ORTHOFIX INTERNATIONAL N V
Form 10-K
February 29, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

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	N/A
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer 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 x

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 x

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 x 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

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

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, 2015, as reported by the Nasdaq Global Select Market, was approximately $624.0 million.

As of February 26, 2016, 18,373,800 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the 2016 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Annual Report.

Orthofix International N.V.

Form 10-K for the Year Ended December 31, 2015

Table of Contents

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “intends,” “predicts,” “potential,” or “continue” or other comparable termino These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. 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, or the risk factors described in Item 1A under the heading Risk Factors, to reflect new information, the occurrence of future events or circumstances or otherwise.

The forward-looking statements in this filing do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: the expected sales of our products, including recently launched products; the continuation of our ongoing share repurchase program; an investigation by the Division of Enforcement of the Securities Exchange Commission (the “SEC”) and related securities class action litigation arising out of our prior accounting review and restatements of financial statements; our review of allegations of improper payments involving our Brazil-based subsidiary (which review is described in Part I, Item 3, “Legal Proceedings”); the geographic concentration of certain accounts receivable in countries or territories that are facing severe fiscal challenges; unanticipated expenditures; changing relationships with customers, suppliers, strategic partners and lenders; changes to and the interpretation of governmental regulations; the resolution of pending litigation matters (including our indemnification obligations with respect to certain product liability claims against our former sports medicine global business unit (as further described in Part I, Item 3, “Legal Proceedings”); our ongoing compliance obligations under a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (and related terms of probation) and a deferred prosecution agreement with the U.S. Department of Justice; risks relating to the protection of intellectual property; changes to the reimbursement policies of third parties; the impact of competitive products; changes to the competitive environment; the acceptance of new products in the market; conditions of the orthopedic and spine industries; credit markets and the global economy; corporate development and market development activities, including acquisitions or divestitures; unexpected costs or operating unit performance related to recent acquisitions; and other risks described in Part I, Item 1A, “Risk Factors” as well as in other reports that we file with the SEC in the future.

PART I

Item 1. Business

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

Company Overview

We are a diversified, global medical device company focused on improving patients’ lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, TX, the Company has four strategic business units that include BioStim, Biologics, Extremity Fixation and Spine Fixation. Orthofix products are widely distributed via the Company’s sales representatives, distributors and its subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as the Musculoskeletal Transplant Foundation (“MTF”) and the Texas Scottish Rite Hospital for Children.

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

Orthofix International N.V. is a limited liability company operating under the laws of Curaçao. The Company was formed on October 19, 1987 under the laws of the Netherlands Antilles, with the principal executive office in the Netherlands Antilles on the island of Curaçao. Curaçao became a separate and autonomous country on October 10, 2010. Our executive offices in Curaçao are located at 7 Abraham de Veerstraat, Curaçao. Our filings with the Securities and Exchange Commission (the “SEC”), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and Annual Proxy Statement on Schedule 14A and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information on our website or connected to our website is not incorporated by reference into this report. Our Internet website is located at http://www.orthofix.com. Our SEC filings are also available on the SEC Internet website at http://www.sec.gov.

Business Segments

We manage our business by our four strategic business units (“SBUs”), which are comprised of BioStim, Biologics, Extremity Fixation, Spine Fixation, and supported by Corporate activities. Financial information regarding our reportable business segments and certain geographic information is included in Part II, Item 7 of this report and Note 12 to the Consolidated Financial Statements in Item 8 of this report.

Net Sales by SBU

The table below presents net sales by SBU reporting segment. Net sales include product sales and marketing service fees.

	Year ended December 31,		
	2015	2014	2013

(U.S. Dollars in thousands)	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
BioStim	$164,955	41.6 %	$154,676	38.5 %	$145,085	36.5 %
Biologics	59,832	15.1 %	55,881	13.9 %	53,746	13.5 %
Extremity Fixation	96,034	24.2 %	109,678	27.3 %	103,359	26.0 %
Spine Fixation	75,668	19.1 %	82,042	20.4 %	95,421	24.0 %
Total net sales	$396,489	100.0 %	$402,277	100.0 %	$397,611	100.0 %

Additional financial information regarding our business segments can be found in Item 7 under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as in Item 8 under the heading “Financial Statements and Supplementary Data.”

BioStim

The BioStim SBU manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). These devices utilize Orthofix's patented pulsed electromagnetic field ("PEMF") technology, which is supported by strong basic mechanism of action data in the scientific literature as well as strong level one randomized controlled clinical trials in the medical literature. Current research and clinical studies are underway to identify potential new clinical indications. This SBU uses distributors and sales representatives to sell its devices to hospitals, doctors and other healthcare providers, primarily in the U.S.

Biologics

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

Extremity Fixation

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

Spine Fixation

The Spine Fixation SBU specializes in the design, development and marketing of a portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products through a network of distributors, sales representatives, and affiliates to sell spine products to hospitals, doctors and other healthcare providers, globally.

Business Strategy

Our business strategy is to develop and deliver advanced repair and regenerative solutions to the spine and orthopedic markets in order to facilitate bone fusion and healing as well as correct bone and spine deformities. Our strategy for growth and profitability includes the following initiatives by SBU:

BioStim: Provide osteogenesis stimulation devices that deliver noninvasive treatment for promoting healing in fractured bones and spinal fusions. Our key initiatives are:

- Invest in basic science, clinical and evidence-based research to support broader indications for our stimulation products; and
- Invest in product development for next generation osteogenesis technology.

Biologics: Provide a portfolio of regenerative tissues and products that provide physicians with additional surgical options that augment their surgical procedures and results. Our key initiatives are:

- Continue to focus our sales efforts on Trinity ELITE® and leverage its market acceptance;
- Enhance our distribution network through an increase in distributor partners in our existing markets; and
- Accelerate new tissue development projects with MTF.

Extremity Fixation: Provide external and internal temporary to definitive fixation devices used in fracture repair, deformity correction and bone reconstruction. Our key initiatives are:

- Continue to focus our sales efforts on driving adoption of TL-HEX TrueLok Hexapod System® and Galaxy Fixation® System product lines; and
- Develop and acquire premium products for temporary fixation, deformity correction and pediatrics.

Spine Fixation: Provide a portfolio of surgical products that allow physicians to successfully treat a variety of spinal conditions. Our key initiatives are:

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

Other Financial and Business Initiatives:

- Continue to identify, recruit and hire highly talented and experienced commercial and corporate leaders;
- Expand our geographic sales coverage to high priority countries and U.S. territories where we currently are underpenetrated;
- Drive sales in the U.S. by expanding our integrated delivery networks, group purchasing organizations and regional hospital system commercial contracting team and expertise;
- Invest in a reimbursement strategy and team dedicated to addressing the requirements of third party payors. This team will be supported with evidence-based clinical research and cost effectiveness studies coordinated by our research team;
- Continue to enhance physician relationships through extensive product education and training programs;
- Achieve more effective and efficient business processes, systems and controls throughout the organization; and
- Increase our research and development and clinical investments in our core technologies of osteogenesis stimulation and regenerative tissue forms.

Corporate

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

Products

Our revenues are derived from the sales of products and marketing service fees. Marketing service fee sales are comprised of fees earned for the marketing of tissue forms including Trinity Evolution®, Trinity ELITE® and VersaShield®, all three of which are derived from our partnership with MTF.

The following table identifies our principal products by trade name and describes their primary applications:

Product	Primary Application
BioStim Solutions	
Cervical-Stim®	Pulsed electromagnetic field ("PEMF") non-invasive cervical spine regenerative stimulator used to enhance bone growth
Spinal-Stim®	PEMF non-invasive lumbar spine regenerative stimulator used to enhance bone growth
Physio-Stim®	PEMF non-invasive long bone regenerative stimulator used to enhance bone growth in non-union factures
Biologic Solutions	
AlloQuent® Structural Allografts	Interbody devices made of cortical bone that are designed to restore the space that has been lost between two or more vertebrae due to a degenerated disc
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
Extremity Fixation Solutions	
Fixator	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus™, XCaliber® and Gotfried P.C.C.P®
Eight-Plate Guided Growth System®	Treatment for bowed legs or knock knees of children
LRS Advanced Limb Reconstruction System®	External fixation for limb lengthening and corrections of deformity

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

Product	Primary Application
Centronail® Ankle Compression Nailing System (“ACN”)	An extension of the Centronail® range of intermedullary nails
Ankle Hindfoot Nail (“AHN”)	A differentiated solution for hindfoot fusions
Contours™ Lapidus Plating System™ (“LPS”)	A plate design contoured specifically for a tarsometatarsal (“TMT”) fusion
Contours PHP Proximal Humeral Plate™ (“PHP”)	An innovative plating solution for fraction fixation of the proximal humerus
Contours VPS® Volar Plating System™ III	The 3rd generation of plates to treat distal radius fractures
Spine Fixation Solutions	
3°™ /Reliant™ Anterior Cervical Plating Systems	Plating systems implanted during anterior cervical spine fusion procedures
Hallmark® Anterior Cervical Plate System	A cervical plating system implanted during anterior cervical spine fusion procedures
Ascent® LE Posterior Occipital Cervico-Thoracic (“POCT”) System	A system of pedicle screws and rods implanted during a posterior spinal fusion procedure involving the stabilization of several degenerated or deformed cervical vertebrae
NewBridge® Laminoplasty Fixation System	A device implanted during a posterior surgical procedure designed to expand the cervical vertebrae and relieve pressure on the spinal canal
ATHLET™ Vertebral Body Replacement (“VBR”) System	A lordotic, modular vertebral body replacement system intended for use in the thoracolumbar spine
Construx® Mini PEEK Spacer System	Smaller, unibody versions of the Construx PEEK VBR System, implanted as a cervical interbody or partial vertebrectomy solution
CONSTRUX® Mini PEEK/ Titanium Composite™ (“PTC”) Spacer System™	A cervical interbody with porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
Construx® PEEK VBR System	A modular device implanted during the replacement of degenerated or deformed spinal vertebrae to provide additional anterior support
NGage® Surgical Mesh System	A modular metallic interbody implant placed between two vertebrae designed to restore disc space and increase stability that has been lost due to degeneration or deformity
PILLAR® PL & TL PEEK VBR System	Interbody devices for Posterior Lumbar Interbody Fusion (“PLIF”) and Transforaminal Lumbar Interbody Fusion (“TLIF”) procedures
FORZA® Spacer System	Interbody devices for PLIF and TLIF procedures

PILLAR® AL PEEK Partial VBR System	An intervertebral body fusion device for Anterior Lumbar Interbody Fusion (“ALIF”) procedures
PILLAR® SA PEEK Spacer System	An intervertebral body fusion device that incorporates screw fixation to optimize implant stability
Firebird® Spinal Fixation System	A system of rods, crossbars and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure
Firebird® Deformity Correction System	An extension to the Firebird® Spinal Fixation System that provides additional instrument and implant options for complex thoracolumbar spine procedures
Phoenix® Minimally Invasive Spinal Fixation System	A multi-axial extended reduction screw body used with the Firebird® Spinal Fixation System designed to be implanted during a posterior thoracolumbar spine fusion procedure

Product	Primary Application
Phoenix® Compression Destraction Extension ("CDX™")	An extension to the Phoenix® Minimally Invasive Spinal Fixation System that provides additional implant and instrument options for complex deformity spinal fixation
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
SFS™ Spinal Fixation System	A system of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, cross-connectors that provides simple, reliable and comprehensive stabilization solution for spinal non-cervical fixation
Samba-Screw® System	A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients
ProView® Minimal Access Portal ("MAP") System	An instrument system for minimally invasive posterior lumbar spinal fusion, including tubular and expandable retractors, a percutaneous screw delivery system and the ONYX ™ System for Disc removal and interbody space preparation
Unity® Lumbosacral Fixation System	A plating system implanted during anterior lumbar spine fusion procedures
LONESTAR® Cervical Stand Alone ("CSA")	A stand-alone spacer system designed to provide the biomechanical strength to a tradition or minimal invasive ACDF procedure with less disruption of patient anatomy and preserve the anatomical profile
SKYHAWK® Lateral Interbody Fusion System & Lateral Plate System	Provides a complete solution for the surgeon to perform a Lateral Lumbar Interbody Fusion, an approach to spinal fusion in which the surgeon access the intervertebral disc space using a surgical approach from the patient's side that disturbs fewer structures and tissues
QUADRx™ Lateral Retractor	A retractor with a straightforward 4 blade design that requires no sequential dilation prior to retractor placement over the guide wire and creates a rectangular aperture that provides adaptability to both patient anatomy and surgeon technique
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

We have proprietary rights in all of the above products with the exception of Cemex®, Eight-Plate Guided Growth System® and Contour VPS®. We have the exclusive distribution rights for the Cemex® in Italy and for the Eight-Plate Guided Growth System® and Contour VPS® worldwide.

We have numerous trademarked products and services including but not limited to the following: Orthofix®, Blackstone™, Spinal-Stim®, Cervical-Stim®, 3°™, Reliant™, Hallmark®, Firebird®, Ascent®, Construx®, Unity®, NGage®, Newbridge®, Trinity ELITE®, Trinity Evolution®, VersaShield®, PILLAR®, Alloquent®, ProView®, ProCallus®,

XCaliber®, VeroNail®, Centronail®, PREFIX™, Gotfried P.C.C.P®, Physio-Stim®, TrueLok™, Galaxy Fixation System® and TL-HEX™, LONESTAR®, SKYHAWK® and CENTURION®.

BioStim

Spinal Regenerative Solutions

Regenerative stimulators 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 regenerative stimulation devices, Spinal-Stim® and Cervical-Stim®, through our subsidiary, Orthofix Inc. Our stimulation products use a PEMF technology designed to enhance the growth of bone tissue following surgery and are placed externally over the site to be healed. Research data shows that our PEMF signal induces mineralization and results in a process that stimulates new regeneration at the spinal fusion site. We have sponsored independent research at Cleveland Clinic, New York University and University of Medicine and Dentistry of New Jersey, where scientists conducted animal and cellular studies to identify the mechanisms of action of our PEMF signals on bone and efficacy of healing. From this effort, a total of six studies have been published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength as well as proliferation and differentiation of cells involved in regeneration and healing. Furthermore, we believe that the research work with Cleveland Clinic allowing for characterization and visualization of the Orthofix PEMF waveform is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data along with additional clinical data could represent new clinical indication opportunities for our regenerative stimulation solutions.

Some spine fusion patients are at greater risk of not achieving a solid fusion of new bone around the fusion site. These patients typically have one or more risk factors such as smoking, obesity or diabetes, or their surgery involves the revision of a failed fusion or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical regenerative stimulation has been shown to significantly increase the probability of fusion success. Spinal-Stim® is a non-invasive spinal fusion stimulator system commercially available in the U.S. since 1990 and approved in Europe. Spinal-Stim® is designed for the treatment of the lower thoracic and lumbar regions of the spine. The device uses proprietary technology and a wavelength to generate a PEMF signal. The U.S. Food and Drug Administration (the “FDA”) has approved Spinal-Stim® 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 Cervical-Stim® stimulator product remains the only FDA-approved bone growth stimulator on the market indicated for use as an adjunct to cervical (upper) spine fusion surgery in patients at high-risk for non-fusion. The FDA approved this device in 2004, and it has been commercially available in the U.S. since 2005.

Orthopedic Regenerative Solutions

Our Physio-Stim® regenerative stimulator products use PEMF technology similar to that described previously in the discussion of our spine stimulators. The primary difference is that the Physio-Stim® physical configuration is designed for use on long bones.

A bone’s regenerative power results in most fractures healing naturally within a few months. In certain situations, however, fractures do not heal or heal slowly, resulting in “non-unions.” Traditionally, orthopedists have treated such fracture conditions surgically, often by means of a bone graft with fracture fixation devices, such as bone plates, screws or intramedullary rods. These are examples of “invasive” treatments. Our patented regenerative stimulators are designed to use a low level of PEMF signals to activate the body’s natural healing process.

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

Biologics

The regenerative solutions offered as part of our biologics’ portfolio include solutions for a variety of musculoskeletal defects used in spinal and extremity orthopedic procedures.

Regenerative Solutions

Our premier biologics tissues include Trinity ELITE® and Trinity Evolution®, 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; harvesting autograft adds risk of an additional surgical procedure and related patient discomfort in conjunction with a repair surgery.

To offer 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 market Collage® 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 market VersaShield®, 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. VersaShield® 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 a marketing fee through our collaboration with MTF for Trinity Evolution®, Trinity ELITE®, and VersaShield®. Under our Agreements with MTF, 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 our Trinity Evolution® and Trinity ELITE® technologies. We market our VersaShield® under a private label brand via a non-exclusive marketing agreement for the tissue form.

