ORTHOFIX INTERNATIONAL N V
Form 10-K
February 27, 2017

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, 2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Curaçao	98-1340767
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
7 Abraham de Veerstraat	
Curaçao	N/A
(Address of principal executive offices)	(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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, 2016, as reported by the Nasdaq Global Select Market, was approximately $767.8 million.

As of February 24, 2017, 17,946,539 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 pursuant to Regulation 14A in connection with the 2016 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, 2016

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Forward-Looking Statements

This 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 c 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 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 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 diversified, global medical device company focused on improving patients’ lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, we have four strategic business units (“SBUs”): BioStim, Biologics, Extremity Fixation and Spine Fixation. Our products are widely distributed by our sales representatives, distributors and subsidiaries. In addition, we are collaborating on research and development activities with leading clinical organizations such as Brown University, Sinai Hospital of Baltimore, Cleveland Clinic, Texas Scottish Rite Hospital for Children, and the Musculoskeletal Transplant Foundation (“MTF”).

We have administrative and training facilities in the United States (“U.S.”), Italy, Brazil, the United Kingdom (“U.K.”), France, Germany, and Puerto Rico and manufacturing facilities in the U.S. and Italy. We directly distribute products in the U.S., Italy, the U.K., Germany, France, Brazil, and Puerto Rico. 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 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, Biologics, Extremity Fixation, and Spine Fixation, which accounted for 43%, 14%, 25%, and 18%, respectively, of our total net sales in 2016. The chart below presents net sales, which includes product sales and marketing service fees, by SBU for each of the years ended December 31, 2016, 2015, and 2014.

Financial information regarding our reportable business segments and certain geographic information is included in Part II, Item 7 of this report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Note 15 to the Consolidated Financial Statements in Item 8 of this 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 (non-unions). 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. We currently have research and clinical studies underway to identify potential clinical indications for treating odontoid fractures and osteoarthritis of the knee. This SBU uses distributors and direct sales representatives to sell 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 initiatives are:

- Invest in basic science, clinical and evidence-based research to support broader indications for our stimulation products;
- Invest in product development for next generation bone growth therapy technology; and
- Expand patient access to our stimulation products through improved insurance coverage policies.

BioStim Products

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

Product	Primary Application
CervicalStim	Pulsed electromagnetic field ("PEMF") non-invasive cervical spinal fusion therapy used to enhance bone growth
SpinalStim	PEMF non-invasive lumbar spinal fusion therapy used to enhance bone growth
PhysioStim	PEMF non-invasive long bone healing therapy used to enhance bone growth in non-union factures

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. We have sponsored independent 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.

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 spinal fusion 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 lower thoracic and lumbar regions 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 (upper) 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 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. will be accompanied by a new application for mobile devices called Stim onTrack. Designed for use with smartphones and other mobile devices, the Stim onTrack tool helps patients follow their prescription, including daily treatment reminders and a device usage calendar. The mobile app also includes a first-to-market feature that enables physicians to receive real-time data on how their patients are adhering to prescribed treatment protocols. The Stim onTrack 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.

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 issued 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. We expect the validation of PEMF electrical stimulation from this leading surgical society will further support our efforts to expand the availability and use of the therapy to the many patients who can benefit from it.

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 physical configuration is designed for use on long bones.

A bone's regenerative power results in most fractures healing naturally within a few months. In certain situations, however, fractures do not heal or heal slowly, resulting in "non-unions." 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 bone healing therapy products are designed to use a low level of PEMF signals to activate the body's natural healing process.

Our systems offer portability, rechargeable battery operation, integrated component design, patient monitoring capabilities and the ability to cover a large treatment area without factory calibration for specific patient application.

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 regeneration tissue forms. Biologics markets its tissues primarily in the U.S. through a network of independent sales representatives to supply to hospitals and healthcare providers. 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 initiatives are:

- Continue to focus our sales and marketing efforts on the Trinity ELITE tissue form and leverage its market acceptance;
- Enhance and expand our distribution network through an increase in distributor partners in underpenetrated U.S. markets;
- Expand the accepted utilization of the Trinity ELITE tissue form in additional surgical applications; and
- Invest in and accelerate new tissue development projects with MTF.

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.

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 globally through a network of distributors and sales representatives to sell 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 initiatives are:

- Continue to focus our sales efforts on driving adoption of TL-HEX TrueLok Hexapod System and Galaxy Fixation System product lines;
- Develop and acquire premium products for temporary fixation, deformity correction, pediatric applications and foot and ankle procedures; and
- Increase global acceptance and use of our products through education and sales force expansion.

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
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	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 limb lengthening and deformity correction

TL-HEX TrueLok Hexapod System(“TL-HEX”)	Hexapod external fixation system for trauma and deformity correction with associated software
Galaxy Fixation System	External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps
PREFIX and PREFIX 2	External fixation range for temporary fixation of fractures in trauma
VeroNail Trochanteric Nailing System	Trochanteric titanium nailing system for hip fractures
Centronail Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail
Cemex	Bone cement

Product	Primary Application
OSCAR	Ultrasonic bone cement removal
Centronail Ankle Compression Nailing System (“ACN”)	An extension of the Centronail range of intermedullary nails
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 PHP Proximal Humeral Plate (“PHP”)	An innovative plating solution for fraction fixation of the proximal humerus
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 from outside the skin with minimal invasion into the body. These fixation devices use screws that are inserted into the bone on either side of the fracture site, to which the fixator body is attached externally. The bone segments are aligned by manipulating the external device using patented ball joints and, when aligned, are locked in place for stabilization. External fixation may also be used as temporary devices in complex trauma cases to stabilize the fracture prior to treating it definitively. We believe external fixation is among the most minimally invasive surgical options for fracture management. Also, we believe external fixation is the ideal treatment option for highly complex fractures, patients who have fractures close to joints, or patients with known risk factors or co-morbidities.

