ORTHOFIX INTERNATIONAL N V
Form 10-K
March 31, 2014
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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, 2013

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	
(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 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 registrant s most recently completed second fiscal quarter, June 28, 2013, as reported by the Nasdaq Global Select Market, was approximately $497.5 million.

As of March 24, 2014, 18,187,194 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant s Definitive Proxy Statement to be filed with the Commission in connection with the 2014 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Form 10-K.

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Orthofix International N.V.

Form 10-K for the Year Ended December 31, 2013

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Explanatory Note

Orthofix International N.V. (together with its respective consolidated subsidiaries and affiliates, the Company, sometimes referred to as we, us, or our) is filing this Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (this Report or this Form 10-K) with the Securities and Exchange Commission (the SEC) following the filing (i) on March 24, 2014 of an amendment to its Annual Report on Form 10-K for the year ended December 31, 2012, an amendment to its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 (collectively, the Amendments), and its Quarterly Report on Form 10-Q for the quarter period ended June 30, 2013 and (ii) on March 25, 2014 of its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013. We experienced delays in filing this Form 10-K with the SEC because of the independent review by the Audit Committee (the Audit Committee) of the Company s Board of Directors into certain accounting matters (the Independent Review), which review led to the restatement of our previously issued consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010 and for the interim quarterly period ended March 31, 2013, as well as the correction of similar errors in prior periods. For additional information regarding this restatement and related matters, you should refer to the Amendments filed on March 24, 2014. We also filed with the SEC on March 18, 2014 a Form 12b-25 reporting our inability to file this Report on the due date prescribed by SEC rules because of the Independent Review and the restatement. Pursuant to Rule 12b-25, we have filed this Report prior to the fifteenth calendar day following the prescribed filing date of March 17, 2014.

This Form 10-K reflects the effects of the restatement of the Company s previously issued consolidated financial statements for the fiscal years ended December 31, 2012 and 2011 in Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Part II, Item 8, Financial Statements and Supplementary Data, in both textual and tabular form. In addition, the Company is including restated consolidated financial information for the fiscal years ended December 31, 2010 and 2009 in Part II, Item 6, Selected Financial Data. We do not plan to amend any previously filed reports in connection with the restatement other than as described above.

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Forward-Looking Statements

This Form 10-K 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 o terminology. 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 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 Audit Committee review and financial restatement described herein and related legal proceedings (including potential action by the Division of Enforcement of the SEC and pending securities class action litigation), the Company s review of allegations of improper payments involving the Company s Brazil-based subsidiary (which review is described in Part I, Item 3, Legal Proceedings), the Company s non-compliance with certain Nasdaq Stock Market LLC listing rules, and related pending hearings proceedings in connection therewith, the expected sales of our products, including recently launched products, 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, and the government investigation of, our former sports medicine global business unit) (as further described in Part I, Item 3, Legal Proceedings) and other reports that we will file in the future), 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 industry, credit markets and the 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 in the future.

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PART I

Item 1. Business

In this Form 10-K, the terms we, us, our, Orthofix, the Company and our Company refer to the combined operations of all 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 developing and delivering innovative repair and regenerative solutions to the spine and orthopedic markets. Our products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them achieve a more active and mobile lifestyle. We design, develop, manufacture, market and distribute medical devices used principally by musculoskeletal medical specialists for spine and orthopedic applications. Our main products are spinal implant products human cellular and tissue based products (HCT/P products) used in surgical procedures, non-invasive regenerative stimulation products used to enhance bone growth and the success rate of spinal fusions and to treat non-union fractures, and external and internal fixation devices used in fracture repair, limb lengthening and bone reconstruction. Our products also include bone cement and devices for removal of bone cement used to fix artificial implants.

We have administrative and training facilities in the United States (U.S.), Brazil, the United Kingdom, France, Germany, Puerto Rico and Italy and manufacturing facilities in the U.S. and Italy. We directly distribute our products in the U.S., the United Kingdom, Italy, Germany, France, Belgium, Brazil, Australia, and Puerto Rico. In several other markets we 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 Form 10-K. 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

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 strategic business units (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 Operating Decision Maker (the CODM) reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information has been prepared based on our four SBUs reporting segments. These four segments are discussed below.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for a portfolio of market leading devices for enhancing bone fusion that utilize Orthofix s patented pulsed electromagnetic (PEMF) technology. These Food and Drug Administration-approved Class 3 medical devices are indicated as an adjunctive treatment to enhance fusion success in cervical and lumbar spine fusion as well as a therapeutic treatment for non-healing

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fractures outside of the spine (non-unions). The PEMF technology is supported by a strong clinical background on mechanism of action in the scientific literature and current research and clinical studies are underway to identify potential new clinical indications.

