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 b