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. In 2009, improvements on size, flexibility and ease of use were implemented for the release of the LRS Advanced Limb Reconstruction System.

The Galaxy Fixation System, which was released in 2012, incorporates a streamlined combination of clamps with both pin-to-bar and bar-to-bar coupling capabilities that provide a complete range of applications and reduce inventory. It also includes specific units for the elbow, shoulder and wrist. While the rigidity and stability allows for use in definitive fixation, the design also addresses the need for rapid stabilization for temporary fixation in large trauma centers.

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 is 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 TL-HEX; therefore, external supports from both systems can be connected to each other when building fixation blocks.

Another one of our external fixation devices is the XCaliber fixator, which is made from a lightweight radiolucent material and provided in three configurations to cover long bone fractures, fractures near joints and ankle fractures. The radiolucency of XCaliber fixators allows X-rays to pass through the device and provides the surgeon with improved X-ray visualization of the fracture and alignment. These three configurations cover a broad range of fractures. The XCaliber fixators are provided pre-assembled in sterile kits to decrease time in the operating room.

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. We believe we have a full line of bone screws to meet the demands of the market. Adding to the XCaliber bone screw product line are also cylindrical screws first released for the US market and which we expect will be following in international markets. The type of screw is geared towards the trauma applications of the Galaxy Fixation System.

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 Centronail Titanium Nailing System, which is designed to stabilize fractures in the femur, tibia, supracondylar and humerus. Its main advantages are it is made of titanium, offers improved mechanical distal targeting and instrumentation and has a design that requires significantly less inventory.
- The Ankle Hindfoot Nail from Orthofix, which is an arthrodesis nailing system designed to improve upon the stability, simplicity, and flexibility of current hindfoot nails.
- The VeroNail product, which marks Orthofix’s entry into the intramedullary hip nailing market. Designed for use in hip fractures, the product provides a minimally-invasive screw and nail design intended 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 Contours LPS (Lapidus Plating System), which is sold in the U.S. and is intended for the correction of moderate to severe forefoot hallus valgus (HV), accompanying bunions and associated instability. The Lapidus Plating System consists of plates, screws and instrumentation. The anatomical plates are low-profile, titanium, (left and right) designed specifically for 1st metatarsocuneiform joint arthrodesis allowing compression across the joint achieved through a delta-shaped hole and compression screws. Lapidus Plating System screws are titanium, low-profile and self-tapping, and include locking, non-locking, and bone compression screws in a variety of lengths.

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 specializes in the design, development and marketing of 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 strategy for the Spine Fixation SBU is to accelerate the sales pace of our portfolio of surgical products that allow physicians to successfully treat a variety of spinal conditions. Our key initiatives are:

- Continue to expand U.S. sales force coverage, engagement and exclusivity; and
- Increase our new product introduction pace through product acquisitions, licensing agreements, and a more streamlined and productive new product development process.

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
Hallmark Anterior Cervical Plate System	A cervical plating system implanted during anterior cervical spine fusion procedures
Ascent LE Posterior Occipital Cervico-Thoracic (“POCT”) System	A system of pedicle screws and rods implanted during a posterior spinal fusion procedure involving the stabilization of several degenerated or deformed cervical vertebrae
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
PILLAR PL & TL PEEK Vertebral Body Replacement (“VBR”) System	Interbody devices for Posterior Lumbar Interbody Fusion (“PLIF”) and Transforaminal Lumbar Interbody Fusion (“TLIF”) procedures
FORZA Spacer System	Interbody devices for PLIF and TLIF procedures
FORZA PTC Spacer System	A posterior lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a Polyetheretherketones (“PEEK”) core to maintain imaging characteristics
PILLAR SA PTC PEEK Spacer System	A standalone 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
Firebird Deformity Correction System	An extension to the Firebird Spinal Fixation System that provides additional instrument and implant options for complex thoracolumbar spine procedures
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
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
Samba-Screw System	

	A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients
LONESTAR Cervical Stand Alone (“CSA”)	A stand-alone spacer system designed to provide the biomechanical strength to a tradition or minimal invasive Anterior Cervical Discectomy and Fusion (“ACDF”) procedure with less disruption of patient anatomy and 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 access the intervertebral disc space using a surgical approach from the patient’s side that disturbs fewer structures and tissues
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

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 Polyetheretherketones ("PEEK"). The majority of the implants that we offer are made of titanium metal. This includes the 3°, Reliant and Hallmark cervical plates. Additionally, the Spinal Fixation System ("SFS"), 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 which are implanted during posterior fusion procedures. The Firebird Modular and pre-assembled Spinal Fixation System is designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our product ProView MAP System. To complement our plate and screw based 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.

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 Brown University, 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 items, some of which have resulted in new products. We believe our policy of accommodating such requests enhances our reputation in the medical community.

In 2016, 2015 and 2014 we incurred $28.8 million, $26.4 million and $25.0 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 giving 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.

Corporate Compliance and Ethics Program

It is a 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. The program is intended to promote legal compliance and ethical business practices throughout our domestic and international businesses. It is designed to meet U.S. Sentencing Commission Guidelines for effective organizational compliance and ethics programs and to prevent and detect violations of applicable federal, state and local laws. Key elements of 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;
- 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 devices deemed to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, 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 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.

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 FDA’s Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device or as a biologic or as 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.

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.

Accreditation Requirements

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.

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. 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.

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 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 the domestic 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.

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

In addition, U.S. federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information such as medical records, and restrict the use and disclosure of that protected information. At the federal level, the Department of Health and Human Services 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.

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, Biologics, Extremity Fixation, and Spine Fixation. See the chart below for the distribution of sales between each of our SBUs for each of the years ended December 31, 2016, 2015, and 2014.

Sales, Marketing and Distributor Network

We have a broad distribution network comprised of direct sales representatives and distributors. This established distribution network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products worldwide in over 70 countries.