Biologics

The Biologics SBU provides a portfolio of regenerative products 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 distributes its tissues through a network of distributors, sales, representatives and affiliates to market to hospitals, doctors, and other healthcare providers, primarily in the U.S. Our partnership with MTF allows us to exclusively market our Trinity Evolution ® and Trinity Elite ® tissue forms for musculoskeletal defects to enhance bone fusion.

Extremity Fixation

The Extremity Fixation SBU offers products 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. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This SBU uses both distributors and direct sales representatives to sell orthopedics 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 and affiliates. This SBU uses distributors and direct sales representatives 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 regenerative stimulation devices that are designed to enhance the growth of bone tissue and will successfully increase the success of bone fusion. Our key initiatives are:

- Expand the breadth and depth of account-level customer base;
- Leverage our market leadership position in spine regenerative stimulation to increase market share in long-bone regenerative stimulation market; and

Invest in clinical, evidence-based and cost effective research in addition to basic science and clinical research to support broader indications for our stimulation products.

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

Continually add to the current distribution by targeting field of use distribution and other business units customers, relationships, and hospital access;

Penetrate new and un-tapped Orthopedics fields of use such as: Trauma, Joint Revisions and Craniomaxillofacial; and

Continue to convert existing Trinity Evolution business to our newest state of the art product, Trinity ELITE.

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

- Increase coverage in the U.S. and existing international markets and expand into additional high potential countries;
- Implement a worldwide sales productivity process that will drive an increase in market penetration in each country; and
- Develop and acquire premium products for temporary fixation, deformity correction and pediatrics, rather than generic fixation products.

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

- Rationalize our cost structure to increase the margin contribution of this business;
- Achieve higher average selling prices through discount sharing with our sales force, contracting expertise and new product introductions; and
- Increase new product introductions through product acquisitions and an improved and more prolific 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 have little or no presence;
- Drive sales in the U.S. by expanding our IDN, 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; and

Achieve more effective and efficient business processes and controls throughout the organization.

Corporate

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

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External Net Sales By SBU:

The table below presents external net sales for continuing operations by SBU reporting segment:

(U.S. Dollars in thousands)	External Net Sales by SBU Year ended December 31, 2013		2012		2011	
	Net Sales	Percent of Total Net Sales	Net Sales (Restated)	Percent of Total Net Sales (Restated)	Net Sales (Restated)	Percent of Total Net Sales (Restated)
BioStim	$ 147,910	37%	$ 181,959	41%	$ 188,136	43%
Biologics	53,769	13%	53,730	12%	42,919	10%
Extremity Fixation	103,385	26%	112,009	25%	119,521	27%
Spine Fixation	95,470	24%	99,883	22%	91,395	20%
Total Net Sales	$ 400,534	100%	$ 447,581	100%	$ 441,971	100%

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.

Products

Our revenues are generally derived from the sales of products and marketing service fees in four SBUs, BioStim, Biologics, Extremity Fixation (which is comprised of bone repair products unrelated to the spine), and Spine Fixation (which is comprised of our Spine Repair Implants), and which accounted for 37%, 13%, 26%, and 24%, respectively, of our total net sales in 2013. Marketing service fee sales is comprised of fees earned for the marketing of tissue forms including Trinity Evolution ®, Trinity Elite and Versashield.

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 long bone non-invasive regenerative stimulator used to enhance bone growth in non-union factures
Biologic Solutions	

Alloquent ® 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 ®	VersaShield is a thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands

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Product	Primary Application
Collage Synthetic Osteoconductive Scaffold	A bone void filler
Extremity Fixation Solutions	
Fixation	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus ®, XCaliber and Gotfried PC.C.P®
Eight-Plate Guided Growth System ®	Treatment for bowed legs or knock knees of children
Limb Reconstruction System (LRS) and LRS ADVanced	External fixation for lengthenings 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
Centronail ® Ankle Compression Nailing System (ACN)	A differentiated solution for hindfoot fusions
Contours ® Lapidus Plating System (LPS)	A plate design contoured specifically for a tarsometatarsal (TMT) fusion
ContoursProximal Humerus Plate ® (PHP)	An innovative plating solution for fraction fixation of the proximal humerus.
ContoursVolar Plating System (VPS) III	The 3rd generation of plates to treat distal radius fractures.
Spine Fixation Solutions	
3 Degree /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)	A system of pedicle screws and rods implanted during a posterior spinal fusion procedure involving the stabilization of several degenerated or deformed cervical

