ORTHOFIX INTERNATIONAL N V
Form 10-K
February 26, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017

or

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

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Curaçao	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, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

Orthofix International N.V.

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

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Forward-Looking Statements

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

Trademarks

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

PART I

Item 1. Business

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

Company Overview

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

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

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

Available Information and Orthofix Website

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

Business Segments

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

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

BioStim

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

BioStim Strategy

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

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

BioStim Products

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

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

Spinal Therapy

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

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

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

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

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

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

Orthopedic Therapy

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

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

Future Applications

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

Extremity Fixation

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

Extremity Fixation Strategy

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

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

Extremity Fixation Products

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

Product	Primary Application
External Fixator	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus, XCaliber and Gotfried P.C.C.P
Eight-Plate + Guided Growth System	The 2nd generation plate for treatment for bowed legs or knock knees of children
LRS Advanced Limb Reconstruction System	External fixation for limb lengthening and corrections of deformity
TrueLok	Ring fixation system for trauma, limb lengthening, and deformity correction
TL-HEX TrueLok Hexapod System (“TL-HEX”)	Hexapod external fixation system for trauma and deformity correction with associated software
HEX RAY	An innovative software to manage pre-operation and post-operation planning in connection with the TL-HEX system
Galaxy Fixation System	External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps
VeroNail Trochanteric Nailing System	Trochanteric titanium nailing system for hip fractures
Centronail Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail

Ankle Hind Foot Nailing System (“AHN”)	An extension of the Centronail range of intramedullary nails
Chimaera Hip Fracture System	A strong, versatile hip nail that allows fixation to be adapted to the type of fracture being treated
Agile Nail	A small rigid intramedullary nail to treat adolescent patients
MJ FLEX	An innovative elastic nail with a unique design to be used in pediatric patients
OSCAR	Ultrasonic bone cement removal
Ankle Hindfoot Nail (“AHN”)	A differentiated solution for hindfoot fusions

Product	Primary Application
Contours Lapidus Plating System (“LPS”)	A plate design contoured specifically for a tarsometatarsal (“TMT”) fusion
Contours VPS Volar Plating System III	The 3rd generation of plates to treat distal radius fractures

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

External Fixation

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

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

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

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

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

Building on the TrueLok brand, the TL-HEX TrueLok Hexapod System was released in 2012 in international markets and in 2015 in the U.S. TL-HEX is a hexapod-based system designed at Texas Scottish Rite Hospital for Children as a three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. The system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings’ position is adjusted either rapidly

or gradually in precise increments to perform bone segment repositioning in three-dimensional space. All the basic components from the TrueLok Ring Fixation System (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) can be utilized with the TL-HEX system; therefore, external supports from both systems can be connected to each other when building fixation blocks.

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

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

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

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

Internal Fixation

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

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

In addition to treating bone fractures, we also design, manufacture and distribute devices intended to treat congenital bone conditions, such as angular deformities (e.g., bowed legs in children), or degenerative diseases, as well as

conditions resulting from a previous trauma. An example of a product offered in this area is the Eight-Plate Guided Growth System.

Spine Fixation

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

Spine Fixation Strategy

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

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

Spine Fixation Products

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

Product	Primary Application
FORZA XP Expandable Spacer System	A titanium expandable spacer system for Posterior Lumbar Interbody Fusion (“PLIF”) and Transforaminal Lumbar Interbody Fusion (“TLIF”) procedures featuring a large graft window with the ability to pack post expansion in situ
CETRA Anterior Cervical Plate System	An anterior cervical plate system offering a low profile plate with an intuitive locking mechanism, large graft windows, a high degree of screw angulation and simplified instrumentation
CONSTRUX Mini PEEK / Titanium Composite (“PTC”) Spacer System	A cervical interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a Polyetheretherketones (“PEEK”) core to maintain imaging characteristics
FORZA PTC Spacer System	A posterior lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
PILLAR SA PTC PEEK Spacer System	A standalone Anterior Lumbar Interbody Fusion (“ALIF”) lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
FIREBIRD / FIREBIRD NXG Spinal Fixation System	A system of rods, crossbars and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure
JANUS Midline Fixation Screw	An addition to the Firebird Spinal Fixation System designed to achieve more cortical bone purchase in the medial to lateral trajectory when compared to traditional pedicle screws and provides surgeons with the option of a midline approach
Connector System for revisions	A comprehensive system to reduce the complexity of revising and extending existing spinal constructs; this eliminates the need to remove existing hardware