In our largest market, the U.S., our sales, marketing and distribution network is comprised of several sales forces addressing different business units. 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 Biologics, Extremity Fixation and Spine Fixation SBUs.

Outside the U.S., we employ direct sales representatives and contract with independent distributors. In order to provide support to our independent distribution 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, 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.

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 Biologics and BioStim SBUs, compete principally with similar products marketed by Zimmer Biomet, Inc.; DJO Global; and Bioventus. The Spine Fixation and Biologics HCT/P 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. We attempt to avoid competing based solely on price. Overall cost and medical effectiveness, innovation, reliability, after-sales 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 and orthopedic products, and subcontract the manufacture of a substantial portion of the component parts. We design and develop our spinal implant and AlloQuent Allograft HCT/Ps and subcontract the manufacture of a significant portion of our parts and instruments. 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. 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—Corporate Compliance 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, 2016, we had 938 employees worldwide. Of these, 632 were employed in the U.S. and 306 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 181 at December 31, 2016, 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. The investment is recorded in other long-term assets as an available for sale debt security and interest is recorded in interest income. For additional discussion see Note 6 to the Consolidated Financial Statements in Item 8 of this report.

Item 1A. Risk Factors

In addition to the other information contained in this 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 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 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.

If we fail to comply with the terms of our Corporate Integrity Agreement (and a related term of probation) we may be subject to criminal prosecution and/or exclusion from federal healthcare programs.

On June 6, 2012, in connection with our settlement of a U.S. government investigation and related qui tam complaint related to our bone growth therapy business, and our settlement of a U.S. government investigation and related qui tam complaint related to Blackstone Medical, Inc. (“Blackstone”), we entered into a five-year corporate integrity agreement (the “CIA”) with the Office of Inspector General of the Department of Health and Human Services (“HHS-OIG”). The CIA requires that we continue to maintain, during the term of the CIA, a compliance program designed to promote compliance with federal healthcare and FDA requirements. The CIA requires that we conduct certain compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations. We are also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. The CIA provides that in the event of an uncured material breach of the CIA, we could be excluded from participation in federal healthcare programs and/or subject to prosecution and subject to other monetary penalties, each of which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

In connection with this settlement and the guilty plea of our subsidiary, Orthofix Inc., to one felony count of obstruction of a federal audit (18 U.S.C. §1516), the court imposed a five-year term of probation on Orthofix Inc., with special conditions that mandate certain non-disparagement obligations and order Orthofix Inc. to continue complying with the terms of the CIA through the expiration of its term. In the event that we fail to satisfy these terms of probation, we could be subject to additional criminal penalties or prosecution, which could have a material adverse

effect on our business, financial condition, results of operations and cash flows.

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, expanding our Compliance department in both number and quality of personnel, 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 and abuse laws, and could face substantial penalties if we are determined not to have fully complied with such laws.

Healthcare fraud and abuse regulation 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);
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- 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 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 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 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 Centers for Medicare and Medicaid Services ("CMS"), in its ongoing implementation of the Medicare program, has obtained a related technical assessment of the medical study literature to determine how the literature addresses spinal fusion surgery in the Medicare population. The impact that this information will 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, 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 other regulatory clearances or approvals to develop and market a medical device can be costly and time-consuming, and is subject to the risk that such 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 is currently suspended until 2018;
- 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;

- 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; and
- establishes an Independent Payment Advisory Board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

The 2016 federal elections are likely to result in significant changes in and uncertainty with respect to implementation of the ACA and related regulations and policies, including possible repeal and replacement of the ACA. We cannot predict with any certainty the content, timing or effect of any legislation, regulations or policies seeking to amend, repeal and/or replace the ACA. However, it is possible that such legislation could adversely affect our business, cash flows, financial condition and/or results of operations.

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, Biologics, Extremity Fixation and Spine Fixation 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 2016, we continued to make improvements in revenues related to several new products we introduced to the market over the past three years, including the TL-HEX TrueLok Hexapod System, Galaxy Fixation System, Firebird NXG Spinal Fixation System, FORZA PTC Spacer System, Samba-Screw System, LONESTAR CSA, SKYHAWK Lateral Interbody Fusion System & Lateral Plate System, and CENTURION POCT System, 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 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 fails 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 and are generally prohibited from selling any products that compete with ours. 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 disproportionately affected by the global recession 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, 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 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 or successfully complete the acquisition.

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.

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.

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 2016 have had an unfavorable impact of $2.6 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 enter into currency hedges from time to time.

Our global operations may expose us to tax risks

We are subject to taxes in the United States 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 potential legislation to reform the U.S. taxation of international business; increases in non-deductible expenses; 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. and Victory Medical Limited 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 "2015 Credit Agreement") providing for a five-year secured revolving credit facility of $125 million. 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 United States and United Kingdom domiciled subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the 2015 Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the 2015 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 were in compliance with the negative covenants, and there were no events of default, at December 31, 2016 (and in prior periods). However, there can be no assurance that the Company would be able to meeting 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 increase growth by identifying, pursuing and implementing 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.

Risks Related to Our Domicile

Provisions of Curaçao law may have adverse consequences for our shareholders.

We are organized under the laws of Curacao and our corporate affairs are governed by our Articles of Association and the corporate law of Curaçao as laid down in Book 2 of the Curaçao Civil Code ("CCC"). Although certain of the provisions of the CCC resemble certain of the provisions of the corporation laws of a number of states in the U.S., principles of law relating to such matters as the validity of corporate procedures, the fiduciary duties of management and the rights of our shareholders may differ from those that would apply if the Company were incorporated in a jurisdiction within the U.S. For example, there is no statutory right of appraisal under Curaçao corporate law, nor is there a right for shareholders of a Curaçao corporation to sue a corporation derivatively. In addition, we have been advised by Curaçao counsel that it is unlikely that (1) the courts of Curaçao would enforce judgments entered by U.S. courts predicated upon the civil liability provisions of the U.S. federal securities laws and (2) actions can be brought in Curaçao in relation to liabilities predicated upon the U.S. federal securities laws.