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

Extremity Fixation

The medical devices offered in our Extremity Fixation SBU include both internal and external fixation solutions for extremity repair and deformity correction, both for adults and children.

Extremity Repair Solutions

Our fracture repair products consist of fixation devices designed to stabilize a broken bone until it can heal. Our fracture repair products come in two main types: external devices and internal devices. With these devices, we can treat simple and complex fracture patterns along with achieving deformity corrections.

External Fixation

External fixation devices are used to stabilize fractures from outside the skin with minimal invasion into the body. These fixation devices use screws that are inserted into the bone on either side of the fracture site, to which the fixator body is attached externally. The bone segments are aligned by manipulating the external device using patented ball joints and, when aligned, are locked in place for stabilization. External fixation may also be used as temporary devices in complex trauma cases to stabilize the fracture prior to treating it definitively. We believe that external fixation is among the most minimally invasive surgical options for fracture management. Also, we believe external fixation is the ideal treatment option for highly complex fractures, patients who have fractures close to the joints, or patients with known risk factors or co-morbidities.

The LRS Advanced Limb Reconstruction System® uses callus distraction to lengthen bone in a variety of procedures. It can be used in monofocal lengthening and corrections of deformity. Its multifocal procedures include bone transport, simultaneous compression and distraction at different sites, bifocal lengthening and correction of deformities with shortening. In 2009, improvements on size, flexibility and ease of use were implemented for the release of the LRS Advanced Limb Reconstruction System®.

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

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

Building on the TrueLok™ brand, in the international markets, TL-HEX™ TrueLok Hexapod System® was released in 2012. 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. In essence, the system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings' position is adjusted either rapidly or gradually in precise increments to perform bone segment

repositioning in three-dimensional space. All the basic components from the TrueLok Ring Fixation System (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) can be utilized with TL-HEX™; therefore external supports from both systems can be connected to each other when building fixation blocks. As with any other hexapod-type external fixator, for successful application of the TL-HEX™, an associated software is also available (www.tlhex.com).

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

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

Internal Fixation

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

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

In addition to the treatment of 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

Neck and back pain is a common health problem for many people throughout the world and often requires surgical or non-surgical intervention for improvement. Neck and back problems are usually of a degenerative or neurological nature and are generally more prevalent among the older population. As the population ages, we believe physicians will see an increasing number of patients with degenerative spine issues who wish to have a better quality of life than that experienced by previous generations. Treatment options for spine disorders are expected to expand to fill the existing gap between conservative pain management and invasive surgical options, such as spine fusion.

We believe our spine products are positioned to address the needs of spine patients. Our products currently address the cervical fusion segment as well as the lumbar fusion segment, which is the largest sub-segment of the spine market.

We offer a wide array of spinal repair products used during surgical procedures intended to treat a variety of spine conditions. Many of these surgeries are fusion procedures in the cervical, thoracic and lumbar spine that utilize metal plates, rods and screws, interbody spacers, Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, as well as vertebral body replacement devices to promote bone growth.

Spinal Repair Solutions

The human spine is made up of 33 interlocking vertebrae that protect the spinal cord and provide structural support for the body. The top seven vertebrae make up the cervical spine, which bears the weight of the skull and provides the largest range of motion. The next 17 mobile vertebrae encompass the thoracic and lumbar, or thoracolumbar, sections of the spine. The thoracic spine (12 vertebrae) helps to protect the organs of the chest cavity by attaching to the rib cage, and is the least mobile segment of the spine. The lumbar spine (five vertebrae) carries the greatest portion of the body's weight, allowing a degree of flexion, extension and rotation thus handling the majority of the bending movement. Additionally, five fused vertebrae make up the sacrum (part of the pelvis) and four vertebrae make up the final part of the spine, the coccyx.

Spinal bending and rotation are accomplished through the vertebral discs located between each vertebra. Each disc is made up of a tough fibrous exterior, called the annulus, which surrounds a soft core called the nucleus. Excess pressure, deformities, injury or disease can lead to a variety of conditions affecting the vertebrae and discs that may ultimately require medical intervention in order to relieve patient pain and restore stability in the spine.

Spinal fusion is the permanent union of two or more vertebrae to immobilize and stabilize the affected portion of the spine. Most fusion surgeries involve the placement of a bone graft between the affected vertebrae, which is typically held in place by metal implants that also provide stability to the spine until the desired growth of new bone can complete the fusion process. These implants typically consist of some combination of rods, screws and plates that are designed to remain in the patient even after the fusion has occurred.

Most fusion procedures performed on the lumbar area of the spine are done from the posterior, or back, while the majority of cervical fusions are performed from the anterior, or front, of the body. However, the growing use of interbody devices specially designed for an anterior approach has resulted in the increasing use this approach for many lumbar surgeries. Interbody devices are small hollow implants typically made of bone, metal or a thermoplastic compound called Polyetheretherketones ("PEEK") that are placed between the affected vertebrae to restore the space lost by the degenerated disc. The hollow spaces within these interbody devices are typically packed with some form of bone grafting material designed to accelerate the formation of new bone around the graft, which ultimately results in the desired fusion.

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 PEEK. The majority of the implants that we offer are made of titanium metal. This includes the 3°™, Reliant® and Hallmark® cervical plates. Additionally, the Spinal Fixation System ("SFS"), the Firebird® Spinal Fixation System, the Phoenix® Minimally Invasive Spinal Fixation System, the Ascent®, Ascent® LE, and the Centurion® POCT Systems are sets of rods, cross connectors and screws which are implanted during posterior fusion procedures. The Firebird® Modular and pre-assembled Spinal Fixation System is designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our product ProView® MAP System. To complement our plate and screw based fixation options we offer an entire portfolio of cervical and thoracolumbar PEEK interbody devices within our Pillar® and Forza® product lines. This interbody portfolio includes two stand-alone devices, Lonestar® and Pillar SA®, as well as the Construx® Mini PTC™ system, a novel titanium composite spacer which offers a superior alternative to other plasma spray coated options currently available on the market. We also offer specialty plates and screws that are used in less common procedures, and as such, are not manufactured by many device makers. These specialty implants include the Newbridge® Laminoplasty Fixation

System that is designed to expand the cervical vertebrae and relieve pressure on the spinal canal, the Samba-Screw® System used in Sacroiliac Joint Fixation, as well as the Unity® plate which is used in anterior lumbar fusion procedures.

Product Development

Our research and development departments are responsible for new product development. We work regularly with certain institutions referred to below as well as with physicians and other consultants on the long-term scientific planning and evolution of our research and development efforts. These efforts are performed in accordance with best practices on interactions with healthcare professionals as set forth, for example, in the AdvaMed Code of Ethics ("AdvaMed Code") and the Eucomed Code of Business Practices ("Eucomed Code"). Our primary research and development facilities are located in Verona, Italy and Lewisville, Texas.

We maintain interactive relationships with spine and orthopedic centers in the U.S., Europe, and South and Central America, including research and clinical organizations such as the MTF, the Orthopedic Research and Education Foundation and the Texas Scottish Rite Hospital for Children. Several of the products that we market have been developed through these collaborations. In

addition, we regularly receive suggestions for new products 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 a substantial number of requests for the production of customized items, some of which have resulted in new products. We believe our policy of accommodating such requests enhances our reputation in the medical community.

In 2015, 2014 and 2013 we incurred $26.4 million, $25.0 million and $26.8 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 as well as non-disclosure agreements to protect our proprietary intellectual property. We own numerous U.S. and foreign patents and have numerous pending patent applications and license rights under patents held by third parties. Our primary products are patented in major markets in which they are sold. There can be no assurance 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 for the conduct of our business. We rely on confidentiality 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 to the licensor a percentage of sales. However, while assignments or licenses to us generally are irrevocable, there is no assurance that these arrangements will continue to be made available to us on terms that are acceptable to us, or at all. The terms of our license and assignment agreements vary in length from a specified number of years to the life of product patents or the economic life of the product. These agreements generally provide for royalty payments and termination rights in the event of a material breach.

Corporate Compliance and Government Regulation

Corporate Compliance and Ethics Program

We have a comprehensive compliance program, which we branded the Integrity Advantage™ Program, which is overseen by our Chief Compliance Officer throughout our Company. It is a fundamental policy of our Company to conduct business in accordance with the highest ethical and legal standards. Our corporate compliance and ethics program is designed to promote legal compliance and ethical business practices throughout our domestic and international businesses.

Our Integrity Advantage™ Program is designed to meet U.S. Sentencing Commission Guidelines for effective organizational compliance and ethics programs and to prevent and detect violations of applicable federal, state and local laws. Key elements of the Integrity Advantage™ 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 Business Conduct;
- Methods for communicating compliance concerns, including anonymous reporting mechanisms;
- Investigation and remediation measures to ensure prompt response to reported matters and timely corrective action;
- Compliance education and training for employees and contracted business associates;
- Auditing and monitoring controls to promote compliance with applicable laws and assess program effectiveness;
- Disciplinary guidelines to enforce compliance and address violations;

Exclusion lists screening of employees, and contracted business associates; and
Risk assessments to identify areas of compliance risk.

For information regarding the Company's current review of allegations of potential improper payments involving the Company's Brazil-based subsidiary, see Part I, Item 3, "Legal Proceedings."

Government Regulation

Our research, development and clinical programs, as well as 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 wish to commercially distribute in the U.S. will be 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. Devices deemed to pose low risk are placed in class I. Those devices that are considered moderate risk are class II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device, a process generally known as 510(k) clearance. Some low risk class I devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring approval of a PMA.

Manufacturers of most class II medical devices are required to obtain 510(k) clearance prior to marketing their devices. To obtain 510(k) clearance, a company must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" in intended use and in technological and performance characteristics to another legally marketed 510(k)-cleared "predicate device." By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. With certain exceptions, most of our products are subject to the 510(k) clearance process. On January 27, 2010, the FDA requested comments on actions that the FDA's Center for Devices and Radiological Health ("CDRH") can consider taking to strengthen the 510(k) review process conducted by the CDRH. In August 2010, the FDA published a series of recommended changes to the 510(k) review process.

Class III medical devices are required to undergo the PMA approval process in which the manufacturer must establish the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will typically conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. By statute, the FDA has 180 days to review the PMA application, although, generally, review of the application can take between one and three years, or longer. Once approved, a new PMA or a PMA Supplement is required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Our regenerative bone growth stimulation products are classified as Class III by the FDA, and have been approved for commercial distribution in the U.S. through the PMA process.

In addition, our Biologics business markets tissue for bone repair and reconstruction under the brand names Trinity Evolution® and Trinity ELITE® which are allogeneic bone matrices comprised of cancellous bone containing viable stem cells and a demineralized cortical bone component. We believe these allografts are properly classified under FDA's Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device or as a biologic or as a drug. We believe they are regulated under Section 361 of the Public Health

Service Act and C.F.R. Part 1271. Biologics 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. We believe that these tissues are properly classified by the FDA as minimally-manipulated tissue and are covered by FDA’s “Good Tissues Practices” regulations, which cover all stages of allograft processing. There can be no assurance our suppliers of the Trinity Evolution®, Trinity ELITE® and allograft products will continue to meet applicable regulatory requirements or that those requirements will not be changed in ways that could adversely affect our business. Further, there can be no assurance these products will continue to be made available to us or that applicable regulatory standards will be met or remain unchanged. Moreover, products derived from human tissue or bones are from time to time subject to recall for certain administrative or safety reasons and we may be affected by one or more such recalls. For a description of these risks, see Item 1A Risk Factors.

The medical devices we develop, manufacture, distribute and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining FDA clearance and other regulatory approvals to develop and market a medical device, particularly from the FDA, can be costly and time-consuming, and there can be no

assurance such approvals will be granted on a timely basis, if at all. While we believe we have obtained all necessary clearances and approvals for the manufacture and sale of our products and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance. 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 FDA and other foreign governmental agencies if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; regulations pertaining to voluntary recalls; and notices of corrections or removals.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA and European Notified Bodies to determine our compliance with FDA's QSR and other international regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. In addition to the domestic FDA inspections, all manufacturing facilities of the Company are subject to annual Notified Body inspections. No major findings have been received and certification has been granted or maintained. 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 those actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations or cash flows. For a description of these risks, see Item 1A Risk Factors.

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.

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, 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 items of durable medical equipment, prosthetic, orthotic supplies ("DMEPOS") via the implementation of its competitive bidding program. The initial implementation was terminated shortly after it began in 2008 and the Centers for Medicare and Medicaid Services ("CMS") began the rebid process in 2009 ("Round 1 Rebid") with implementation of the rebid round occurring on January 1, 2011. Payment rates for certain DMEPOS items included in the Round 1 Rebid product categories, which categories do not currently include our products, will be determined based on bid prices rather than the current Medicare DMEPOS fee schedule. CMS has released the geographical areas included in Round 2 of the program, yet final decisions concerning which products will be affected have not been announced. The Company's bone growth stimulation products are exempt from this competitive bidding process.

Our subsidiary Orthofix Inc. received accreditation status by the Accreditation Commission for Health Care, Inc. ("ACHC") for the services of 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, CMS required DMEPOS suppliers to become accredited. By attaining

accreditation, Orthofix Inc. has demonstrated its commitment to maintain a higher level of competency and strive for excellence in its products, services, and customer satisfaction.

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.

In addition, U.S. federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information such as medical records and restrict the use and disclosure of that protected information. At the federal level, the Department of Health and Human Services promulgates health information privacy and security rules under HIPAA. These rules protect health information by regulating its use and disclosure, including for research and other purposes. Failure of a HIPAA "covered entity" to comply with HIPAA regarding such "protected health information" could constitute a violation of federal law, subject to civil and criminal penalties. Covered entities include healthcare providers (including 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.

On February 1, 2013, the Centers for Medicare & Medicaid Services ("CMS") published a final rule that makes information publicly available about payments or other transfers of value from certain manufacturers of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid, and the Children's Health Insurance Program ("CHIP"), defined as applicable manufacturers, to physicians and teaching hospitals, which are defined as covered recipients. Called the "National Physician Payment Transparency Program: Open Payments," this is one of many steps in the Affordable Care Act designed to create greater transparency in health care markets.

The final rule, which implements Section 6002 of the Affordable Care Act, also makes information publicly available about physician (or immediate family members of a physician) ownership or investment interests in applicable manufacturers and group purchasing organizations ("GPOs").

The law specifies that applicable manufacturers must report annually to the Secretary of Health and Human Services all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) from applicable manufacturers to covered recipients. In addition to reporting on payments, applicable manufacturers, as well as applicable GPOs, must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities. However, the law does not require applicable manufacturers or applicable GPOs to report ownership or investment interests held by teaching hospitals. The law requires CMS to provide applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors at least 45 days to review, dispute and correct their reported information before posting it on a publicly available website. The information on the website must be easily aggregated, downloaded and searchable.

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 (including China) 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 generally derived from the sales of products in four SBUs, BioStim, Biologics, Extremity Fixation, and Spine Fixation, which accounted for 42%, 15%, 24%, and 19%, respectively, of our total net sales in 2015.

Sales, Marketing and Distributor Network

We have established a broad distribution network comprised of direct sales representatives and distributors. This established distribution network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products worldwide in over 65 countries.

In our largest market, the U.S., our sales, marketing and distribution network is comprised of several sales forces addressing different business units. A hybrid distribution network of direct sales representatives and independent distributors addresses the BioStim SBU for regenerative stimulation products. Primarily an independent distribution network supplemented by some direct sales representatives addresses the Biologics SBU. A hybrid distribution network of both direct sales representatives and distributors addresses the Extremity Fixation SBU. Primarily an independent distribution network addresses the Spine Fixation SBU.

Outside the U.S., we employ both direct sales representatives and distributors within our international sales subsidiaries. We also utilize independent distributors in Europe, the Far East, the Middle East and Central and South America in countries where we do not have subsidiaries. In order to provide support to our independent distribution network, we have a group of sales and marketing specialists who regularly visit independent distributors to provide training and product support.

Marketing and Product Education

We seek to market our products principally to medical professionals, hospitals, government health agencies and organizations that contract on a large scale.

We support our sales force through specialized training workshops in which surgeons and sales specialists participate. We also produce marketing and training materials, including materials outlining surgical procedures, for our customers, sales force and distributors in a variety of languages using printed, video and multimedia formats.

