for which such manufacturer sells its medical devices; this excise tax was previously suspended until December 31, 2017. On January 22, 2018, the President signed the Extension of Continuing Appropriations Act, 2018, which extended the moratorium on the tax until December 31, 2019.
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

Certain legislative changes to and regulatory changes under the ACA have occurred in the 115th United States Congress. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the ACA remain possible. Any such future changes, depending on their nature, could have an adverse effect on our ability to maintain or increase sales of any of our products and achieve profitability.

We are subject to differing customs and import/export rules in several jurisdictions in which we operate.

We import and export our products to and from a number of different countries around the world. These product movements involve subsidiaries and third parties operating in jurisdictions with different customs and import/export rules and regulations. Customs authorities in such jurisdictions may challenge our treatment of customs and import/export rules relating to product shipments under aspects of their respective customs laws and treaties. If we are unsuccessful in defending our treatment of customs and import/export classifications, we may be subject to additional customs duties, fines or penalties that could adversely affect our profitability.

Risks Related to our Business and Industry

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a group purchasing organization or similar entity excludes us from being a supplier.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators and third-party payors to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This has resulted and may continue to result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations ("GPOs"), independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions. If a GPO were to exclude us from their supplier list, our net sales could be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products.

The industry in which we operate is highly competitive. New developments by others could make our products or technologies non-competitive or obsolete.

The medical devices industry is highly competitive. We compete with a large number of companies, many of which have significantly greater financial, manufacturing, marketing, distribution and technical resources than we do. Many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Furthermore, we may not be able to successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. For more information regarding our competitors, see Item 1, "Business," under the subheading "Competition."

In addition, the orthopedic medical device industry in which we compete is undergoing, and is characterized by, rapid and significant technological change. We expect competition to intensify as technological advances are made. New technologies and products developed by other companies are regularly introduced into the market, which may render our products or technologies non-competitive or obsolete.

Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third parties.

Our ability to market our BioStim, Extremity Fixation, Spine Fixation, and Biologics products successfully depends, in part, on the acceptance of the products by independent third parties (including hospitals, physicians, other healthcare providers and third-party payors) as well as patients. Unanticipated side effects or unfavorable publicity concerning any of our products could have an adverse effect on our ability to maintain hospital approvals or achieve acceptance by prescribing physicians, managed care providers and other retailers, customers and patients.

Our allograft and mesenchymal stem cell allografts could expose us to certain risks that could disrupt our business.

Our Biologics business markets allograft tissues that are derived from human cadaveric donors, and our ability to market the tissues depends on our supplier continuing to have access to donated human cadaveric tissue, as well as the maintenance of high standards by the supplier in its processing methodology. The supply of such donors is inherently unpredictable and can fluctuate over time. The allograft tissues are regulated under the FDA's HCT/P regulatory paradigm and not as a medical device or as a biologic or drug. There can be no assurance that the FDA will not at some future date re-classify the allograft tissues, and the reclassification of this product from a human tissue to a medical device could have adverse consequences for us or for the supplier of this product and make it more difficult or expensive for us to conduct this business by requiring premarket clearance or approval as well as compliance with additional post-market regulatory requirements.

We may not be able to successfully introduce new products to the market, and market opportunities that we expect to develop for our products may not be as large as we expect.

During 2017, we continued to make improvements in revenues related to several new products we introduced to the market over the past several years, including the TL-HEX TrueLok Hexapod System, Galaxy Fixation System, Ankle Hind Foot Nailing System, Firebird NXG Spinal Fixation System, FORZA PTC Spacer System, Samba-Screw System, SKYHAWK Lateral Interbody Fusion System & Lateral Plate System, CENTURION POCT System, PILLAR SA PTC PEEK Spacer System, JANUS Midline Fixation Screw, and the Cetra Anterior Cervical Plate, among others. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians) and obtain regulatory approvals, which can depend, among other things, on the product achieving broad clinical acceptance, the level of third-party reimbursement and the introduction of competing technologies. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

Growing our business requires that we properly educate and train physicians regarding the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products.

Acceptance of our products depends in part on our ability to (i) educate the medical community as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies, and (ii) train physicians in the proper use and implementation of our products. We support our sales force and distributors through specialized training workshops in which surgeons and sales specialists participate. We also produce marketing materials, including

materials outlining surgical procedures, for our sales force and distributors in a variety of languages using printed, video and multimedia formats. To provide additional advanced training for surgeons, consistent with the AdvaMed Code and the MedTech Code, we organize monthly multilingual teaching seminars in multiple locations. However, we may not be successful in our efforts to educate the medical community and properly train physicians. If physicians are not properly trained, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products.

We may be adversely affected by any disruption in our information technology systems, which could adversely affect our cash flows, operating results and financial condition.

Our operations are dependent upon our information technology systems, which encompass all of our major business functions. We rely upon such information technology systems to manage and replenish inventory, to fill and ship customer orders on a timely basis, to coordinate our sales activities across all of our products and services and to coordinate our administrative activities. A substantial disruption in our information technology systems for any prolonged time period (arising from, for example, system capacity limits from unexpected increases in our volume of business, outages or delays in our service) could result in delays in receiving inventory and supplies or filling customer orders and adversely affect our customer service and relationships. Our systems might be damaged or interrupted by natural or man-made events or by computer viruses, physical or electronic break-ins and similar disruptions affecting the global Internet. There can be no assurance that such delays, problems, or costs will not have a material adverse effect on our cash flows, operating results and financial condition.

As our operations grow in both size and scope, we will continuously need to improve and upgrade our systems and infrastructure while maintaining the reliability and integrity of our systems and infrastructure. An expansion of our systems and infrastructure may require us to commit substantial financial, operational and technical resources before the volume of our business increases, with no assurance that the volume of business will increase. In particular, we recently upgraded our financial reporting system and other information technology systems as part of our infrastructure initiative, Project Bluecore. These and any other upgrades to our systems and information technology, or new technology, now and in the future, require that our management and resources be diverted from our core business to assist in compliance with those requirements. There can be no assurance that the time and resources our management will need to devote to these upgrades, service outages or delays due to the installation of any new or upgraded technology (and customer issues therewith), or the impact on the reliability of our data from any new or upgraded technology will not have a material adverse effect on our cash flows, operating results and financial condition.

A significant portion of our operations run on a single Enterprise Resource Planning (“ERP”) platform. To manage our international operations efficiently and effectively, we rely heavily on our ERP system, internal electronic information and communications systems and on systems or support services from third parties. Any of these systems are subject to electrical or telecommunications outages, computer hacking or other general system failure. It is also possible that future acquisitions will operate on different ERP systems and that we could face difficulties in integrating operational and accounting functions of new acquisitions. Difficulties in upgrading or expanding our ERP system or system-wide or local failures that affect our information processing could adversely affect our cash flows, operating results and financial condition.

We may be adversely affected by a failure or compromise from a cyberattack or data breach, which could have an adverse effect on our business

We rely on information technology (IT) systems to perform our business operations, including processing, transmitting and storing electronic information, and interacting with customers, suppliers, healthcare payers, and other third parties. Like other medical device companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information, and changing customer patterns. In addition, third parties may attempt to hack into our products to obtain data relating to patients or disrupt performance of our products or to access our proprietary information. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. In the U.S., Federal and State privacy and security laws require certain of our operations to protect the confidentiality of personal information including patient medical records and other health information. In Europe, the Data

Protection Directive requires us to manage individually identifiable information in the EU and, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. We believe that we meet the expectations of applicable regulations and that the ongoing costs of compliance with such rules are not material to our business. However, there is no guarantee that we will be able to comply with these regulations, or otherwise avoid the negative reputational and other affects that might ensue from a significant data breach or failure to comply with applicable data privacy regulations, each of which could have significant adverse effects on our business, financial condition or results of operations.

We are dependent on third-party manufacturers for many of our products.

We contract with third-party manufacturers to produce many of our products, like many other companies in the medical device industry. If we or any such manufacturer fail to meet production and delivery schedules, it can have an adverse impact on our ability to sell such products. Further, whether we directly manufacture a product or utilize a third-party manufacturer, shortages and spoilage of materials, labor stoppages, product recalls, manufacturing defects and other similar events can delay production and inhibit our ability to bring a new product to market in timely fashion. For example, the supply of the Trinity Evolution and Trinity ELITE allografts are derived from human cadaveric donors, and our ability to market the tissues depends on our single supplier continuing to have access to donated human cadaveric tissue, as well as, the maintenance of high standards by the supplier in its processing methodology.

Termination of our existing relationships with our independent sales representatives or distributors could have an adverse effect on our business.

We sell our products in many countries through independent distributors. Generally, our independent sales representatives and our distributors have the exclusive right to sell our products in their respective territories. The terms of these agreements vary in length, generally from one to ten years. Under the terms of our distribution agreements, each party has the right to terminate in the event of a material breach by the other party and we generally have the right to terminate if the distributor does not meet agreed sales targets or fails to make payments on time. Any termination of our existing relationships with independent sales representatives or distributors could have an adverse effect on our business unless and until commercially acceptable alternative distribution arrangements are put in place. In addition, we operate in areas of the world that have been or may be disproportionately affected by recessions and we bear risk that existing or future accounts receivable may be uncollected if these distributors or hospitals experience disruptions to their business that cause them to discontinue paying ongoing accounts payable or become insolvent.

We depend on our senior management team.

Our success depends upon the skill, experience and performance of members of our senior management team, who have been critical to the management of our operations and the implementation of our business strategy. We do not have key man insurance on our senior management team, and the loss of one or more key executive officers could have a material adverse effect on our operations and development.

In order to compete, we must attract, retain and motivate key employees, and our failure to do so could have an adverse effect on our results of operations.

In order to compete, we must attract, retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing, research, development, finance and support positions. Hiring and retaining qualified executives, engineers, technical staff and sales representatives are critical to our business, and competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified executives and key employees, we utilize stock-based incentive awards such as employee stock options. If the value of such stock awards does not appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain and motivate our employees could be adversely impacted, which could negatively affect our results of operations and/or require us to increase the amount we expend on cash and other forms of compensation.

Our business is subject to economic, political, regulatory and other risks associated with international sales and operations.

Since we sell our products in many different countries, our business is subject to risks associated with conducting business internationally. We anticipate that net sales from international operations will continue to represent a substantial portion of our total net sales. In addition, a number of our manufacturing facilities and suppliers are located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

- changes in a specific country's or region's political or economic conditions;
- trade protection measures and import or export licensing requirements or other restrictive actions by foreign governments;
- consequences from changes in tax or customs laws;
- difficulty in staffing and managing widespread operations;
- differing labor regulations;
- differing protection of intellectual property;
- unexpected changes in regulatory requirements; and
- violation by our independent agents of the FCPA or other anti-bribery or anti-corruption laws.

Risks Related to our Intellectual Property

We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality, or assure the protection, of these assets.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that compete directly with, ours. Numerous patents covering our technologies have been issued to us, and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the U.S. Some patent applications in the U.S. are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by several months, we may not be the first to invent, or file patent applications on any of our discoveries. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to, or licensed by, us and may not provide adequate protection or competitive advantages for our products. Patents that are issued may be challenged, invalidated or circumvented by our competitors. Furthermore, our patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary expertise and continuing technological innovation that we protect, in part, by entering into confidentiality agreements with assignors, licensees, suppliers, employees and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. If patents are not issued with respect to our products arising from research, we may not be able to maintain the confidentiality of information relating to these products. In addition, if a patent relating to any of our products lapses or is invalidated, we may experience greater competition arising from new market entrants.

Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.

There has been substantial litigation in the medical device industry with respect to the manufacture, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to defend against allegations relating to the infringement of patent or proprietary rights of third parties. Any such litigation could, among other things:

- require us to incur substantial expense, even if we are successful in the litigation;
- require us to divert significant time and effort of our technical and management personnel;
- result in the loss of our rights to develop or make certain products; and
- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation.

Although patent and intellectual property disputes within the orthopedic medical devices industry have often been settled through assignments, licensing or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. Furthermore, the required assignments or licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a judicial or administrative proceeding or a failure to obtain necessary assignments or licenses could prevent us from manufacturing and selling some products or increase our costs to market these products.

Risks Related to Litigation and Product Liability Matters

We may be subject to product and other liability claims that may not be covered by insurance and could require us to pay substantial sums. Moreover, fluctuations in insurance expense could adversely affect our profitability.

We are subject to an inherent risk of, and adverse publicity associated with, product liability and other liability claims, whether or not such claims are valid. We maintain product liability insurance coverage in amounts and scope that we believe are reasonable and adequate. There can be no assurance, however, that product liability or other claims will not exceed our insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. A successful product liability claim that exceeds our insurance coverage limits could require us to pay substantial sums and could have a material adverse effect on our financial condition.

In addition to product liability insurance coverage, we hold a number of other insurance policies, including directors' and officers' liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted.

Risks Related to Our Financial Results and Need for Financing

Our quarterly operating results may fluctuate.

Our quarterly operating results have fluctuated significantly in the past. Our future quarterly operating results may fluctuate significantly, and we may experience losses depending on a number of factors, including the extent to which our products continue to gain or maintain market acceptance, the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks, the timing and level of reimbursement for our products by third-party payors, the extent to which we are subject to government regulation or enforcement and other factors, many of which are outside our control.

We have loaned $15 million to an early stage company and may not be able to recoup our investment.

On March 4, 2015, we entered into an option agreement with eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The option agreement provided us with an exclusive option until September 2016 to acquire eNeura, which we ultimately did not exercise. In consideration for the option, (i) we paid a non-refundable $0.3 million fee to eNeura, and (ii) we loaned eNeura $15 million pursuant to a convertible, secured promissory note that was issued to us, which note matures on March 4, 2019.

eNeura is using the proceeds of our loan to fund product development work related to its business and to fund its ongoing operations and no assurance can be made that eNeura's business will ultimately be successful. Although the promissory note is secured by many of eNeura's assets (including its intellectual property assets), no assurance can be made that eNeura will be able to repay the promissory note when due in the event that the promissory note does not convert to equity. In such an event, we could lose all or a substantial portion of our $15 million loan investment. In addition, if a change in control of eNeura (generally defined as a third-party acquisition of fifty percent or more of eNeura's voting equity or all or substantially all of eNeura's assets) occurs prior to the maturity date on March 4, 2019, the eNeura Note will automatically convert into preferred stock of eNeura, and the value of such preferred stock could be less than the principal amount of the note.

We face risks related to foreign currency exchange rates.

Because some of our revenue, operating expenses, assets and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or earn revenue in currencies other than the U.S. dollar, any change in the values of those foreign currencies relative to the U.S. dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we have

potential foreign exchange exposure. The fluctuations of foreign exchange rates during 2017 have had a favorable impact of $1.6 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time.

Our global operations may expose us to tax risks

We are subject to taxes in the U.S. and numerous foreign jurisdictions. Significant judgment and interpretation of tax laws are required to estimate our tax liabilities. Tax laws and rates in various jurisdictions may be subject to significant change as a result of political and economic conditions. Our effective income tax rate could be adversely affected by changes in those tax laws, including the Tax Cuts and Jobs Act (the "Tax Act") that was enacted on December 22, 2017; changes in the mix of earnings among tax jurisdictions; changes in the valuation of our deferred tax assets and liabilities; and the resolution of matters arising from tax audits.

Certain of our subsidiaries sell products directly to other Orthofix subsidiaries or provide marketing and support services to other Orthofix subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates, and we must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Tax authorities in these jurisdictions may challenge our treatment of such intercompany transactions. If we are unsuccessful in defending our treatment of intercompany transactions, we may be subject to additional tax liability or penalty, which could adversely affect our profitability.

Our subsidiaries, Orthofix Holdings, Inc., Victory Medical Limited, and Orthofix International B.V. maintain a $125 million secured revolving credit facility secured by a pledge of substantially all of our property.

On August 31, 2015, the Company, through its subsidiaries, Orthofix Holdings, Inc. and Victory Medical Limited (collectively the "Borrowers"), entered into a credit agreement (the "Credit Agreement") providing for a five-year secured revolving credit facility of $125 million. On December 8, 2017, the Company amended the Credit Agreement and the primary provision of the Credit Agreement to be amended, among other things, was to add the Company's subsidiary, Orthofix International B.V. as a Borrower, Guarantor, and a loan party. No amounts have been drawn on the credit facility as of the date hereof, but the Company may draw on this facility in the future.

The Company and certain of its existing and future U.S., U.K., and Netherlands domiciled subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries.

The Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay subordinated indebtedness and enter into affiliate transactions. In addition, the Credit Agreement contains financial covenants requiring us on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the facility may be accelerated and/or the lenders' commitments terminated.

We believe that we are in compliance with the negative covenants, and there were no events of default, at December 31, 2017 (and in prior periods). However, there can be no assurance that the Company would be able to meet such financial covenants in future fiscal quarters. The failure to do so could result in an event of default under such agreement, which could have a material adverse effect on our financial position in the event that we have significant amounts drawn under the facility at such time.

Risks Related to Potential Acquisitions and Divestitures

Our efforts to identify, pursue and implement new business opportunities (including acquisitions) may be unsuccessful and may have an adverse effect on our business.

Our growth depends, in large part, on our ability to identify, pursue and implement new business opportunities that expand our product offerings, capabilities and geographic presence, and we compete with other medical device companies for these opportunities. Our efforts to identify such opportunities focus primarily on potential acquisitions of new businesses, products or technologies, licensing arrangements, commercialization arrangements and other transactions with third parties. We may not be able to identify business opportunities that meet our strategic criteria or are acceptable to us or our shareholders. Even if we are able to identify acceptable business opportunities, we may not be able to pursue or implement such business opportunities (or, in the case of acquisitions or other transactions, complete such acquisitions or other transactions) in a timely manner or on a cost-effective basis (or at all), and we may not realize the expected benefits of such business opportunities. If we are not able to identify, pursue and implement new business opportunities, it will adversely affect our ability to grow our business.