Item 1B. Unresolved Staff Comments
None.

Item 2. Properties
Our principal facilities as of December 31, 2016 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	Curitiba, Brazil	1,065	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 12 to the Consolidated Financial Statements in Item 8 of this report.

Item 4. Mine Safety Disclosures
Not applicable.

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PART II

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

Market for Our Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "OFIX." As of February 24, 2017 we had 290 holders of record of our common stock. The closing price of our common stock on February 24, 2017 was $38.01. 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
2015		
First Quarter	$35.89	$28.31
Second Quarter	37.84	31.84
Third Quarter	40.41	31.83
Fourth Quarter	41.71	32.51
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

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.

Repurchases of Common Stock

The Company's Board of Directors authorized a share repurchase plan in the fourth quarter of 2015 for the purchase of up to $75 million of our common stock through September 2017. We 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 Securities Exchange Act of 1934, as amended ("the Exchange Act"). Repurchases were made from cash on hand and cash generated from operations. The following table sets forth information with respect to shares of our common stock purchased by the Company during the fourth quarter of 2016.

Period	Average Price	Total Number

	Total Number of Shares Purchased	Paid Per Share	of Shares Purchased under Approved Stock Repurchase Program	Maximum Dollar Value of Shares Yet to be Purchased under Approved Stock Repurchase Program
October 2016	211,671	$ 39.82	211,671	$ —
November 2016	—	—	—	—
December 2016	—	—	—	—
	211,671	$ 39.82		$ —

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2016.

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, 2011. 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.

	Year ended December 31,				
(U.S. Dollars, in thousands, except margin and per share data)	2016	2015	2014	2013	2012
Consolidated operating results					
Net sales	$409,788	$396,489	$402,277	$397,611	$440,189
Gross profit	321,935	309,964	303,365	290,699	339,463
Gross margin	79 %	78 %	75 %	73 %	77 %
Operating income (loss) (1)	21,067	9,255	17,136	(11,192)	74,872
Net income (loss) from continuing operations	3,497	(2,342)	(3,744)	(18,205)	45,121
Net loss from discontinued operations	(441)	(467)	(4,793)	(10,607)	(2,269)
Net income (loss) (2)	$3,056	$(2,809)	$(8,537)	$(28,812)	$42,852
Net income (loss) per common share – basic					
Net income (loss) from continuing operations	$0.19	$(0.12)	$(0.20)	$(0.97)	$2.38
Net loss from discontinued operations	(0.02)	(0.03)	(0.26)	(0.57)	(0.12)
Net income (loss)	$0.17	$(0.15)	$(0.46)	$(1.54)	$2.26
Net income (loss) per common share – diluted					
Net income (loss) from continuing operations	$0.19	$(0.12)	$(0.20)	$(0.97)	$2.33
Net loss from discontinued operations	(0.02)	(0.03)	(0.26)	(0.57)	(0.12)
Net income (loss)	$0.17	$(0.15)	$(0.46)	$(1.54)	$2.21

(1) Includes the following:

- Charges related to U.S. Government resolutions in 2016 and 2012 of $14.4 million and $1.3 million, respectively
- Legal, accounting, and other professional fees incurred in 2016, 2015, 2014, and 2013 of $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
- Goodwill impairment charge in 2013 of $19.2 million

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

	As of December 31,				
(U.S. Dollars, in thousands)	2016	2015	2014	2013	2012
Consolidated financial position					
Total assets	$372,103	$400,222	$392,956	$411,975	$464,546
Long-term debt	—	—	—	20,000	20,016
Shareholders' equity	263,477	290,311	299,627	295,863	356,439

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 Form 10-K.

Executive Summary

We are a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, we have four strategic business units ("SBUs") that are also our reporting segments: BioStim, Biologics, Extremity Fixation and Spine Fixation. Our products are distributed by our sales representatives and distributors in over 70 countries.

Our corporate objectives include leveraging our significantly expanded distribution footprint in each of our SBUs and the new product pipelines in our Extremity Fixation and Spine Fixation businesses to accelerate growth in each of our SBUs. Additionally, we intend to increase the utilization of our BioStim products, which we estimate are currently only prescribed for one third of the patients who are on label and can benefit from its use. We believe the North American Spine Society's ("NASS") positive coverage recommendation, along with our recently launched next generation Spinal Stimulation and Cervical Stimulation devices, will help these patients gain access to this proven therapy.

Notable highlights and accomplishments in 2016 include the following:

- Net sales were $409.8 million, an increase of 3.4% on a reported basis and 4.0% on a constant currency basis; specifically, we grew BioStim, our largest and most profitable SBU, and Extremity Fixation above the market growth rates.
- Net margin, a non-GAAP financial measure, which is calculated by subtracting sales and marketing expense from gross profit, was $140.6 million, an increase of 6.6% from the prior year; net income from continuing operations was $3.5 million, an increase of $5.8 million from the prior year.
- We received both US FDA and European Union CE Mark approval for our next generation of spinal and cervical stimulation devices.
- We completed our $75 million share repurchase program.
- We completed Project Bluecore, which positions us to explore and execute on strategic opportunities.
- We initiated a planned restructuring, which primarily affects our Extremity Fixation SBU, to streamline costs, improve operational performance, and wind down a non-core business.
- We are exiting an era of heavy investment with a rebuilt infrastructure, robust compliance program, and strong financial controls.