System	vertebrae
Tempus Cervical Plate	A cervical plating system implanted during anterior cervical spine fusion procedures

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Product	Primary Application
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
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 PTC(TM) PEEK Titanium Composite 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	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 TM Spinal Fixation System which provides additional instrument and implant options for complex thoraco-lumbar 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 thoraco-lumbar spine fusion procedure
SFS Spinal Fixation System	A system of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, cross-connectors which provides simple, reliable and comprehensive stabilization solution for spinal non-cervical fixation
ICON Spinal Fixation System	Multi axial pedicle screws, mono axial pedicle screws, reduction screws, set screws, multi-axial bodies, offset bodies, cross connectors and rods that allow the surgeon to build a spinal implant construct. The ICON Module Spinal Fixation System is intended for posterior, non-cervical pedicle fixation
Samba Screw	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

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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 ®, Origen DBM, 3 Degree , Reliant , Hallmark®, Firebird , Ascent®, Construx ®, Unity ®, NGage ®, Newbridge ®, Trinity Elite ®, Trinity Evolution ®, PILLAR , Alloquent®, ProView , ProCallus ®, XCaliber , VeroNail®, Centronail ®, PREFIX , Gotfried PC.C.P®, Physio-Stim ®, TrueLok , Galaxy Fixation System and TL-HEX .

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 regenerative at the spinal fusion site. We have sponsored independent research at the 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 regenerative 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 indicator 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.

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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 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 VeraShield , 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 Musculoskeletal Transplant Foundation (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, and market our VersaShield under a private label brand via a non-exclusive marketing agreement for the tissue form.

To date, our Biologics are offered only 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.

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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. We believe external fixation allows micromovement at the fracture site, which is beneficial to the formation of new bone. 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.

External devices are designed in large part to be used for the same types of conditions that can be treated by internal fixation devices. The difference is that the external fixator is a monolateral or circular device attached with screws to the fractured bone from outside the skin of the arm or leg. The choice of whether to use an internal or external fixation device is driven in large part by physician preference although it may also be related to the fracture complexity and anatomical location. Some patients, however, favor internal fixation devices for aesthetic reasons.

The Limb Reconstruction System (LRS) 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.

Our newest 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 and shoulder. 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 minute 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, we believe TrueLok is a simple, stable, versatile ring fixation system superior to the traditional Ilizarov ring 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

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three-dimensional space. All components of the TL-HEX are compatible with the TrueLok Ring Fixation System; therefore external supports from both systems can be connected to each other when building fixation blocks. 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) should be utilized with the TL-HEX . 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 which 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, i.e., humerus, femur and tibia. Alternatively, a plate is attached by screws to an area such as a broken wrist or hip. Examples of our internal fixation devices include:

The Centronail ® nailing system is designed to stabilize fractures in the femur, tibia, supracondylar and recently the humerus. We believe that it has all the attributes of the Orthofix Nailing System, but has additional advantages, including that it is made of titanium, offers improved mechanical distal targeting and instrumentation and has a design which requires significantly reduced inventory.

The Centronail® Ankle Compression Nail from Orthofix is an arthrodesis nailing system designed to improve upon the stability, simplicity, and flexibility of current hindfoot nails. This product was released in the US market in 2012.

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) in the US. This system 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. Instrumentation includes a threaded drill guide, drill bits, depth gauge, screw sleeve, ratcheting AO wrench, and plate bender.

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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 include 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 both operatively and post-operatively. 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, or vertebral body replacement devices, and HCT/P, as well as interbody spacers 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 highest 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 mesh cages and other interbody devices has resulted in the increasing use of an anterior, or frontal, approach to many

lumbar surgeries. Interbody devices are small hollow implants typically made of either 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

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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.