In addition, pursuing and implementing new business opportunities (particularly acquisitions) may involve significant costs and entail risks, uncertainties and disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology or operating in a particular geographic region. We may be unable to integrate a new business, product or technology effectively, or we may incur significant charges related to an acquisition or other business opportunity (for example, amortization of acquired assets or asset impairment charges), which may adversely affect our business, financial condition and results of operations. Newly acquired technology or products may require additional development efforts prior to commercial sale, including clinical testing and approval by the FDA and applicable foreign regulatory authorities; such additional development efforts may involve significant expense and ultimately be unsuccessful. Any cross-border acquisitions or transactions may involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. To the extent we issue additional equity in connection with acquisitions, this may dilute our existing shareholders.

We may incur significant costs or retain liabilities associated with disposition activity.

We may from time to time sell, license, assign or otherwise dispose of or divest assets, the stock of subsidiaries or individual products, product lines or technologies, which we determine are no longer desirable for us to own, some of which may be material. Any such activity could result in our incurring costs and expenses from these efforts, some of which could be significant, as well as retaining liabilities related to the assets or properties disposed of even though, for instance, the income-generating assets have been disposed of. These costs and expenses may be incurred at any time and may have a material impact on our results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities as of December 31, 2017 are as follows:

Facility	Location	Approx. Square Feet	Ownership
Manufacturing, warehousing, distribution, research and development, and administrative facility for Corporate and all SBUs	Lewisville, TX	140,000	Leased
Research and development, component manufacturing, quality control and training facility for fixation products and sales management, distribution and administrative facility for Italy	Verona, Italy	38,000	Owned
International distribution center for Orthofix products	Verona, Italy	18,000	Leased
Mechanical workshop for Orthofix products	Verona, Italy	9,000	Leased
Sales management, distribution and administrative facility for United Kingdom	Maidenhead, England	8,068	Leased
Sales management, distribution and administrative facility for Brazil	São Paulo, Brazil	21,617	Leased
Sales management, distribution and administrative facility for France	Arcueil, France	8,500	Leased
Sales management, distribution and administrative facility for Germany	Ottobrunn, Germany	16,145	Leased
Sales management, distribution and administrative facility for Puerto Rico	Guaynabo, Puerto Rico	5,400	Leased

Item 3. Legal Proceedings

For a description of our material pending legal proceedings, refer to Note 11 to the Consolidated Financial Statements in Item 8 of this Annual Report.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Our Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "OFIX." As of February 23, 2018, we had 262 holders of record of our common stock. The closing price of our common stock on February 23, 2018 was $53.68. The following table shows the high and low sales prices for our common stock for each of the two most recent fiscal years.

	High	Low
2016		
First Quarter	$ 41.90	$ 36.35
Second Quarter	47.25	40.77
Third Quarter	47.52	42.13
Fourth Quarter	42.01	34.56
2017		
First Quarter	$ 39.91	$ 34.47
Second Quarter	46.60	36.40
Third Quarter	49.89	43.05
Fourth Quarter	55.25	48.22

Dividends

We have not paid dividends to holders of our common stock in the past and have no present intention to pay dividends in the foreseeable future. We currently intend to retain all of our consolidated earnings to finance the continued growth of our business.

In the event that we decide to pay a dividend to holders of our common stock in the future with dividends received from our subsidiaries, we may, based on prevailing rates of taxation, be required to pay additional withholding and income tax on such amounts.

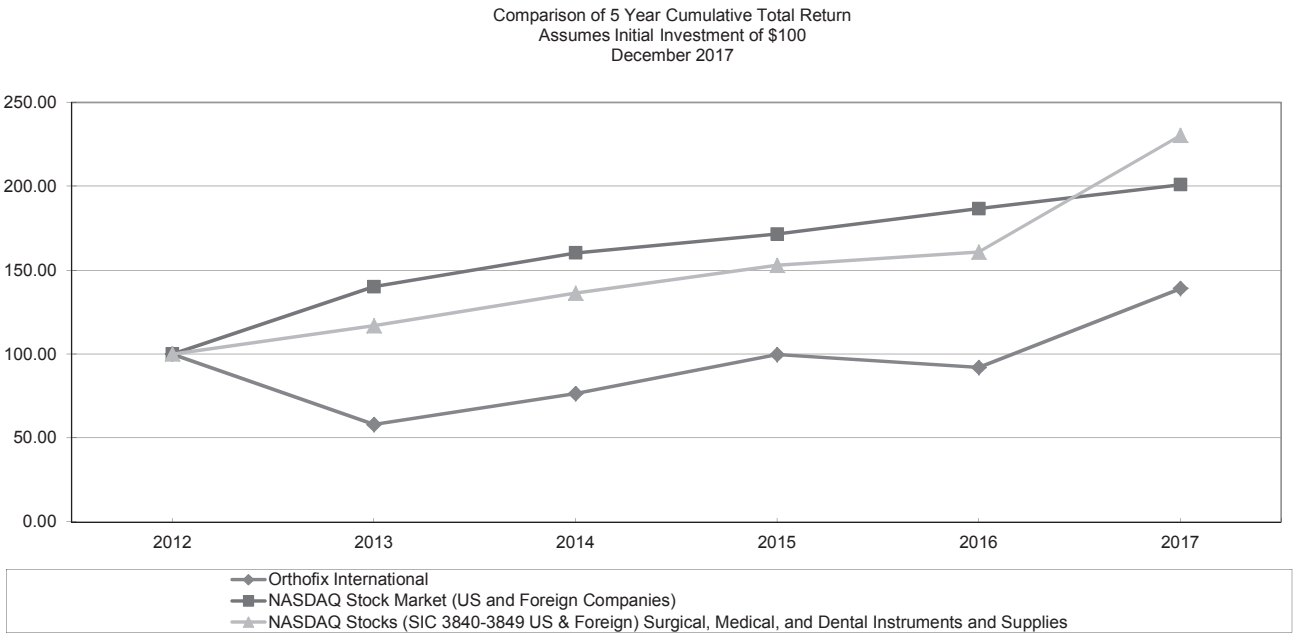
Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2017.

Performance Graph

The following performance graph is not deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C or to the liabilities of Section 18 of the Exchange Act. This information will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent we specifically incorporate this information by reference.

The graph below compares the five-year total shareholder return on Orthofix common stock with the returns of two indexes: the Nasdaq Stock Market and Nasdaq stocks for surgical, medical, and dental instruments and supplies. The graph assumes that you invested $100 in Orthofix Common Stock and in each of the indexes on December 31, 2012. Points on the graph represent the performance as of the last business day of each of the years indicated.



Item 6. Selected Financial Data

The following selected financial data has been derived from our audited consolidated financial statements.

(U.S. Dollars, in thousands, except margin and per share data)	Year ended December 31, 2017	2016	2015	2014	2013
Consolidated operating results					
Net sales	$ 433,823	$ 409,788	$ 396,489	$ 402,277	$ 397,611
Gross profit	340,786	321,935	309,964	303,365	290,699
Gross margin	79%	79%	78%	75%	73%
Operating income (loss) (1)	40,811	21,067	9,255	17,136	(11,192)
Net income (loss) from continuing operations	7,291	3,497	(2,342)	(3,744)	(18,205)
Net loss from discontinued operations	(1,068)	(441)	(467)	(4,793)	(10,607)
Net income (loss) (2)	$ 6,223	$ 3,056	$ (2,809)	$ (8,537)	$ (28,812)
Net income (loss) per common share – basic					
Net income (loss) from continuing operations	$ 0.40	$ 0.19	$ (0.12)	$ (0.20)	$ (0.97)
Net loss from discontinued operations	(0.06)	(0.02)	(0.03)	(0.26)	(0.57)
Net income (loss)	$ 0.34	$ 0.17	$ (0.15)	$ (0.46)	$ (1.54)
Net income (loss) per common share – diluted					
Net income (loss) from continuing operations	$ 0.39	$ 0.19	$ (0.12)	$ (0.20)	$ (0.97)
Net loss from discontinued operations	(0.05)	(0.02)	(0.03)	(0.26)	(0.57)
Net income (loss)	$ 0.34	$ 0.17	$ (0.15)	$ (0.46)	$ (1.54)

(1) Includes the following:

- Legal, accounting, and other professional fees incurred in 2017, 2016, 2015, 2014, and 2013 of $3.4 million, $2.0 million, $9.1 million and $15.6 million, and $12.9 million, respectively, in connection with the accounting review and restatements through March 2015 and legal fees associated with the SEC Investigation, Securities Class Action Complaint and Brazil subsidiary compliance review. In addition, the Company received an insurance settlement related to these matters of approximately $6 million in 2017
- Charges related to U.S. Government resolutions in 2016 of $14.4 million
- Goodwill impairment charge in 2013 of $19.2 million

(2) Dividends have not been paid in any of the years presented

(U.S. Dollars, in thousands)	As of December 31, 2017	2016	2015	2014	2013
Consolidated financial position					
Total assets	$ 405,354	$ 372,103	$ 400,222	$ 392,956	$ 411,975
Long-term debt	—	—	—	—	20,000
Shareholders' equity	296,608	263,477	290,311	299,627	295,863

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

The following discussion and analysis of our financial condition and result of operations should be read in conjunction with "Forward-Looking Statements" and our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report.

Executive Summary

We are a global medical device company focused on musculoskeletal healing products and value-added services. Headquartered in Lewisville, Texas, we have four strategic business units ("SBUs") that are also our reporting segments: BioStim, Extremity Fixation Spine Fixation, and Biologics. Our products are distributed by our sales representatives and distributors in over 60 countries.

Notable highlights and accomplishments in 2017 include the following:

- Net sales were $433.8 million, an increase of 5.9% on a reported basis and 5.5% on a constant currency basis; as net sales increased for each of our SBUs.
- Net income from continuing operations was $7.3 million, an increase of 108.5% from the prior year.
- Non-GAAP Net margin, an internal metric that we define as gross profit less sales and marketing expense, was $142.4 million, an increase of 1.3% from the prior year.

Results of Operations

The following table presents certain items in our consolidated statements of operations as a percent of net sales:

	Year ended December 31,		
	2017 (%)	2016 (%)	2015 (%)
Net sales	100.0	100.0	100.0
Cost of sales	21.4	21.4	21.8
Gross profit	78.6	78.6	78.2
Sales and marketing	45.7	44.2	44.9
General and administrative	17.2	18.2	22.0
Research and development	6.9	7.0	6.7
SEC / FCPA matters and related costs	(0.6)	0.5	2.3
Charges related to U.S. Government resolutions	—	3.6	—
Operating income	9.4	5.1	2.3
Net income (loss) from continuing operations	1.7	0.9	(0.6)
Net loss from discontinued operations	(0.3)	(0.2)	(0.1)
Net income (loss)	1.4	0.7	(0.7)

Net Sales by Strategic Business Unit

The following table presents net sales, which includes product sales and marketing service fees, by SBU:

				Percentage Change			
				2017/2016	2017/2016 Constant Currency	2016/2015	2016/2015 Constant Currency
(U.S. Dollars, in thousands)	2017	2016	2015	Reported		Reported	
BioStim	$ 185,900	$ 176,561	$ 164,955	5.3%	5.3%	7.0%	7.0%
Extremity Fixation	103,242	102,683	96,034	0.5%	-0.9%	6.9%	9.6%
Spine Fixation	81,957	72,632	75,668	12.8%	12.7%	-4.0%	-4.0%
Biologics	62,724	57,912	59,832	8.3%	8.3%	-3.2%	-3.2%
Net sales	$ 433,823	$ 409,788	$ 396,489	5.9%	5.5%	3.4%	4.0%

BioStim

BioStim manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. BioStim uses distributors and sales representatives to sell its devices to hospitals, healthcare providers, and patients.

2017 Compared to 2016

Net sales increased $9.3 million or 5.3%

- Increased as we continue to leverage the engagement of our expansive sales force, the positive North American Spine Society ("NASS") coverage recommendation and the launch of our next generation products and Stim on Track

2016 Compared to 2015

Net sales increased $11.6 million or 7.0%

- Increased order counts from an expanding customer base as the number of unique physicians who prescribed our products increased in 2016 by approximately 5%
- Order to cash process improvements implemented within the past 18 months, which increased the overall percentage we collect on orders, resulting in an increase in collections from third-party payors of approximately 9% compared to the prior year

Extremity Fixation

Extremity Fixation offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. Extremity Fixation distributes its products globally through a network of distributors and sales representatives to sell orthopedic products to hospitals and healthcare providers.

2017 Compared to 2016

Net sales increased $0.6 million or 0.5%

- Growth in the U.S. and the U.K., largely due to the continued adoption of our TL-HEX product line
- Increase of $1.5 million attributable to a favorable impact from foreign currency translation
- Partially offset by a decrease of $3.6 million related to our Extremity Fixation restructuring, which consists of the divestiture of a non-core business in the U.K. and a reduction in sales in Brazil and Puerto Rico as we convert from a direct sales model to the use of stocking distributors
- And additionally offset by a decrease in cash collections from specific international stocking distributors whose revenue is recognized upon cash receipt

2016 Compared to 2015

Net sales increased $6.6 million or 6.9%

- Includes the negative impact from foreign currency translation of $2.6 million in 2016; on a constant currency basis, net sales increased $9.2 million, or 9.6%
- Increase in cash collections of approximately 18% in 2016 from distributors whose revenue is recognized upon cash receipt
- Growth in the U.S. due to the onboarding of new distributors and the continued adoption of our TL-HEX product line, which grew by approximately 50% in the U.S. compared to the prior year

Spine Fixation

Spine Fixation designs, develops and markets a broad portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products globally through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.

2017 Compared to 2016

Net sales increased $9.3 million or 12.8%

- Increase of 20.6% in U.S. sales due to the addition of new distributor partners in the last several quarters; the uptake of recent product introductions, including our PTC family product lines and Cetra; and improved legacy distributor engagement
- Despite strong performance in certain locations, such as Australia, year-over-year international sales decreased largely due to a decrease in order volumes from international stocking distributors

2016 Compared to 2015

Net sales decreased $3.0 million or 4.0%

- Exclusion from a large national hospital group purchasing organization in the second quarter of 2016
- Loss of several key surgeon customers in early 2016
- Decrease in cash collections of approximately 6% in 2016 from distributors whose revenue is recognized upon cash receipt
- Partially offset by revenue from additional distributors added in 2016

Biologics

Biologics provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. Biologics markets its tissues to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives.

2017 Compared to 2016

Net sales increased $4.8 million or 8.3%

- Increase in volume for our Trinity products primarily driven by the addition of new distributors over the past year
- Benefit from improving performance from our national distribution partner and the reacquisition of a national hospital contract

2016 Compared to 2015

Net sales decreased $1.9 million or 3.2%

- A growing number of competitors in the stem cell allograft market and an associated 2.4% reduction in average selling price for our products
- Exclusion from a large national hospital group purchasing organization in the second quarter of 2016
- Partially offset by an increase in the total number of independent distributors in 2016

Gross Profit and Non-GAAP Net Margin

(U.S. Dollars, in thousands)	2017	2016	2015	Percentage Change 2017/2016	Percentage Change 2016/2015
Gross profit	$ 340,786	$ 321,935	$ 309,964	5.9%	3.9%
Sales and marketing	198,370	181,287	178,080	9.4%	1.8%
Non-GAAP net margin	$ 142,416	$ 140,648	$ 131,884	1.3%	6.6%
Gross margin	78.6%	78.6%	78.2%	0.0%	0.4%
Non-GAAP net margin	32.8%	34.3%	33.3%	-1.5%	1.1%

2017 Compared to 2016

Non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, increased $1.8 million

- Gross profit increased $18.9 million
    - Largely driven by the increase in net sales for our each of SBUs, as gross margin remained relatively flat
    - Partially offset by an increase of $0.2 million in expense relating to our Extremity Fixation and U.S. restructurings
- Sales and marketing expense increased $17.1 million
    - Primarily relating to higher commission expenses in 2017, relating to geographic mix in Extremity Fixation and higher commission rates from new distributors for Biologics and Spine Fixation, and an increase in other compensation costs as a result of the increase in net sales

2016 Compared to 2015

Non-GAAP net margin increased $8.8 million

- Gross profit increased $12.0 million
    - Increase in sales for BioStim and Extremity Fixation, partially offset by a decrease in sales for Biologics and Spine Fixation
    - Improved operating efficiencies through the absorption of fixed costs
    - Increase in inventory reserves of $1.7 million for certain slower moving product lines and obsolete inventory, a portion of which is a result of our planned restructuring in Brazil
- Sales and marketing expense increased $3.2 million
    - Increase in compensation and benefits costs, including commissions, as a result of the increase in net sales
    - Partially offset by a reduction of certain indirect tax liabilities of $3.1 million in 2016
    - Also partially offset by a decrease in bad debt expense of $2.3 million related to Puerto Rico

The following table presents non-GAAP net margin by reporting segment. The reasons for the changes in non-GAAP net margin by SBU are generally consistent with the information provided above for gross profit and sales and marketing expense.