	while providing stability at adjacent levels
CENTURION Posterior Occipital Cervico-Thoracic (“POCT”) System	A multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome that allow the surgeon to build a spinal implant construct
SAMBA-SCREW System	A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients
FIREBIRD Deformity Correction System	An extension to the Firebird Spinal Fixation System that provides additional instrument and implant options for complex thoracolumbar spine procedures

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

PILLAR PL & TL PEEK Vertebral Body Replacement (“VBR”) System	PEEK interbody devices for PLIF and TLIF procedures

Spinal Repair Solutions

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

Biologics

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

Biologics Strategy

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

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

Biologics Products

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

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

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

Regenerative Solutions

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

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

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

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

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

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

Product Development

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

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

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

Patents, Trade Secrets, Assignments and Licenses

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

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

Compliance and Ethics Program

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

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

- Due diligence reviews of high risk intermediaries and exclusion lists screening of employees and contracted business associates; and
- Risk assessments to identify areas of compliance risk.

Government Regulation

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

Our research, development and clinical programs, and our manufacturing and marketing operations, are subject to extensive regulation in the U.S. and other countries. Most notably, all of our products sold in the U.S. are subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act as implemented and enforced by the FDA. The regulations that cover our products and facilities vary widely from country to country. The amount of time required to obtain approvals or clearances from regulatory authorities also differs from country to country.

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

The medical devices we develop, manufacture, distribute and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining FDA clearance and other regulatory approvals to develop and market a medical device, particularly from the FDA, can be costly and time-consuming, and there can be no assurance such approvals will be granted on a timely basis, if at all. While we believe we have obtained all necessary clearances and approvals for the manufacture and sale of our products and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance.

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

Our Biologics SBU markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE, our allogeneic bone matrices comprised of cancellous bone containing viable stem cells and a demineralized cortical bone component. These allografts are regulated under the FDA's Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device, biologic or a drug. The Biologics SBU also distributes certain surgical implant products known as "allograft" products that are derived from human tissues and which are used for bone reconstruction or repair and are surgically implanted into the human body. These tissues are regulated by the FDA as minimally-manipulated tissue and covered by FDA's "Good Tissues Practices" regulations, which cover all stages of allograft processing. There can be no assurance our suppliers of the

Trinity Evolution, Trinity ELITE and allograft products will continue to meet applicable regulatory requirements or that those requirements will not be changed in ways that could adversely affect our business. Further, there can be no assurance these products will continue to be made available to us or that applicable regulatory standards will be met or remain unchanged. Moreover, products derived from human tissue or bones are from time to time subject to recall for certain administrative or safety reasons and we may be affected by one or more such recalls. For a description of these risks, see Item 1A Risk Factors.

Certain Other Product and Manufacturing Regulations

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include: product listing and establishment registration; Quality System Regulation ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; labeling regulations and governmental prohibitions against the promotion of

products for uncleared, unapproved or off-label uses or indications; clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices; approval of product modifications that affect the safety or effectiveness of one of our PMA approved devices; Medical Device Adverse Event Reporting regulations, which require that manufacturers report to the FDA and other foreign governmental agencies if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; regulations pertaining to voluntary recalls; and notices of corrections or removals.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA and European Notified Bodies to determine our compliance with the FDA's QSR and other international regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. In addition to FDA inspections, all manufacturing facilities of the Company are subject to annual Notified Body inspections.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices. Our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. For a description of these risks, see Item 1A Risk Factors.