Our products provide a wide array of implants designed for use primarily in cervical, thoracic and lumbar fusion surgeries. These implants are made of metal, bone, or PEEK. The majority of implants offered by our products are made of titanium metal. This includes the 3 Degree , Reliant and Hallmark® cervical plates. Additionally, the Spinal Fixation System (SFS), the Firebird Spinal Fixation Systems, the Phoenix Minimally Invasive Spinal Fixation System, the Ascent ® and Ascent ® LE POCT Systems are sets of rods, crossbars and screws which are implanted during posterior fusion procedures. The Firebird Modular and pre-assembled Spinal Fixation System are designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our product ProView MAP System. We also offer specialty plates that are used in less common procedures, and as such, are not manufactured by many device makers. These specialty plates include the Newbridge ® Laminoplasty Fixation System that is designed to expand the cervical vertebrae and relieve pressure on the spinal canal, as well as the Unity ® plate which is used in anterior lumbar fusion procedures.

We also offer a variety of devices made of PEEK, including vertebral body replacements and interbody devices. Vertebral body replacements are designed to replace a patient s degenerated or deformed vertebrae. On the other hand, interbody devices, or cages, are designed to replace a damaged disc, restoring the space that had been lost between two vertebrae.

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 2013, 2012 and 2011 we incurred $26.8 million, $28.6 million and $22.9 million, respectively, on 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

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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 regulatory 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 Federal Drug Administration (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.

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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, cancellous bone matrices containing viable stem cells. 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 which 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

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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 FDA 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 Reporting regulations, which require that manufacturers report to FDA 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 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. In June 2011, the FDA preannounced an inspection to close out the March 2009 Warning Letter issued to Blackstone Medical, Inc., and to determine compliance to Orthofix s Quality System Requirements as well as to our Tissue Distribution program. At the close of the inspection, Orthofix received one Quality System observation on a form 483 however the FDA inspector concluded that all the corrective actions pertinent to the warning letter were adequately completed. When the FDA concludes that an inspection is closed under 21 C.F.R. 20.64 (d) (3), it will release a copy of the Establishment Inspection Report (EIR) to the inspected establishment. Orthofix received its EIR for the June 2011 inspection in August 2011 indicating that this inspection was closed. The corrective action associated with the one observation on the 483 was fully corrected by Orthofix and verified by the FDA in January 2012 during a routine inspection of the Lewisville facility. At the conclusion of the January inspection the FDA issued a 483 due to minor deficiencies within our quality systems. The Company replied with a formal response, and after reviewing the evidence the FDA determined our corrective action adequate and the audit was closed. 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.

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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 policy holder 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

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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 which 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.

In order to give applicable manufacturers and applicable GPOs sufficient time to prepare, data collection began on August 1, 2013. Applicable manufacturers and applicable GPOs will report the data for August through December of 2013 to CMS by March 31, 2014 and CMS will release the data publicly by September 30, 2014.

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 37%, 13%, 26%, and 24%, respectively, of our total net sales in 2013.

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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 50 countries.

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

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 and group purchasing organizations (GPOs), which are organizations that contract on a large scale. We believe there is a developing focus on marketing to GPOs and large national accounts that reflects a trend toward large scale procurement efforts in the healthcare industry.

We support our sales force 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. 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 which features a lecture room, classroom, workshop and 7-station bioskills laboratory. In 2013, these product education seminars were attended by over 2,508 surgeons around the world; seminars 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 courses in product application for local surgeons. We also provide sales training at our training center in Lewisville, Texas 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 SBU s, compete principally with similar products marketed by Biomet Spine, a business unit of Biomet, Inc; DJO Incorporated; and the Exogen product line owned by Smith and Nephew plc. and Essex Woodland, 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.; De Puy Synthes, a division of Johnson and Johnson; Stryker Corp.;

Zimmer, Inc.; NuVasive; Biomet Spine; and various smaller public and private companies. For external and internal fixation devices, our principal competitors include De Puy Synthes; Zimmer, Inc.; Stryker Corp.; Smith & Nephew plc; and Biomet Orthopedics, a business unit of Biomet, Inc.

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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, but subcontract their manufacture and packaging. Through subcontracting, 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 United Kingdom. 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 business is generally not seasonal in nature. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. In addition, we do not consider the backlog of firm orders to be material.

Capital Expenditures

We incurred tangible and intangible capital expenditures in the amount of $29.7 million, $28.8 million and $25.8 million in 2013, 2012 and 2011, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. In 2013, we invested $29.7 million in capital expenditures of which the most significant item was $17.3 million related to instrumentation and tooling. We currently plan to invest approximately $24.3 million in capital expenditures during 2014 to support the planned expansion of our business. We expect these capital expenditures to be financed principally with cash generated from operations.

Employees

At December 31, 2013, we had 889 employees worldwide. Of these, 596 were employed in the U.S. and 293 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 150 at December 31, 2013, 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 889 employees, 368 were employed in sales and marketing functions, 186 in general and administrative roles, 192 in production and operations

and 143 in research and development.