(U.S. Dollars, in thousands)	2017	2016	2015	Percentage Change 2017/2016	Percentage Change 2016/2015
BioStim	$ 77,369	$ 75,469	$ 67,878	2.5%	11.2%
Extremity Fixation	31,071	30,526	29,493	1.8%	3.5%
Spine Fixation	8,730	8,650	8,547	0.9%	1.2%
Biologics	25,692	26,891	27,226	-4.5%	-1.2%
Corporate	(446)	(888)	(1,260)	-49.8%	-29.5%
Non-GAAP net margin	$ 142,416	$ 140,648	$ 131,884	1.3%	6.6%

General and Administrative Expense

(U.S. Dollars, in thousands)	2017	2016	2015	Percentage Change 2017/2016	Percentage Change 2016/2015
General and administrative	$ 74,388	$ 74,404	$ 87,157	0.0%	-14.6%
As a percentage of net sales	17.2%	18.2%	22.0%	-0.9%	-3.8%

2017 Compared to 2016

General and administrative expense decreased less than $0.1 million

- Decrease of $3.6 million from a reduction in Project Bluecore expenses, as the project was completed in 2016
- Decrease in share-based compensation expense of $3.5 million, largely driven by a net decrease in expense attributable to performance-based and market-based awards
- Core expense reductions through savings in other professional fees of $2.0 million
- Partially offset by an increase in spending of $5.7 million for evaluation of strategic investments
- Further offset by an unfavorable change related to legal settlements of $3.5 million, largely as a result of a favorable commercial litigation settlement received in 2016 of $3.0 million

2016 Compared to 2015

General and administrative expense decreased $12.8 million

- Decreases in professional fees of $7.9 million, largely associated with the completion in 2016 of our internal control remediation efforts and Project Bluecore, a company-wide infrastructure initiative to improve the reliability and efficiency of our systems, processes, and reporting
- Reduced legal costs of $6.9 million, largely due to legal settlements incurred in the prior year and a commercial legal settlement in 2016 whereby we received $3.0 million
- The moratorium on the medical device tax in 2016, which decreased expense by $1.3 million
- Reduction in other controllable expenses
- Overall decrease was partially offset by increased share-based compensation expense of $8.1 million, including $5.7 million associated with the determination in 2016 that achieving the performance criteria related to certain of our performance-based vesting restricted stock awards is probable

Research and Development Expense

(U.S. Dollars, in thousands)	2017	2016	2015	Percentage Change 2017/2016	Percentage Change 2016/2015
Research and development	$ 29,700	$ 28,803	$ 26,389	3.1%	9.1%
As a percentage of net sales	6.9%	7.0%	6.7%	-0.1%	0.3%

2017 Compared to 2016

Research and development expense increased $0.9 million

- Increase in costs associated with clinical trials of $0.7 million, primarily due to invested resources to identify potential new indications for our PEMF technology, such as for osteoarthritis of the knee or as an adjunct to rotator cuff repair
- Increase in costs largely attributable to the initiation of the Company's U.S. restructuring plan in 2017, which primarily affected our corporate shared services, and resulted in an increase in expense of $0.5 million

2016 Compared to 2015

Research and development expense increased $2.4 million

- Increased costs associated with clinical trials of $1.5 million, primarily due to invested resources to identify potential new clinical indications for our PEMF technology and to develop our next generation of bone growth stimulators, which were recently approved by the FDA and European Commission
- A $1.3 million investment made in the first quarter of 2016 to expand the processing and storage capabilities of MTF, the supplier of our Trinity Evolution and Trinity ELITE tissue forms

SEC / FCPA Matters and Related Costs

				Percentage Change	
(U.S. Dollars, in thousands)	2017	2016	2015	2017/2016	2016/2015
SEC / FCPA matters and related costs	$ (2,483)	$ 2,005	$ 9,083	-223.8%	-77.9%
As a percentage of net sales	-0.6%	0.5%	2.3%	-1.1%	-1.8%

2017 Compared to 2016

SEC/FCPA matters and related costs decreased $4.5 million

- We received a favorable insurance settlement in 2017 of approximately $6 million associated with prior costs incurred related to SEC and FCPA matters
- Pursuant to our settlement of the SEC Investigation and FCPA matters in Brazil, we agreed to retain an independent compliance consultant for one year to review and test the Company's FCPA compliance program, which began in March 2017 and resulted in an increase in expense of $1.8 million

2016 Compared to 2015

SEC/FCPA matters and related costs decreased $7.1 million

- Decreased legal fees incurred as part of our two prior financial restatements completed in March 2015 and the related SEC Investigation; expected to continue declining in future periods
- Costs incurred in 2015 were related to the second of these two restatements and legal costs from the resulting SEC Investigation and class action complaint

Charges Related to U.S. Government Resolutions

				Percentage Change	
(U.S. Dollars, in thousands)	2017	2016	2015	2017/2016	2016/2015
Charges related to U.S. Government resolutions	$ —	$ 14,369	$ —	-100.0%	—
As a percentage of net sales	0.0%	3.6%	0.0%	-3.6%	3.6%

We recorded $14.4 million in 2016 for our settlements with the Division of Enforcement of the SEC related to the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments in Brazil. For additional information, see Note 11 to the Consolidated Financial Statements.

Non-operating Income (Expense)

				Percentage Change	
(U.S. Dollars, in thousands)	2017	2016	2015	2017/2016	2016/2015
Interest income (expense), net	$ (416)	$ 763	$ (489)	-154.5%	-256.0%
Other expense, net	(4,004)	(2,806)	(259)	42.7%	983.4%

Non-operating income and expense largely consists of interest income and expense, transaction gains and losses from changes in foreign currency exchange rates, and other-than-temporary impairments on the eNeura debt security. Interest income is primarily

from our eNeura debt security; however, we discontinued recognizing interest income on the debt security in 2017. Foreign exchange gains and losses are a result of several of our foreign subsidiaries holding trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional currency.

In 2017 and 2016, we recorded other-than-temporary impairments on the eNeura debt security of $5.6 million and $2.7 million before taxes, respectively. For additional discussion see Note 6 and Note 9 to the Consolidated Financial Statements in Item 8 of this Annual Report.

Income Taxes

				Percentage Change	
(U.S. Dollars, in thousands)	**2017**	**2016**	**2015**	**2017/2016**	**2016/2015**
Income tax expense	$ 29,100	$ 15,527	$ 10,849	87.4%	43.1%
Effective tax rate	80.0%	81.6%	127.5%	-1.6%	-45.9%

2017 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the increase in income before income taxes, partially offset by the charge related to recording the impact of the Tax Act. The primary factors affecting our effective tax rate for 2017 are as follows:

- The charge related to recognizing the impact of the Tax Act
- Increases in unrecognized tax benefits
- Current period losses in jurisdictions where we do not currently receive a tax benefit

On December 22, 2017, the Tax Act was signed into law, making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. We have calculated our best estimate of the impact of the Tax Act in our year end income tax provision in accordance with our understanding of the Tax Act and guidance available as of the date of this filing. As a result, we have recorded $8.3 million of additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. This provisional amount related to remeasurement of certain deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future was $8.6 million. The provisional amount related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings was zero. We also recorded a benefit of $0.3 million related to an income tax liability recorded in 2016 related to repatriation of earnings from our subsidiary in Puerto Rico.

2016 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the increase in income before income taxes. The primary factors affecting our effective tax rate for 2016 are as follows:

- Expenses categorized as “Charges related to U.S. Government resolutions”, which represent settlement payments with substantially no tax benefit
- A change in estimate relating to the deductible amount of certain compensation expenses
- Increases in unrecognized tax benefits
- Expiration of certain foreign net operating loss carryforwards and current period losses in jurisdictions where we do not currently receive a tax benefit

Liquidity and Capital Resources

Cash and cash equivalents at December 31, 2017 were $81.2 million compared to $39.6 million at December 31, 2016.

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	2017	2016	Change
Net cash from operating activities	$ 53,341	$ 44,707	$ 8,634
Net cash from investing activities	(16,474)	(21,947)	5,473
Net cash from financing activities	3,538	(46,112)	49,650
Effect of exchange rate changes on cash	1,180	(739)	1,919
Net change in cash and cash equivalents	$ 41,585	$ (24,091)	$ 65,676

The following table presents free cash flow, a non-GAAP financial measure, which is calculated by subtracting capital expenditures from net cash from operating activities.

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	2017	2016	Change
Net cash from operating activities	$ 53,341	$ 44,707	$ 8,634
Capital expenditures	(16,948)	(18,334)	1,386
Free cash flow	$ 36,393	$ 26,373	$ 10,020

Operating Activities

Cash flows from operating activities increased $8.6 million

- Increase in net income of $3.2 million
- Net increase of $10.6 million for non-cash gains and losses, primarily related to deferred income taxes, share-based compensation expense, and the other-than-temporary impairments incurred relating to the eNeura debt security
- Net decrease of $5.1 million relating to changes in working capital, primarily attributable to increases in our inventory balance as a result of new product introductions and increases in accounts receivable as a result of the increase in net sales, and partially offset by a decrease in our other current liabilities

Our two primary working capital accounts are trade accounts receivable and inventory. Day's sales in receivables were 53 days at December 31, 2017 compared to 52 days at December 31, 2016. Inventory turns were 1.1 times as of December 31, 2017 compared to 1.4 times at December 31, 2016, as a result of increased inventory due to new product introductions, primarily in our Spine Fixation and Extremity Fixation SBUs.

U.S. Government Resolutions

In December 2016, we submitted offers of settlement to the SEC relating to (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments in Brazil, and placed $14.4 million into escrow for subsequent distribution to the SEC relating to these matters. In January 2017, the SEC approved our offers of settlement and the amounts were released to the SEC. For additional information, see Note 11 to the Notes to the Consolidated Financial Statements.

Investing Activities

Cash flows from investing activities increased $5.5 million

- Decrease in capital expenditures of $1.4 million, largely as a result of completing Project Bluecore in 2016
- Increase due to the purchase of certain inventory and intellectual property assets of $2.6 million in 2016 and an increase in our investment in Bone Biologics, Inc. of $1.0 million during 2016

Financing Activities

Cash flows from financing activities increased $49.7 million

- Increase of $63.4 million related to the share repurchase plan, which was completed in 2016
- Partially offset by a decrease in net proceeds of $13.3 million from the issuance of common shares
- Further offset by debt issuance costs of $0.4 million paid in 2017 in relation to the amendment of our Credit Agreement

Credit Facilities

On August 31, 2015, we entered into a Credit Agreement, which provided a five year $125 million secured revolving credit facility. On December 8, 2017, we amended the Credit Agreement with JPMorgan, the Administrative Agent, and certain lenders party thereto. The primary provision of the amendment, among other things, was to add our subsidiary, Orthofix International B.V., as a Borrower, Guarantor, and a loan party. In addition, two of our subsidiaries, Orthofix Limited and Orthofix II B.V. were also added as Guarantors and loan parties.

Borrowings under the Credit Agreement may be used for, among other things, working capital and other general corporate purposes (including share repurchases, permitted acquisitions and permitted payments of dividends and other distributions). As of December 31, 2017, we have not made any borrowings under the credit facility. For additional information regarding the credit facility, see Note 8 to the Notes to the Consolidated Financial Statements contained herein.

We had no borrowings and an unused available line of credit of €5.8 million ($7.0 million and $6.1 million) at December 31, 2017 and 2016, respectively, on our Italian line of credit. This unsecured line of credit provides us the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

Unremitted Foreign Earnings

Our current intention is to indefinitely reinvest substantially all of our other unremitted foreign earnings (residing outside Curaçao). During the first quarter of 2017, we changed our intention related to unremitted foreign earnings in our Seychelles subsidiary. The tax impact was minimal. As an entity incorporated in Curaçao, “foreign earnings” refer to both U.S. and non-U.S. earnings. Furthermore, only income sourced in the U.S. is subject to U.S. income tax. Unremitted foreign earnings decreased from $372.5 million at December 31, 2016 to $335.7 million at December 31, 2017. Determining the additional income tax that may be payable if such earnings are repatriated is not practicable.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2017:

	Payments Due by Period				
(U.S. Dollars, in thousands)	Total	2018	2019 - 2021	2022	2023 and thereafter
Operating leases	$ 21,606	$ 3,017	$ 4,833	$ 1,600	$ 12,156
Inventory purchase commitments (1)	1,939	1,939	—	—	—
Total (2)	$ 23,545	$ 4,956	$ 4,833	$ 1,600	$ 12,156

(1) We have inventory purchase commitments with third-party manufacturers. Due to the uncertainty of our future purchasing requirements, obligations under these agreements are included in the preceding table at the amount committed through December 31, 2017, all of which are due in 2018.

(2) We may be required to make payments related to our uncertain tax positions. However, we are unable to reliably estimate the timing of cash settlement, if any, with the respective taxing authorities. Accordingly, unrecognized tax benefits, including interest and penalties, of $27.8 million as of December 31, 2017 have been excluded from the contractual obligations table above. For further information, see Note 17 to the Notes to the Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of December 31, 2017, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors.

Critical Accounting Estimates

Our discussion of operating results is based upon the consolidated financial statements and accompanying notes. The preparation of these statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. On an ongoing basis, we evaluate these estimates, which are based on historical experience and various other assumptions that management believe to be reasonable under the circumstances at that point in time. Actual results may differ, significantly at times, from these estimates.

We believe the estimates described below are the most critical in preparing our consolidated financial statements. We have reviewed these critical accounting estimates with the Audit Committee of the Board of Directors.

Revenue Recognition

The process for recognizing revenue involves significant assumptions and judgments for certain of our revenue streams. Revenue recognition policies are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, non-GAAP net margin, operating income, and net income.

For revenue derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of our stimulation products, we recognize revenue when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

For revenue derived from distributor agreements, we recognize revenue once the product is delivered to the end customer (the "sell-through method"). Because we do not have reliable information about when our distributors sell the product through to end customers, we use cash collection from distributors as a basis for revenue recognition under the sell-through method. When we sell to these distributors, we consider whether to match the related cost of sales expense with revenue or to recognize expense upon shipment. In making this assessment, we consider the financial viability of our distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped is reasonably assured at the time of shipment to these distributors. In instances where the distributor is determined to be financially viable, we defer the costs of sales until the revenue is recognized.

On January 1, 2018, the Company will adopt Accounting Standards Update ("ASU") 2014-09 – Revenue From Contracts with Customers. For additional information regarding the impact of ASU 2014-09, see Note 1 to the Notes to the Consolidated Financial Statements contained herein under the subheading "Recently issued accounting standards."

Allowance for Doubtful Accounts and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collections, write-offs, and payor reimbursement experience are integral parts of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. Our estimates are periodically tested against actual collection experience. We believe our allowance for doubtful accounts is sufficient to cover customer credit risks; however, a 10% change in our allowance for doubtful accounts as of December 31, 2017 would result in an increase or decrease to sales and marketing expense of $0.8 million. Additionally, we believe our estimate to establish contractual allowances is sufficient to cover customer credit risks;

however, a 10% change in our reserve for contractual allowances as of December 31, 2017 would result in an increase or decrease to net sales of $0.6 million. Our allowance for doubtful accounts and estimation of contractual allowances are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, non-GAAP net margin, operating income, net income, and trade accounts receivable.

Inventory Allowances

Reserves for excess, slow moving, and obsolete inventory are calculated as the difference between the cost of inventory and market value, and are based on assumptions and judgments about new product launch periods, overall product life cycles, forecasted demand, and market conditions. In the event of a decrease in demand for our products, or a higher incidence of inventory obsolescence, we could be required to increase our inventory reserves, which would increase cost of sales and decrease gross profit. Our inventory allowance is a "critical accounting estimate" because changes in the assumptions used to develop the estimate could materially affect key financial measures, including gross profit, non-GAAP net margin, operating income, net income, and inventory. We regularly evaluate our exposure for inventory write-downs. If conditions or assumptions used in determining the market value change, additional inventory adjustments in the future may be necessary.

Goodwill

We test goodwill at least annually for impairment, and between annual tests if indicators of potential impairment exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. Assessing goodwill impairment involves a high degree of judgment due to the estimates and assumptions used. We believe the estimates and assumptions involved in the impairment assessment to be critical because significant changes in such estimates and assumptions could materially affect key financial measures, including net income.

In the fourth quarter of 2017, we performed a qualitative assessment for our annual goodwill impairment analysis, which did not result in any impairment charge. This qualitative analysis considered all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance and relevant entity-specific events. In the fourth quarter of 2016, we performed a quantitative impairment analysis that did not result in an impairment charge.

Fair Value Measurements

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value of the eNeura debt security is based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring us to develop our own assumptions. One of the more significant unobservable inputs used in the fair value measurement of the eNeura debt security is the discount rate. Holding other inputs constant, an increase in the discount rate of 5% would result in a decrease in fair value of the debt security of $1.1 million, whereas a decrease in the discount rate of 5% would result in an increase in the fair value of the debt security of $1.0 million.

Further, we are required to determine whether any decline in the fair value below the cost basis of the eNeura debt security is other than temporary. In making this determination, we consider our intentions to hold or sell the security, whether it more likely than not that we will be required to sell the security before the recovery of its amortized cost basis, and our best estimate of the amount that we ultimately expect to collect from the security. The estimated amount we expect to collect is based upon significant unobservable inputs, requiring us to develop our own assumptions, including the probability of holding the security to maturity or converting the security to equity.

Our fair value measurements are a "critical accounting estimate" because changes in the assumptions used to develop the estimate could materially affect key financial measures.

Litigation and Contingent Liabilities

From time to time, we are parties to or targets of lawsuits, investigations and proceedings, including product liability, personal injury, patent and intellectual property, health and safety and employment and healthcare regulatory matters, which are handled and defended in the ordinary course of business. These lawsuits, investigations or proceedings could involve a substantial number of claims and could also have an adverse impact on our reputation and customer base. Although we maintain various liability insurance programs for liabilities that could result from such lawsuits, investigations or proceedings, we are self-insured for a significant portion of such liabilities.

We accrue for such claims when it is probable that a liability has been incurred and the amount can be reasonably estimated. The assessments of whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that we consider in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, our experience in similar matters and the experience of other companies, the facts available to us at the time of assessment, and how we intend to respond, or have responded, to the proceeding, investigation or claim. Our assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where we are not currently able to reasonably estimate the range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where we believe a reasonable estimate of loss, or range of loss, can be made. In such instances, we believe that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

Changes in the facts and circumstances associated with a claim could have a material impact on our results of operations and cash flows in the period that reserve estimates are revised. We believe our insurance coverage and reserves are sufficient to cover currently estimated exposures, but we cannot give any assurance that we will not incur liabilities in excess of recorded reserves or our present insurance coverage. Litigation and contingent liabilities are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including operating income and net income.

Tax Matters

We and each of our subsidiaries are taxed at the rates applicable within each of their respective jurisdictions. Our income tax expense, effective tax rate, deferred tax assets and deferred tax liabilities will vary according to the jurisdiction in which profits arise. Further, certain of our subsidiaries sell products directly to our other subsidiaries or provide administrative, marketing and support services to our other subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates. The tax authorities in such jurisdictions may challenge our treatments under residency criteria, transfer pricing provisions, or other aspects of their respective tax laws, which could affect our composite tax rate and provisions.