To provide additional advanced training for surgeons, consistent with the AdvaMed Code and the Eucomed Code guidelines, we organize regular multilingual teaching seminars in multiple locations. Those places include our facility in Verona, Italy, various locations in Latin America and the Orthofix Institute for Research, Training and Education in the North American Operations and Training Center in Lewisville, Texas. The Orthofix Institute is a state of the art facility that features a lecture room, classroom, workshop and a 7-station bioskills laboratory. In 2015, over 1,600 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. Each year many of our sales representatives and distributors independently conduct basic product training and education courses to local surgeons. We also regularly provide sales training at our training center in Lewisville, Texas, with our sales representatives in the field and in regional locations throughout the world. Additionally, we have implemented a web-based sales training program, which provides ongoing education for our sales representatives.

Competition

Our regenerative stimulation products, which are part of our Biologics and BioStim SBUs, compete principally with similar products marketed by Biomet Spine, a business unit of Zimmer Biomet, Inc; DJO Incorporated; and the Exogen product line owned by Smith and Nephew plc. and Essex Woodlands, a private equity firm. Our spinal implant, HCT/P products, and Trinity Evolution® and Trinity ELITE®, HCT/Ps from which we derive marketing fees, 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 external and internal 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 innovation, ease of use, versatility, cost and patient acceptability. We attempt to avoid competing based solely on price. Overall cost and medical effectiveness, innovation, reliability, after-sales service and training are the most prevalent methods of competition in the markets for our products, and we believe we compete effectively.

Manufacturing and Sources of Supply

We generally design, develop, assemble, test and package our stimulation and orthopedic products, and subcontract the manufacture of a substantial portion of the component parts. We design and develop our spinal implant and Alloquent® Allograft HCT/Ps and subcontract the manufacture of a significant portion of the parts and instruments. Through subcontracting a portion of our manufacturing, we attempt to maintain operating flexibility in meeting demand while focusing our resources on product development, education and marketing as well as quality assurance standards. Although certain of our key raw materials are obtained from a single

source, we believe alternate sources for these materials are available. Further, we believe an adequate inventory supply is maintained to avoid product flow interruptions. We have not experienced difficulty in obtaining the materials necessary to meet our production schedules.

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 Trinity Evolution® and Trinity ELITE® to our customers.

Our products are currently manufactured and assembled in the U.S., Italy, and the U.K. We believe our plants comply in all material respects with the requirements of the FDA and all relevant regulatory authorities outside the U.S. For a description of the laws to which we are subject, see Item 1—Business—Corporate Compliance and Government Regulation. We actively monitor each of our subcontractors in order to maintain manufacturing and quality standards and product specification conformity.

Our financial condition, results of operations and cash flows are impacted by seasonality trends as revenue associated with elective procedures tends to be higher later in the year and lower in the beginning of the year. In addition, we do not consider the backlog of firm orders to be material.

Capital Expenditures

We incurred tangible and intangible capital expenditures of $27.9 million, $18.5 million and $29.7 million in 2015, 2014 and 2013, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. In 2015 and 2014, the most significant capital expenditure was $16.0 million related to project Bluecore, our infrastructure initiative to improve the reliability and efficiency of our systems, processes and reporting as well as drive down our overhead expenses, and tooling. We plan to invest approximately $15 to $18 million in capital expenditures during 2016 to support this initiative, which will continue through the end of 2016. See Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for additional information on Bluecore. We expect these capital expenditures to be financed principally with cash generated from operations.

Employees

At December 31, 2015, we had 927 employees worldwide. Of these, 616 were employed in the U.S. and 311 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 170 at December 31, 2015, 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. Of our 927 employees, 403 were employed in sales and marketing functions, 214 in general and administrative roles, 204 in production and operations and 106 in research and development.

eNeura Debt Security

On March 4, 2015, the Company entered into an Option Agreement (the “Option Agreement”) with eNeura, Inc. (“eNeura”), a privately held medical technology company that is developing devices for the treatment of migraines. The Option Agreement provides the Company with an exclusive option to acquire eNeura (the “Option”) during the 18-month period following the grant of the Option. In consideration for the Option, (i) the Company paid a non-refundable $0.3 million fee to eNeura, and (ii) eNeura issued a Convertible Promissory Note (the “eNeura Note”) to the Company. The principal amount of the eNeura Note is $15.0 million and interest accrues at 8.0%. The eNeura

Note will mature on the earlier of (i) March 4, 2019, or (ii) exercise of the Option. The interest is not due until the note matures and will be forgiven if the Company exercises the option. The investment is recorded in other long-term assets as an available for sale debt security and interest is recorded in interest income. For additional discussion see Note 10 to the Consolidated Financial Statements in Item 8 of this report.

Item 1A.Risk Factors

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

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

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

On June 6, 2012, in connection with our settlement of a U.S. government investigation and related qui tam complaint related to our regenerative stimulation business, and our settlement of a U.S. government investigation and related qui tam complaint related to Blackstone Medical, Inc. (“Blackstone”), we entered into a five-year corporate integrity agreement (the “CIA”) with the Office of Inspector General of the Department of Health and Human Services (“HHS-OIG”). The CIA acknowledges the existence of our current compliance program, and requires that we continue to maintain during the term of the CIA a compliance program designed to promote compliance with federal healthcare and Food and Drug Administration (“FDA”) requirements. We are also required to maintain several elements of the existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that we conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations. Pursuant to the CIA, we are required to notify the HHS-OIG in writing, among other things, of: (i) any ongoing government investigation or legal proceeding involving an allegation that the Company has committed a crime or has engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws related to compliance with federal healthcare programs or FDA requirements; and (iii) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by federal healthcare programs. We are also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. The CIA provides that in the event of an uncured material breach of the CIA, we could be excluded from participation in federal healthcare programs and/or subject to prosecution and subject to other monetary penalties, each of which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

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

We are investigating allegations involving potential improper payments with respect to our subsidiary in Brazil, which has caused an extension of the term of our existing Deferred Prosecution Agreement in connection with a prior FCPA settlement.

In 2012, the Company entered into definitive agreements with the U.S. Department of Justice (the "DOJ") and the SEC agreeing to settle a self-initiated and self-reported internal investigation of our Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the Foreign Corrupt Practices Act (the "FCPA"). As part of the settlement, we entered into a three-year deferred prosecution agreement ("DPA") with the DOJ and a consent to final judgment (the "Consent") with the SEC. The DOJ agreed not to pursue any criminal charges against us in connection with the Promeca matter if we comply with the terms of the DPA. The DPA takes note of our self-reporting of this matter to the DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by us. The DPA and the Consent collectively require, among other things, that with respect to anti-bribery compliance matters we shall continue to cooperate fully with the government in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, we have represented that we have implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws. We are periodically reporting to the government during the term of the DPA regarding such remediation and implementation of compliance measures.

In August 2013, the Company's internal legal department was notified of certain allegations involving potential improper payments with respect to its Brazilian subsidiary, Orthofix do Brasil Ltda. The Company engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the FCPA. Consistent with the provisions of these agreements, the Company contacted the DOJ and the SEC in August 2013 to voluntarily self-report the Brazil-related allegations. On June 15, 2015, the Company and the DOJ agreed to extend the term of the DPA for two months (through September 17, 2015) to permit the DOJ additional time to evaluate the Company's compliance with the internal controls and compliance undertakings in the DPA and to further investigate the Brazil-related allegations. On September 17, 2015, the DOJ extended the term of the DPA for an additional ten months (through July 17, 2016), stating that the Company's efforts to comply with the internal controls and compliance requirements of the DPA during the first eighteen months of the DPA were insufficient.

In the event that the DOJ were to determine in the future to criminally prosecute us for the FCPA-related matters we have self-reported, we could be subject to penalties that could have a material adverse effect our business, financial condition, results of operations or cash flows.

The SEC Enforcement Staff's investigation and a pending securities class action complaint have resulted in significant costs and expenses, have diverted resources and could have a material adverse effect on our business, financial condition, results of operations or cash flows.

As further described in Part I, Item 3, "Legal Proceedings" of this Form 10-K, in July 2013, the Audit Committee (the "Audit Committee") of the Board of Directors of the Company began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in a March 2014 completed multi-year restatement of our historical consolidated financial statements. In March 2015, we completed a further multi-year restatement of historical consolidated financial statements.

We initiated contact with the staff of the Division of Enforcement of the SEC (the "SEC Enforcement Staff") in July 2013 to advise them of the initiation of the Audit Committee's review and the then-potential restatement of our annual audited and interim unaudited consolidated financial statements. The SEC is conducting a formal investigation of these matters, and both the Company and the Audit Committee are cooperating fully with the SEC. Since our initial contact, we have received requests from the SEC for documents and other information concerning various accounting practices, internal controls and business practices, and it is anticipated that we may receive additional such requests in the future. We have further provided notice concerning these matters to HHS-OIG pursuant to our CIA with HHS-OIG, which is described in more detail in Part I, Item 3, "Legal Proceedings."

As also further described in Part I, Item 3, "Legal Proceedings" of this Form 10-K, on August 14, 2013, a securities class action complaint against the Company was filed in the United States District Court for the Southern District of New York arising out of the restatement of our prior consolidated financial statements and the matters described above. The lead plaintiff's complaint, as amended, purports to bring claims on behalf of persons who purchased the Company's common stock between March 2, 2010 and July 29, 2013. The complaint asserts that the Company and four of its former executive officers, Alan W. Milinazzo, Robert S. Vaters, Brian McCollum, and Emily V. Buxton (collectively, the "Individual Defendants"), violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Securities and Exchange Commission Rule 10b-5 ("Rule 10b-5") by making false or misleading statements in or relating to the Company's financial statements. The complaint further asserts that the Individual Defendants were liable as control persons under Section 20(a) of the Exchange Act for any violation by the Company of Section 10(b) of the Exchange Act or Rule 10b-5. As relief, the complaint requests compensatory damages on behalf of the proposed class and lead plaintiff's attorneys' fees and costs. On March 6, 2015, the court granted the defendants' motion to dismiss as to Mr. Milinazzo and denied it with respect to the Company and the other Individual Defendants.

On October 22, 2015, following negotiations facilitated by an independent mediator, the Company, the remaining Individual Defendants and their insurers reached an agreement in principle with the plaintiff, individually and on behalf of the class it purports to represent, to settle and release all claims with respect to this matter and to dismiss the action with prejudice subject to final court approval. Under the terms of the agreement in principle, the Company, through its insurers, would make a payment to the plaintiff, and the class it purports to represent, to resolve all claims related to the matter, including any claims for plaintiff counsel's fees and expenses. On December 7, 2015, all parties to the action executed and filed with the Court a proposed settlement agreement whose terms are consistent with the above-described agreement in principle. On December 18, 2015, the Court entered a preliminary approval order which, among other things, preliminarily approved the terms of the proposed settlement agreement, subject to a final approval hearing scheduled for April 28, 2016. The Company has previously incurred and expensed fees and expenses in connection with this matter up to and exceeding its insurance policy deductible and its insurers have undertaken to cover the full amount of the settlement payment, if the proposed settlement is finally approved by the Court.

We have incurred and/or expect to incur significant professional fees and other costs in responding to the SEC investigation and in defending against the class action complaint. If we do not prevail in or successfully settle the pending complaint or any other

litigation, we may be required to pay a significant amount of monetary damages that may be in excess of our insurance coverage. Further, if the SEC were to conclude that enforcement action is appropriate, or if HHS-OIG were to conclude that we violated the CIA, we could be required to pay large civil penalties and fines. The SEC also could impose other sanctions against us or certain of our current and former directors and officers. Any of these events could have a material adverse effect on our business, financial condition, results of operations or cash flows. Additionally, while we believe we have made appropriate judgments in determining the errors and correct adjustments in preparing our restated consolidated financial statements, the SEC could disagree with the manner in which we have accounted for and reported these adjustments. Accordingly, there is a risk that we could have to further restate our historical consolidated financial statements, amend prior filings with the SEC or take other actions not currently contemplated.

The potential for additional litigation or other proceedings or enforcement actions could adversely affect us, require significant management time and attention, result in significant legal expenses or damages, and cause our business, financial condition, results of operations or cash flows to suffer.

The matters that led to the SEC investigation and the class action complaint described above have also exposed us to greater risks associated with litigation, regulatory proceedings and government enforcement actions. We and current and former members of our senior management may in the future be subject to additional litigation or governmental proceedings relating to such matters. Subject to certain limitations, we are obligated to indemnify our current and former officers and directors in connection with any such lawsuits or governmental proceedings and related litigation or settlement amounts. Regardless of the outcome, these lawsuits and any other litigation or governmental proceedings that may be brought against us or our current or former officers and directors, could be time-consuming, result in significant expense and divert the attention and resources of our management and other key employees. An unfavorable outcome in any of these matters could exceed coverage provided under potentially applicable insurance policies. Any such unfavorable outcome could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Further, we could be required to pay damages or additional penalties or have other remedies imposed against us, or our current or former directors or officers, which could harm our reputation, business, financial condition, results of operations or cash flows.

Continuing negative publicity may have a material adverse effect on our business, financial condition, results of operations or cash flows.

As a result of the restatement of our consolidated financial statements and related matters, the ongoing SEC investigation, the securities class action complaint and our recent non-compliance with Nasdaq listing rules, we have been the subject of negative publicity. This negative publicity may adversely affect our stock price and may harm our reputation and our relationships with current and future investors, lenders, customers, suppliers and employees. As a result, our business, financial condition, results of operations or cash flows may be materially adversely affected.

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

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

- the federal Health Care Programs Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing and discounting policies, and relationships with healthcare practitioners and providers, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, 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);

federal false claims laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal government payors that are false or fraudulent; and state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payors, including commercial insurers.

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

In addition, it is possible that one or more private insurers with whom we do business may attempt to use any penalty we might be assessed or any exclusion from federal or state healthcare program business as a basis to cease doing business with us. If this were to occur, it could also have a material adverse effect on our business and financial position.

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, doctors and other healthcare providers. 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 or reimbursement rates for, our products could have an impact on our ability to sell our products. In addition, third-party payors may deny reimbursement if they determine that a device or product provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. These policies and criteria may be revised from time-to-time.

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

The Centers for Medicare and Medicaid Services ("CMS"), in its ongoing implementation of the Medicare program, has obtained a related technical assessment of the medical study literature to determine how the literature addresses spinal fusion surgery in the Medicare population. The impact that this information will have on Medicare coverage policy for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. It is also possible that the government's focus on coverage of off-label uses of devices approved by the FDA could lead to changes in coverage policies regarding off-label uses by TriCare, Medicare and/or Medicaid. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Globally, our products are sold in many countries, such as the U.K., France, and Italy, which have publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales.

As required by law, CMS has continued efforts to implement a competitive bidding program for selected durable medical equipment, prosthetic, orthotic supplies ("DMEPOS") items paid for by the Medicare program. In this program, Medicare rates are based on bid amounts for certain products in designated geographic areas, rather than the Medicare fee schedule amount. Only those suppliers selected through the competitive bidding process within each designated competitive bidding area (CBA) are eligible to have their products reimbursed by Medicare. CMS completed the Round 1 Rebid process in the last quarter of 2012. The implementation of Rebid for Round 1 occurred on January 1, 2013 and for Round 2 on July 1, 2013. Our products are not yet included in the competitive bidding process. We cannot predict which products from any of our businesses will ultimately be affected or whether or when the competitive bidding process will be extended to our businesses. While some of our products are designated by FDA as Class III medical devices and thus are not currently included within the competitive bidding program, some of our products may be encompassed within the program at varying times. There can be no assurance that the implementation of the competitive bidding program will not have an adverse impact on the sales of some of our

products.

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

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

The approval or clearance by governmental authorities, including the FDA in the U.S., is generally required before any medical devices may be marketed in the U.S. or other countries. We cannot predict whether, in the future, the U.S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition, results of operations or cash flows. The process of obtaining FDA clearance and other regulatory clearances or approvals to develop and market a medical device can be costly and time-consuming, and is subject to the risk that such approvals will not be granted on a timely basis, if at all. The regulatory

process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices. The FDA has the ability to change the regulatory classification of a cleared or approved device from a higher to a lower regulatory classification, which could materially adversely impact our ability to market or sell our devices. In addition, we may be subject to compliance action, 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.

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 ("ACA") and other United States healthcare reform legislation on us remains uncertain.

In 2010 federal legislation to reform the United States healthcare system was enacted into law. The ACA is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. The ACA mandated certain CMS demonstration projects to test the effects of new approaches for paying for health services and delivering care, including bundled payments, value-based purchasing programs, establishment of accountable care organizations, a focus on patient-centered homes and physician payment reforms that incentivize the delivery of high quality, resource-conscious health care. Several provisions of the ACA specifically impact the medical equipment industry, including the elimination of the full inflation update to the DMEPOS fee schedule for the years 2011 through 2014. Instead, beginning in 2011, the ACA reduced the inflation update for DMEPOS by a "productivity adjustment" factor intended to reflect productivity gains in delivering health care services. For 2014, the update factor is 1.0% (reflecting a 1.8% inflation update that is partially offset by a 0.8% "productivity adjustment").