Accreditation Requirements

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

Third-Party Payor Requirements

Our products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid, and Tricare or private insurance plans and healthcare networks. Third-party payors may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. Also, non-government third-party payors are increasingly challenging the medical necessity and prices paid for our products and services. The Medicare program is expected to continue to implement a new payment mechanism for certain DMEPOS items via the implementation of its competitive bidding program. Bone growth stimulation products are currently exempt from this competitive bidding process.

Laws Regulating Healthcare Fraud and Abuse; State Healthcare Laws

Our sales and marketing practices are also subject to a number of U.S. laws regulating healthcare fraud and abuse such as the federal Anti-Kickback Statute and the federal Physician Self-Referral Law (known as the “Stark Law”), the Civil False Claims Act and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) as well as numerous state laws regulating healthcare and insurance. These laws are enforced by the Office of Inspector General within the U.S. Department of Health and Human Services, the U.S. Department of Justice, and other federal, state and local agencies. Among other things, these laws and others generally: (1) prohibit the provision of anything of value in exchange for the referral of patients for, or the purchase, order, or recommendation of, any item or service reimbursed by a federal healthcare program, (including Medicare and Medicaid); (2) require

that claims for payment submitted to federal healthcare programs be truthful; (3) prohibit the transmission of protected healthcare information to persons not authorized to receive that information; and (4) require the maintenance of certain government licenses and permits.

Laws Protecting the Confidentiality of Health Information

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

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

Physician Payments Sunshine Provision of the Affordable Care Act

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

Sales, Marketing and Distribution

General Trends

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

Strategic Business Units

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

Sales Network

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

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

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

Marketing and Product Education

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

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

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

Competition

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

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

Manufacturing and Sources of Supply

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

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

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

Employees

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

eNeura Debt Security

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

Item 1A. Risk Factors

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

Risks Related to our Legal and Regulatory Environment

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

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

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

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

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

In connection with our self-reported FCPA violations, we instituted extensive remediation measures, including terminating employees, as well as relationships with third-party representatives and distributors, conducting a global

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions,

ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of the foregoing actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations or cash flows.

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

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

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

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

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

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

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

Risks Related to our Business and Industry

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

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

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

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

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

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

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

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

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

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

During 2017, we continued to make improvements in revenues related to several new products we introduced to the market over the past several years, including the TL-HEX TrueLok Hexapod System, Galaxy Fixation System, Ankle Hind Foot Nailing System, Firebird NXG Spinal Fixation System, FORZA PTC Spacer System, Samba-Screw System, SKYHAWK Lateral Interbody Fusion System & Lateral Plate System, CENTURION POCT System, PILLAR SA PTC PEEK Spacer System, JANUS Midline Fixation Screw, and the Cetra Anterior Cervical Plate, among others. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians) and obtain regulatory approvals, which can depend, among other things, on the product achieving broad clinical acceptance, the level of third-party

reimbursement and the introduction of competing technologies. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

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

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

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

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

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

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

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

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

We rely on information technology (IT) systems to perform our business operations, including processing, transmitting and storing electronic information, and interacting with customers, suppliers, healthcare payers, and other

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

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

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

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

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

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

We depend on our senior management team.

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

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

In order to compete, we must attract, retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing, research, development, finance and support positions. Hiring and retaining qualified executives, engineers, technical staff and sales representatives are critical to our business, and competition

for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified executives and key employees, we utilize stock-based incentive awards such as employee stock options. If the value of such stock awards does not appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain and motivate our employees could be adversely impacted, which could negatively affect our results of operations and/or require us to increase the amount we expend on cash and other forms of compensation.

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

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

- require us to incur substantial expense, even if we are successful in the litigation;
- require us to divert significant time and effort of our technical and management personnel;
- result in the loss of our rights to develop or make certain products; and

- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation.