We sometimes engage in transactions in which tax consequences may be subject to uncertainty. We account for these uncertain tax positions in accordance with applicable accounting guidance, which requires significant judgment in assessing the estimated tax consequences of a transaction. We evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. We measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We re-evaluate our income tax positions periodically to consider factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues under audit and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision.

We establish a valuation allowance when measuring deferred tax assets if it is more likely than not that certain deferred tax assets will not be realized in the foreseeable future. This process requires significant judgment as we must project the current tax liability and estimate the deferred tax assets and liabilities into future periods, including net operating loss and tax credit carry forwards. In assessing the need for a valuation allowance, we consider recent operating results, availability of taxable income in carryback years, future reversals of taxable temporary differences, future taxable income projections (exclusive of reversing temporary differences) and all prudent and feasible tax planning strategies.

On December 22, 2017, Staff Accounting Bulletin No. 118 (“SAB 118”) was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, we have determine that the $8.6 million of the deferred tax expense recorded in connection with the remeasurement of certain deferred tax assets and liabilities and the zero transition tax on the mandatory deemed repatriation of foreign earnings was a provisional amount and a reasonable estimate at December 31, 2017. Additional work is necessary for a more detailed analysis of our deferred tax assets and liabilities and our historical foreign earnings as well as potential correlative adjustments. Any subsequent adjustment to those amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete.

Tax matters are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net income.

Share-based compensation

Determining the appropriate fair value model and calculating the fair value of employee stock awards requires estimates and judgments. Our share-based compensation is a “critical accounting estimate” because changes in the assumptions used to develop estimates of fair value or the requisite service period could materially affect key financial measures, including gross profit, non-GAAP net margin, operating income, and net income.

We use the Black-Scholes valuation model to calculate the fair value of service-based stock options. The value is recognized as expense over the service period net of actual forfeitures. The expected term of options granted is estimated based on a number of factors, including the vesting and expiration terms of the award, historical employee exercise behavior for both options that are currently outstanding and options that have been exercised or are expired, the historical volatility of our common stock and an employee’s average length of service. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award. We estimate expected volatility based on the historical volatility of our stock.

We use the Monte Carlo valuation methodology to calculate the fair value of market-based stock options and stock units. The value is recognized as expense over the requisite service period and adjusted for forfeitures as they occur. The Monte Carlo methodology that we use to estimate the fair value of market-based options incorporates the possibility that the market condition may not be satisfied.

The fair value of performance-based restricted stock awards and stock units is calculated based upon the closing stock price at the date of grant. The value is recognized as expense over the derived requisite service period beginning in the period in which they are deemed probable to vest. Vesting probability is assessed based upon forecasted earnings and financial results and requires significant judgment.

Non-GAAP Financial Measures

We believe that providing non-GAAP financial measures that exclude certain items provides investors with greater transparency to the information used by senior management in its financial and operational decision-making. We believe it is important to provide investors with the same non-GAAP metrics that senior management uses to supplement information regarding the performance and underlying trends of our business operations in order to facilitate comparisons to historical operating results and internally evaluate the effectiveness of our operating strategies. Disclosure of these non-GAAP financial measures also facilitates comparisons of our underlying operating performance with other companies in the industry that also supplement their GAAP results with non-GAAP financial measures.

The non-GAAP financial measures used in this Annual Report may have limitations as analytical tools and should not be considered in isolation or as a replacement for GAAP financial measures. Some of the limitations associated with the use of these non-GAAP financial measures are that they exclude items that reflect an economic cost that can have a material effect on cash flows. Similarly, certain non-cash expenses, such as equity compensation expense, do not directly impact cash flows, but are part of total compensation costs accounted for under GAAP.

Constant Currency

Constant currency is a non-GAAP measure, which is calculated by using foreign currency rates from the comparable, prior-year period, to present net sales at comparable rates. Constant currency can be presented for numerous GAAP measures, but is most commonly used by management to analyze net sales without the impact of changes in foreign currency rates.

Non-GAAP Net Margin

Non-GAAP net margin is an internal metric that we define as gross profit less sales and marketing expense. Non-GAAP net margin is the primary metric used by our Chief Operating Decision Maker in managing the business.

Free Cash Flow

Free cash flow is a non-GAAP financial measure, which is calculated by subtracting capital expenditures from net cash from operating activities. Free cash flow is an important indicator of how much cash is generated or used by our normal business operations, including capital expenditures. Management uses free cash flow as a measure of progress on its capital efficiency and cash flow initiatives.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can impact sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We may use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes.

We are exposed to interest rate risk in connection with our Revolving Credit Facility, which bears interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base rate (as defined in the Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant. As we do not have any balance outstanding associated with the Credit Agreement as of December 31, 2017, this risk is currently minimal.

We believe that a concentration of credit risk related to our trade accounts receivable is limited because our customers are geographically dispersed and the end users are diversified across several industries. It is reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these customers operate, or other factors, could affect the future realization of these accounts receivable balances.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Brazilian Real, or Great Britain Pound. We are subject to cost of sales currency exposure when we produce products in foreign currencies such as the Euro, Brazilian Real, or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when our subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. For the year ended December 31, 2017, we recorded a foreign currency gain of $1.9 million on the statement of operations resulting from gains and losses in foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that fluctuate during the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the year ended December 31, 2017 and unfavorably impacted during the year ended December 31, 2016 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations during 2017 and 2016 versus the same periods in 2016 and 2015. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results. An analysis was performed to determine the sensitivity of our current year net sales and operating income to changes in foreign currency exchange rates. We determined that if the U.S. Dollar decreased in value by 10% relative to all foreign currencies of our international operations it would result in an increase in net sales of $8.1 million and an increase in operating income of $1.5 million. If the U.S. Dollar increased in value by 10% relative to all foreign currencies of our international operations it would result in a decrease in net sales of $8.1 million and a decrease in operating income of $1.5 million.

Item 8. Financial Statements and Supplementary Data

See “Index to Consolidated Financial Statements” on page F-1 of this Form 10-K.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

At the end of the period covered by this Annual Report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our President and Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Form 10-K, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in the Exchange Act Rule 13a-15(f)). The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding the 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.

Internal control over financial reporting is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation of reliable financial statements for external purposes in accordance with U.S. GAAP. Because of the inherent limitations in any internal control, no matter how well designed, misstatements may occur and not be prevented or detected. Accordingly, even effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Further, the evaluation of the effectiveness of internal control over financial reporting was made as of a specific date, and continued effectiveness in future periods is subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies and procedures may decline.

In connection with the preparation and filing of this Form 10-K, the Company's management, including our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017 based on the framework set forth in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company's management concluded that, as of December 31, 2017, the Company's internal control over financial reporting is effective based on the specified criteria.

Ernst & Young has issued an audit report on the effectiveness of our internal control over financial reporting, which follows this report.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter of 2017 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Orthofix International N.V.

Opinion on Internal Control over Financial Reporting

We have audited Orthofix International N.V.'s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Orthofix International N.V. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and our report dated February 26, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible 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 Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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.

/s/ Ernst & Young LLP

Dallas, Texas

February 26, 2018

Item 9B. Other Information

Not applicable.

PART III

Information required by Items 10, 11, 12, 13 and 14 of Form 10-K is omitted from this Annual Report and will be filed in a definitive proxy statement or by an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report.

Item 10. Directors, Executive Officers and Corporate Governance

We will provide information that is responsive to this Item 10 regarding executive compensation in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Information About Directors,” “Section 16 (a) Beneficial Ownership Reporting Compliance” and others possibly elsewhere therein. That information is incorporated in this Item 10 by reference.

Item 11. Executive Compensation

We will provide information that is responsive to this Item 11 regarding executive compensation in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Executive Compensation,” and possibly elsewhere therein. That information is incorporated in this Item 11 by reference.

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

We will provide information that is responsive to this Item 12 regarding ownership of our securities by certain beneficial owners and our directors and executive officers, as well as information with respect to our equity compensation plans, in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the captions “Security Ownership of Certain Beneficial Owners and Management and Related Stockholders” and “Equity Compensation Plan Information,” and possibly elsewhere therein. That information is incorporated in this Item 12 by reference.

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

We will provide information that is responsive to this Item 13 regarding transactions with related parties and director independence in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Certain Relationships and Related Transactions,” and possibly elsewhere therein. That information is incorporated in this Item 13 by reference.

Item 14. Principal Accountant Fees and Services

We will provide information that is responsive to this Item 14 regarding principal accountant fees and services in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Principal Accountant Fees and Services,” and possibly elsewhere therein. That information is incorporated in this Item 14 by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of report on Form 10-K

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

1. Financial Statements

   See "Index to Consolidated Financial Statements" on page F-1 of this Form 10-K.

2. Financial Statement Schedules

   No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

3. Exhibits

Exhibit Number	Description
2.1	Stock Purchase Agreement, dated as of April 23, 2012, by and among Breg, Inc., Orthofix Holdings, Inc. and Breg Acquisition Corp. (filed as an exhibit to the Company's Current Report on Form 8-K filed April 24, 2012 and incorporated herein by reference).
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's Annual Report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and incorporated herein by reference).
10.1	Credit Agreement, dated as of August 31, 2015, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Current Report on Form 8-K filed September 1, 2015 and incorporated herein by reference).
10.2	First Amendment to Credit Agreement dated as of March 7, 2016 but effective as of February 29, 2016, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference).
10.3*	Second Amendment to Credit Agreement dated as of December 8, 2017, among Orthofix Holdings, Inc., Victory Medical Limited, and Orthofix International B.V. as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent.
10.4†	Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
10.5	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.6†	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference).

Exhibit Number	Description
10.7†	Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2013 and incorporated herein by reference).
10.8	Amendment No. 4 to Matrix Commercialization Collaboration Agreement, entered into on April 1, 2014, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed April 7, 2014 and incorporated herein by reference).
10.9†	Amendment No. 5 to Matrix Commercialization Collaboration Agreement, entered into on March 10, 2016, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed March 14, 2016 and incorporated herein by reference).
10.10†	Amendment No. 6 to Matrix Commercialization Collaboration Agreement, entered into on December 29, 2017, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc.
10.11	Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.12*	Orthofix International N.V. Second Amended and Restated Stock Purchase Plan.
10.13	Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference).
10.14	Amendment No. 1 to the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Form 10-Q filed on August 4, 2015 and incorporated herein by reference).
10.15	Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed January 7, 2009, and incorporated herein by reference).
10.16	Form of Non-Employee Director Restricted Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Form 10-Q filed on August 7, 2017 and incorporated herein by reference).
10.17	Form of Time-Based Vesting Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.18	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.19	Form of Time-Based Vesting Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (*annual grant*) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.20	Form of Time-Based Vesting Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (*initial grant*) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.21	Form of 2016 Employee Performance Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.22	Form of Employee Performance Vesting Restricted Stock and Performance Share Unit Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – June 2015 Grants (filed as an exhibit to the Company's Form 10-Q filed on August 4, 2015 and incorporated herein by reference).
10.23	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-June 2016 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).

Exhibit Number	Description
10.24	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-June 2016 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.25	Form of Employee Performance Vesting Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – June 2014 Grants (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.26	Form of Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – 2014 and 2015 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.27	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.28	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.29	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.30	Form of Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.31	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (2011 and 2012 grants—vesting over 3 years) (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.32	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants made under the 2004 Long Term Incentive Plan prior to the adoption of the 2012 Long Term Incentive Plan) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.33	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (2009 through 2012 grants) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.34	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants—vesting over 3 years) (filed as an exhibit to the Company's Current Report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.35	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants— year cliff vesting) (filed as an exhibit to the Company's Current Report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.36	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2011 grants—vesting over 3 years) (filed as an exhibit to the Company's Current Report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.37	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the Company's Current Report on Form 8-K filed June 20, 2008 and incorporated herein by reference).

Exhibit Number	Description
10.38	Form of Indemnity Agreement (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by reference).
10.39	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.40	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.41	Inducement Grant Non-Qualified Stock Option Agreement, dated March 13, 2013, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Current Report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.42	Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan, dated March 13, 2013, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Current Report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.43	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.44	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.45	Change in Control and Severance Agreement, dated July 7, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.46	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.47	Change in Control and Severance Agreement, dated September 7, 2016, between Orthofix International N.V. and Davide Bianchi (filed as an exhibit to the Company's Current Report on Form 8-K filed September 9, 2016 and incorporated herein by reference).
10.48	Amended Employment Contract, dated September 7, 2016, between Orthofix International N.V. and Davide Bianchi (filed as an exhibit to the Company's Current Report on Form 8-K filed September 9, 2016 and incorporated herein by reference).
10.49	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Robert Allen Goodwin II (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.50	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley V. Niemann (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.51	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Raymond Fujikawa (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.52	Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Kimberley Elting (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.53	Letter Agreement, dated July 7, 2016, between Jeffrey M. Schumm, Orthofix International N.V. and Orthofix Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).

Exhibit Number	Description
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer and Certification of Chief Financial Officer.
101	The following financial statements from Orthofix International N.V. on Form 10-K for the year ended December 31, 2017 filed on February 26, 2018, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Consolidated Statements of Changes in Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.

* Filed with this Form 10-K.

† Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. This exhibit has been filed separately with the Secretary of the Commission without redactions pursuant to our Application Requesting Confidential Treatment under the Securities Exchange Act of 1934.

Item 16. Form 10-K Summary

None

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.

ORTHOFIX INTERNATIONAL N.V.

Dated: February 26, 2018

By: /s/ BRADLEY R. MASON
Name: **Bradley R. Mason**
Title: **President and Chief Executive Officer, Director**

Dated: February 26, 2018

By: /s/ DOUG RICE
Name: **Doug Rice**
Title: **Chief Financial 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.

Name	Title	Date
/s/ BRADLEY R. MASON **Bradley R. Mason**	President and Chief Executive Officer, Director (Principal Executive Officer)	February 26, 2018
/s/ DOUG RICE **Doug Rice**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2018
/s/ RONALD A. MATRICARIA **Ronald A. Matricaria**	Chairman of the Board of Directors	February 26, 2018
/s/ LUKE FAULSTICK **Luke Faulstick**	Director	February 26, 2018
/s/ JAMES HINRICHS **James Hinrichs**	Director	February 26, 2018
/s/ ALEXIS V. LUKIANOV **Alexis V. Lukianov**	Director	February 26, 2018
/s/ LILLY MARKS **Lilly Marks**	Director	February 26, 2018
/s/ MICHAEL E. PAOLUCCI **Michael E. Paolucci**	Director	February 26, 2018
/s/ MARIA SAINZ **Maria Sainz**	Director	February 26, 2018

ORTHOFIX INTERNATIONAL N.V.

Statement of Management's Responsibility for Financial Statements

To the Shareholders of Orthofix International N.V.:

Management is responsible for the preparation of the consolidated financial statements and related information that are presented in this report. The consolidated financial statements, which include amounts based on management's estimates and judgments, have been prepared in conformity with accounting principles generally accepted in the United States. Other financial information in the report to shareholders is consistent with that in the consolidated financial statements.

The Company maintains accounting and internal control systems to provide reasonable assurance at a reasonable cost that assets are safeguarded against loss from unauthorized use or disposition, and that the financial records are reliable for preparing financial statements and maintaining accountability for assets. These systems are augmented by written policies, an organizational structure providing division of responsibilities and careful selection and training of qualified personnel.

The Company engaged Ernst & Young LLP independent registered public accountants to audit and render an opinion on the consolidated financial statements in accordance with auditing standards of the Public Company Accounting Oversight Board (United States). These standards include an assessment of the systems of internal controls and test of transactions to the extent considered necessary by them to support their opinion.

The Board of Directors, through its Audit Committee consisting solely of outside directors of the Company, meets periodically with management and our independent registered public accountants to ensure that each is meeting its responsibilities and to discuss matters concerning internal controls and financial reporting. Ernst & Young LLP has full and free access to the Audit Committee.

James F. Hinrichs
Chairman of the Audit Committee

Bradley R. Mason
President and Chief Executive Officer, Director

Doug Rice
Chief Financial Officer

ORTHOFIX INTERNATIONAL N.V.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Orthofix International N.V.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orthofix International N.V. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2002.

Dallas, Texas
February 26, 2018

ORTHOFIX INTERNATIONAL N.V.

Consolidated Balance Sheets as of December 31, 2017 and 2016

(U.S. Dollars, in thousands except share and per share data)	2017	2016
Assets		
Current assets		
Cash and cash equivalents	$ 81,157	$ 39,572
Restricted cash	—	14,369
Trade accounts receivable, less allowances of $8,405 and $8,396 at December 31, 2017 and 2016, respectively	63,437	57,848
Inventories	81,330	63,346
Prepaid expenses and other current assets	25,877	19,238
Total current assets	251,801	194,373
Property, plant and equipment, net	45,139	48,916
Patents and other intangible assets, net	10,461	7,461
Goodwill	53,565	53,565
Deferred income taxes	23,315	47,325
Other long-term assets	21,073	20,463
Total assets	**$ 405,354**	**$ 372,103**
Liabilities and shareholders' equity		
Current liabilities		
Trade accounts payable	$ 18,111	$ 14,353
Other current liabilities	61,295	69,088
Total current liabilities	79,406	83,441
Other long-term liabilities	29,340	25,185
Total liabilities	108,746	108,626
Contingencies (Note 11)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,278,833 and 17,828,155 issued and outstanding as of December 31, 2017 and 2016, respectively	1,828	1,783
Additional paid-in capital	220,591	204,095
Retained earnings	70,402	64,179
Accumulated other comprehensive income (loss)	3,787	(6,580)
Total shareholders' equity	296,608	263,477
Total liabilities and shareholders' equity	**$ 405,354**	**$ 372,103**

The accompanying notes form an integral part of these consolidated financial statements.

ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Operations and Comprehensive Income (Loss)
For the years ended December 31, 2017, 2016 and 2015

(U.S. Dollars, in thousands, except share and per share data)	2017	2016	2015
Net sales	$ 433,823	$ 409,788	$ 396,489
Cost of sales	93,037	87,853	86,525
Gross profit	340,786	321,935	309,964
Sales and marketing	198,370	181,287	178,080
General and administrative	74,388	74,404	87,157
Research and development	29,700	28,803	26,389
SEC / FCPA matters and related costs	(2,483)	2,005	9,083
Charges related to U.S. Government resolutions (Note 11)	—	14,369	—
Operating income	40,811	21,067	9,255
Interest income (expense), net	(416)	763	(489)
Other expense, net	(4,004)	(2,806)	(259)
Income before income taxes	36,391	19,024	8,507
Income tax expense	(29,100)	(15,527)	(10,849)
Net income (loss) from continuing operations	7,291	3,497	(2,342)
Discontinued operations (Note 11)			
Loss from discontinued operations	(1,759)	(638)	(1,827)
Income tax benefit	691	197	1,360
Net loss from discontinued operations	(1,068)	(441)	(467)
Net income (loss)	**$ 6,223**	**$ 3,056**	**$ (2,809)**
Net income (loss) per common share—basic			
Net income (loss) from continuing operations	$ 0.40	$ 0.19	$ (0.12)
Net loss from discontinued operations	(0.06)	(0.02)	(0.03)
Net income (loss) per common share—basic	**$ 0.34**	**$ 0.17**	**$ (0.15)**
Net income (loss) per common share—diluted			
Net income (loss) from continuing operations	$ 0.39	$ 0.19	$ (0.12)
Net loss from discontinued operations	(0.05)	(0.02)	(0.03)
Net income (loss) per common share—diluted	**$ 0.34**	**$ 0.17**	**$ (0.15)**
Weighted average number of common shares:			
Basic	18,117,405	18,144,019	18,795,194
Diluted	18,498,745	18,463,161	18,795,194
Other comprehensive income (loss), before tax			
Unrealized gain (loss) on derivative instrument	—	(360)	202
Unrealized gain (loss) on debt securities	3,830	(1,744)	(3,348)
Reclassification adjustment for loss on debt securities in net income	5,585	2,727	–
Currency translation adjustment	4,552	(726)	(3,907)
Other comprehensive income (loss) before tax	13,967	(103)	(7,053)
Income tax benefit (expense) related to items of other comprehensive income (loss)	(3,600)	(245)	1,203
Other comprehensive income (loss), net of tax	10,367	(348)	(5,850)
Comprehensive income (loss)	$ 16,590	$ 2,708	$ (8,659)

The accompanying notes form an integral part of these consolidated financial statements.

ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2017, 2016 and 2015

(U.S. Dollars, in thousands, except share data)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
At December 31, 2014	18,611,495	$ 1,861	$ 232,788	$ 65,360	$ (382)	$ 299,627
Net loss	—	—	—	(2,809)	—	(2,809)
Other comprehensive loss, net of tax	—	—	—	—	(5,850)	(5,850)
Share-based compensation	—	—	7,214	—	—	7,214
Common shares issued	342,192	34	3,670	—	—	3,704
Retirement of repurchased common stock	(293,991)	(29)	(11,546)	—	—	(11,575)
At December 31, 2015	**18,659,696**	**$ 1,866**	**$ 232,126**	**$ 62,551**	**$ (6,232)**	**$ 290,311**
Cumulative effect adjustment from adoption of ASU 2016-09	—	—	2,032	(1,428)	—	604
Net income	—	—	—	3,056	—	3,056
Other comprehensive loss, net of tax	—	—	—	—	(348)	(348)
Share-based compensation	—	—	15,966	—	—	15,966
Common shares issued	713,140	71	17,242	—	—	17,313
Retirement of repurchased common stock	(1,544,681)	(154)	(63,271)	—	—	(63,425)
At December 31, 2016	**17,828,155**	**$ 1,783**	**$ 204,095**	**$ 64,179**	**$ (6,580)**	**$ 263,477**
Net income	—	—	—	6,223	—	6,223
Other comprehensive income, net of tax	—	—	—	—	10,367	10,367
Share-based compensation	—	—	12,557	—	—	12,557
Common shares issued	450,678	45	3,939	—	—	3,984
At December 31, 2017	**18,278,833**	**$ 1,828**	**$ 220,591**	**$ 70,402**	**$ 3,787**	**$ 296,608**

The accompanying notes form an integral part of these consolidated financial statements.

ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Cash Flows
For the years ended December 31, 2017, 2016 and 2015

(U.S. Dollars, in thousands)	2017	2016	2015
Cash flows from operating activities			
Net income (loss)	$ 6,223	$ 3,056	$ (2,809)
Adjustments to reconcile net income (loss) to net cash from operating activities			
Depreciation and amortization	20,124	20,841	20,923
Amortization of debt costs and other assets	1,712	1,569	1,752
Provision for doubtful accounts	1,639	1,117	3,431
Deferred income taxes	21,286	10,460	(1,156)
Share-based compensation	12,557	15,966	7,214
Gain on sale of assets	—	—	(3,099)
Other-than-temporary impairment on debt securities	5,585	2,727	—
Other	1,398	1,061	2,854
Changes in operating assets and liabilities			
Restricted cash	14,369	(14,369)	—
Trade accounts receivable	(6,562)	392	(1,547)
Inventories	(15,645)	(5,284)	3,136
Prepaid expenses and other current assets	(6,352)	701	8,697
Other long-term assets	1,490	(3,333)	(1,321)
Trade accounts payable	2,324	(1,771)	3,011
Other current liabilities	(11,412)	6,537	1,515
Other long-term liabilities	4,605	5,037	1,009
Net cash from operating activities	**53,341**	**44,707**	**43,610**
Cash flows from investing activities			
Capital expenditures for property, plant and equipment	(14,665)	(16,432)	(27,197)
Capital expenditures for intangible assets	(2,283)	(1,902)	(702)
Purchase of debt securities	—	—	(15,250)
Proceeds from sale of assets	—	—	4,800
Other investing activities	474	(3,613)	—
Net cash from investing activities	**(16,474)**	**(21,947)**	**(38,349)**
Cash flows from financing activities			
Proceeds from issuance of common shares	7,783	19,720	5,254
Payments related to withholdings for share-based compensation	(3,800)	(2,407)	(1,550)
Payment of debt issuance costs	(445)	—	(1,825)
Changes in restricted cash	—	—	34,424
Repurchase and retirement of common shares	—	(63,425)	(11,575)
Net cash from financing activities	**3,538**	**(46,112)**	**24,728**
Effect of exchange rate changes on cash	1,180	(739)	(3,141)
Net change in cash and cash equivalents	41,585	(24,091)	26,848
Cash and cash equivalents at the beginning of the year	39,572	63,663	36,815
Cash and cash equivalents at the end of the year	**$ 81,157**	**$ 39,572**	**$ 63,663**
Supplemental disclosure of cash flow information			
Cash paid during the year for:			
Interest	$ 811	$ 672	$ 852
Income taxes	$ 3,265	$ 4,423	$ 3,160

The accompanying notes form an integral part of these consolidated financial statements

ORTHOFIX INTERNATIONAL N.V.

Notes to the Consolidated Financial Statements

Business and basis of consolidation

Orthofix International N.V. and its subsidiaries (the "Company") is a global medical device company focused on musculoskeletal healing products and value-added services. Headquartered in Lewisville, Texas, the Company has four strategic business units ("SBUs"): BioStim, Extremity Fixation, Spine Fixation, and Biologics. Orthofix products are widely distributed via the Company's sales representatives and distributors.

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

1. Significant accounting policies

The preparation of financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate these estimates, including those related to contractual allowances, doubtful accounts, inventories, goodwill, income taxes, fair value measurements, litigation and contingent liabilities, and share-based compensation. We base our estimates on historical experience, future expectations and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Information on our accounting policies and methods used in the preparation of our consolidated financial statements are included, where applicable, in their respective footnotes that follow.

Significant Accounting Policy	Footnote Reference
Inventories	2
Property, plant and equipment	3
Patents and other intangible assets	4
Goodwill	5
Long-term debt	8
Fair value measurements	9
Contingencies	11
Revenue recognition and accounts receivable	13
Share-based compensation	15
Defined contribution plans and deferred compensation	16
Income taxes	17

The following is a discussion of accounting policies and methods used in our consolidated financial statements that are not presented within other footnotes.

Market risk

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. The Company's objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, the Company seeks to balance its non-U.S. dollar denominated income and expenditures. During 2016 and 2015, the Company made use of a cross-currency swap agreement to manage cash flow exposure generated from foreign currency fluctuations. This cross-currency swap matured and was settled on December 30, 2016.

The financial statements for operations outside the United States are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders' equity, are translated to U.S. dollars at year end exchange rates and revenue and expense items are translated at weighted average rates of exchange prevailing during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income (loss) component of shareholders' equity. Transactional foreign currency gains and losses, including those generated from intercompany operations, are included in other expense, net and were a gain of $1.9 million, and losses of less than $0.1 million and $3.5 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Financial instruments and concentration of credit risk

Financial instruments that could subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents and accounts receivable. Generally, the cash is held at large financial institutions and cash equivalents consist of highly liquid money market funds. The Company performs ongoing credit evaluations of customers, generally does not require collateral, and maintains a reserve for potential credit losses. The Company believes that a concentration of credit risk related to the accounts receivable is limited because customers are geographically dispersed and end users are diversified across several industries.

Net sales to our customers based in Europe were approximately $57 million in 2017, which results in a substantial portion of our trade accounts receivable balance as of December 31, 2017. It is at least reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these distributors operate, or other factors, could affect the future realization of these accounts receivable balances.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

In 2016, restricted cash consisted of amounts held in escrow as of December 31, 2016, to fund the payment of settlement amounts for charges related to U.S. Government resolutions, as further discussed in Note 11.

Derivative Instruments

The Company manages its exposure to fluctuating cash flows resulting from changes in interest rates and foreign exchange rates within the consolidated financial statements according to its hedging policy. The policy requires the Company to formally document the relationship between the hedging instrument and hedged item, as well as its risk-management objective and strategy for undertaking the hedge transaction. For instruments designated as a cash flow hedge, the Company formally assesses (both at the hedge's inception and on an ongoing basis) whether the derivative used in the hedging transaction has been effective in offsetting changes in the cash flows of the hedged item and whether such derivative may be expected to remain effective in future periods. If it is determined that a derivative is not (or has ceased to be) effective as a hedge, the Company discontinues the related hedge accounting prospectively.

The Company records all derivatives as either assets or liabilities on the balance sheet at their respective fair values. For a cash flow hedge, the effective portion of the derivative's change in fair value (i.e., gains or losses) is initially reported as a component of other comprehensive income, net of related taxes, and subsequently reclassified into net earnings in the period the hedged transaction affects earnings.

On September 30, 2010, the Company entered into a cross-currency swap agreement to manage its cash flows related to foreign currency exposure for a portion of an intercompany note receivable of a U.S. dollar functional currency subsidiary that was denominated in Euro. Both the cross-currency swap and the related Euro denominated intercompany note matured and were settled on December 30, 2016.

Research and development costs

Expenditures related to the collaborative arrangement with MTF Biologics ("MTF") are expensed based on the terms of the related agreement. Expenditures incurred under the collaborative arrangement with MTF totaled $0.9 million in 2017 and $1.3 million in 2016. No expenditures were incurred in 2015. Expenditures for research and development are expensed as incurred.

Recently issued income tax accounting guidance

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (the "Tax Act"). See Note 17 for further discussion.

Further, in January 2018, the FASB released guidance on the accounting for tax on the global intangible low taxed income ("GILTI") provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of deemed return on tangible assets of foreign corporations. The guidance indicated that either accounting for deferred taxes related to GILTI inclusion or to treat any taxes on GILTI inclusion as a period cost are both acceptable methods subject to an accounting policy election. The Company is currently evaluating this policy decision.

Recently issued accounting standards

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Revenue Recognition (ASU 2014-09, as amended)	Requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. Applied either retrospectively or as a cumulative effect adjustment as of the adoption date.	January 1, 2018	In 2015, the Company established a cross-functional implementation team to analyze the impact of the standard on the Company's contract portfolio by reviewing the Company's current accounting policies and practices to identify potential differences that would result from applying the requirements of the new standard to the Company's contracts. In addition, the implementation team identified and implemented appropriate changes to the Company's business processes, systems, and controls to support recognition and disclosure under the new standard. The implementation team has reported the findings and progress of the project to management and to the Audit Committee on a frequent basis over the last two years. In the fourth quarter of 2017, the Company finalized its assessment of the new standard, including the review of contracts within each SBU and the drafting of new policies and procedures. Adoption of this ASU has a material impact related to the timing of revenue recognition, primarily for Extremity Fixation and Spine Fixation product sales to stocking distributors, which are currently accounted for using the sell-through method. Subsequent to adoption, revenue associated with these sales will be recorded at the time of the sale instead of deferring recognition until cash is received. The Company will adopt the standard using the modified retrospective transition method and will record a cumulative effect adjustment as of January 1, 2018, which will result in a significant increase in accounts receivable and a decrease in inventories, with these changes offset by an adjustment to the Company's opening retained earnings of approximately $5 million. Prior periods will not be retrospectively adjusted. Adopting this guidance will also result in material changes to the Company's disclosures for revenue recognition and contracts with customers.
Financial Instruments (ASU 2016-01)	Requires entities to measure equity investments, except in limited circumstances, at fair value and recognize any changes in fair value in net income. Applied prospectively.	January 1, 2018	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Leases (ASU 2016-02)	Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach.	January 1, 2019	The Company is currently in process of establishing a cross-functional implementation team to analyze the impact of the standard on the Company's lease portfolio and to evaluate the impact this ASU may have on its consolidated financial statements; however, the Company expects this guidance will materially impact the Company's balance sheet, resulting in current operating lease obligations being reflected on the consolidated balance sheet.
Income Taxes (ASU 2016-16)	Reduces complexity by requiring the recognition of current and deferred income taxes for an intra-entity asset transfer, other than inventory, when the transfer occurs. Applied using a modified retrospective approach.	January 1, 2018	During the third and fourth quarters of 2017, the Company executed two intra-entity asset transfers that resulted in prepaid income taxes of $8.6 million. The Company will adopt the new standard using a modified retrospective approach as of January 1, 2018, which will result in a reduction of prepaid income taxes and an increase in deferred tax assets with these change offset by an adjustment to the Company's opening retained earnings of approximately $2.1 million. However, the Company does not expect this guidance to have a material impact relating to its consolidated statements of operations and comprehensive income (loss) or to its consolidated statements of cash flows.
Statement of Cash Flows (ASU 2016-18)	Reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. Applied retrospectively.	January 1, 2018	The Company believes this ASU will materially impact its consolidated statement of cash flows. Adoption of this ASU is expected to result in an increase in net cash from operating activities of $14.4 million for the year ended December 31, 2016 and would have resulted in a decrease in net cash from operating activities of $14.4 million for the year ended December 31, 2017, if this ASU had been early adopted.
Goodwill (ASU 2017-04)	Eliminates Step 2 of the current goodwill impairment test, which requires a hypothetical purchase price allocation to measure goodwill impairment. A goodwill impairment loss will instead be measured at the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the recorded amount of goodwill.	January 1, 2020	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements. However, the Company does not expect this ASU to have a significant impact on its financial statements or disclosures.
Comprehensive Income (ASU 2018-02)	Allows entities to reclassify from accumulated other comprehensive income to retained earnings stranded tax effects resulting from the Tax Act.	January 1, 2019	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

2. Inventories

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess, obsolete or impaired items, which is reviewed and updated on a periodic basis by management. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Italy, cost is determined on a weighted-average basis, which approximates the first-in, first-out ("FIFO") method. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Texas, standard costs, which approximates actual cost on the FIFO method, is used to value inventory. Standard costs are reviewed annually by management, or more often in the event circumstances indicate a change in cost has occurred.

Work-in-process, finished products, field inventory and consignment inventory include material, labor and production overhead costs. Field inventory represents immediately saleable finished products inventory that is in the possession of the Company's independent sales representatives. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals.

Deferred cost of sales result from transactions where the Company has shipped product or performed services for which all revenue recognition criteria have not yet been met. Once all revenue recognition criteria have been met, the revenue and associated cost of sales are recognized.

	December 31,	
(U.S. Dollars, in thousands)	2017	2016
Raw materials	$ 6,067	$ 7,978
Work-in-process	12,487	9,505
Finished products	11,244	15,985
Field inventory	40,262	22,021
Consignment inventory	8,935	4,428
Deferred cost of sales	2,335	3,429
Inventories	$ 81,330	$ 63,346

The Company adjusts the value of its inventory to the extent management determines that the cost cannot be recovered due to obsolescence or other factors. In order to make these determinations, management uses estimates of future demand and sales prices for each product to determine the appropriate inventory reserves and to make corresponding adjustments to the carrying value of these inventories to reflect the lower of cost or market value.

3. Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Costs include all expenditures necessary to place the asset in service, including freight and sales and use taxes. Property, plant and equipment includes instrumentation held by customers, which is generally used to facilitate the implantation of the Company's products. The useful lives of these assets are as follows:

	Years
Buildings	25 to 33
Plant and equipment	1 to 10
Instrumentation	3 to 4
Computer software	3 to 7
Furniture and fixtures	4 to 8

The Company evaluates the useful lives of these assets on an annual basis. Depreciation is computed on a straight-line basis over the useful lives of the assets. Depreciation of leasehold improvements is computed over the shorter of the lease term or the useful life of the asset. Total depreciation expense was $18.3 million, $19.0 million and $19.2 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Expenditures for maintenance and repairs and minor renewals and improvements, which do not extend the lives of the respective assets, are expensed as incurred. All other expenditures for renewals and improvements are capitalized. The assets and related accumulated depreciation are adjusted for property retirements and disposals, with the resulting gain or loss included in earnings. Fully depreciated assets remain in the accounts until retired from service.