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,		
	2016	2015	2014

	(%)	(%)	(%)
Net sales	100.0	100.0	100.0
Cost of sales	21.4	21.8	24.6
Gross profit	78.6	78.2	75.4
Sales and marketing	44.2	44.9	41.4
General and administrative	18.2	22.0	19.6
Research and development	7.0	6.7	6.2
Restatements and related costs	0.5	2.3	3.9
Charges related to U.S. Government resolutions	3.6	—	—
Operating income	5.1	2.3	4.3
Net income (loss) from continuing operations	0.9	(0.6)	(0.9)
Net loss from discontinued operations	(0.2)	(0.1)	(1.2)
Net income (loss)	0.7	(0.7)	(2.1)

Net Sales by Strategic Business Unit

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

				Percentage Change			
				2016/2015	2016/2015	2015/2014	2015/2014
(U.S Dollars, in thousands)	2016	2015	2014	Reported	Constant Currency	Reported	Constant Currency
BioStim	$176,561	$164,955	$154,676	7.0 %	7.0 %	6.6 %	6.7 %
Biologics	57,912	59,832	55,881	-3.2%	-3.2 %	7.1 %	7.1 %
Extremity Fixation	102,683	96,034	109,678	6.9 %	9.6 %	-12.4 %	1.0 %
Spine Fixation	72,632	75,668	82,042	-4.0%	-4.0 %	-7.8 %	-7.3 %
Net sales	$409,788	$396,489	$402,277	3.4 %	4.0 %	-1.4 %	2.4 %

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, doctors and other healthcare providers, and patients.

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

2015 Compared to 2014

Net sales increased $10.3 million or 6.6% due to additional market penetration through our direct and distributor sales channels in 2015.

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 primarily in the U.S. through a network of distributors and independent sales representatives to supply to hospitals, doctors, and other healthcare providers.

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

2015 Compared to 2014

Net sales increased $4.0 million or 7.1%

- An increase in the total number of independent distributors in 2015
- Increased sales from existing distributors in 2015
- Partially offset by anticipated competitive pricing pressures, resulting in a 3.6% reduction in average selling price

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, doctors, and other health providers.

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

2015 Compared to 2014

Net sales decreased $13.6 million or 12.4%

- Includes the negative impact from foreign currency translation of $14.7 million in 2015; on a constant currency basis, net sales increased $1.1 million, or 1.0%, due to increased demand for our products
    - Partially offset by the impact of macroeconomic challenges in certain of our markets

Spine Fixation

Spine Fixation specializes in the design, development and marketing of 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, doctors and other healthcare providers.

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

2015 Compared to 2014

Net sales decreased $6.4 million or 7.8%

- Short-term negative impact from our reorganization of the U.S. sales force in late 2014
- Decrease in cash collections in 2015 from distributors whose revenue is recognized upon cash receipt
- Partially offset by revenue from additional distributors added in 2015 as part of our sales force rebuilding and expansion initiatives

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Net Margin

(U.S Dollars, in thousands)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
Gross profit	$321,935	$309,964	$303,365	3.9%	2.2 %
Sales and marketing	181,287	178,080	166,547	1.8%	6.9 %
Net margin	$140,648	$131,884	$136,818	6.6%	-3.6 %
Gross margin	78.6 %	78.2 %	75.4 %	0.4%	2.8 %
Net margin	34.3 %	33.3 %	34.0 %	1.1%	-0.7 %

2016 Compared to 2015

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

2015 Compared to 2014

Net margin decreased $4.9 million

- Gross profit increased $6.6 million
  - Increase in sales mix from our BioStim and Biologics SBUs, which have higher margins, relative to our other SBUs
  - Improved inventory management and operating efficiencies
- Sales and marketing expense increased $11.5 million
  - Increase in sales and field-based training personnel as part of the rebuilding and expansion of our sales organization
  - Sales commission quota overachievement in certain territories, resulting in increased compensation costs, including commissions, of approximately $6.8 million
  - Increase in bad debt expense of $2.4 million, of which $2.0 million related to Puerto Rico

The following table presents net margin by reporting segment. The reasons for the changes in 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)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
BioStim	$75,469	$67,878	$66,096	11.2 %	2.7 %

Biologics	26,891	27,226	26,629	-1.2 %	2.2 %
Extremity Fixation	30,526	29,493	31,586	3.5 %	-6.6 %
Spine Fixation	8,650	8,547	14,243	1.2 %	-40.0 %
Corporate	(888)	(1,260)	(1,736)	-29.5%	-27.4 %
Net margin	$140,648	$131,884	$136,818	6.6 %	-3.6 %

General and Administrative Expense

(U.S Dollars, in thousands)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
General and administrative	$74,404	$87,157	$79,074	-14.6%	10.2 %
As a percentage of net sales	18.2 %	22.0 %	19.6 %	-3.8 %	2.4 %

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

2015 Compared to 2014

General and administrative expense increased $8.1 million

- Legal settlements totaling $5.3 million in 2015
- Increased spending of $1.6 million associated with the strengthening of our infrastructure as part of Project Bluecore
- Increased share-based compensation expense of $1.5 million
- Increased professional fees and personnel costs as part of our internal controls remediation efforts
- Overall decrease partially offset by the impact of changes in foreign exchange rates

Research and Development Expense

(U.S Dollars, in thousands)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
Research and development	$28,803	$26,389	$24,994	9.1%	5.6 %
As a percentage of net sales	7.0 %	6.7 %	6.2 %	0.3%	0.5 %

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

2015 Compared to 2014

Research and development expense increased $1.4 million due primarily to increased consulting fees and clinical trial costs as we invested resources to identify potential new clinical indications for our PEMF technology and for new product developments in Spine Fixation and Extremity Fixation.

Restatements and Related Costs

(U.S Dollars, in thousands)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
Restatements and related costs	$2,005	$9,083	$15,614	-77.9%	-41.8 %
As a percentage of net sales	0.5 %	2.3 %	3.9 %	-1.8 %	-1.6 %

2016 Compared to 2015

Restatements 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

2015 Compared to 2014

Restatements and related costs decreased $6.5 million due to decreased consulting fees relating to our two prior financial restatements, the resulting SEC Investigation, and the Securities Class Action Complaint.