Section 6002 of the ACA, the Physician Payment Sunshine Act, requires medical device, pharmaceutical and biologics manufacturers that participate in U.S. federal health care programs to make annual disclosures regarding payments or transfers of value to physicians and teaching hospitals, including physicians who serve as consultants. The recordkeeping requirements have been in place since August 1, 2013. Applicable Manufacturers and GPOs must submit annual reports to CMS by March 31st for payments and transfers of value made in the prior calendar

year. Reports are made available to the public on CMS' website. Failure to fully and accurately disclose transfers of value to physicians and teaching hospitals could subject us to civil monetary penalties. Several states also have enacted specific marketing and payment disclosure requirements, and other states may do so in the future.

We expect the new law will have a significant impact upon various aspects of our business operations. However, it is unclear how the new law will impact patient access to new technologies or reimbursement rates under the Medicare program. Many of the details of the new law will be included in new and revised regulations, which have not yet been promulgated, and require additional guidance and specificity to be provided by the Department of Health and Human Services, Department of Labor and Department of the Treasury. Accordingly, while it is too early to understand fully and predict the ultimate impact of the new law on our business, the legislation could have a material adverse effect on our business, cash flows, financial condition or results of operations.

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 being one of their suppliers, 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.

Obsolete inventories as a result of changes in demand for our products and change in life cycles of our products could adversely affect our business, operating results and financial condition.

The life cycles of some of our products depend heavily upon the life cycles of the end-products into which our products are designed. End-market products with short life cycles require us to manage closely our production and inventory levels. Inventory may also become obsolete because of adverse changes in end-market demand. We may in the future be adversely affected by obsolete or excess inventories, which may result from unanticipated changes in the estimated total demand for our products or the estimated life cycles of the end-products into which our products are designed. In addition, some customers restrict how far back the date of manufacture for our products can be and certain customers may stop ordering products from us and go out of business due to adverse economic conditions; therefore, some of our product inventory may become obsolete and, thus, adversely affect our business, operating results and financial condition.

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

Our ability to market our BioStim, Biologics, Extremity Fixation and Spine Fixation products successfully depends, in part, on the acceptance of the products by independent third parties (including hospitals, doctors, 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.

We could be subject to indemnification obligations under our agreement with the purchaser of our former sports medicine business unit.

In May 2012, we sold our former sports medicine business unit, Breg, Inc., to an affiliate of Water Street Healthcare Partners II, L.P. pursuant to a stock purchase agreement between us and the buyer. Under the stock purchase agreement, we agreed to indemnify the buyer with respect to certain specified matters, including (i) an ongoing U.S. government investigation and certain ongoing product liability matters relating to a previously owned infusion pump product line, and (ii) product liability claims relating to pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. These matters are further described under the subheading “Matters Related to Our Former Breg Subsidiary and Possible Indemnification Obligations” in Part I, Item 3, “Legal Proceedings”. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with certain of these

indemnified matters. In the event they are substantial, it could have a material adverse effect on our business, financial condition, results of operations or cash flows.

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.

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.

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

Our Biologics business markets tissue under the brand names Trinity Evolution® and Trinity ELITE®. Trinity Evolution® and Trinity ELITE® 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. We believe that Trinity Evolution® and Trinity ELITE® are properly classified 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 Trinity Evolution® and Trinity ELITE®, 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. The success of our Trinity Evolution® and Trinity ELITE® allografts will depend on these products achieving broad market acceptance, which can depend on the product achieving broad clinical acceptance, the level of third-party reimbursement and the introduction of competing technologies. Because Trinity Evolution ® and Trinity Elite are classified as HCT/Ps, they can from time to time be subject to recall for safety or administrative reasons.

Our Biologics business also distributes allograft products that are derived from human tissue harvested from cadavers that are used for bone reconstruction or repair, which are surgically implanted into the human body. We believe these allograft products are properly classified as HCT/P products and not as a medical device or a biologic or drug. There can be no assurance that the FDA would agree that this regulatory classification applies to these products and any regulatory reclassification could have adverse consequences for us or for the suppliers of these products and make it more difficult or expensive for us to conduct this business by requiring premarket clearance or approval and compliance with additional post-market regulatory requirements. Moreover, the supply of these products to us could be interrupted by the failure of our suppliers to maintain high standards in performing required donor screening and infectious disease testing of donated human tissue used in producing allograft implants. Our allograft implant business could also be adversely affected by shortages in the supply of donated human tissue or negative publicity concerning methods of recovery of tissue and product liability actions arising out of the distribution of allograft implant products.

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 2015, we continued to make improvements in revenues related to several new products we introduced to the market over the past three years, including the CONSTRUX® Mini PTC™ PEEKTI Composite Spacer System™, Phoenix® Minimally Invasive Spinal Fixation System, the Firebird® Deformity Correction System, the FORZA® Spacer System, TL-HEX TrueLok Hexapod System®, Galaxy Fixation® System, Contours LPS™ (Lapidus Plating System), Centronail® Ankle Compression Nail, 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 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 Eucomed Code guidelines, we organize monthly multilingual teaching seminars in multiple locations, including our Orthofix Institute for Research, Training and Education in the North American Operations and Training Center in Lewisville, Texas. 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 are currently upgrading 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, will require that our management and resources be diverted from our core business to assist in compliance with those requirements. There can be no assurance that the time and resources our management will need to devote to these upgrades, service outages or delays due to the installation of any new or upgraded technology (and customer issues therewith), or the impact on the reliability of our data from any new or upgraded technology will not have a material adverse effect on our cash flows, operating results and financial condition.

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

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

We contract with third-party manufacturers to produce most of our products, like many other companies in the medical device industry. If we or any such manufacturer fails to meet production and delivery schedules, it can have an adverse impact on our ability to sell such products. Further, whether we directly manufacture a product or utilize a third-party manufacturer, shortages and spoilage of materials, labor stoppages, product recalls, manufacturing defects and other similar events can delay production and inhibit our ability to bring a new product to market in timely fashion. For example, the supply of Trinity Evolution® and Trinity ELITE® 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. Further, because Trinity Evolution® and Trinity ELITE® are classified as HCT/Ps, they could from time to time be subject to recall for safety or administrative reasons.

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 depend on our senior management team.

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

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

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

We are party to numerous contractual relationships.

We are party to numerous contracts in the normal course of our business. We have contractual relationships with suppliers, distributors and agents, as well as service providers. In the aggregate, these contractual relationships are necessary for us to operate our business. From time to time, we amend, terminate or negotiate our contracts. We are also periodically subject to, or make claims of breach of contract, or threaten legal action relating to our contracts. These actions may result in litigation. At any one time, we have a number of negotiations under way for new or amended commercial agreements. We devote substantial time, effort and expense to the administration and negotiation of contracts involved in our business. However, these contracts may not continue in effect past their current term or we may not be able to negotiate satisfactory contracts in the future with current or new business partners.

We have loaned $15 million to an early stage company as part of our option to acquire it, and may not be able to recoup our investment or successfully complete the acquisition.

On March 4, 2015, we entered into an option agreement with eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The option agreement provides us with an exclusive option until September 2016 to acquire eNeura. In consideration for the option, (i) we paid a non-refundable $250,000 fee to eNeura, and (ii) we loaned eNeura $15 million pursuant to a convertible, secured promissory note that was issued to us.

eNeura is using the proceeds of our loan to fund product development work related to its business and to fund its ongoing operations. 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 we do not choose to exercise our option to acquire eNeura or convert the promissory note to equity. In such an event, we could lose all or a substantial portion of our $15 million loan investment.

Further, while we believe that eNeura has made recent progress on product design improvements, initiating a new clinical trial, and initial U.S. commercialization efforts, no assurance can be made that eNeura’s business will ultimately be successful. In particular, in the event that we ultimately exercise our option to acquire eNeura, we will need to integrate eNeura’s business into our own. Such integration may involve numerous risks, including the need to successfully continue eNeura’s product development, and incorporate potential products into our own sales, marketing and distribution channels. A failure to overcome these risks or any other problems encountered in connection with the acquisition could adversely affect our business, prospects and financial condition.

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

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

We 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 2015 have had an unfavorable impact of $15.3 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we enter into currency hedges from time to time. At December 31, 2015, we had a cross-currency swap to hedge a €9.6 million foreign currency exposure.

We are subject to differing tax rates in several jurisdictions in which we operate.

We have subsidiaries in several countries. 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. 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.

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.

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
- application of the FCPA and other anti-bribery or anti-corruption laws to our operations.

Compliance with government regulations and customer demands regarding the use of “conflict minerals” may result in increased costs and may have a negative impact on our business, results of operations and financial condition.

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 imposes new disclosure requirements regarding the use of certain minerals, which are mined from the Democratic Republic of Congo and adjoining countries, known as conflict minerals. When these new requirements are implemented, they could affect the pricing, sourcing and availability of minerals used in the manufacture of semiconductor devices (including our products). There will be additional costs associated with complying with the disclosure requirements, such as costs related to determining the source of any conflict minerals used in our products. Our supply chain is complex and we may be unable to verify the origins for all metals used in our products. Customers may demand that the products they purchase be free of conflict minerals. Therefore, we may encounter challenges with our customers and stockholders if we are unable to certify that our products are conflict free. The implementation of this requirement could affect the sourcing and availability of products we purchase from

suppliers in the future. This may reduce the number of suppliers that may be able to provide conflict free products, and may affect our ability to obtain products in sufficient quantities to meet customer demand or at competitive prices.

We may incur costs and undertake new debt and contingent liabilities in a search for acquisitions, and we may be unsuccessful in our search for such acquisitions or have difficulty integrating any acquired businesses or product lines.

We continue to search for viable acquisition candidates that would expand our market sector or global presence. We also seek additional products appropriate for current distribution channels. The search for an acquisition of another company or product line by us could result in our incurring costs from such efforts as well as the undertaking of new debt and contingent liabilities from such searches or acquisitions. Such costs may be incurred at any time and may vary in size depending on the scope of the acquisition or product transactions and may have a material impact on our results of operations.

In addition, we compete with other medical device companies for these opportunities, and we may be unable to consummate such acquisitions on commercially reasonable terms, or at all. To the extent we are able to make acquisitions; we may experience difficulties in integrating any acquired companies or products into our existing business, including attrition of key personnel from acquired companies or businesses, and significant costs, charges or write downs. In addition, unforeseen operating difficulties integrating acquired companies or businesses could require us to devote significant financial and managerial resources that would otherwise be available to our existing businesses. 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.

Our subsidiaries, Orthofix Holdings, Inc. and Victory Medical Limited, maintain a $125 million secured revolving credit facility that expires in August 2020.

On August 31, 2015, the Company, through its subsidiaries, Orthofix Holdings, Inc. and Victory Medical Limited (collectively the “Borrowers”), entered into a credit agreement providing for a five-year secured revolving credit facility of $125 million. This loan arrangement replaced a prior credit facility that Orthofix Holdings had entered into in 2010. At the time of implementation in August 2015, no amounts were drawn. No amounts have been drawn on the credit facility as of December 31, 2015, but the Company may draw on this facility in the future.

The Company and certain of its existing and future United States and United Kingdom domiciled subsidiaries (collectively, the “Guarantors”) are required to guarantee the repayment of the Borrowers’ obligations under the 2015 Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the 2015 Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries.

The credit agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with

others, dispose of assets, pay dividends and distributions, repay subordinated indebtedness and enter into affiliate transactions. In addition, the credit agreement contains financial covenants requiring us on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. The credit agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the facility may be accelerated and/or the lenders' commitments terminated.

We believe that we were in compliance with the negative covenants, and there were no events of default, at December 31, 2015 (and in prior periods). However, there can be no assurance that the Company would be able to meeting such financial covenants in future fiscal quarters. The failure to do so could result in an event of default under such agreement, which could have a material adverse effect on our financial position.

Our results of operations could vary as a result of the methods, estimates and judgments we use in applying our accounting policies.

The methods, estimates and judgments we use in applying our accounting policies have a significant impact on our consolidated results of operations (see Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” under the subheading “Critical Accounting Policies and Estimates”). Such methods, estimates and judgments are, by their nature, subject to substantial risks, uncertainties and assumptions, and factors may arise over time that leads us to change our methods, estimates and judgments. Changes in those methods, estimates and judgments could significantly affect our results of operations.

Valuation adjustments to “goodwill”, which represents a significant portion of our total assets, may adversely affect our net income and we may never realize the full value of our intangible assets.

A significant portion of our assets is comprised of goodwill. We may not receive the recorded value for our goodwill if we sell or liquidate our business or assets. The material concentration of goodwill increases the risk of a large charge to earnings if recoverability of goodwill is impaired, which would have an adverse effect on our net income.

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

We were organized under the laws of the Netherlands Antilles in 1987, with our principal executive office in the Netherlands Antilles located on the island of Curaçao. Prior to October 10, 2010, the Netherlands Antilles, together with Aruba and the Netherlands, formed the Kingdom of the Netherlands, with Curaçao being an island territory of the Netherlands Antilles. Under a constitutional reform of the Kingdom of the Netherlands, agreed upon among the Netherlands Antilles, Aruba and the Netherlands, the Netherlands Antilles was dissolved effective October 10, 2010. Also effective October 10, 2010, Curaçao became an individual constitutional entity within the Kingdom of the Netherlands, having its own government and laws. As a result of the constitutional reform and the dissolution of the Netherlands Antilles, the Netherlands Antilles law ceased to exist and the Company is now a Curaçao legal entity subject to Curaçao law. Although Curaçao has become a separate and autonomous country with its own laws and regulations, the civil and corporate Netherlands Antilles law, as they applied to the Company before October 10, 2010, did not change under the constitutional reform. In effect, Curaçao has adopted the Netherlands Antilles civil and corporate law (to which the Company was subject) that was in effect prior to October 10, 2010.

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

Item 1B. Unresolved Staff Comments
None.

Item 2. Properties

Our principal facilities as of December 31, 2015 are:

Facility	Location	Approx. Square Feet	Ownership
Manufacturing, warehousing, distribution and research and development facility for Spine and Orthopedics Products and administrative facility for Corporate, Spine, and Biologics	Lewisville, TX	140,000	Leased
Research and development, component manufacturing, quality control and training facility for fixation products and sales management, distribution and administrative facility for Italy	Verona, Italy	38,000	Owned
International Distribution Center for Orthofix products	Verona, Italy	18,000	Leased
Sales management, distribution and administrative facility for United Kingdom	Maidenhead, England	18,460	Leased
Sales management, distribution and administrative facility for Brazil	Curitiba, Brazil	1,065	Leased
Sales management, distribution and administrative facility for Brazil	São Paulo, Brazil	21,617	Leased
Sales management, distribution and administrative facility for France	Arcueil, France	8,500	Leased
Sales management, distribution and administrative facility for Germany	Ottobrunn, Germany	16,145	Leased
Sales management, distribution and administrative facility for Puerto Rico	Guaynabo, Puerto Rico	2,996	Leased

Item 3. Legal Proceedings

We are party to outstanding legal proceedings, investigations and claims as described below. We believe that it is unlikely that the outcome of each of these matters, including the matters discussed below, will have a material adverse effect on our Company and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on our net earnings (if any) in any particular quarter. However, we cannot predict with any certainty the final outcome of any legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims made against us as described in the paragraphs below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

We record accruals for certain outstanding legal proceedings, investigations or claims when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, we do not accrue the loss. However, if the loss (or an

additional loss in excess of the accrual) is at least a reasonable possibility and material, then we disclose a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If we cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

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

In addition to the matters described in the paragraphs below, in the normal course of our business, we are involved in various lawsuits from time to time and may be subject to certain other contingencies. To the extent losses related to these contingencies are both probable and reasonably estimable we accrue appropriate amounts in the accompanying financial statements and provide disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonably estimable. We believe losses are individually and collectively immaterial as to a possible loss and range of loss.

Matters Related to the Audit Committee's Review and the Restatement of Certain of our Consolidated Financial Statements.

Audit Committee Review

In July 2013, the Audit Committee of our Board of Directors began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in a restatement of our previously filed consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010 and the fiscal quarter ended March 31, 2013, as well as the restatement of certain financial information for the fiscal years ended December 31, 2009, 2008 and 2007. This restatement, which we completed and filed in March 2014, is referred to herein as the "Original Restatement."

In connection with the Company's preparation of its consolidated interim quarterly financial statements for the fiscal quarter ended June 30, 2014, the Company determined that certain entries with respect to the previously filed financial statements contained in the filings containing the Original Restatement were not properly accounted for under U.S. GAAP. As a result, the Company determined in August 2014 to restate its previously filed consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 and quarterly reporting periods contained within the fiscal years ended December 31, 2013 and 2012, as well as the fiscal quarter ended March 31, 2014. This restatement, which we completed in March 2015, is referred to herein as the "Further Restatement."