	December 31,	
(U.S. Dollars, in thousands)	2017	2016
Cost		
Buildings	$ 3,725	$ 3,225
Plant and equipment	47,588	43,745
Instrumentation	75,818	71,962
Computer software	48,604	44,720
Furniture and fixtures	7,605	8,308
Construction in progress	769	1,907
	184,109	173,867
Accumulated depreciation	(138,970)	(124,951)
Property, plant and equipment, net	$ 45,139	$ 48,916

The Company capitalizes system development costs related to its internal use software during the application development stage. Costs related to preliminary project activities and post implementation activities are expensed as incurred. Internal-use software is amortized on a straight-line basis over its estimated useful life, generally three to seven years.

Long-lived assets are evaluated for impairment whenever events or changes in circumstances have occurred that would indicate impairment. For purposes of the evaluation, the Company groups its long-lived assets with other assets and liabilities at the lowest level of identifiable cash flows if the asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the asset (asset group) exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the asset (asset group), the Company will write the carrying value down to the fair value in the period identified.

The Company generally determines fair value of long-lived assets as the present value of estimated future cash flows. In determining the estimated future cash flows associated with the assets, the Company uses estimates and assumptions about future revenue contributions, cost structures and remaining useful lives of the asset (asset group). The use of alternative assumptions, including estimated cash flows, discount rates, and alternative estimated remaining useful lives could result in different calculations of impairment.

4. Patents and other intangible assets

Patents and other intangible assets are recorded at cost, or when acquired as a part of a business combination at estimated fair value. These assets are amortized on a straight-line basis over the useful lives of the assets. The Company's weighted average amortization period for developed technologies is 11 years.

	December 31,	
(U.S. Dollars, in thousands)	2017	2016
Cost		
Patents	$ 38,621	$ 38,348
License and other	10,276	7,611
Trademarks—finite lived	533	319
	49,430	46,278
Accumulated amortization		
Patents	(34,151)	(34,717)
License and other	(4,625)	(3,962)
Trademarks—finite lived	(193)	(138)
	(38,969)	(38,817)
Patents and other intangible assets, net	$ 10,461	$ 7,461

Amortization expense for intangible assets was $1.8 million, $1.8 million and $1.7 million for the years ended December 31, 2017, 2016 and 2015, respectively. Future amortization expense for intangible assets is estimated as follows:

(U.S. Dollars, in thousands)	Amortization
2018	$ 2,352
2019	1,909
2020	1,366
2021	1,321
2022	1,314
Thereafter	2,199
Total	$ 10,461

5. Goodwill

The Company tests goodwill at least annually for impairment. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. The Company assesses goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment.

At the beginning of the fourth quarter of 2017, the Company performed a qualitative assessments for its annual goodwill impairment analysis, which did not result in an impairment charge for either the BioStim or Biologics reporting units, the only reporting units with goodwill. This qualitative analysis considers all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance, and relevant entity-specific events. In 2016 the Company performed a quantitative impairment analysis that did not result in an impairment charge and in 2015 the Company performed a qualitative assessment, which did not result in any impairment charge.

The following table presents the net carrying value of goodwill by reportable segment:

	December 31,	
(U.S. Dollars, in thousands)	2017	2016
BioStim	$ 42,678	$ 42,678
Extremity Fixation	—	—
Spine Fixation	—	—
Biologics	10,887	10,887
Goodwill	$ 53,565	$ 53,565

6. Long-term investments

Debt securities

On March 4, 2015, the Company entered into an Option Agreement (the “Option Agreement”) with eNeura, Inc. (“eNeura”), a privately held medical technology company that is developing devices for the treatment of migraines. The Option Agreement provided the Company with an exclusive option to acquire eNeura (the “Option”) during the 18-month period following the grant of the Option, which expired in September 2016 without the Company exercising the option. In consideration for the Option, (i) the Company paid a non-refundable $0.3 million fee to eNeura, and (ii) the Company loaned eNeura $15.0 million pursuant to a Convertible Promissory Note (the “eNeura Note”) that was issued to the Company. The principal amount of the eNeura Note is $15.0 million and interest accrues at 8.0%. The eNeura Note will mature on March 4, 2019 and interest is due when the eNeura Note matures, provided that if a change in control of eNeura (generally defined as a third party acquisition of fifty percent or more of eNeura’s voting equity or all or substantially all of eNeura’s assets) occurs prior to the maturity date, the eNeura Note will automatically convert into preferred stock of eNeura at a fixed price equal to $7.30 per share. The investment is recorded in other long-term assets as an available for sale debt security at fair value and interest is recorded in interest income; however, the Company discontinued recognition of interest on the eNeura Note in the first quarter of 2017.

As of March 31, 2017, the fair value of the debt security was determined to be $9.0 million, which represented a $3.2 million decrease from its fair value as of December 31, 2016. The Company recorded this decrease in the fair value in other comprehensive income (loss) as an unrealized loss on debt securities. Further, based upon the Company's best estimate of the amount it expected to recover at the time, the Company recorded an other-than-temporary impairment of $5.6 million during the first quarter of 2017. This other-than-temporary impairment was reclassified from accumulated other comprehensive loss and is included within other expense. See Note 9 for further discussion. As of December 31, 2017, the fair value of the debt security is $16.1 million, which represents a net increase of $7.1 million in relation to the balance as of March 31, 2017, and compares to an amortized cost basis of $9.0 million. The Company recorded this increase in the fair value in other comprehensive income as an unrealized gain on debt securities.

Equity investment and warrants

As of December 31, 2017, the Company holds common stock of Bone Biologics, Inc. ("Bone Biologics") totaling $2.5 million and warrants to purchase 458 thousand shares at a weighted average exercise price of $1.18 per share. These instruments are recorded within other long-term assets. The fair value of these instruments has not been estimated, and is instead recorded at cost, as the fair value is not readily determinable. In addition, there have been no events or changes in circumstances that would indicate a significant adverse effect on the fair value of the instruments. Under the terms of the warrant purchase agreements, the warrants to purchase common stock in Bone Biologics are exercisable over a seven year period, which expire between 2020 and 2021, and are transferable by the holder to other parties.

7. Other current liabilities

	December 31,	
(U.S. Dollars, in thousands)	2017	2016
Accrued expenses	$ 6,984	$ 6,155
Salaries, bonuses, commissions and related taxes payable	24,635	19,636
Accrued distributor commissions	9,192	9,379
Accrued legal and settlement expenses	7,673	23,081
Non-income taxes payable	3,180	7,301
Other payables	9,631	3,536
Other current liabilities	$ 61,295	$ 69,088

Extremity Fixation restructuring plan

In December 2016, the Company approved and initiated a planned restructuring, which primarily affects the Extremity Fixation SBU, to streamline costs, improve operational performance, and wind down a non-core business. The Extremity Fixation restructuring plan consists of primarily severance charges, professional fees and the write-down of certain assets. The Company expects to incur total pre-tax expense of approximately $3.3 million in connection with this restructuring activity and has incurred cumulative costs to date of $3.3 million, largely within cost of sales and operating expenses. The Company had an accrual of $1.5 million as of December 31, 2016 in other current liabilities related to the planned restructuring. In 2017, the Company incurred costs of $1.3 million and made payments of $2.1 million relating to these activities, resulting in a remaining accrual of $0.7 million as of December 31, 2017.

U.S. restructuring plan

In September 2017, the Company approved and executed an additional restructuring plan, which primarily affects the entity's corporate shared services in the U.S. to streamline costs and to improve operational performance. The U.S. restructuring plan consists primarily of severance charges. The Company estimates total pre-tax expense of approximately $1.7 million in connection with this restructuring activity, all of which was incurred in 2017, and recorded within cost of sales and operating expenses. Payments were made in 2017 of $0.6 million relating to these activities; therefore, $1.1 million is accrued within other current liabilities as of December 31, 2017.

8. Long-term debt

On August 31, 2015, the Company, through its subsidiaries Orthofix Holdings and Victory Medical Limited ("Victory Medical", and collectively with Orthofix Holdings, the "Borrowers"), entered into a Credit Agreement (the "Credit Agreement") with JPMorgan, as Administrative Agent, and certain lenders party thereto. The Credit Agreement provides for a five year $125 million secured revolving credit facility (the "Facility"). The Credit Agreement has a maturity date of August 31, 2020. As of December 31, 2017, the Company has no borrowings outstanding under the Credit Agreement.

Borrowings under the Credit Agreement may be used for, among other things, working capital and other general corporate purposes (including share repurchases, permitted acquisitions and permitted payments of dividends and other distributions) of the Company and certain of its subsidiaries. The Facility is generally available in U.S. Dollars with up to $50 million of the Facility also available to be borrowed in Euros and Pounds Sterling (together with U.S. Dollars, the "Agreed Currencies"). The Credit Agreement further permits up to $25 million of the Facility to be utilized for the issuance of letters of credit in the Agreed Currencies. The Borrowers have the ability to increase the amount of the Facility by an aggregate amount of up to $50 million (which increase may take the form of one or more increases to the revolving credit commitments and/or the issuance of one or more new Term A loans) upon satisfaction of certain conditions precedent and receipt of additional commitments by one or more existing or new lenders.

Borrowings under the Facility bear interest at a floating rate, which is, at the Borrowers' option, either LIBOR plus an applicable margin ranging from 1.75% to 2.5% or a base rate plus an applicable margin ranging from 0.75% to 1.5% (in each case subject to adjustment based on the Company's total leverage ratio). An unused commitment fee ranging from 0.25% to 0.4% (subject to adjustment based on the Company's total leverage ratio) is payable quarterly in arrears based on the daily amount of the undrawn portion of each lender's revolving credit commitment under the Facility. Fees are payable on outstanding letters of credit at a rate equal to the applicable margin for LIBOR loans, plus certain customary fees payable solely to the issuer of the letter of credit.

The Company and certain of its subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries. The Credit Agreement contains customary affirmative and negative covenants, including limitations on the Company's and its subsidiaries' ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay subordinated indebtedness and enter into affiliate transactions.

In addition, the Credit Agreement contains financial covenants requiring the Company on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. The Company is in compliance with all required financial covenants as of December 31, 2017. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated.

In conjunction with obtaining the Facility, the Company incurred debt issuance costs of $1.8 million which are being amortized over the life of the Facility. The debt issuance costs are included in other long-term assets, net of accumulated amortization. As of December 31, 2017 and 2016, debt issuance costs, net of accumulated amortization, were $1.0 million and $1.3 million, respectively. Debt issuance costs amortized or expensed related to the Facility and the Amendment totaled $1.0 million, $0.4 million, and $0.6 million for the years ended December 31, 2017, 2016, and 2015, respectively.

On December 8, 2017, the Company amended the Credit Agreement with JPMorgan, the Administrative Agent, and certain lenders party thereto. The primary provision of the Credit Agreement to be amended, among other things, was to add the Company's subsidiary, Orthofix International B.V., as a Borrower, Guarantor, and a loan party. In addition, two of the Company's subsidiaries, Orthofix Limited and Orthofix II B.V. were also added as Guarantors and loan parties.

The Company has an unused available line of credit of €5.8 million ($7.0 million and $6.1 million) at December 31, 2017 and 2016, respectively, in its Italian line of credit. This unsecure line of credit provides the Company the option to borrow amounts in Italy at rates, which are determined at the time of borrowing.

9. Fair value measurements

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Non-financial assets and liabilities of the Company measured at fair value include any long-lived assets or equity method investments that are impaired in a currently reported period. The authoritative guidance also describes three levels of inputs that may be used to measure fair value:

Level 1: quoted prices in active markets for identical assets and liabilities

Level 2: observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3: unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

The Company's financial instruments include cash equivalents, restricted cash, foreign certificates of deposit, treasury securities, collective trust funds, trade accounts receivable, accounts payable, long-term secured debt, equity securities, available for sale debt securities, common stock warrants, and deferred compensation plan liabilities. The carrying value of restricted cash, trade accounts receivable and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's credit facilities carry a floating rate of interest, and therefore, the carrying value is considered to approximate the fair value. The Company's equity securities and common stock warrants are recorded at cost, as the fair value of these instruments is not readily available. See Note 6 for further discussion.

The Company's collective trust funds, treasury securities, foreign certificates of deposit, debt securities, and deferred compensation plan liabilities are the only financial instruments recorded at fair value on a recurring basis as follows:

(U.S. Dollars, in thousands)	Balance December 31, 2017	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 100	$ —	$ 100	$ —
Treasury securities	556	556	—	—
Debt security	16,050	—	—	16,050
Total	$ 16,706	$ 556	$ 100	$ 16,050
Liabilities				
Deferred compensation plan	$ (1,379)	$ —	$ (1,379)	$ —
Total	$ (1,379)	$ —	$ (1,379)	$ —

(U.S. Dollars, in thousands)	Balance December 31, 2016	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 1,584	$ —	$ 1,584	$ —
Treasury securities	467	467	—	—
Certificates of deposit	468	468	—	—
Debt security	12,220	—	—	12,220
Total	$ 14,739	$ 935	$ 1,584	$ 12,220
Liabilities				
Deferred compensation plan	$ (1,452)	$ —	$ (1,452)	$ —
Total	$ (1,452)	$ —	$ (1,452)	$ —

The fair value of treasury securities and certificates of deposit are determined based on quoted prices in active markets for identical assets, therefore, the Company has categorized these instruments as Level 1 financial instruments. The certificates of deposit were held in foreign currencies and carried a contractual maturity of two years from the date of purchase and matured in 2017.

The fair value of the Company's collective trust funds and deferred compensation plan liabilities are determined based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets; therefore, the Company has categorized these instruments as Level 2 financial instruments.

The fair value of the debt security, including accrued interest, is based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. One of the more significant unobservable inputs used in the fair value measurement of the debt security is the discount rate. Holding other inputs constant, changes in the discount rate could result in a significant change in the fair value of the debt security. As of December 31, 2017, the fair value of the debt security is $16.1 million, a net increase of $3.8 million during 2017, which the Company recorded in other comprehensive income as an unrealized gain on debt securities.

The Company evaluates any declines in fair value each quarter to determine if impairments are other-than-temporary. Based upon the Company's best estimate of the amount it expected to recover at the time, the Company recorded an other-than-temporary impairment of $5.6 million in the first quarter of 2017. The Company also recorded an other-than-temporary impairment of $2.7 million in 2016. These other-than-temporary impairments were reclassified from accumulated other comprehensive loss and are included within other expense.

The following table provides a reconciliation of the beginning and ending balances for debt securities measured at fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	2017	2016
Balance at January 1	$ 12,220	$ 12,658
Accrued interest income	—	1,306
Gains or losses recorded for the period		
Recognized in net income	(5,585)	(2,727)
Recognized in other comprehensive income	9,415	983
Balance at December 31	$ 16,050	$ 12,220

10. Commitments

Leases

The Company has entered into operating leases for facilities and equipment. These leases are non-cancellable and typically do not contain renewal options. Certain leases contain rent escalation clauses for which the Company recognizes the expense on a straight-line basis. Rent expense under the Company's operating leases for the years ended December 31, 2017, 2016 and 2015 was approximately $3.1 million, $3.0 million and $3.0 million, respectively.

Future minimum lease payments under operating leases as of December 31, 2017 are as follows:

(U.S. Dollars, in thousands)	
2018	$ 3,017
2019	2,018
2020	1,240
2021	1,575
2022	1,600
Thereafter	12,156
Total	$ 21,606

Inventory purchase commitments

The Company had inventory purchase commitments with third-party manufactures for $1.9 million and $1.2 million as of December 31, 2017, and 2016, respectively.

11. Contingencies

The Company records accruals for certain outstanding legal proceedings, investigations or claims when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed. In addition, legal fees and other directly related costs are expensed as incurred.

In addition to the matters described in the paragraphs below, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. The Company believes any losses related to these matters are individually and collectively immaterial as to a possible loss and range of loss.

January 2017 SEC Settlements

In January 2017, the U.S. Securities and Exchange Commission (the "SEC") approved the Company's offers of settlement in connection with the SEC's investigations of accounting matters leading to the Company's prior restatement of financial statements and the Company's review of improper payments with respect to its subsidiary in Brazil. Both investigations were initiated in 2013 and involved matters self-reported to the SEC by the Company. The settlements approved by the SEC resolved these two matters, and included payments totaling $14.4 million by the Company to the SEC of amounts previously accrued and funded into escrow by the Company during 2016. In connection with the Brazil-related settlement, the Company agreed to retain an independent compliance consultant for one year to review and test the Company's compliance program related to the U.S. Foreign Corrupt Practices Act. The Company's engagement with its independent compliance consultant began in March 2017. In addition, in the fourth quarter of 2017 the Company received a favorable insurance settlement of approximately $6 million associated with prior costs incurred related to these matters, which the Company has recognized within the in SEC / FCPA matters and related costs line of the consolidated statement of operations and comprehensive income (loss).

Discontinued Operations – Matters Related to Breg and Possible Indemnification Obligations

On May 24, 2012, the Company sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. ("Water Street"). Under the terms of the agreement, the Company indemnified Water Street and Breg with respect to certain specified matters.

At the time of its divestiture by the Company, Breg was engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases were filed, mostly in California state court. In September 2014, the Company entered into a master settlement agreement resolving then pending pre-close cold therapy claims. Currently pending is a post-close cold therapy claim in California state court. As of December 31, 2017, the Company has an accrual of $1.7 million recorded within other current liabilities; however, the actual liability could be higher or lower than the amount accrued.

Charges incurred as a result of this indemnification are reflected as discontinued operations in our Consolidated Statements of Operations and Comprehensive Income (Loss).

12. Shareholders' equity

Dividends

The Company has not paid dividends to holders of its common stock in the past. Certain subsidiaries of the Company have restrictions on their ability to pay dividends in certain circumstances pursuant to the Credit Agreement. In the event that the Company decides to pay a dividend to holders of its common stock in the future with dividends received from its subsidiaries, the Company may, based on prevailing rates of taxation, be required to pay additional withholding and income tax on such amounts received from its subsidiaries.