Charges Related to U.S. Government Resolutions

(U.S Dollars, in thousands)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
Charges related to U.S. Government resolutions	$14,369	$—	$—	—	—
As a percentage of net sales	3.6 %	0.0 %	0.0 %	3.6%	0.0 %

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 12 to the Consolidated Financial Statements.

Non-operating Income (Expense)

(U.S Dollars, in thousands)	2016	2015	2014	Percentage Change 2016/2015	2015/2014
Interest income (expense), net	$763	$(489)	$(1,785)	-256.0%	-72.6 %
Other income (expense), net	(2,806)	(259)	(2,895)	983.4 %	-91.1 %

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. 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 2016, we recorded an other-than-temporary impairment on the eNeura debt security of $2.7 million. For additional discussion see Note 10 to the Consolidated Financial Statements in Item 8 of this report.

Income Taxes

				Percentage Change	
(U.S Dollars, in thousands)	2016	2015	2014	2016/2015	2015/2014
Income tax expense	$15,527	$10,849	$16,200	43.1%	-33.0%
Effective tax rate	81.6%	127.5%	130.1%	—	—

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

2015 Effective Tax Rate

The primary factors affecting our effective tax rate for 2015 were as follows:

- Expiration of certain foreign net operating loss carryforwards and current period losses in jurisdictions where we do not currently receive a tax benefit
- The mix of earnings among tax jurisdictions
- Recording a valuation allowance on the net deferred tax assets in Puerto Rico

Liquidity and Capital Resources

Cash and cash equivalents at December 31, 2016 were $39.6 million compared to $63.7 million at December 31, 2015.

	Year Ended December, 31,		
(U.S Dollars, in thousands)	2016	2015	Change
Net cash from operating activities	$44,707	$43,610	$1,097
Net cash from investing activities	(21,947)	(38,349)	16,402
Net cash from financing activities	(46,112)	24,728	(70,840)
Effect of exchange rate changes on cash	(739)	(3,141)	2,402
Net change in cash and cash equivalents	$(24,091)	$26,848	$(50,939)

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)	2016	2015	Change
Net cash from operating activities	$44,707	$43,610	$1,097
Capital expenditures	(18,334)	(27,899)	9,565
Free cash flow	$26,373	$15,711	$10,662

Operating Activities

Cash flows from operating activities increased $1.1 million

- Increase in net income of $5.9 million
- Net increase of $21.8 million for non-cash gains and losses, primarily related to increases in deferred income taxes and share-based compensation expense
- Overall increase partially offset by a decrease of $26.6 million relating to the funding of the U.S. Government resolutions discussed below and changes in working capital accounts, primarily attributable to changes in inventories, prepaid expenses and other current assets, trade accounts payable, and other current liabilities

Our two primary working capital accounts are trade accounts receivable and inventory. Day's sales in receivables were 52 days at December 31, 2016 compared to 55 days at December 31, 2015. Inventory turns were 1.4 times as of December 31, 2016 compared to 1.5 times at December 31, 2015.

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 12 to the Notes to the Consolidated Financial Statements.

Investing Activities

Cash flows from investing activities increased $16.4 million

- Purchase of the eNeura debt security for $15.3 million in 2015
- Decrease in capital expenditures of $9.6 million, largely as a result of completing Project Bluecore; in 2017, we expect capital expenditures to be in the range of $13 million to $16 million
- Overall increase partially offset by proceeds of $4.8 million from the sale of assets in 2015
- Overall increase also partially offset by 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

Infrastructure Initiative

In 2014, we initiated "Project Bluecore," a multi-year, company-wide process and systems improvement initiative to improve the reliability and efficiency of our systems, processes, and reporting as well as drive down overhead expenses. Project Bluecore had numerous work streams primarily focused around re-implementing our Oracle ERP system worldwide, improving our financial controls and reporting, streamlining our order to cash processes and collections, and optimizing our supply chain for cost reductions and field inventory visibility, among other upgrades. This project was completed in 2016 following the re-implementation of our Oracle ERP platform in the U.S. and Italy. Over the life of the project, we spent approximately $27.5 million. Of this amount, approximately $18.6 million was capitalized.

Financing Activities

Cash flows from financing activities decreased $70.8 million

- Repurchases of our common stock under the share repurchase plan authorized by the Board of Directors; in 2016, we repurchased approximately 1.5 million shares for $63.4 million as compared to the repurchase of 0.3 million shares for $11.6 million in 2015
- The removal of the restricted cash requirement associated with our credit facility in 2015, which resulted in a decrease in cash flows from financing activities of $34.4 million when compared to 2015
- Overall decrease partially offset by an increase in net proceeds of $13.6 million from the issuance of common shares and by payments of $1.8 million in debt issuance costs during 2015 associated with our credit facility

Credit Facilities

On August 31, 2015, we entered into a five year $125 million secured revolving credit facility. As of December 31, 2016, 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 ($6.1 million and $6.3 million) at December 31, 2016 and 2015, 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.

Share Repurchase Plan

In August 2015, our Board of Directors authorized a share repurchase plan, authorizing the purchase of up to $75 million of our common stock through September 2017. We completed the share repurchase plan in the fourth quarter of 2016. Over the life of the plan, we repurchased 1,838,672 shares of common stock for $75.0 million, at an average purchase price of $40.79.