SEC Investigation

In connection with the initiation of the Audit Committee's independent review, we initiated contact with the staff of the Division of Enforcement of the SEC (the "SEC Enforcement Staff") in July 2013 to advise them of these matters. The Audit Committee and the Company, through respective counsel, have been in direct communication with the SEC Enforcement Staff regarding these matters. The SEC is conducting a formal investigation of these matters, and both the Company and the Audit Committee are cooperating fully with the SEC.

In connection with the above-referenced communications, the Company has received requests from the SEC for documents and other information concerning various accounting practices, internal controls and business practices, and other related matters. Such requests cover the years ended December 31, 2011 and 2012, and in some instances, prior periods. It is anticipated that we may receive additional requests from the SEC in the future, including with respect to the Further Restatement.

We have previously provided notice concerning our communications with the SEC to the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS-OIG") pursuant to our corporate integrity agreement with HHS-OIG (which agreement is described below in this Item 3).

We cannot predict if, when or how this matter will be resolved or what, if any, actions we may be required to take as part of any resolution of these matters. Any action by the SEC, HHS-OIG or other governmental agency could result in civil or criminal sanctions against us and/or certain of our current and former officers, directors and employees. At this stage in the matter, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

Securities Class Action Complaint

On August 14, 2013, a securities class action complaint against the Company, currently styled Tejinder Singh v. Orthofix International N.V., et al. (No.:1:13-cv-05696-JGK), was filed in the United States District Court for the Southern District of New York arising out of the then anticipated restatement of our prior financial statements and the matters described above. Since the date of original filing, the complaint has been amended.

The lead plaintiff's complaint, as amended, purports to bring claims on behalf of persons who purchased the Company's common stock between March 2, 2010 and July 29, 2013. The complaint asserts that the Company and four of its former executive officers, Alan W. Milinazzo, Robert S. Vaters, Brian McCollum, and Emily V. Buxton (collectively, the "Individual Defendants"), violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Securities and Exchange Commission Rule 10b-5 ("Rule 10b-5") by making false or misleading statements in or relating to the Company's financial statements. The complaint further asserts that the Individual Defendants were liable as control persons under Section 20(a) of the

Exchange Act for any violation by the Company of Section 10(b) of the Exchange Act or Rule 10b-5. As relief, the complaint requests compensatory damages on behalf of the proposed class and lead plaintiff's attorneys' fees and costs. On March 6, 2015, the court granted the defendants' motion to dismiss as to Mr. Milinazzo and denied it with respect to the Company and the other Individual Defendants.

On October 22, 2015, following negotiations facilitated by an independent mediator, the Company, the remaining Individual Defendants and their insurers reached an agreement in principle with the plaintiff, individually and on behalf of the class it purports to represent, to settle and release all claims with respect to this matter and to dismiss the action with prejudice subject to final court approval. Under the terms of the agreement in principle, the Company, through its insurers, would make a payment to the plaintiff, and the class it purports to represent, to resolve all claims related to the matter, including any claims for plaintiff counsel's fees and expenses. On December 7, 2015, all parties to the action executed and filed with the Court a proposed settlement agreement whose terms are consistent with the above-described agreement in principle. On December 18, 2015, the Court entered a preliminary approval order which, among other things, preliminarily approved the terms of the proposed settlement agreement, subject to a final approval hearing scheduled for April 28, 2016. The Company has previously incurred and expensed fees and expenses in connection with this matter up to and exceeding its insurance policy deductible and its insurers have undertaken to cover the full amount of the settlement payment, if the proposed settlement is finally approved by the Court. The Company has accrued both the amount of the settlement payment under the agreement in principle, and a corresponding insurance receivable from its insurers, with respect to these matters.

Deferred Prosecution Agreement and Review of Potential Improper Payments Involving Brazil Subsidiary

In 2012, the Company entered into definitive agreements with the U.S. Department of Justice (the "DOJ") and the SEC agreeing to settle a self-initiated and self-reported internal investigation of our Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the Foreign Corrupt Practices Act (the "FCPA"). As part of the settlement, we entered into a three-year deferred prosecution agreement ("DPA") with the DOJ and a consent to final judgment (the "Consent") with the SEC. The DOJ agreed not to pursue any criminal charges against us in connection with the Promeca matter if we comply with the terms of the DPA. The DPA takes note of our self-reporting of this matter to the DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by us. The DPA and the Consent collectively require, among other things, that with respect to anti-bribery compliance matters we shall continue to cooperate fully with the government in any future matters related to corrupt payments, false books and records or inadequate internal controls. In that regard, we have represented that we have implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws. We are periodically reporting to the government during the term of the DPA regarding such remediation and implementation of compliance measures.

In August 2013, the Company's internal legal department was notified of certain allegations involving potential improper payments with respect to its Brazilian subsidiary, Orthofix do Brasil Ltda. The Company engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the FCPA. Consistent with the provisions of these agreements, the Company contacted the DOJ and the SEC in August 2013 to voluntarily self-report the Brazil-related allegations. On June 15, 2015, the Company and the DOJ agreed to extend the term of the DPA for two months (through September 17, 2015) to permit the DOJ additional time to evaluate the Company's compliance with the internal controls and compliance undertakings in the DPA and to further investigate the Brazil-related allegations. On September 17, 2015, the DOJ extended the term of the DPA for an additional ten months (through July 17, 2016), stating that the Company's efforts to comply with the internal controls and compliance requirements of the DPA during the first eighteen months of the DPA were insufficient.

In the event that the DOJ were to determine in the future to criminally prosecute us for the FCPA-related matters we have self-reported, we be could subject to penalties, the amount or range of which we currently cannot reasonably

estimate.

IMSS Matter

Basing its claims on the same or similar events that resulted in the DPA and the Consent, the Instituto Mexicano del Seguro Social ("IMSS") brought legal action against the Company in October 2014. In February 2016, the Company reached a settlement agreement with IMSS, whereby the Company agreed to pay $1.0 million in cash and, once all regulatory hurdles are cleared, an in-kind payment in the form of products and training valued at $3.0 million. The combined settlement of $4.0 million was accrued as of December 31, 2015 within general and administrative expense. The Company made no admission of liability or wrongdoing and IMSS agreed that no portion of the payments will be characterized as the payment of fines, penalties, or other punitive assessment.

Corporate Integrity Agreement with HHS-OIG

As previously disclosed, on June 6, 2012, we entered into a definitive settlement agreement with the United States of America, acting through the DOJ and on behalf of HHS-OIG; the TRICARE Management Activity, through its General Counsel; the Office of Personnel Management, in its capacity as administrator of the Federal Employees Health Benefits Program; the United States Department of Veteran Affairs; and the qui tam relator, pursuant to which we agreed to pay $34.2 million (plus interest at a rate of 3% from May 5, 2011 through the day before payment was made) to settle criminal and civil matters related to the promotion and marketing of our regenerative stimulator devices (which we have also described in the past as our "bone growth stimulator devices"). In connection with such settlement agreement, Orthofix Inc., our wholly owned subsidiary, also pled guilty to one felony count of obstruction of a June 2008 federal audit (§18 U.S.C. 1516) and paid a criminal fine of $7.8 million and a mandatory special assessment of $400. Also as previously disclosed, on October 29, 2012, we, through our subsidiary, Blackstone Medical, Inc., entered into a definitive settlement agreement with the U.S. government and the qui tam relator, pursuant to which we paid $32 million to settle claims (covering a period prior to Blackstone's acquisition by us) concerning the compensation of physician consultants and related matters. All of the $32 million we paid pursuant to such settlement was funded by proceeds we received from an escrow fund established in connection with our acquisition of Blackstone in 2006.

On June 6, 2012, in connection with these settlements, we also entered into a five-year corporate integrity agreement with HHS-OIG (the "CIA"). The CIA acknowledges the existence of our current compliance program and requires that we continue to maintain during the term of the CIA a compliance program designed to promote compliance with federal healthcare and FDA requirements. We are also required to maintain several elements of our previously existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that we conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations.

Pursuant to the CIA, we are required to notify the HHS-OIG in writing, among other things, of: (i) any ongoing government investigation or legal proceeding involving an allegation that the Company has committed a crime or has engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws related to compliance with federal healthcare programs or FDA requirements; and (iii) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by federal healthcare programs. We are also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. The CIA provides that in the event of an uncured material breach of the CIA, we could be excluded from participation in federal healthcare programs and/or subject to monetary penalties.

Matters Related to Our Former Breg Subsidiary and Possible Indemnification Obligations

On May 24, 2012, we sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. (“Water Street”) pursuant to a stock purchase agreement (the “Breg SPA”). Under the terms of the Breg SPA, upon closing of the sale, the Company and its subsidiary, Orthofix Holdings, Inc., agreed to indemnify Water Street and Breg with respect to certain specified matters, including the following:

- Breg was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008. Since 2008, numerous product liability cases have been filed in the United States alleging that the local anesthetic, when dispensed by such infusion pumps inside a joint, causes a rare arthritic condition called “chondrolysis.” The Company incurred losses for settlements and judgments in connection with these matters during 2015, 2014 and 2013 of $0.3 million, $3.8 million and $6.7 million, respectively. In addition, several cases remain outstanding for which the Company currently cannot reasonably estimate the possible loss, or range of loss.
- At the time of its divestiture, Breg was currently and had been engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court, alleging the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units or who would not have purchased the units had

they known they could be injured. In September 2014, the Company entered into a master settlement agreement resolving all pending pre-close claims. Pursuant to the terms of the settlement agreement, the Company paid approximately $1.3 million, and additional amounts owed under the settlement were paid directly by the Company's insurance providers. These amounts paid by the Company were recorded as an expense in discontinued operations during the quarter ended June 30, 2014. Remaining cold therapy claims include a putative consumer class of individuals who did not suffer physical harm following use of the devices, and an appeal of an adverse July 2012 California jury verdict and a post-close cold therapy claim pending in California state court. As of December 31, 2015, we have an accrual of $5.7 million for the July 2012 verdict and post-close cold therapy liabilities; however, the actual liability could be higher or lower than the amount accrued. The putative class action is at an early stage and the Company currently cannot reasonably estimate the possible loss, or range of loss.

Item 4. Mine Safety Disclosure

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." The following table shows the quarterly range of high and low sales prices for our common stock as reported by Nasdaq® for each of the two most recent fiscal years ended December 31, 2015. As of February 24, 2016 we had 311 holders of record of our common stock. The closing price of our common stock on February 24, 2016 was $37.22.

	High	Low
2014		
First Quarter	$30.38	$20.50
Second Quarter	36.25	29.68
Third Quarter	36.63	30.13
Fourth Quarter	31.01	27.91
2015		
First Quarter	$35.89	$28.31
Second Quarter	37.84	31.84
Third Quarter	40.41	31.83
Fourth Quarter	41.71	32.51

Dividend Policy

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

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 received from our subsidiaries.

Repurchases of Equity Securities

The Company's Board of Directors authorized a share repurchase plan in the fourth quarter of 2015, authorizing the purchase of up to $75 million of the Company's common stock through and including September 2017. Under the program, common share repurchases are expected to consist primarily of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Securities Exchange Act of 1934, as amended, though the Company may also make repurchases through block trades or privately negotiated transactions. Repurchases may be made from cash on hand, cash generated from operations, and/or borrowings under the Company's new secured revolving credit facility. The program does not obligate the Company to acquire any specific number of shares and may be discontinued at any time. The following table sets forth information with respect to shares of our common stock purchased by the Company during the fourth quarter of 2015.

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased under Approved Stock Repurchase Program	Maximum Dollar Value of Shares Yet to be Purchased under Approved Stock Repurchase Program
October 2015	—	$ —	—	$75,000,000
November 2015	114,773	$ 39.55	114,773	$70,460,983
December 2015	179,218	$ 39.26	293,991	$63,424,851
Total as of December 31, 2015	293,991	$ 39.37		$63,424,851

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2015.

Exchange Controls

Although there are Curaçao laws that may impose foreign exchange controls on us and that may affect the payment of dividends, interest or other payments to nonresident holders of our securities, including the shares of common stock, we have been granted an exemption from such foreign exchange control regulations by the Central Bank of Curaçao and St. Maarten. Other jurisdictions in which we conduct operations may have various currency or exchange controls. In addition, we are subject to the risk of changes in political conditions or economic policies that could result in new or additional currency or exchange controls or other restrictions being imposed on our operations. For a description of these risks, see Item 1A Risk Factors. As to our securities, Curaçao law and our Articles of Association impose no limitations on the rights of persons who are not residents in or citizens of the Curaçao to hold or vote such securities.

Taxation

Orthofix International N.V. was organized under the laws of the Netherlands Antilles and is headquartered in Curaçao. On October 10, 2010, the Netherlands Antilles ceased to exist and Curaçao became a separate and autonomous country. As of October 10, 2010, the laws as they existed under the Netherlands Antilles automatically became the laws of the country of Curaçao. Our tax rulings and agreements as they existed under the Netherlands Antilles remain in effect. Under the laws of the country of Curaçao as currently in effect, a holder of shares of common stock who is not a resident of, and during the taxable year has not engaged in trade or business through a permanent establishment in Curaçao will not be subject to Curaçao income tax on dividends paid with respect to the shares of common stock or on gains realized during that year on sale or disposal of such shares; Curaçao does not impose a withholding tax on dividends paid by us. There are no gift or inheritance taxes levied by Curaçao when, at the time of such gift or at the time of death, the relevant holder of common shares was not domiciled in Curaçao. No reciprocal tax treaty presently exists between Curaçao and the U.S.

Performance Graph

The following performance graph in this Item 5 of this Annual Report on Form 10-K is not deemed to be “soliciting material” or to be “filed” with the SEC or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934 or to the liabilities of Section 18 of the Securities Exchange Act of 1934, and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent we specifically incorporate it by reference into such a filing.

The graph below compares the five-year total return to shareholders for Orthofix common stock with comparable 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, 2010. 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 consolidated financial data for the years ended December 31, 2015, 2014, 2013, 2012, and 2011, have been derived from our audited consolidated financial statements. The financial data as of December 31, 2015 and 2014 and for the years ended December 31, 2015, 2014 and 2013 should be read in conjunction with, and are qualified in their entirety by, reference to Item 7 under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes thereto included elsewhere in this Form 10-K.

	Year ended December 31,				
	2015	2014	2013	2012	2011
	(U.S. Dollars in thousands, except margin and per share data)				
Consolidated operating results					
Net sales	$396,489	$402,277	$397,611	$440,189	$435,519
Gross profit	309,964	303,365	290,699	339,463	339,104
Gross profit margin	78 %	75 %	73 %	77 %	78 %
Total operating income (loss) (2)	9,255	17,136	(11,192)	74,872	6,611
Net (loss) income from continuing operations	(2,342)	(3,744)	(18,205)	45,121	(15,806)
Net loss from discontinued operations	(467)	(4,793)	(10,607)	(2,269)	(1,892)
Net (loss) income (1) (2)	$(2,809)	$(8,537)	$(28,812)	$42,852	$(17,698)
Net income (loss) per share of common stock:					
Basic:					
Net (loss) income from continuing operations	$(0.12)	$(0.20)	$(0.97)	$2.38	$(0.87)
Net loss from discontinued operations	(0.03)	(0.26)	(0.57)	(0.12)	(0.10)
Net (loss) income	$(0.15)	$(0.46)	$(1.54)	$2.26	$(0.97)
Net income (loss) per share of common stock:					
Diluted:					
Net (loss) income from continuing operations	$(0.12)	$(0.20)	$(0.97)	$2.33	$(0.87)
Net loss from discontinued operations	(0.03)	(0.26)	(0.57)	(0.12)	(0.10)
Net (loss) income	$(0.15)	$(0.46)	$(1.54)	$2.21	$(0.97)
Weighted average number of common shares outstanding:					
Basic:	18,795,194	18,459,054	18,697,228	18,977,263	18,219,343
Diluted:	18,795,194	18,459,054	18,697,228	19,390,413	18,219,343

(1) The Company has not paid any dividends in any of the years presented.