Share Repurchase Plan

In August 2015, the Company's Board of Directors authorized a share repurchase plan, authorizing the purchase of up to $75 million of the Company's common stock through and including September 2017. The Company completed the share repurchase plan in the fourth quarter of 2016. Under the program, common shares repurchased consisted of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Exchange Act, as amended. Repurchases were made from cash on hand and cash generated from operations. For the year ended December 31, 2016, the Company repurchased 1,544,681 shares of common stock for $63.4 million with an average price per share of $41.06, which were all retired upon repurchase.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of foreign currency translation adjustments; the effective portion of the gain (loss) on the Company's cross-currency swap, which was designated and accounted for as a cash flow hedge (expired in 2016); and the unrealized (gains) losses on the Company's debt security. The components of and changes in accumulated other comprehensive income (loss) are as follows:

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Derivatives	Debt Security	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2015	$ (4,389)	$ 228	$ (2,071)	$ (6,232)
Other comprehensive loss	(726)	(360)	(1,744)	(2,830)
Income taxes	—	132	659	791
Reclassification adjustments to:				
Other expense, net	—	—	2,727	2,727
Income taxes	—	—	(1,036)	(1,036)
Balance at December 31, 2016	$ (5,115)	$ —	$ (1,465)	$ (6,580)
Other comprehensive income	4,552	—	3,830	8,382
Income taxes	—	—	(1,475)	(1,475)
Reclassification adjustments to:				
Other expense, net	—	—	5,585	5,585
Income taxes	—	—	(2,125)	(2,125)
Balance at December 31, 2017	$ (563)	$ —	$ 4,350	$ 3,787

13. Revenue recognition and accounts receivable

The table below presents net sales, which includes product sales and marketing service fees, for each of the years ended December 31, 2017, 2016, and 2015.

	For the year ended December 31,		
(U.S. Dollars, in thousands)	2017	2016	2015
Product sales	$ 373,538	$ 355,652	$ 341,084
Marketing service fees	60,285	54,136	55,405
Net sales	$ 433,823	$ 409,788	$ 396,489

Product sales primarily consist of stimulation devices and internal and external fixation products. Marketing service fees are received from MTF based on total sales of biologics tissues and relates solely to the Biologics SBU. Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs for products shipped to customers are included in cost of sales, and were $3.0 million, $2.0 million and $2.2 million for the years ended December 31, 2017, 2016 and 2015, respectively.

BioStim

BioStim revenue is largely attributable to the U.S. and is comprised of third-party payor transactions and wholesale revenue.

The largest portion of BioStim revenue is derived from third-party payors. This includes commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of the Company's stimulation products. Revenue is recognized when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

Wholesale revenue is related to the sale of the Company's bone growth stimulators directly to physicians and other healthcare providers. Wholesale revenues are typically recognized upon shipment and receipt of a confirming purchase order.

Extremity Fixation and Spine Fixation

Extremity Fixation and Spine Fixation products are distributed world-wide, with U.S. sales largely comprised of commercial revenue and international sales derived from commercial sales and through stocking distributor arrangements.

Commercial revenue is related to the sale of the Company's internal and external fixation products, generally representing hospital customers. Revenues are recognized when these products have been utilized and a confirming purchase order has been received from the hospital. Revenue for certain government entities is recorded on a cash-basis as collectability is not reasonably assured.

For revenue from stocking distributor arrangements, the Company recognizes revenue once the product is delivered to the end customer (the "sell-through method"). Because the Company does not have reliable information about when its stocking distributors sell the product through to end customers, the Company uses cash collection from stocking distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company is legally entitled to the accounts receivable at the time of shipment, the Company has not recognized accounts receivables or any corresponding deferred revenues associated with stocking distributor transactions for which revenue is recognized on the sell-through method.

For stocking distributor arrangements, the Company also considers whether to match the related cost of sales with revenue or to recognize cost of sales upon shipment. In making this assessment, the Company considers the financial viability of its stocking distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped is reasonably assured at the time of shipment to these stocking distributors. In instances where the stocking distributor is determined to be financially viable, the Company defers the costs of sales until the revenue is recognized.

Biologics

Biologics revenue is largely attributable to the U.S. and is primarily related to a collaborative arrangement with MTF, which extends through July 28, 2027, through which the Company markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE. The Company has exclusive global marketing rights for Trinity Evolution as well as non-exclusive marketing rights for other products, and receives marketing fees from MTF based on total sales. MTF is considered the primary obligor in these arrangements and therefore the Company recognizes these marketing service fees on a net basis within net sales upon shipment of the product to the customer.

Marketing service fees received from MTF were $60.3 million, or approximately 96% of total Biologics revenues, for the year ended December 31, 2017. As MTF is the Company's single supplier for the Trinity Evolution and Trinity EITE tissue forms, which are derived from human cadaveric donors, any event or circumstance that would impact MTF's continued access to donated human cadaveric tissue or the Company's ability to market these tissues may adversely impact the Company's financial results.

Trade Accounts Receivable and Allowances

Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. The Company's estimates are periodically tested against actual collection experience.

The Company will generally sell receivables from certain Italian hospitals each year. During 2017, 2016, and 2015 the Company sold €9.8 million, €10.0 million, and €10.9 million ($11.2 million, $11.1 million, and $11.9 million) of receivables, respectively. The estimated related fee for 2017, 2016, and 2015 was $0.3 million, $0.4 million and $0.5 million, respectively, which is recorded as interest expense. Trade accounts receivables sold without recourse are removed from the balance sheet at the time of sale.

14. Business segment information

We manage our business by our four SBUs: BioStim, Extremity Fixation, Spine Fixation, and Biologics. These SBUs represent the operating segments for which our Chief Executive Officer, who is also Chief Operating Decision Maker (the "CODM"), reviews financial information and makes resource allocation decisions among business units. The primary metric used by the CODM in managing the Company is non-GAAP net margin, an internal metric that the Company defines as gross profit less sales and marketing expense. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. Accordingly, our reporting segment information has been prepared based on our four SBUs.

BioStim

The BioStim SBU manufactures, distributes, and provides support services of market leading bone growth stimulator devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). This SBU uses distributors and sales representatives to sell its devices to hospitals, healthcare providers, and patients, primarily in the U.S.

Extremity Fixation

The Extremity Fixation SBU offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This SBU specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures. Extremity Fixation distributes its products through a network of distributors and sales representatives to sell orthopedic products to hospitals, and healthcare providers, globally.

Spine Fixation

The Spine Fixation SBU designs, develops and markets a broad portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers, globally.

Biologics

The Biologics SBU provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This SBU specializes in the marketing of the Company's exclusive regeneration tissue forms and distributes its tissues to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives. Our partnership with MTF allows us to exclusively market our Trinity Evolution and Trinity ELITE tissue forms for musculoskeletal defects to enhance bony fusion.

Corporate

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its holding company subsidiaries, along with activities not necessarily identifiable within the four SBUs.

The table below presents net sales by reporting segment:

	Year Ended December 31,					
	2017		2016		2015	
(U.S. Dollars, in thousands)	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
BioStim	$ 185,900	42.9%	$ 176,561	43.1%	$ 164,955	41.6%
Extremity Fixation	103,242	23.8%	102,683	25.1%	96,034	24.2%
Spine Fixation	81,957	18.9%	72,632	17.7%	75,668	19.1%
Biologics	62,724	14.4%	57,912	14.1%	59,832	15.1%
Net sales	$ 433,823	100.0%	$ 409,788	100.0%	$ 396,489	100.0%

The following table presents Non-GAAP net margin, and internal metric that the Company defines as gross profit less sales and marketing expense, by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2017	2016	2015
BioStim	$ 77,369	$ 75,469	$ 67,878
Extremity Fixation	31,071	30,526	29,493
Spine Fixation	8,730	8,650	8,547
Biologics	25,692	26,891	27,226
Corporate	(446)	(888)	(1,260)
Non-GAAP net margin	$ 142,416	$ 140,648	$ 131,884
General and administrative	74,388	74,404	87,157
Research and development	29,700	28,803	26,389
SEC / FCPA matters and related costs	(2,483)	2,005	9,083
Charges related to U.S. Government resolutions	—	14,369	—
Operating income	$ 40,811	$ 21,067	$ 9,255
Interest income (expense), net	(416)	763	(489)
Other expense, net	(4,004)	(2,806)	(259)
Income before income taxes	$ 36,391	$ 19,024	$ 8,507

The following table presents depreciation and amortization by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2017	2016	2015
BioStim	$ 2,133	$ 2,754	$ 2,933
Extremity Fixation	6,040	5,742	6,636
Spine Fixation	6,949	8,118	10,050
Biologics	752	1,011	1,157
Corporate	4,250	3,216	147
Total	$ 20,124	$ 20,841	$ 20,923

Geographical information

The following data includes net sales by geographic destination:

(U.S. Dollars, in thousands)	2017	2016	2015
U.S.	$ 345,145	$ 316,873	$ 305,505
Italy	17,059	16,664	15,655
United Kingdom	8,725	10,362	11,376
Brazil	10,356	11,334	13,512
Others	52,538	54,555	50,441
Net sales	$ 433,823	$ 409,788	$ 396,489

The following data includes property, plant and equipment by geographic area:

(U.S. Dollars, in thousands)	2017	2016
U.S.	$ 34,008	$ 38,398
Italy	7,658	7,013
United Kingdom	382	617
Brazil	475	769
Others	2,616	2,119
Total	$ 45,139	$ 48,916

15. Share-based compensation

At December 31, 2017, the Company had stock option and award plans, and an employee stock purchase plan.

2012 Long Term Incentive Plan

The Board of Directors adopted the Orthofix International N.V. 2012 Long-Term Incentive Plan (the "2012 LTIP") on April 13, 2012, subject to shareholder approval, which was subsequently provided by shareholder ratification. The 2012 LTIP provides for the grant of options to purchase shares of the Company's common stock, stock awards (including restricted stock, unrestricted stock, and stock units), stock appreciation rights, performance-based awards and other equity-based awards. All of the Company's employees and the employees of the Company's subsidiaries and affiliates are eligible and may receive awards under the 2012 LTIP. In addition, the Company's non-employee directors and consultants and advisors who perform services for the Company and the Company's subsidiaries and affiliates may receive awards under the 2012 LTIP. Incentive share options, however, are only available to the Company's employees. Awards granted under the 2012 LTIP expire no later than ten years after the date of grant. The Company reserves a total of 3,200,000 shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2017, there were 881,322 options outstanding under the 2012 LTIP Plan, of which 402,820 were exercisable. In addition, there were 381,204 shares of unvested restricted stock outstanding, some of which contain performance conditions, and 241,864 units of performance stock units outstanding under the plan as of December 31, 2017.

2004 Long Term Incentive Plan

The 2004 Long Term Incentive Plan (the "2004 LTIP Plan") reserved 3.1 million shares for issuance (in addition to shares (i) available for future awards as of June 29, 2004 under prior plans or (ii) that become available for future issuance upon the expiration or forfeiture after June 29, 2004 of awards upon prior plans). At December 31, 2017, there were 55,500 options outstanding under the 2004 LTIP Plan, all of which were exercisable; in addition, there were no shares of unvested restricted stock outstanding.

Stock Purchase Plan

The Orthofix International N.V. Amended and Restated Stock Purchase Plan (the "Stock Purchase Plan") provides for the issuance of shares of the Company's common stock to eligible employees and directors of the Company and its subsidiaries that elect to participate in the plan and acquire shares of common stock through payroll deductions (including executive officers).

During each purchase period, eligible employees may designate between 1% and 25% of their compensation to be deducted for the purchase of common stock under the plan (or such other percentage in order to comply with regulations applicable to Employees domiciled in or resident of a member state of the European Union). For eligible directors, the designated percentage will be an amount equal to his or her annual or other director compensation paid in cash for the current plan year. The purchase price of the shares under the plan is equal to 85% of the fair market value on the first day of the plan year (which is a calendar year, running from January 1 to December 31) or, if lower, on the last day of the plan year.

Due to the compensatory nature of such plan, the Company records the related share based compensation in the consolidated statement of operations. The aggregate number of shares reserved for issuance under the Stock Purchase Plan is 1,850,000. As of December 31, 2017, 1,504,445 shares had been issued.

Share-Based Compensation Expense

Share-based compensation expense is recorded in the same line of the consolidated statements of operations as the employee's cash compensation. The following tables present the detail of share-based compensation by line item in the consolidated statements of operations as well as by award type, for the years ended December 31, 2017, 2016 and 2015:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2017**	**2016**	**2015**
Cost of sales	$ 486	$ 553	$ 440
Sales and marketing	1,471	1,230	1,304
General and administrative	9,671	13,132	5,051
Research and development	929	1,051	419
Total	$ 12,557	$ 15,966	$ 7,214

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2017**	**2016**	**2015**
Stock options	$ 2,388	$ 2,021	$ 1,437
Time-based restricted stock awards	5,540	6,016	4,606
Performance-based restricted stock awards	462	5,716	—
Performance-based and market-based restricted stock units	2,904	948	—
Stock purchase plan	1,263	1,265	1,171
Total	$ 12,557	$ 15,966	$ 7,214

The income tax benefit related to this expense was $3.4 million, $4.3 million, and $1.6 million for the years ended December 31, 2017, 2016, and 2015, respectively.

Stock Options

The fair value of service-based stock options is determined using the Black-Scholes valuation model, with such value recognized as expense over the service period, which is typically four years, net of actual forfeitures. The fair value of market-based stock options is determined at the date of the grant using the Monte Carlo valuation methodology, with such value recognized as expense over the requisite service period adjusted for forfeitures as they occur. The Monte Carlo methodology incorporates into the valuation the possibility that the market condition may not be satisfied.

A summary of the Company's assumptions used in determining the fair value of the stock options granted during the year is shown in the following table.

	Year Ended December 31,		
Assumptions:	**2017**	**2016**	**2015**
Expected term (in years)	4.5	4.5	4.5
Expected volatility	31.2%	30.6% – 32.3%	31.1% – 31.6%
Risk free interest rate	1.93%	1.07% – 1.92%	1.37% – 1.54%
Dividend yield	—	—	—
Weighted average grant date fair value	$ 13.32	$ 11.79	$ 9.49

The expected term of the options granted is estimated based on a number of factors, including the vesting and expiration terms of the award, historical employee exercise behavior for both options that are currently outstanding and options that have been exercised or are expired, the historical volatility of the Company's common stock and an employee's average length of service. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award. Expected volatility is estimated based on the historical volatility of the Company's stock.

Summaries of the status of the Company's stock option plans as of December 31, 2017 and 2016 and changes during the year ended December 31, 2017 are presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2016	1,137,179	$ 36.05	
Granted	165,595	$ 46.10	
Exercised	(152,027)	$ 34.14	
Forfeited	(63,925)	$ 42.50	
Outstanding at December 31, 2017	1,086,822	$ 37.47	7.06
Vested and expected to vest at December 31, 2017	1,086,822	$ 37.47	7.06
Exercisable at December 31, 2017	608,320	$ 34.33	5.94

The table below summarizes the options outstanding and exercisable by exercise price range as of December 31, 2017:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$21.78 – $27.97	111,874	5.08	$ 24.12	111,874	$ 24.12
$27.98 – $32.28	110,400	5.36	$ 31.12	91,326	$ 30.90
$33.12 – $33.12	140,475	7.50	$ 33.12	70,242	$ 33.12
$33.24 – $36.25	121,875	6.74	$ 35.51	83,213	$ 35.71
$36.46 – $38.40	39,750	8.55	$ 37.92	12,376	$ 37.64
$38.82 – $38.82	150,000	5.20	$ 38.82	150,000	$ 38.82
$39.66 – $41.37	65,500	6.12	$ 40.23	43,000	$ 40.25
$42.89 – $42.89	22,000	8.74	$ 42.89	5,500	$ 42.89
$44.39 – $44.39	163,138	8.50	$ 44.39	40,789	$ 44.39
$46.10 – $46.10	161,810	9.50	$ 46.10	—	$ —
$21.78 – $46.10	1,086,822	7.06	$ 37.47	608,320	$ 34.33

As of December 31, 2017, the unamortized compensation expense relating to options granted and expected to be recognized was $2.9 million. This amount is expected to be recognized through July 2021 or over a weighted average period of approximately 1.5 years. The total intrinsic value of options exercised was $2.2 million, $4.3 million and $0.7 million for the years ended December 31, 2017, 2016 and 2015, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2017 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the shares that had exercise prices that were lower than the $54.70 closing price of the Company's stock on December 31, 2017. The aggregate intrinsic value of options outstanding was $18.7 million, $3.3 million and $8.0 million for the years ended December 31, 2017, 2016, and 2015, respectively. The aggregate intrinsic value of options exercisable was $12.4 million, $2.2 million and $4.3 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Time-based Restricted Stock Awards and Stock Units

During the year ended December 31, 2017, the Company granted to employees and non-employee directors 143,469 shares of restricted stock or stock units, which vest at various dates through December 2021. The compensation expense, which represents the fair value of the stock measured at the market price at the date of grant, is recognized on a straight-line basis over the vesting period, which is typically four years, net of actual forfeitures. The aggregate fair value of restricted stock that vested during the years ended December 31, 2017, 2016 and 2015 was $7.3 million, $7.2 million and $6.1 million, respectively. Unamortized compensation expense related to restricted stock amounted to $11.0 million at December 31, 2017, and is expected to be recognized over a weighted average period of approximately 2.4 years. The aggregate intrinsic value of restricted stock outstanding was $17.8 million, $13.0 million and $14.9 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Performance-based Restricted Stock Awards

The fair value of performance-based restricted stock awards is calculated based upon the closing stock price at the date of grant. Such value is recognized as expense over the derived requisite service period beginning in the period in which they are deemed probable to vest, net of actual forfeitures. Vesting probability is assessed based upon forecasted earnings and financial results.

During the years ended December 31, 2017 or 2016, the Company did not grant any performance-based restricted stock awards to employees. During the year ended December 31, 2015, the Company granted to employees 110,660 shares of performance-based restricted stock, which vest based upon the achievement of certain earnings or return on invested capital targets as of and for any of the years ended December 31, 2016, 2017, or 2018. Approximately $0.5 million and $5.7 million of compensation expense has been recorded for the years ended December 31, 2017 and 2016, respectively, associated with these performance-based vesting restricted stock awards. No expense was recorded for the year ended December 31, 2015, related to performance-based restricted stock. The fair value of performance-based stock awards that vested during the year ended December 31, 2017, was $4.9 million. No performance-based stock awards vested during the years ended December 31, 2016 or 2015. Unamortized compensation expense related to performance-based restricted stock amounted to $0.4 million at December 31, 2017, which is contingent upon meeting certain performance-based vesting criteria and is expected to be recognized over a weighted average period of approximately 1.0 year. The aggregate intrinsic value of performance-based restricted stock awards outstanding was $3.0 million, $7.0 million and $7.6 million for the years ended December 31, 2017, 2016, and 2015, respectively.