Unremitted Foreign Earnings

During 2016, we changed our intention related to unremitted earnings in our Puerto Rico subsidiary and certain of our United Kingdom subsidiaries. As a result of the change in intention, we recorded $1.3 million of income tax expense for the remitted and unremitted earnings of each of these subsidiaries. Our current intention is to indefinitely reinvest substantially all of our 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 increased from $184.6 million at December 31, 2015 to $198.9 million at December 31, 2016. 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, 2016:

	Payments Due by Period				
(U.S Dollars, in thousands)	Total	2017	2018 - 2020	2021	2022 and thereafter
Operating leases	$8,377	$3,009	$5,260	$108	$ —
Inventory purchase commitments (1)	1,170	1,170	—	—	—
Total (2)	$9,547	$4,179	$5,260	$108	$ —

(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, 2016, all of which are due in 2017.

(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 $21.4 million as of December 31, 2016 have been excluded from the contractual obligations table above. For further information, see Note 18 to the Notes to the Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of December 31, 2016, 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, 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 placed on and accepted by the patient and all perfunctory 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.

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, 2016 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, 2016 would result in an increase or decrease to net sales of $0.7 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, 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, 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, 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.

During 2016, we voluntarily changed our annual goodwill testing date from the end of the fourth quarter, December 31, to the beginning of the fourth quarter, October 1. We believe this change in the method of applying the accounting principle is preferable, as it more closely aligns the annual impairment testing date with the most current information from the budgeting and strategic planning process and provides management with additional time to complete its annual assessment in advance of our year-end reporting. The change did not delay, accelerate or avoid an impairment charge. This change was not applied retrospectively, as it is impracticable to do so because retrospective application would require application of significant estimates and assumptions with the use of hindsight. Accordingly, the change has been applied prospectively.

In the fourth quarter of 2016, we performed a quantitative impairment analysis that did not result in an impairment charge. In 2015 and 2014, we performed qualitative assessments 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.

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 securities 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 $1.9 million, whereas a decrease in the discount rate of 5% would result in an increase in the fair value of the debt security of $1.9 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.

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, 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 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 performance 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 it 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 the 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 filing 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.

Net Margin

Net margin is a non-GAAP financial measure, which is calculated by subtracting sales and marketing expense from gross profit. 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 vary sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We 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. Through December 30, 2016, we had a cross-currency swap in place to minimize foreign currency exchange risk related to a Euro denominated intercompany note. Both the cross-currency swap and the Euro denominated intercompany note matured on December 30, 2016.

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, 2016, 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, 2016, we recorded a foreign currency loss of less than $0.1 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 unfavorably impacted during the years ended December 31, 2016 and 2015 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations during 2016 and 2015 versus the same periods in 2015 and 2014. 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 $1.0 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 $1.0 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 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, 2016 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, 2016, 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 2016 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Orthofix International N.V.

We have audited Orthofix International N.V.'s (the Company) internal control over financial reporting as of December 31, 2016, 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). Orthofix International N.V.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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.

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.

In our opinion, Orthofix International N.V. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Orthofix International N.V. as of December 31, 2016 and 2015, and 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, 2016 of Orthofix International N.V. and our report dated February 27, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas

February 27, 2017

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.

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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 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†	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).
10.4	

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).

10.5† 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).

10.6† 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).

Exhibit Number	Description
10.7	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).
10.8†	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).
10.9	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).
10.10	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)
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17	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).
10.18	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).
10.19	

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).

10.20 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).

10.21 Form of Employee Performance Vesting Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 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).

10.22 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).

Exhibit Number	Description
10.23	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).
10.24	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).
10.25	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).
10.26	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).
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).
10.32	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).
10.33	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).

10.34 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).

10.35 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).

10.36* Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley R. Mason.

10.37 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).

Exhibit Number	Description
10.38	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).
10.39	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).
10.40*	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Doug Rice.
10.41	Employment Agreement, effective as of April 24, 2015, by and between Orthofix Inc. and Doug Rice (filed as an exhibit to the Company's current report on Form 8-K filed April 29, 2015 and incorporated herein by reference).
10.42	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).
10.43*	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Michael M. Finegan.
10.44	Form of Amendment to Stock Option Agreements (for Michael M. Finegan) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.45	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).
10.46	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).
10.47	Amended and Restated Employment Agreement, effective as of November 20, 2014, by and between Orthofix International N.V., Davide Bianchi and, solely for purposes of certain specified provisions, Orthofix AG (filed as an exhibit to the Company's current report on Form 8-K filed November 28, 2014 and incorporated herein by reference).
10.48	Employment Agreement, effective as of April 15, 2015, by and between Blackstone Medical, Inc. and Robert Allen Goodwin II (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).
10.49*	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Robert Allen Goodwin II.
10.50*	

	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley V. Niemann.
10.51*	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Raymond Fujikawa.
10.52*	Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Kimberley Elting.
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).
10.54	Employment Agreement, entered into on December 9, 2010, by and between Orthofix Inc. and Jeffrey M. Schumm (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).

Exhibit Number	Description
10.55	Settlement Agreement, entered into on June 6, 2012, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, the TRICARE Management Activity, through its General Counsel, the Office of Personnel Management , in its capacity as administrator of the Federal Employees Health Benefits Program, the United States Department of Veteran Affairs, Orthofix International N.V. and relator Jeffrey J. Bierman (filed as an exhibit to the Company's current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
10.56	Amended Plea Agreement entered into on December 14, 2012, among the United States Attorney for the District of Massachusetts, the Department of Justice and Orthofix Inc. (filed as an exhibit to the Company's current report on Form 8-K filed December 19, 2012 and incorporated herein by reference).
10.57	Corporate Integrity Agreement, entered into on June 6, 2012, between the Office of Inspector General of the Department of Health and Human Services and Orthofix International N.V. (filed as an exhibit to the Company's current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
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, 2016 filed on February 27, 2017, 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 27, 2017 By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer, Director