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

Risks Related to Litigation and Product Liability Matters

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

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

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

Risks Related to Our Financial Results and Need for Financing

Our quarterly operating results may fluctuate.

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

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

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

eNeura is using the proceeds of our loan to fund product development work related to its business and to fund its ongoing operations and no assurance can be made that eNeura's business will ultimately be successful. Although the promissory note is secured by many of eNeura's assets (including its intellectual property assets), no assurance can be made that eNeura will be able to repay the promissory note when due in the event that the promissory note does not

convert to equity. In such an event, we could lose all or a substantial portion of our $15 million loan investment. In addition, if a change in control of eNeura (generally defined as a third-party acquisition of fifty percent or more of eNeura's voting equity or all or substantially all of eNeura's assets) occurs prior to the maturity date on March 4, 2019, the eNeura Note will automatically convert into preferred stock of eNeura, and the value of such preferred stock could be less than the principal amount of the note.

We face risks related to foreign currency exchange rates.

Because some of our revenue, operating expenses, assets and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or earn

revenue in currencies other than the U.S. dollar, any change in the values of those foreign currencies relative to the U.S. dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we have potential foreign exchange exposure. The fluctuations of foreign exchange rates during 2017 have had a favorable impact of $1.6 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time.

Our global operations may expose us to tax risks

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

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

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

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

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

The Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay subordinated indebtedness and enter into affiliate transactions. In addition, the Credit Agreement contains financial covenants requiring us on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. The Credit Agreement also includes events of default customary for facilities of

this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the facility may be accelerated and/or the lenders' commitments terminated.

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

Risks Related to Potential Acquisitions and Divestitures

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

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

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

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

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

Item 1B. Unresolved Staff Comments
None.

Item 2. Properties
Our principal facilities as of December 31, 2017 are as follows:

Facility	Location	Approx. Square Feet	Ownership
Manufacturing, warehousing, distribution, research and development, and	Lewisville, TX	140,000	Leased

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

Item 3. Legal Proceedings
For a description of our material pending legal proceedings, refer to Note 11 to the Consolidated Financial Statements in Item 8 of this Annual Report.

Item 4. Mine Safety Disclosures
Not applicable.

PART II

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

Market for Our Common Stock

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

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

Dividends

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

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

Recent Sales of Unregistered Securities

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

Performance Graph

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

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

Item 6. Selected Financial Data

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

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

(1) Includes the following:

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

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

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

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

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

Executive Summary

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

Notable highlights and accomplishments in 2017 include the following:

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

Results of Operations

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

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

Net Sales by Strategic Business Unit

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

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

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BioStim

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

2017 Compared to 2016

Net sales increased $9.3 million or 5.3%

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

2016 Compared to 2015

Net sales increased $11.6 million or 7.0%

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

Extremity Fixation

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

2017 Compared to 2016

Net sales increased $0.6 million or 0.5%

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

2016 Compared to 2015

Net sales increased $6.6 million or 6.9%

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

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Spine Fixation

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

2017 Compared to 2016

Net sales increased $9.3 million or 12.8%

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

2016 Compared to 2015

Net sales decreased $3.0 million or 4.0%

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

Biologics

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

2017 Compared to 2016

Net sales increased $4.8 million or 8.3%

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

2016 Compared to 2015

Net sales decreased $1.9 million or 3.2%

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

Gross Profit and Non-GAAP Net Margin

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

2017 Compared to 2016

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

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

2016 Compared to 2015

Non-GAAP net margin increased $8.8 million

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

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

(U.S. Dollars, in thousands)	2017	2016	2015	Percentage Change 2017/2016	2016/2015

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

General and Administrative Expense

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

2017 Compared to 2016

General and administrative expense decreased less than $0.1 million

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

2016 Compared to 2015

General and administrative expense decreased $12.8 million

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

Research and Development Expense

(U.S. Dollars, in thousands)	2017	2016	2015	Percentage Change 2017/2016	Percentage Change 2016/2015
Research and development	$29,700	$28,803	$26,389	3.1 %	