Performance-based and Market-based Restricted Stock Units

The Company's performance-based stock units ("PSUs") consist of awards that contain either market conditions or performance conditions as a requirement for vesting.

The fair value of market-based PSUs is determined at the date of the grant using the Monte Carlo valuation methodology, with any discounts for post-vesting restrictions estimated using the Chaffe Model. The Monte Carlo methodology incorporates into the valuation the possibility that the market condition may not be satisfied. Such value is recognized on a straight-line basis over the vesting period, net of actual forfeitures. During the years ended December 31, 2017 and 2016, the Company granted 94,902 and 96,245 shares, respectively, of market-based PSUs to executive officers and certain employees. The awards, if the market conditions are achieved, will be settled in shares of common stock, with one share of common stock issued per PSU if targets are achieved at the 100% level. Awards may be achieved at a minimum level of 50% and a maximum of 200%. The market conditions for the 2016 and 2017 awards are based on the Company's stock achieving certain total shareholder return targets relative to specified index companies during a 3-year performance period beginning in July 2016 and July 2017, respectively. The Company recorded $2.9 million and $0.9 million in compensation expense for the years ended December 31, 2017 and 2016, respectively, and no expense for the year ended December 31, 2015, related to market-based PSUs. Unamortized compensation expense for market-based PSUs amounted to $5.9 million at December 31, 2017, and is expected to be recognized over a weighted average period of approximately 2.0 years. The aggregate intrinsic value of market-based PSUs outstanding was $10.2 million, $3.5 million, and $0.0 million for the years ended December 31, 2017, 2016, and 2015, respectively.

The fair value of performance-based PSUs is calculated based upon the closing stock price at the date of grant. Such value is recognized as expense over the derived requisite service period beginning in the period in which the awards are deemed probable to vest. Vesting probability is assessed based upon forecasted earnings and financial results. During the year ended December 31, 2015, the Company granted 55,330 shares of performance-based PSUs to employees, which vest based upon the achievement of certain earnings or return on invested capital targets for the year ended December 31, 2018. The Company has not recorded any compensation expense for the years ended December 31, 2017, 2016, or 2015 related to these 2015 performance-based PSUs as the requisite service period has not yet begun. Unamortized compensation expense related to these 2015 performance-based PSUs

amounts to $1.8 million at December 31, 2017 and is expected to be recognized over a weighted average period of approximately 1.0 year, if all performance conditions are met. The aggregate intrinsic value of performance-based PSUs outstanding was $3.0 million, $2.0 million, and $2.2 million for the years ended December 31, 2017, 2016, and 2015, respectively.

A summary of the status of our restricted stock and stock units as of December 31, 2017 and 2016 and changes during the year ended December 31, 2017 are presented below:

	Time-based Awards and Units		Performance-based Awards		Performance-based or Market-based Stock Units	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2016	358,919	$ 38.27	192,310	$ 34.45	151,575	$ 43.54
Granted	143,469	$ 46.42	—	$ —	94,902	$ 54.49
Vested	(157,807)	$ 37.04	(136,980)	$ 34.99	—	$ —
Cancelled	(18,707)	$ 38.59	—	$ —	(4,613)	$ 49.09
Non-vested as of December 31, 2017	325,874	$ 42.44	55,330	$ 33.12	241,864	$ 47.73

16. Defined contribution plans and deferred compensation

Defined Contribution Plans

Orthofix Inc. sponsors a defined contribution plan (the "401(k) Plan") covering substantially all full time U.S. employees. The 401(k) Plan allows participants to contribute up to 15% of their pre-tax compensation, subject to certain limitations, with the Company matching 100% of the first 2% of the employee's base compensation and 50% of the next 4% of the employee's base compensation if contributed to the 401(k) Plan. During the years ended December 31, 2017, 2016 and 2015, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $2.0 million, $1.9 million and $2.0 million, respectively.

The Company also operates defined contribution pension plans for its international employees meeting minimum service requirements. The Company's expenses for such pension contributions during each of the years ended December 31, 2017, 2016 and 2015 were $1.1 million, $1.0 million and $1.1 million, respectively.

Deferred Compensation Plans

Under Italian Law, our Italian subsidiary accrues, on behalf of its employees, deferred compensation, which is paid on termination of employment. The accrual for deferred compensation is based on a percentage of the employee's current annual remuneration plus an annual charge. Deferred compensation is also accrued for the leaving indemnity payable to agents in case of dismissal, which is regulated by a national contract and is equal to approximately 3.5% of total commissions earned from the Company. The Company's relations with its Italian employees, who represent 21.5% of total employees at December 31, 2017, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. The Company is not a party to any other collective bargaining agreement.

The Orthofix Deferred Compensation Plan, administered by the Board of Directors of the Company, effective January 1, 2007, and as amended and restated effective January 1, 2009, is a plan intended to allow a select group of key management and highly compensated employees of the Company to defer the receipt of compensation that would otherwise be payable to them. As of January 1, 2011 the Company disallowed further contributions into the plan and any new plan participants. Distributions are made in accordance with the requirements of Code Section 409A.

The Company's expense for both deferred compensation plans described above was approximately $0.1 million for each of the years ended December 31, 2017, 2016, and 2015. There were $0.2 million in deferred compensation payments made in 2017, $0.1 million in 2016, and none in 2015. The balance in other long-term liabilities as of December 31, 2017 and 2016 was $1.4 million and $1.5 million, respectively, and represents the amount which would be payable if all the employees and agents had terminated employment at that date.

17. Income taxes

Income (loss) from continuing operations before provision for income taxes consisted of the following:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2017	2016	2015
U.S.	$ 27,774	$ 23,006	$ 15,480
Non-U.S.	8,617	(3,982)	(6,973)
Income before income taxes	$ 36,391	$ 19,024	$ 8,507

The provision for income taxes on continuing operations consists of the following:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2017	2016	2015
U.S.			
Current	$ 3,620	$ 558	$ 6,792
Deferred	20,222	9,296	(1,146)
	23,842	9,854	5,646
Non-U.S.			
Current	4,062	4,509	3,661
Deferred	1,196	1,164	1,542
	5,258	5,673	5,203
Income tax expense	$ 29,100	$ 15,527	$ 10,849

The rate reconciliation for continuing operations presented below is based on the U.S. federal income tax rate, rather than the Company's country of domicile tax rate. The Company believes, given the large proportion of taxable income earned in the United States, such disclosure is more meaningful.

	2017		2016		2015	
(U.S. Dollars, in thousands, except percentages)	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ 12,737	35.0%	$ 6,658	35.0%	$ 2,978	35.0%
State taxes, net of U.S. federal benefit	1,598	4.4	395	2.1	521	6.1
Foreign rate differential, including withholding taxes	(3,849)	(10.6)	(805)	(4.2)	(1,934)	(22.7)
Charges related to U.S. Government resolutions	—	—	2,050	10.8	—	—
Valuation allowances, net	3,548	9.7	6,149	32.3	10,952	128.7
Change in estimate on compensation expenses	—	—	(2,151)	(11.3)	—	—
Italian subsidiary intangible asset	(381)	(1.0)	(1,477)	(7.8)	(2,076)	(24.4)
Change of intention for foreign earnings	—	—	1,300	6.8	—	—
Domestic manufacturing deduction	(818)	(2.2)	—	—	(469)	(5.5)
Unrecognized tax benefits, net of settlements	6,002	16.5	3,049	16.0	406	4.8
Impact of the Tax Act	8,347	22.9	—	—	—	—
Other, net	1,916	5.3	359	1.9	471	5.5
Income tax expense/effective rate	$ 29,100	80.0%	$ 15,527	81.6%	$ 10,849	127.5%

On December 22, 2017, the Tax Act was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a U.S. corporate rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. The Company has calculated its best estimate of the impact of the Tax Act in the 2017 income tax provision in accordance with its understanding of the Tax Act and guidance available as of the date of this filing. As a result, the Company recorded $8.3 million of additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. The provisional amount related to the remeasurement of certain deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future was $8.6 million. The provisional amount related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings was zero. The Company also recorded a benefit of $0.3 million related to an income tax liability recorded in 2016 related to repatriation of earnings from our subsidiary in Puerto Rico.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, we have determine that the $8.6 million of the deferred tax expense recorded in connection with the remeasurement of certain deferred tax assets and liabilities and the zero transition tax on the mandatory deemed repatriation of foreign earnings was a provisional amount and a reasonable estimate at December 31, 2017. Additional work is necessary for a more detailed analysis of the Company's deferred tax assets and liabilities and its historical foreign earnings as well as potential correlative adjustments. Any subsequent adjustment to those amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete.

During 2016, the Company revised its estimate relating to the deductibility of certain compensation expenses. This change in estimate reduced income tax expense and increased net income from continuing operations by $2.4 million and increased earnings per share by $0.13 for the year ended December 31, 2016.

The Company's deferred tax assets and liabilities are as follows:

	December 31,	
(U.S. Dollars, in thousands)	2017	2016
Intangible assets and goodwill	$ 2,271	$ 2,628
Inventories and related reserves	11,298	17,665
Deferred revenue and cost of goods sold	6,816	11,263
Other accruals and reserves	2,336	4,066
Accrued compensation	4,054	6,747
Allowance for doubtful accounts	2,617	2,898
Accrued interest	—	4,621
Net operating loss carryforwards	42,675	37,930
Other, net	2,369	3,032
	74,436	90,850
Valuation allowance	(46,271)	(41,701)
Deferred tax asset	$ 28,165	$ 49,149
Withholding taxes	(381)	(648)
Property, plant and equipment	(4,469)	(1,176)
Deferred tax liability	(4,850)	(1,824)
Net deferred tax assets	$ 23,315	$ 47,325

The Company accounts for income taxes using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and income tax basis of assets and liabilities, and for operating losses and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the years in which those items are expected to be realized. Tax law and rate changes are recorded in the period such changes are enacted. The Company establishes a valuation allowance when it is more likely than not that certain deferred tax assets will not be realized in the foreseeable future.

The valuation allowance is primarily attributable to net operating loss carryforwards and temporary differences in certain foreign jurisdictions. The net increase in the valuation allowance of $4.6 million during the year principally relates to the increase of valuation allowances on net operating loss carryforwards in foreign jurisdictions.

The Company has state net operating loss carryforwards of approximately $11.6 million that will begin to expire in 2018. Additionally, the Company has net operating loss carryforwards in various foreign jurisdictions of approximately $167.3 million that begin to expire in 2018, the majority of which relate to the Company's Netherlands operations.

During 2016, the Company changed its intention related to unremitted foreign earnings in its Puerto Rico subsidiary and certain United Kingdom subsidiaries. As a result of the change in intention, the Company recorded $ 1.3 million of income tax expense for the remitted and unremitted earnings in each of these subsidiaries. During the first quarter of 2017, the Company changed its intention related to unremitted foreign earnings in its Seychelles subsidiary. The tax impact was minimal. The Company's current intention is to indefinitely reinvest substantially all of its other unremitted foreign earnings (residing outside Curaçao). As an entity

incorporated in Curaçao, "foreign earnings" refer to both U.S. and non-U.S. earnings. Furthermore, only income sourced in the U.S. is subject to U.S. income tax. Unremitted foreign earnings decreased from $372.5 million at December 31, 2016 to $335.7 million at December 31, 2017. Determining the additional income tax that may be payable if such earnings are repatriated is not practicable.

The Company records a benefit for uncertain tax positions when the weight of available evidence indicates that it is more likely than not, based on an evaluation of the technical merits, that the tax position will be sustained on audit. The tax benefit is measured as the largest amount that is more than 50% likely to be realized upon settlement. The Company re-evaluates income tax positions periodically to consider changes in facts or circumstances such as changes in or interpretations of tax law, effectively settled issues under audit, and new audit activity. The Company includes interest and any applicable penalties related to income tax issues as part of income tax expense in its consolidated financial statements.

The Company's unrecognized tax benefit was $22.5 million and $18.4 million for the years ended December 31, 2017 and 2016, respectively. The Company recorded interest and penalties on unrecognized tax benefits of $2.3 million, $2.1 million, and $0.2 million for the years ended December 31, 2017, 2016, and 2015, respectively, and had approximately $5.3 million and $3.0 million accrued for payment of interest and penalties as of December 31, 2017 and 2016, respectively. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. The Company believes it is reasonably possible that, in the next 12 months, the amount of unrecognized tax benefits related to the resolution of federal, state and foreign matters could be reduced by $2.4 million to $3.6 million as audits close and statutes expire.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2017, 2016, and 2015 follows:

(U.S. Dollars, in thousands)	2017	2016	2015
Balance as of January 1,	$ 18,384	$ 15,763	$ 15,597
Additions for current year tax positions	787	77	332
Increases (decreases) for prior year tax positions	3,361	2,551	(86)
Settlements of prior year tax positions	—	—	—
Expiration of statutes	(10)	(7)	(80)
Balance as of December 31,	$ 22,522	$ 18,384	$ 15,763

The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction and in certain state and foreign jurisdictions, including Italy and the United Kingdom. The statute of limitations with respect to federal and state tax filings is closed for years prior to 2012. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to 2012.

During the third quarter of 2015, the Internal Revenue Service commenced an examination of the Company's federal income tax return for 2012. The Company reasonably expects to conclude this examination in the first half of 2018 with no material impact on the financial statements. In October 2016, the Company was notified of an examination of its federal income tax return for 2013 and in December 2017, the examination for 2013 was concluded with no change. In November 2017, the Company was notified of an examination of its federal income tax return for 2015. The Company cannot reasonably determine if this examination, or any state and local tax examinations, will have a material impact on its financial statements and cannot predict the timing regarding resolution of these tax examinations.

18. Earnings per share (EPS)

Basic EPS is computed using the weighted average number of common shares outstanding during each of the respective years. Diluted EPS is computed using the weighted average number of common and common equivalent shares outstanding during each of the respective years using the treasury stock method. The difference between basic and diluted shares, if any, largely results from common equivalent shares, which represents the dilutive effect of the assumed exercise of certain outstanding share options, the assumed vesting of restricted stock granted to employees and directors, or the satisfaction of certain necessary conditions for contingently issuable shares (see Note 15).

For each of the three years ended December 31, 2017, no adjustments were made to net income (loss) for purposes of calculating basic and diluted EPS. The following is a reconciliation of the weighted average shares used in the diluted EPS computations.

	Year Ended December 31,		
	2017	2016	2015
Weighted average common shares-basic	18,117,405	18,144,019	18,795,194
Effect of diluted securities:			
Unexercised stock options and employee stock purchase plan	209,691	161,092	—
Unvested time-based restricted stock awards	123,592	138,291	—
Unvested performance-based restricted stock awards	48,057	19,759	—
Weighted average common shares-diluted	18,498,745	18,463,161	18,795,194

No adjustment was made for any common stock equivalents for the year ended December 31, 2015, because the effect would have been anti-dilutive. There were 418,859, 542,555 and 1,033,731 outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the years ended December 31, 2017, 2016 and 2015, respectively, because inclusion of these awards was anti-dilutive or, for performance-based and market-based awards, all necessary conditions have not been satisfied by the end of the respective period.

19. Quarterly financial data (unaudited)

	2017				
(U.S. Dollars, in thousands, except per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
Net sales	$ 102,738	$ 108,942	$ 105,247	$ 116,896	$ 433,823
Cost of sales	22,581	23,177	23,717	23,562	93,037
Gross profit	80,157	85,765	81,530	93,334	340,786
Operating expense	74,238	77,767	72,496	75,474	299,975
Operating income	5,919	7,998	9,034	17,860	40,811
Net income (loss) from continuing operations	(2,308)	4,735	3,348	1,516	7,291
Net income (loss)	$ (2,654)	$ 3,853	$ 3,456	$ 1,568	$ 6,223
Net income (loss) per common share — basic:					
Net income (loss) from continuing operations	$ (0.13)	$ 0.26	$ 0.18	$ 0.08	$ 0.40
Net income (loss)	$ (0.15)	$ 0.21	$ 0.19	$ 0.09	$ 0.34
Net income (loss) per common share — diluted:					
Net income (loss) from continuing operations	$ (0.13)	$ 0.26	$ 0.18	$ 0.08	$ 0.39
Net income (loss)	$ (0.15)	$ 0.21	$ 0.19	$ 0.08	$ 0.34

	2016				
(U.S. Dollars, in thousands, except per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
Net sales	$ 98,679	$ 104,075	$ 98,497	$ 108,537	$ 409,788
Cost of sales	22,137	22,516	19,880	23,320	87,853
Gross profit	76,542	81,559	78,617	85,217	321,935
Operating expense	69,467	84,254	69,346	77,801	300,868
Operating income (loss)	7,075	(2,695)	9,271	7,416	21,067
Net income (loss) from continuing operations	4,576	(6,346)	10,384	(5,117)	3,497
Net income (loss)	$ 3,840	$ (7,444)	$ 9,896	$ (3,236)	$ 3,056
Net income (loss) per common share — basic:					
Net income (loss) from continuing operations	$ 0.25	$ (0.35)	$ 0.57	$ (0.29)	$ 0.19
Net income (loss)	$ 0.21	$ (0.41)	$ 0.55	$ (0.18)	$ 0.17
Net income (loss) per common share — diluted:					
Net income (loss) from continuing operations	$ 0.24	$ (0.35)	$ 0.56	$ (0.29)	$ 0.19
Net income (loss)	$ 0.20	$ (0.41)	$ 0.54	$ (0.18)	$ 0.17

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COMMON STOCK

Approximately 262 shareholders of record.
Traded on the NASDAQ
Symbol: OFIX

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