(2) Operating income includes charges related to U.S. Government resolutions of $1.3 million and $57.1 million for the years ended December 31, 2012 and 2011, respectively. Operating income (loss) in 2015, 2014 and 2013 include costs incurred of $9.1 million, $15.6 million and $12.9 million, respectively, for legal and other professional services in connection with the Audit Committee's independent review of certain accounting matters and the multi-year restatements of our consolidated financial statements that we filed in March 2014 and March

2015. Operating loss in 2013 also includes a goodwill impairment charge of $19.2 million.

	As of December 31,				
	2015	2014	2013	2012	2011 (Unaudited)
	(U.S. Dollars in thousands, except share data)				
Consolidated financial position					
Total assets	$400,222	$392,956	$411,975	$464,546	$ 676,160
Long-term debt	—	—	20,000	20,016	210,013
Shareholders' equity	290,311	299,627	295,863	356,439	280,304

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

The following discussion and analysis addresses the results of our operations based upon the consolidated financial statements included herein, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). This discussion should be read in conjunction with "Forward-Looking Statements" and our consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K. This discussion and analysis also addresses our liquidity and financial condition and other matters.

General

We are a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, TX, the Company has four strategic business units ("SBUs") that include BioStim, Biologics, Extremity Fixation and Spine Fixation. Orthofix products are widely distributed via the Company's sales representatives, distributors and its subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as the Musculoskeletal Transplant Foundation ("MTF") and the Texas Scottish Rite Hospital for Children.

We have administrative and training facilities in the U.S., Italy, Brazil, the U.K., France, Germany, and Puerto Rico and manufacturing facilities in the U.S. and Italy. We directly distribute products in the U.S., Italy, the U.K., Germany, Austria, France, Brazil, and Puerto Rico. In several of these and other markets, we also distribute our products through independent distributors.

Our reporting currency is the U.S. Dollar. All balance sheet accounts, except shareholders' equity, are translated at year-end exchange rates, and revenue and expense items are translated at weighted average exchange rates prevailing during the year. Gains and losses resulting from foreign currency transactions, including those generated from intercompany operations, are included in other income and expense. Gains and losses resulting from the translation of foreign currency financial statements are recorded in the accumulated other comprehensive income component of shareholders' equity.

Our financial condition, results of operations and cash flows are impacted by seasonality trends as revenue associated with elective procedures tends to be higher later in the year and lower in the beginning of the year. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar denominated income and expenditures. During the year, we used a cross-currency swap to hedge foreign currency fluctuation exposures. Our exposure to changes in interest rates is minimal as we do not currently have an outstanding balance on our Credit Agreement. See Item 7A—"Quantitative and Qualitative Disclosures About Market Risk."

2015 Operational Achievements

Our strategy in 2015 was built upon the following key objectives:

(i) Sales Channel Optimization – During 2015 we continued to expand and improve our sales forces in each of our SBUs. We achieved our aggressive sales channel optimization objective for the year as evidenced by expanding our U.S. sales team by 20%. Going forward, we intend to transition into a steady state of moderate expansion and upgrading of our sales force. Although we invested in sales and marketing expenses at a higher rate this year than

we expect to in the long-term, these investments have been very effective in increasing our revenue.

(ii) Investment in Core Technologies – We invested in our core technologies by focusing on the following areas:

(a) We increased the rate of new product introductions by launching six significant new products and four product line extensions in our repair businesses, including TrueLok Hex and the Unyco monocortical fixation screw in our Extremity Fixation SBU, along with the Centurion posterior cervical system, Janus midline screw, Phoenix MIS Long Construct, LoneStar Cervical interbody, and the relaunched Azure anterior cervical plate in our Spine Fixation SBU.

(b) We invested in preclinical and clinical research, including completing seven clinical studies, to both support the use and reimbursement of our regenerative products and find new indications for our technologies. We are also continuing to work on numerous pre-clinical studies that will support each of our SBUs.

(c) We acquired products and technologies that fill our portfolio gaps and will drive sales. We continue to identify and acquire rights to tuck-in products, which fill gaps in our fixation SBUs. Most recently, we acquired an expandable

vertebral body replacement and have an agreement in principle for an anterior cervical plate in our Spine Fixation SBU, both due to release in 2016. In addition, our option to purchase eNeura extends until September 2016. Since making our initial investment in the first quarter, eNeura has made progress on product design improvements, a new clinical trial, and initial commercialization efforts in the US, which are critical areas for us to consider in deciding whether to exercise our option.

(iii) Improvement of Infrastructure and Control Environment – In 2014 we initiated project "Bluecore," a multi-year, worldwide initiative to improve the reliability and efficiency of our systems, processes, and reporting. In addition to re-implementing our Oracle ERP platform worldwide, we executed numerous work streams designed to improve supply chain management, optimize finance and accounting procedures, and transition to less manual processes with fewer redundancies throughout the Company. Bluecore remains within budget and we expect to go live in the U.S. on our new ERP platform during the second quarter of 2016. During 2015, we spent $21.4 million pursuant to this initiative, $16.0 million of which was capitalized.

2016 Operational Objectives

(i) Sales Channel Expansion and Optimization – Our objective for 2016 is to increase revenue for each of our SBUs at a faster rate than their respective markets by growing and optimizing our sales force while expanding our product portfolio with new and innovative products. Specifically, in 2016, we expect to accelerate our new product development with new product launches and product line extensions. The most important of these product launches is our next generation bone growth stimulation products for the BioStim SBU; a novel hip fracture system for the Extremity Fixation SBU; and the introduction of our Forza line of proprietary interbody products, which represents a significant upgrade and enhancement to our Firebird® pedicle screw system, and a new anterior cervicle plate in the Spine Fixation SBU.

(ii) Improvement of Operating Leverage – During 2016 we expect to drive higher margins by improving our operating leverage and reducing selling, general, and administrative expenses. We expect to make progress on this initiative in 2016 and for this to be a continued focus area in the years ahead.

(iii) Investment in Clinical Research – In order to ensure the long-term success of our Company, we plan to invest significant resources in clinical research, particularly for our regenerative technologies. In 2016, we plan to initiate or continue work on a variety of clinical studies supporting both our existing products and our continued effort to identify new indications for our PEMF technologies.

Critical Accounting Policies and Estimates

Our discussion of operating results is based upon the consolidated financial statements and accompanying notes to the consolidated financial statements prepared in conformity with U.S. GAAP. The preparation of these statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. These estimates and assumptions form the basis for the carrying values of assets and liabilities. On an ongoing basis, we evaluate these estimates, which are based on historical experience and various other assumptions that management believe to be reasonable under the circumstances at that certain point in time. Actual results may differ, significantly at times, from these estimates. We have reviewed our critical accounting policies with the Audit Committee of the Board of Directors.

We believe the following critical accounting policies and estimates affect the significant estimates and judgments we use in preparation of our consolidated financial statements.

Revenue Recognition

Commercial revenue is related to the sale of our implant products, generally representing hospital customers. Revenues are recognized when these products have been utilized and a confirming purchase order has been received from the hospital.

Revenue is also derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of our stimulation products. Revenue is recognized when the stimulation product is placed on and accepted by the patient and all perfunctory documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any

contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment. Revenue for certain government entities is recorded on a cash-basis as collectability is not reasonably assured.

For all distributor revenue, which is primarily related to implant products, we recognize revenue on the sell-through basis, effective April 1, 2013. Prior to this date, we recognized revenue either on a sell-in or sell-through basis, depending on the specific circumstances of the distributor. In some cases we recognized distributor revenue as title and risk of loss passes at either shipment from our facilities or receipt at the distributor's facility, assuming all other revenue recognition criteria had been achieved (the "sell-in method"). In some cases the revenue recognition criteria for distributor sales were not satisfied at the time of shipment or receipt; specifically, the existence of extra-contractual terms or arrangements caused us not to meet the fixed or determinable criteria for revenue recognition in some cases, and in others collectability had not been established. In situations where we are unable to satisfy the requirements to recognize revenue on the sell-in method, we recognize revenue relating to distributor arrangements once the product is delivered to the end customer (the "sell-through method"). Because we do not have reliable information about when our distributors sell the product through to end customers, we use cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases we are legally entitled to the accounts receivable at the time of shipment, we have not recognized accounts receivables or any corresponding deferred revenues associated with distributor transactions for which revenue is recognized on the sell-through method.

For distributors on the sell-in method prior to April 1, 2013, cost of sales were recognized upon shipment. For sell-through distributors, whose revenue is recognized upon cash receipt, we consider whether to match the related cost of sales expense with revenue or to recognize expense upon shipment. In making this assessment, we consider the financial viability of our distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped is reasonably assured at the time of shipment to these distributors. In instances where the distributor is determined to be financially viable, we defer the costs of sales until the revenue is recognized.

Biologics revenue is primarily related to a collaborative arrangement with the MTF. We have exclusive global marketing rights and receive marketing fees from MTF based on products distributed by MTF. MTF is considered the primary obligor in these arrangements and therefore we recognize these marketing service fees on a net basis upon shipment of the product to the customer.

Revenues exclude any value added or other local taxes, intercompany sales, and trade discounts. Shipping and handling costs are included in cost of sales. Revenue recognition policies are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, net margin and net income.

Allowance for Doubtful Accounts and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collection and payor reimbursement experience is an integral part of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. Our estimates are periodically tested against actual collection experience. We believe our allowance for doubtful accounts is sufficient to cover customer credit risks; however, a 10% increase in our allowance for doubtful accounts as of December 31, 2015 would result in an additional charge of $0.9 million. Our allowance for doubtful accounts and contractual allowances are "critical accounting estimates" because changes in the assumptions used to

develop the estimates could materially affect key financial measures, including operating income, net income, and accounts receivable balances.

Inventory Allowances

Inventory, net of an allowance for excess and obsolescence, is stated at the lower of cost or market. Reserves for excess, slow moving, and obsolete inventory are calculated as the difference between the cost of inventory and market, and are based on product life cycle, forecasted demand, and market conditions. Reserves for excess and obsolescence provisions are recorded as adjustments to cost of sales. According to U.S. GAAP, a write-down of inventory to the lower-of-cost-or-market value at the close of a fiscal year creates a new cost basis that subsequently should not be marked up based on changes in underlying circumstances. Our inventory allowance is a “critical accounting estimate” because changes in the assumptions used to develop the estimate could materially affect key financial measures, including gross profit, operating income, net income, and inventory balances. We regularly evaluate our exposure for inventory write-downs. If conditions or assumptions used in determining the market value change, additional inventory adjustments in the future may be necessary.

Goodwill and Other Intangible Assets

In accordance with U.S. GAAP, intangible assets with finite lives are tested for impairment if any adverse conditions exist or change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. If an impairment indicator exists, we test the intangible asset for recoverability. For purposes of the recoverability test, we group our intangible assets with other assets and liabilities at the lowest level of identifiable cash flows if the intangible asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the intangible asset (asset group) exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset (asset group), we will write the carrying value down to the fair value in the period identified. Goodwill and other intangible assets are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including operating income and net income.

We generally calculate fair value of intangible assets as the present value of estimated future cash flows that we expect to generate from the asset using a risk-adjusted discount rate. In determining the estimated future cash flows associated with intangible assets, we use estimates and assumptions about future revenue contributions, cost structures and remaining useful lives of the asset (asset group). The use of alternative assumptions, including estimated cash flows, discount rates, and alternative estimated remaining useful lives could result in different calculations of impairment.

We test goodwill at least annually for impairment, and between annual tests if indicators of potential impairment exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. We assess goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a reporting unit. We have identified four reporting units, which are consistent with our reporting segments; BioStim, Biologics, Extremity Fixation, and Spine Fixation.

In order to calculate the respective carrying values, we initially recorded goodwill based on the purchase price allocation performed at the time of acquisition. Corporate assets and liabilities that directly relate to a reporting unit’s operations are ascribed directly to that reporting unit. Corporate assets and liabilities that are not directly related to a specific reporting unit, but from which the reporting unit benefits, are allocated based on the respective contribution measure of each reporting unit.

As a result of our change in reporting structure in the third quarter of 2013, we allocated goodwill to each reporting unit, and subsequently evaluated the Extremity Fixation and Spine Fixation reporting units for the possible impairment of goodwill, as there were indicators of impairment when completing a qualitative analysis. The result of this step two analysis was a full impairment of the goodwill allocated to our Extremity Fixation, and Spine Fixation reporting units, totaling $19.2 million, or $9.8 million and $9.3 million to each reporting unit, respectively, in 2013. There continue to be no indicators of impairment in our remaining reporting units, which were reevaluated at year end using a qualitative assessment.

The Company’s annual goodwill impairment analysis, which was performed qualitatively during the fourth quarters of 2014 and 2015, did not result in any additional impairment charge for either the BioStim or Biologics reporting units, the reporting units with remaining goodwill. This qualitative analysis, which is referred to as step zero, considered all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance and relevant entity-specific events

Fair Value Measurements

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

Level 1 ~~qu~~oted prices in active markets for identical assets and liabilities

Level 2 ~~ob~~servable inputs other than quoted prices in active markets for identical assets and liabilities

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

The Company’s financial instruments include cash equivalents, restricted cash, certificates of deposit, treasury securities, collective trust funds, trade accounts receivable, accounts payable, long-term secured debt, available for sale equity and debt securities, common stock warrants, derivative securities, and deferred compensation plan liabilities. The carrying value of restricted

cash, trade accounts receivable and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's credit facilities carry a floating rate of interest, and therefore, the carrying value is considered to approximate the fair value. The Company's available for sale equity securities and common stock warrants are recorded at cost, which as of December 31, 2015 and 2014 was $1.8 million, as it is currently impracticable to estimate the fair value of the instruments without incurring excessive costs given the size of the asset and since there have been no events or changes in circumstances that would indicate a significant adverse effect on the fair value of the instruments. The fair value of the Company's debt security is based upon significant unobservable inputs, requiring the Company to develop its own assumptions. One of the more significant unobservable inputs used in the fair value measurement of the Company's debt securities is the discount rate. Holding other inputs constant, an increase in the discount rate of 5% would result in a decrease in fair value of the debt security of $3.6 million, whereas a decrease in the discount rate of 5% would result in an increase in the fair value of the debt security of $6.7 million. Our fair value measurements are a "critical accounting estimate" because changes in the assumptions used to develop the estimate could materially affect key financial measures, specifically as they relate to financial instruments measured using Level 3 inputs.

Litigation and Contingent Liabilities

From time to time, we are parties to or targets of lawsuits, investigations and proceedings, including product liability, personal injury, patent and intellectual property, health and safety and employment and healthcare regulatory matters, which are handled and defended in the ordinary course of business. These lawsuits, investigations or proceedings could involve a substantial number of claims and could also have an adverse impact on our reputation and customer base. Although we maintain various liability insurance programs for liabilities that could result from such lawsuits, investigations or proceedings, we are self-insured for a significant portion of such liabilities. We accrue for such claims when it is probable that a liability has been incurred and the amount can be reasonably estimated. The process of analyzing, assessing and establishing reserve estimates for these types of claims involves judgment. Changes in the facts and circumstances associated with a claim could have a material impact on our results of operations and cash flows in the period that reserve estimates are revised. We believe our insurance coverage and reserves are sufficient to cover currently estimated exposures, but we cannot give any assurance that we will not incur liabilities in excess of recorded reserves or our present insurance coverage. Litigation and contingent liabilities are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including operating income and net income.

Tax Matters

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

We account for uncertain tax positions in accordance with U.S. GAAP, which contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We re-evaluate our income tax positions periodically to consider factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues

under audit and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision. Tax matters are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net income.

We include interest related to tax issues as part of income tax expense in our consolidated financial statements. We record any applicable penalties related to tax issues within the income tax provision.

Share-based compensation

The fair value of service-based stock options are determined using the Black-Scholes valuation model. Such value is recognized as expense over the service period net of estimated forfeitures.

The fair value of market-based stock options are determined at the date of the grant using the Monte Carlo valuation methodology. Such value is recognized as expense over the requisite service period adjusted for estimated forfeitures for each separately vesting tranche of the award. The Monte Carlo methodology that we use to estimate the fair value of market-based options incorporates into the valuation the possibility that the market condition may not be satisfied.

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

We grant performance-based restricted stock awards to executive employees, for which vesting is based upon achieving certain targets for various financial measures. The fair value of performance-based restricted stock awards are recognized, net of estimated forfeitures, over the derived requisite vesting period beginning in the period in which they are deemed probable to vest.

Our share-based compensation is a "critical accounting estimate" because changes in the assumptions used to develop the estimate could materially affect key financial measures, including gross profit, operating income, and net income.