Dated: February 27, 2017 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	President and Chief Executive Officer, Director	February 27, 2017
Bradley R. Mason	(Principal Executive Officer)	
/s/ DOUG RICE	Chief Financial Officer	February 27, 2017
Doug Rice	(Principal Financial and Accounting Officer)	
/s/ RONALD A. MATRICARIA	Chairman of the Board of Directors	February 27, 2017
Ronald A. Matricaria		
/s/ LUKE FAULSTICK	Director	February 27, 2017
Luke Faulstick		
/s/ JAMES HINRICHS	Director	February 27, 2017
James Hinrichs		
/s/ GUY JORDAN	Director	February 27, 2017
Guy Jordan		
/s/ ALEXIS V. LUKIANOV	Director	February 27, 2017

Alexis V. Lukianov		
/s/ LILLY MARKS	Director	February 27, 2017
Lilly Marks		
/s/ ANTHONY MARTIN	Director	February 27, 2017
Anthony Martin		
/s/ MICHAEL E. PAOLUCCI Michael E. Paolucci	Director	February 27, 2017
/s/ MARIA SAINZ Maria Sainz	Director	February 27, 2017

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

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ORTHOFIX INTERNATIONAL N.V.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Orthofix International N.V.

We have audited the accompanying consolidated balance sheets of Orthofix International N.V. ("the Company") as of December 31, 2016 and 2015, and 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, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Orthofix International N.V. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for share-based payments to employees as a result of the early adoption of the amendments to the FASB Accounting Standards Codification resulting from Accounting Standards Update No. 2016-09, "Improvements to Employee Share-Based Payment Accounting," effective January 1, 2016.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Orthofix International N.V.'s internal control over financial reporting as of December 31, 2016, 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 27, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas

February 27, 2017

ORTHOFIX INTERNATIONAL N.V.

Consolidated Balance Sheets as of December 31, 2016 and 2015

(U.S. Dollars, in thousands except share and per share data)	2016	2015
Assets		
Current assets		
Cash and cash equivalents	$39,572	$63,663
Restricted cash	14,369	—
Trade accounts receivable, less allowances of $8,396 and $8,923 at December 31, 2016 and 2015, respectively	57,848	59,839
Inventories	63,346	57,563
Prepaid expenses and other current assets	19,238	31,187
Total current assets	194,373	212,252
Property, plant and equipment, net	48,916	52,306
Patents and other intangible assets, net	7,461	5,302
Goodwill	53,565	53,565
Deferred income taxes	47,325	57,306
Other long-term assets	20,463	19,491
Total assets	$372,103	$400,222
Liabilities and shareholders' equity		
Current liabilities		
Trade accounts payable	$14,353	$16,391
Other current liabilities	69,088	65,597
Total current liabilities	83,441	81,988
Other long-term liabilities	25,185	27,923
Total liabilities	108,626	109,911
Contingencies (Note 12)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 17,828,155 and 18,659,696 issued and outstanding as of December 31, 2016 and 2015, respectively	1,783	1,866
Additional paid-in capital	204,095	232,126
Retained earnings	64,179	62,551
Accumulated other comprehensive loss	(6,580)	(6,232)
Total shareholders' equity	263,477	290,311
Total liabilities and shareholders' equity	$372,103	$400,222

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

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ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Operations and Comprehensive Income (Loss)

For the years ended December 31, 2016, 2015 and 2014

(U.S. Dollars, in thousands, except share and per share data)	2016	2015	2014
Net sales	$409,788	$396,489	$402,277
Cost of sales	87,853	86,525	98,912
Gross profit	321,935	309,964	303,365
Sales and marketing	181,287	178,080	166,547
General and administrative	74,404	87,157	79,074
Research and development	28,803	26,389	24,994
Restatements and related costs	2,005	9,083	15,614
Charges related to U.S. Government resolutions (Note 12)	14,369	—	—
Operating income	21,067	9,255	17,136
Interest income (expense), net	763	(489)	(1,785)
Other expense, net	(2,806)	(259)	(2,895)
Income before income taxes	19,024	8,507	12,456
Income tax expense	(15,527)	(10,849)	(16,200)
Net income (loss) from continuing operations	3,497	(2,342)	(3,744)
Discontinued operations (Note 12)			
Loss from discontinued operations	(638)	(1,827)	(7,157)
Income tax benefit	197	1,360	2,364
Net loss from discontinued operations	(441)	(467)	(4,793)
Net income (loss)	$3,056	$(2,809)	$(8,537)
Net income (loss) per common share—basic			
Net income (loss) from continuing operations	$0.19	$(0.12)	$(0.20)
Net loss from discontinued operations	(0.02)	(0.03)	(0.26)
Net income (loss) per common share—basic	$0.17	$(0.15)	$(0.46)
Net income (loss) per common share—diluted			
Net income (loss) from continuing operations	$0.19	$(0.12)	$(0.20)
Net loss from discontinued operations	(0.02)	(0.03)	(0.26)
Net income (loss) per common share—diluted	$0.17	$(0.15)	$(0.46)
Weighted average number of common shares:			
Basic	18,144,019	18,795,194	18,459,054
Diluted	18,463,161	18,795,194	18,459,054
Other comprehensive loss, before tax			
Unrealized gain (loss) on derivative instrument	(360)	202	307
Unrealized loss on debt securities	(1,744)	(3,348)	–
Reclassification adjustment for loss on debt securities in net income	2,727	–	–
Currency translation adjustment	(726)	(3,907)	(4,133)
Other comprehensive loss before tax	(103)	(7,053)	(3,826)
Income tax related to items of other comprehensive loss	(245)	1,203	(59)
Other comprehensive loss, net of tax	(348)	(5,850)	(3,885)
Comprehensive income (loss)	$2,708	$(8,659)	$(12,422)

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, 2016, 2015 and 2014

(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, 2013	18,102,335	$ 1,810	$ 216,653	$ 73,897	$ 3,503	$ 295,863
Net loss	—	—	—	(8,537)	—	(8,537)
Other comprehensive loss, net of tax	—	—	—	—	(3,885)	(3,885)
Share-based compensation	—	—	5,724	—		