Results of Operations

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

	Year ended December 31,		
	2015	2014	2013
	(%)	(%)	(%)
Net sales	100.0	100.0	100.0
Cost of sales	21.8	24.6	26.9
Gross profit	78.2	75.4	73.1
Operating expenses			
Sales and marketing	44.9	41.4	44.1
General and administrative	22.0	19.6	17.0
Research and development	6.7	6.2	6.7
Restatements and related costs	2.3	3.9	3.3
Impairment of goodwill	—	—	4.8
Total operating income (loss)	2.3	4.3	(2.8)
Net loss from continuing operations	(0.6)	(0.9)	(4.6)
Net loss from discontinued operations	(0.1)	(1.2)	(2.6)
Net loss	(0.7)	(2.1)	(7.2)

Our segment information is prepared on the same basis that management reviews the financial information for operational decision-making purposes. We manage our business by our four SBUs, which are comprised of BioStim, Biologics, Extremity Fixation, Spine Fixation, and supported by Corporate activities. These SBUs represent the

segments for which our Chief Executive Officer, who is our Chief Operating Decision Maker (the "CODM"), reviews financial information and makes resource allocation decisions among business units. Accordingly, our reporting segment information has been prepared based on our four SBUs. The table below presents net sales by SBU. Net sales include product sales and marketing service fees. These four reporting segments are discussed in additional detail below.

(U.S. Dollars in thousands)	Year ended December 31, 2015		2014		2013	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
BioStim	$164,955	41.6 %	$154,676	38.5 %	$145,085	36.5 %
Biologics	59,832	15.1 %	55,881	13.9 %	53,746	13.5 %
Extremity Fixation	96,034	24.2 %	109,678	27.3 %	103,359	26.0 %
Spine Fixation	75,668	19.1 %	82,042	20.4 %	95,421	24.0 %
Total net sales	$396,489	100.0 %	$402,277	100.0 %	$397,611	100.0 %

BioStim

The BioStim SBU manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). These devices utilize Orthofix's patented pulsed electromagnetic field ("PEMF") technology, which is supported by strong basic mechanism of action data in the scientific literature and as well as strong level one randomized controlled clinical trials in the medical literature. Current research and clinical studies are also underway to identify potential new clinical indications. This SBU uses distributors and sales representatives to sell its devices to hospitals, doctors and other healthcare providers, primarily in the U.S.

Biologics

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

Extremity Fixation

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

Spine Fixation

The Spine Fixation SBU specializes in the design, development and marketing of a broad portfolio of implant products used in surgical procedures of the spine. Spine Fixation distributes its products through a network of distributors, sales representatives, and affiliates to sell spine products to hospitals, doctors and other healthcare providers, globally.

Corporate

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

2015 Compared to 2014

Net Sales

The table below presents net sales by SBU reporting segment. Net sales include product sales and marketing service fees.

	Year ended December 31,					
(U.S. Dollars in thousands)	2015	2014	Reported Increase (Decrease)		Constant Currency Increase (Decrease)	
BioStim	$164,955	$154,676	6.6	%	6.7	%
Biologics	59,832	55,881	7.1	%	7.1	%
Extremity Fixation	96,034	109,678	(12.4	)%	1.0	%
Spine Fixation	75,668	82,042	(7.8	)%	(7.3	)%
Total net sales	$396,489	$402,277	(1.4	)%	2.4	%

Net sales decreased $5.8 million in 2015 compared to 2014. The impact of foreign currency decreased sales by $15.3 million in 2015 when compared to 2014. Excluding the impact of changes in foreign currency exchange rates, net sales increased $9.5 million or 2.4%. Net sales include product sales from BioStim, Extremity Fixation and Spine Fixation and marketing service fees from Biologics, which is comprised of biologic sales of Trinity Evolution®, Trinity ELITE® and VersaShield®.

Net Sales by SBU

Net sales in our BioStim SBU increased $10.3 million, or 6.6%, in 2015 compared to 2014. The increase in net sales was primarily due to additional market penetration through our direct and distributor sales channels.

Net sales in our Biologics SBU increased $4.0 million, or 7.1%, in 2015 compared to 2014. The increase in net sales was mainly due to an increase in the total number of independent distributors and increased sales from existing distributors, which was partially offset by anticipated low single digit competitive pricing pressures.

Net sales in our Extremity Fixation SBU decreased $13.6 million, or 12.4%, in 2015 compared to 2014. The decrease in net sales was primarily due to the negative impact of changes in foreign exchange rates in 2015, which resulted in a decrease in net sales of $14.7 million. Excluding the impact of changes in foreign exchange rates, Extremity Fixation net sales increased $1.1 million, or 1.0%. The increase in sales is due to the increase in demand for our products partially offset by the impact of macroeconomic challenges in certain of our markets. The negative impact of foreign exchange rates on net sales was driven primarily by the strengthening of the U.S. Dollar against the Euro and Brazilian Real in 2015. The change in foreign exchange rates between the U.S. Dollar and the Euro negatively impacted sales by approximately $10.3 million and the change in foreign exchange rates between the U.S. Dollar and the Brazilian Real negatively impacted sales by approximately $3.4 million.

Net sales in our Spine Fixation SBU decreased $6.4 million, or 7.8%, in 2015 compared to 2014. The decrease in net sales was primarily due to the short term impact of our reorganization of the U.S. sales force in late 2014 and a decrease in cash collections from distributors whose revenue is recognized upon cash receipt, partially offset by increased revenue from additional distributors added in 2015 as part of our sales force rebuilding and expansion initiatives.

Gross Profit

	Year ended December 31,		Year over year change	
(U.S. Dollars in thousands)	2015	2014	$ Change	% Change
Net sales	$396,489	$402,277	$(5,788)	(1.4)%
Cost of sales	86,525	98,912	(12,387)	(12.5)%
Gross profit	$309,964	$303,365	$6,599	2.2 %

Gross profit as a percent of net sales in 2015 was 78.2% compared to 75.4% in 2014. The increase in gross profit as a percent of net sales was primarily driven by an increased sales mix of our BioStim and Biologics regenerative solutions relative to our other products, improved inventory management and improved operating efficiencies.

Operating Expenses

	Year ended December 31,		Year over year change
(U.S. Dollars in thousands)	2015	2014	

			$ Change	% Change	
Sales and marketing	$178,080	$166,547	$11,533	6.9	%
General and administrative	87,157	79,074	8,083	10.2	%
Research and development	26,389	24,994	1,395	5.6	%
Restatements and related costs	9,083	15,614	(6,531)	(41.8	)%
Total operating expenses	$300,709	$286,229	$14,480	5.1	%

Sales and Marketing Expense

The increase in sales and marketing expense was primarily attributable to an overall increase in sales and field-based training personnel as part of the rebuilding and expansion of our sales organization, as well as sales commission quota overachievement in certain territories, resulting in an increase in compensation costs, including commissions, of approximately $6.8 million. The growth in sales and marketing expense is also partly driven by an increase to bad debt expense of $2.4 million, of which $2.0 million was in response to the recent fiscal and economic difficulties experienced by the Puerto Rico Commonwealth. As a percent of net sales, sales and marketing expense was 44.9% in 2015 compared to 41.4% in 2014.

General and Administrative Expense

The increase in general and administrative expense, inclusive of amortization of intangible assets, was primarily driven by legal settlements totaling $5.3 million in 2015, increased spending of $1.6 million associated with the strengthening of our infrastructure as part of Project Bluecore, increased stock-based compensation expense of $1.5 million, and an increase in professional fees and personnel costs within our finance department as part of our internal controls remediation efforts. These increases were partially offset by the impact of changes in foreign exchange rates between 2015 and 2014. As a percent of net sales, general and administrative expense was 22.0% in 2015 compared to 19.6% in 2014.

Research and Development Expense

The increase in research and development expense was primarily due to increases in consulting fees and clinical trial costs of $1.6 million, when compared to 2014, as the Company invests resources to identify potential new clinical indications for its PEMF technology in BioStim and for new product development in Spine Fixation and Extremity Fixation. As a percent of net sales, research and development expense was 6.7% in 2015 compared to 6.2% in 2014.

Restatements and Related Costs

The decrease in restatements and related costs was primarily due to a reduction in outside consultant costs incurred during our Further Restatement filed in March 2015 when compared to our Original Restatement filed in March 2014. Costs incurred in 2015 relate to the restatement, which was completed in the first quarter of 2015, and the resulting SEC Investigation and Securities Class Action Complaint. In October of 2015, the Company reached an agreement in principle to settle this matter. Under the terms of the agreement, the Company, through its insurers, made a payment to the plaintiff, and the class it purports to represent, to settle the matter. Therefore, we expect costs related to restatements to decrease in future periods due to the settlement.

Non-operating Expenses

	Year ended December 31,		Year over year change	
(U.S. Dollars in thousands)	2015	2014	$ Change	% Change
Interest expense, net	$(489)	$(1,785)	$1,296	(72.6)%
Other expense	(259)	(2,895)	2,636	(91.1)%
Total non-operating expense	$(748)	$(4,680)	$3,932	(84.0)%

Interest Expense, net

The decrease in interest expense, net was primarily driven by interest income of $1.0 million related to the eNeura Convertible Promissory Note and the pay down of all outstanding debt under the Revolving Credit Facility in the third quarter of 2014.

Other Expense

The decrease in other expense, net was primarily due to a $3.1 million gain on the sale of the Company’s Tempus Cervical Plate product line in 2015, which was offset by the effect of foreign exchange transactions due to the strengthening of the U.S. Dollar primarily against the Euro and the Brazilian Real in 2015 as compared to 2014.

Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional currency, which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Taxes

	Year ended December 31,		Year over year change	
(U.S. Dollars in thousands)	2015	2014	$ Change	% Change
Income tax expense	$10,849	$16,200	$(5,351)	(33.0)%
Effective tax rate	127.5 %	130.1 %		

The provision for income taxes as a percentage of pre-tax income from continuing operations was 127.5% for the year ended December 31, 2015 compared with 130.1% for the year ended December 31, 2014. The effective tax rate in both years was primarily impacted by losses in jurisdictions for which we are currently unable to recognize an income tax benefit, as well as recording a valuation allowance on the net deferred tax assets in Puerto Rico in 2015 and in Brazil in 2014.

Discontinued operations

Discontinued operations include losses of approximately $0.5 million and $4.8 million, net of income taxes, in 2015 and 2014, respectively. The losses were primarily from legal settlements and legal costs, which relate to certain specified product liability matters in relation to the Company's former subsidiary, Breg. Orthofix agreed to indemnify Breg and its purchaser with respect to such matters.

Net Loss

Net loss in 2015 was $(2.8) million, or $(0.15) per basic and diluted share compared to $(8.5) million, or $(0.46) per basic and diluted share for 2014.

2014 Compared to 2013

Net Sales

The table below presents net sales by SBU reporting segment. Net sales include product sales and marketing service fees.

	Year ended December 31,			
(U.S. Dollars in thousands)	2014	2013	Reported Increase (Decrease)	Constant Currency Increase (Decrease)
BioStim	$154,676	$145,085	6.6 %	6.6 %
Biologics	55,881	53,746	4.0 %	4.0 %
Extremity Fixation	109,678	103,359	6.1 %	6.4 %
Spine Fixation	82,042	95,421	(14.0) %	(14.0)%
Total net sales	$402,277	$397,611	1.2 %	1.3 %

Net sales increased $4.7 million in 2014 compared to 2013. The change in foreign currency exchange rates negatively impacted sales by $0.3 million in 2014 when compared to 2013. Net sales include product sales from BioStim, Extremity Fixation and Spine Fixation and marketing service fees from Biologics, which is comprised of biologic sales of Trinity Evolution®, Trinity ELITE® and VersaShield®.

Net Sales by SBU

The increase in BioStim net sales was due to enhancements to the sales organization, which included adding management and salespeople in underserved geographies as well as additional sales representatives exclusively dedicated to our Physio-Stim® product line, in addition to the reduction in third-party payor revenue in 2013 driven by our transition to recognize revenue upon accumulation of the full billable package for third-party payors given the increased complexity in insurance billing requirements.

The increase in Biologics net sales was mainly due to an expanded sales channel as well as continued conversion to our next generation cell-based bone growth tissue technology (Trinity ELITE®). These increases were offset slightly by a reduction in marketing fee percentages received for our Trinity products starting in April 2013.

The increase in Extremity Fixation net sales was due to recently expanded product launches and improvement in international collections of cash basis sales. The increase was partially offset by declining revenue in Brazil, which has experienced significant disruption to the sales channel during 2014 as we rebuild our Brazil sales organization.

The decrease in Spine Fixation net sales was due to a loss of sales momentum resulting from our efforts to reorganize the sales force to improve profitability, which began in late 2013 and continued through the first half of 2014.

Gross Profit

(U.S. Dollars in thousands)	Year ended December 31, 2014	2013	Year over year change $ Change	% Change
Net sales	$402,277	$397,611	$4,666	1.2 %
Cost of sales	98,912	106,912	(8,000)	(7.5)%
Gross profit	$303,365	$290,699	$12,666	4.4 %

Gross profit as a percent of net sales in 2014 was 75.4% compared to 73.1% in 2013. The increase in gross profit as a percent of net sales is primarily driven by higher inventory reserves in 2013.

Operating Expenses

(U.S. Dollars in thousands)	Year ended December 31, 2014	2013	Year over year change $ Change	% Change
Sales and marketing	$166,547	$175,468	$(8,921)	(5.1)%
General and administrative	79,074	67,517	11,557	17.1 %
Research and development	24,994	26,768	(1,774)	(6.6)%
Restatements and related costs	15,614	12,945	2,669	20.6 %
Impairment of goodwill	—	19,193	(19,193)	(100.0)%
Total operating expenses	$286,229	$301,891	$(15,662)	(5.2)%

Sales and Marketing Expense

The decrease in sales and marketing expense was due to tighter cost controls of non-variable expenses, along with lower commission rates due to the reorganization of the Brazil and U.S. Spine Fixation sales forces, as well as a decrease in Spine Fixation sales. As a percent of net sales, sales and marketing expense was 41.4% in 2014 compared to 44.1% in 2013.

General and Administrative Expense

The increase in general and administrative expense was primarily due to our investment in the implementation of an internal audit function and focused efforts on key process and control improvements. In addition, we spent $3.8 million in 2014 on Bluecore. Also in 2014, medical insurance payouts were higher than normal causing a large fluctuation from the prior year since the Company is self-insured up to a stop loss threshold. As a percent of net sales, general and administrative expense was 19.7% in 2014 compared to 17.0% in 2013.

Research and Development Expense

The decrease in research and development expense was primarily due to a $2 million payment to MTF in the second quarter of 2013 for the development and commercialization of Trinity ELITE®, which was released in the first half of 2013. As a percent of net sales, research and development expense declined slightly to 6.2% in 2014 compared to 6.7% for the same period last year.

Restatements and Related Costs

As part of our accounting review and restatement of our consolidated financial statements, the Company incurred $15.6 million and $12.9 million for the years ended December 31, 2014 and 2013, respectively.

Impairment of Goodwill

As part of our change in reportable segments, we reallocated goodwill to each new reporting unit, and subsequently evaluated each reporting unit for impairment. As a result of this analysis, a full impairment of the goodwill allocated to our Spine Fixation and Extremity Fixation reporting units, of $19.2 million, was recognized in 2013.

Non-operating Expenses

(U.S. Dollars in thousands)	Year ended December 31, 2014	2013	Year over year change $ Change	% Change
Interest expense, net	$(1,785)	$(1,827)	$42	(2.3)%
Other (expense) income	(2,895)	2,416	(5,311)	(219.8)%
Total non-operating (expense) income	$(4,680)	$589	$(5,269)	(894.6)%

Interest Expense, net

Interest expense, net was $1.8 million in both 2014 and 2013, primarily as the result of substantial repayments of long-term debt during 2013, resulting in a lower year over year outstanding debt balance, and to a lesser extent, lower interest rates, offset by increased fees associated with a larger unused revolver balance.

Other Income (Expense)

Other income for 2013 was primarily due to our receipt of $4.4 million related to the demutualization of a mutual insurance company in which we were an eligible member to share in such proceeds. In addition, 2014 was negatively impacted by foreign exchange rates. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency, which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Taxes

(U.S. Dollars in thousands)	Year ended December 31, 2014	2013	Year over year change $ Change	% Change
Income tax expense	$16,200	$7,602	$8,598	113.1 %
Effective tax rate	130.1 %	(71.7)%		

We recognized a $16.2 million and $7.6 million provision for income tax for 2014 and 2013, respectively. The income tax expense and effective tax rate for the year ended 2014 reflects a disproportionate ratio to the $7.6 million of income tax expense and effective tax rate of (71.7%) for the year ended 2013. The principal factors affecting the Company's 2014 effective tax rate were the Company's mix of earnings amongst various tax jurisdictions, state taxes, changes in the valuation allowance, and changes in income tax reserves.

Discontinued operations

Discontinued operations include losses of approximately $4.8 million and $10.6 million, net of income taxes, in 2014 and 2013, respectively. The losses were primarily from legal settlements and legal costs, which relate to certain specified product liability matters in relation to the Company's former subsidiary, Breg. Orthofix agreed to indemnify Breg and its purchaser with respect to such matters.

Net Loss

Net loss in 2014 was $(8.5) million, or $(0.46) per basic and diluted share, compared to $(28.8) million, or $(1.54) per basic and diluted share for 2013.

Liquidity and Capital Resources

Cash Flow

Cash and cash equivalents at December 31, 2015 were $63.7 million. This compares to cash, cash equivalents of $36.8 million at December 31, 2014. The increase in cash and cash equivalents in 2015 was primarily due to cash provided by operating and financing activities, partially offset by cash used in investing activities and the effect of exchange rate changes on cash.

(U.S. Dollars, in thousands)	Year Ended December, 31, 2015	2014	Year over Year Change
Net cash provided by operating activities	$43,224	$50,958	$(7,734)
Net cash used in investing activities	(38,349)	(19,950)	(18,399)
Net cash provided by (used in) financing activities	25,114	(19,994)	45,108
Effect of exchange rate changes on cash	(3,141)	(3,123)	(18)
Net increase in cash and cash equivalents	$26,848	$7,891	$18,957

Operating Activities

Net cash provided by operating activities is comprised of net loss, non-cash items (including depreciation and amortization, provision for doubtful accounts, share-based compensation, deferred taxes gain on the sale of assets, interest accruals, and impairment losses) and changes in working capital. Net loss decreased $5.7 million to a net loss of $2.8 million in 2015 compared to net loss of $8.5 million in 2014. Non-cash items for 2015 increased $3.8 million to $30.5 million compared to $26.7 million in 2014. Working capital accounts provided $15.5 million of cash in 2015 and provided $32.8 million in 2014. The change in working capital accounts is primarily attributable to trade accounts receivable, inventories, and trade accounts payable. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory reflect day’s sales in receivables of 55 days at December 31, 2015 compared to 56 days at December 31, 2014 and inventory turns of 1.5 and 1.7 times as of December 31, 2015 and December 31, 2014, respectively.

Investing Activities

Net cash used in investing activities increased in 2015 compared to 2014 primarily due to the purchase of debt securities in connection with the Option Agreement entered into with eNeura of $15.3 million and an increase in capital expenditures of $9.4 million as a result of Bluecore. During 2015 and 2014, we invested $27.9 million and $18.5 million in capital expenditures, respectively. These increases were partially offset by proceeds from the sale of assets of $4.8 million in 2015.

Financing Activities

Net cash from financing activities increased in 2015 compared to 2014 primarily due to the repayment of all outstanding long term debt of $20.0 million in 2014 and the removal of the restricted cash requirement at June 30, 2015, as a result of the Company having no outstanding balance on its 2010 secured revolving credit facility and compliance with all required covenants, compared to a restricted cash requirement of $34.4 million as of December 31, 2014. The Company also paid debt issuance costs of $1.8 million as part of the credit facility entered into on

August 31, 2015, which is discussed below. Additionally, during the year ended December 31, 2015, we received proceeds of $3.7 million compared to $10.5 million during 2014 from the issuance of shares of our common stock related to stock purchase plan issuances, stock option exercises, and the vesting of restricted stock awards. In 2015, we used $11.6 million in connection with the share repurchase plan.

Infrastructure Initiative

In 2014, we initiated project “Bluecore,” a multi-year, company-wide process and systems improvement initiative to improve the reliability and efficiency of our systems, processes, and reporting as well as drive down overhead expenses. This project is planned to continue through the end of 2016. Bluecore has numerous work streams primarily focused around re-implementing our Oracle ERP system worldwide, improving our financial controls and reporting, streamlining our order to cash processes and collections, and optimizing our supply chain for cost reductions and field inventory visibility, among other upgrades. The total budget, including operating and capital expenditures, for this project is approximately $30 million for 2015 and 2016, of which $21.4 million was spent in 2015, and approximately $6 million is budgeted for 2016. We expect approximately 85% of this investment will be capitalized.

Credit Facilities

On August 31, 2015, the Company entered into a Credit Agreement (the "2015 Credit Agreement") with JPMorgan Chase Bank, N.A. ("JPMorgan"), as Administrative Agent, and certain lenders party thereto. The 2015 Credit Agreement provides for a five year $125 million secured revolving credit facility and replaces the Company's prior 2010 credit facility, which expired and matured pursuant to its terms on August 30, 2015 with no amounts outstanding. As of December 31, 2015, the Company has not made any borrowings under the 2015 Credit Agreement. For additional information regarding the terms of the 2015 Credit Agreement, see Note 7 to the Notes to the Consolidated Financial Statements contained herein.

The Company had no borrowings and an unused available line of credit of €5.8 million ($6.3 million and $7.0 million) at December 31, 2015 and 2014, respectively, on its Italian line of credit. This unsecured line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

Puerto Rico Commonwealth

Due to the recent fiscal and economic difficulties experienced by the Puerto Rico Commonwealth, which include amongst other factors, failure to satisfy debt service obligations, the issuing of a Fiscal and Economic Growth Plan, and receiving downgrades in credit ratings, the Company increased its accounts receivable reserve estimate, resulting in additional bad debt expense of $2.0 million during the third quarter of 2015. Reserves may increase in the future if economic conditions in Puerto Rico deteriorate further. Beginning October 1, 2015, the Company only recognizes revenue from transactions with government customers in Puerto Rico when cash is received. Thus, the Company expects revenue in Puerto Rico to decline in the near-term.

Share Repurchase Plan

The Company's Board of Directors has authorized a share repurchase plan, authorizing the purchase of up to $75 million of the Company's common stock through and including September 2017. Under the program, common share repurchases are expected to consist primarily of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Securities Exchange Act of 1934, as amended, though the Company may also make repurchases through block trades or privately negotiated transactions. Repurchases may be made from cash on hand, cash generated from operations, and/or borrowings under the Company's new secured revolving credit facility. The program does not obligate the Company to acquire any specific number of shares and may be discontinued at any time. As of December 31, 2015, the Company had repurchased 293,991 shares of common stock for $11.6 million.

Other

We have incurred substantial expenses for legal and other professional services in connection with the multi-year restatements of our consolidated financial statements that we filed in March 2014 and March 2015. These expenses were approximately $37.6 million from July 2013 through December 2015.

The Company's current intention is to indefinitely reinvest the total amount of its unremitted foreign earnings (residing outside Curaçao) in the local jurisdiction. As an entity incorporated in Curaçao, "foreign subsidiaries" refer to both U.S. and non-U.S. subsidiaries. Furthermore, only income sourced in the U.S. is subject to U.S. income tax. Unremitted foreign earnings increased from $374.1 million at December 31, 2014 to $442.1 million at December 31, 2015. The $442.1 million includes $451.7 million in U.S subsidiaries. It is not practicable to determine the amounts of net additional income tax that may be payable if such earnings were repatriated.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2015:

	Payments Due by Period				
(U.S. Dollars in thousands)	Total	2016	2017 - 2019	2020	2021 and thereafter
Operating leases	14,701	3,531	7,709	1,732	1,729
Inventory purchase obligations (1)	1,109	1,109	–	–	–
Total	$15,810	$4,640	$7,709	$1,732	$ 1,729

(1) The Company has inventory purchase commitments with third-party manufactures. Due to the uncertainty of our future purchasing requirements, obligations under these agreements are included in the preceding table at the amount committed through December 31, 2015 all of which are due in 2016.

We may be required to make cash outlays related to our uncertain tax positions. However, due to the uncertainty of the timing of future cash flows associated with our unrecognized tax benefits, we are unable to make reasonably reliable estimates of the period of cash settlement, if any, with the respective taxing authorities. Accordingly, unrecognized tax benefits, inclusive of interest and penalties, of $16.5 million as of December 31, 2015 have been excluded from the contractual obligations table above. For further information on unrecognized tax benefits, see Note 13 to the Notes to the Consolidated Financial Statements contained herein.

Off-balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of December 31, 2015, we had a cross-currency swap in place to minimize foreign currency exchange risk related to a €9.6 million ($10.4 million translated at the December 31, 2015 foreign exchange rate) intercompany note. As of December 31, 2015 the fair value of the cross-currency swap was approximately $2.5 million and is recorded in prepaid expenses and other current assets.

We are exposed to interest rate risk in connection with our Revolving Credit Facility, which bears interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base rate (as defined in the Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant. As the Company does not have any balance outstanding associated with the Credit Agreement as of December 31, 2015, this risk is currently minimal.

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

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Brazilian Real, or Great Britain Pound. We are subject to cost of sales currency exposure when we produce products in foreign currencies such as the Euro, Brazilian Real, or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when our subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. For the year ended December 31, 2015, we recorded a foreign currency loss of $3.5 million on the statement of operations resulting from gains and losses in

foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that fluctuate during the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the years ended December 31, 2015 and 2014 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations during 2015 and 2014 versus the same periods in 2014 and 2013. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results. An analysis was performed to determine the sensitivity of our current year net sales and operating income to changes in foreign currency exchange rates. We determined that if the U.S. Dollar decreased in value by 10% relative to all foreign currencies of our international operations it would result in an increase in net sales of $9.5 million and an increase in operating income of $0.2 million. If the U.S. Dollar increased in value by 10% relative to all foreign currencies of our international operations it would result in a decrease in net sales of $9.5 million and a decrease in operating income of $0.2 million.

Item 8. Financial Statements and Supplementary Data
See “Index to Consolidated Financial Statements” on page F-1 of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
None.

Item 9A. Controls and Procedures
Evaluation of Disclosure Controls and Procedures

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

Management’s Report on Internal Control over Financial Reporting

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

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

In connection with the preparation and filing of this Form 10-K, the Company’s management, including our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the framework set forth in “Internal Control—Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company’s management concluded that, as of December 31, 2015, the Company’s internal control over financial reporting is effective based on the specified criteria.

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

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter of 2015 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Orthofix International N.V.

We have audited Orthofix International N.V.'s (the Company) internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Orthofix International N.V.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Orthofix International N.V. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Orthofix International N.V. as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2015 of Orthofix International N.V. and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas

February 29, 2016

Item 9B. Other Information
Not applicable.

PART III

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

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

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

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

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

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

58

PART IV

Item 15. Exhibits, Financial Statement Schedules

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

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

1. Financial Statements

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

2. Financial Statement Schedules

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

3. Exhibits

Exhibit Number	Description
2.1	Asset Purchase Agreement, dated as of March 8, 2010, by and between Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, Mallinckrodt do BrasilLtda, Kendall de Mexico S.A. de C.V., Novamedix Limited, Novamedix Distribution Limited, Novamedix Services Limited, Promeca S.A. de C.V., Orthofix do Brasil, OrthofixS.r.l., Orthofix S.A., Intavent Orthofix Limited, Breg Mexico S. de R.I. de CV, and Implantes y Sistemas Medicos, Inc. (filed as an exhibit to the Company’s current report on Form 8-K filed March 9, 2010 and incorporated herein by reference).
2.2	Stock Purchase Agreement, dated as of April 23, 2012, by and among Breg, Inc., Orthofix Holdings, Inc. and Breg Acquisition Corp. (filed as an exhibit to the Company’s current report on Form 8-K filed April 24, 2012 and incorporated herein by reference).
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company’s annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2011 and incorporated herein by reference).
10.1	Credit Agreement, dated as of August 30, 2010, among Orthofix Holdings, Inc., Orthofix International N.V. and certain domestic subsidiaries of Orthofix International N.V., the several banks and other financial institutions as may from time to time become parties thereunder, and JPMorgan Chase, N.A. (filed as an exhibit to the Company’s current report on Form 8-K filed August 31, 2010 and incorporated herein by reference).
10.2	First Amendment to Credit Agreement, dated May 4, 2011, among Orthofix Holdings, Inc., a Delaware corporation, Orthofix International N.V. (“Orthofix International”), a Netherlands Antilles corporation, certain domestic direct and indirect subsidiaries of Orthofix International, JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto (filed as an exhibit to the Company’s current report on Form 8-K filed May 5, 2011 and incorporated herein by reference).

10.3	Limited Waiver, entered into on August 14, 2013, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of its wholly owned subsidiaries, and certain lender parties thereto. (filed as an exhibit to the Company's current report on Form 8-K filed August 19, 2013 and incorporated herein by reference).
10.4	Limited Waiver, entered into on August 14, 2014, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of its wholly owned subsidiaries, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed August 19, 2014 and incorporated herein by reference).
10.5	Limited Waiver, entered into on September 30, 2014, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of its wholly owned subsidiaries, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed October 6, 2014 and incorporated herein by reference).
10.6	Commitment Reduction and Limited Waiver, dated as of January 15, 2015, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of their wholly owned subsidiaries, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed January 16, 2015 and incorporated herein by reference).

Exhibit Number	Description
10.7	Limited Waiver, dated as of February 26, 2015, by and among Orthofix International N.V., Orthofix Holdings, Inc. and certain of their wholly owned subsidiaries, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed February 27, 2015 and incorporated herein by reference).
10.8	Credit Agreement, dated as of August 31, 2015, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's current report on Form 8-K filed September 1, 2015 and incorporated herein by reference).
10.9†	Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
10.10	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.11†	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company's annual report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference).
10.12†	Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's current report on Form 8-K filed July 8, 2013 and incorporated herein by reference).
10.13	Amendment No. 4 to Matrix Commercialization Collaboration Agreement, entered into on April 1, 2014, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's current report on Form 8-K filed April 7, 2014 and incorporated herein by reference).
10.14	Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.15	Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference)
10.16	Amendment No. 1 to the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Form 10-Q filed on August 4, 2015 and incorporated herein by reference).
10.17	Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company's current report on Form 8-K filed January 7, 2009, and incorporated herein by reference).

10.18	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-Present Grants (Time-Based Vesting) (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.19	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-Present Grants (Time-Based Vesting) (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.20	Form of Employee Performance Vesting Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014 Grants (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.21	Form of Employee Performance Vesting Restricted Stock and Performance Share Unit Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – June 2015 Grants (filed as an exhibit to the Company's Form 10-Q filed on August 4, 2015 and incorporated herein by reference).
10.22	Form of Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-Present Grants (Time-Based Vesting) (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).

Exhibit Number	Description
10.23	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.24	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan. (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.25	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.26	Form of Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.27	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.28	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.29	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants—vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.30	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants— year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.31	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2011 grants—vesting over 3 years) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.32	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (post-2010 grants—vesting over 3 years) (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.33	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).

10.34 Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by reference).

10.35 Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).

10.36 Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).

10.37 Amendment No. 2 to Amended and Restated Employment Agreement, dated as of October 1, 2011, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed October 4, 2011 and incorporated herein by reference).

10.38 Amendment No. 3 to Amended and Restated Employment Agreement, dated as of August 29, 2012, by and between Orthofix Inc. and Michael Finegan (filed as an exhibit to the Company's current report on Form 8-K filed August 31, 2012 and incorporated herein by reference).

10.39 Employment Agreement, entered into on December 9, 2010, by and between Orthofix Inc. and Jeffrey M. Schumm (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).

Exhibit Number	Description
10.40	Form of Amendment to Stock Option Agreements (for Robert S. Vaters and Michael M. Finegan) (filed as an exhibit to the Company's current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.41	Employment Agreement, effective as of March 13, 2013, by and between Orthofix Inc. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.42	Inducement Grant Non-Qualified Stock Option Agreement, dated March 13, 2013, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.43	Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan, dated March 13, 2013, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's current report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.44	Amended and Restated Employment Agreement, effective as of November 20, 2014, by and between Orthofix International N.V., Davide Bianchi and, solely for purposes of certain specified provisions, Orthofix AG (filed as an exhibit to the Company's current report on Form 8-K filed November 28, 2014 and incorporated herein by reference).
10.45	Employment Agreement, entered into and effective as of May 5, 2014, by and between Orthofix Inc. and Mark A. Heggestad (filed as an exhibit to the Company's current report on Form 8-K filed May 8, 2014 and incorporated herein by reference).
10.46	Inducement Grant Non-Qualified Stock Option Agreement, dated May 5, 2014, between Orthofix International N.V. and Mark A. Heggestad (filed as an exhibit to the Company's current report on Form 8-K filed May 8, 2014 and incorporated herein by reference).
10.47	Inducement Grant Restricted Stock Agreement, dated May 8, 2014, between Orthofix International N.V. and Mark A. Heggestad (filed as an exhibit to the Company's current report on Form 8-K filed May 8, 2014 and incorporated herein by reference).
10.48	Employment Agreement, entered into and effective as of September 4, 2014, between Orthofix Inc. and Doug Rice (filed as an exhibit to the Company's current report on Form 8-K filed September 8, 2014 and incorporated herein by reference).
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