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Item 1A. Risk Factors

In addition to the other information contained in this Form 10-K 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 Form 10-K 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 Form 10-K.

Expenses relating to or arising from the Audit Committee s review of certain accounting matters, including diversion of management s time and attention, may adversely affect our business and results of operations.

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 the restatement of our consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010, and the restatement of our condensed consolidated financial statements at March 31, 2013, as well as the correction of similar errors in prior periods. As a result of this review and the restatement, the filing of our Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2013 and September 30, 2013 were delayed until March 2014 and the filing of this Report was delayed until the date hereof.

As a result of the Audit Committee s review, we have incurred significant expenses to date related to legal, accounting and other professional services in connection with the review, the preparation of restated consolidated financial statements and related matters, and we may continue to incur significant additional expenses with regard to these matters and our remediation efforts. In addition, our President and Chief Executive Officer and our Chief Financial Officer, as well as senior members of our finance and accounting departments and other Company personnel, have spent substantial amounts of time and effort in connection with this review, the restatement and related matters. The significant amount of time and effort spent by our management team on these matters may divert their attention from the operation of our business. The expenses incurred, and expected to be incurred, on the review, the restatement and related matters, and the diversion of the attention of the management team could have, a material adverse effect on our business, financial condition, results of operations or cash flows.

Our management has identified material weaknesses in the Company s internal control over financial reporting which could, if not remediated, result in additional material misstatements in our consolidated financial statements. We may be unable to develop, implement and maintain appropriate controls in future periods.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, and the Sarbanes-Oxley Act of 2002 and SEC rules require that our management report annually on the effectiveness of the Company s internal control over financial reporting and our disclosure controls and procedures. Among other things, our management must conduct an assessment of the Company s internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to audit, the effectiveness of the Company s internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. As disclosed in Part II, Item 9A, Controls and Procedures of this Form 10-K, our management, with the participation of our current President and Chief Executive Officer and our Chief Financial Officer, has determined that we have material weaknesses in the Company s internal control over financial reporting as of December 31, 2013 related to revenue recognition practices for sales to the Company s distributors, inventory reserves, foreign subsidiary oversight and manual journal entry control procedures. Some of these material weaknesses resulted in material misstatements in our previously filed annual audited and interim unaudited consolidated financial statements.

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A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We are actively engaged in developing and implementing a remediation plan designed to address such material weaknesses. However, additional material weaknesses in the Company s internal control over financial reporting may be identified in the future. Any failure to implement or maintain required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, or could result in material misstatements in our consolidated financial statements. These misstatements could result in a further restatement of our consolidated financial statements, cause us to fail to meet our reporting obligations, reduce our ability to obtain financing or cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

Although we are working to remedy the ineffectiveness of the Company s internal control over financial reporting, there can be no assurance as to when the remediation plan will be fully developed, when it will be fully implemented or the aggregate cost of implementation. Until our remediation plan is fully implemented, our management will continue to devote significant time and attention to these efforts. If we do not complete our remediation in a timely fashion, or at all, or if our remediation plan is inadequate, there will continue to be an increased risk that we will be unable to timely file future periodic reports with the SEC and that our future consolidated financial statements could contain errors that will be undetected. Further and continued determinations that there are material weaknesses in the effectiveness of the Company s internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain and require additional expenditures of both money and our management s time to comply with applicable requirements. For more information relating to the Company s internal control over financial reporting (and disclosure controls and procedures) and the remediation plan undertaken by us, see Part II, Item 9A, Controls and Procedures.

Our failure to prepare and timely file our periodic reports with the SEC limits our access to the public markets to raise debt or equity capital.

We did not file a Quarterly Report on Form 10-Q within the timeframe required by the SEC for each of the quarterly periods ended June 30, 2013 and September 30, 2013. Because we have not remained current in our reporting requirements with the SEC, we are limited in our ability to access the public markets to raise debt or equity capital. Our limited ability to access the public markets could prevent us from pursuing transactions or implementing business strategies that we might otherwise believe are beneficial to our business. Until one year after the date we regain and maintain compliance with our SEC reporting obligations, we will be ineligible to use shorter and less costly filings, such as Form S-3, to register our securities for sale. We may use Form S-1 to register a sale of our stock to raise capital or complete acquisitions, but doing so would likely increase transaction costs and adversely impact our ability to raise capital or complete acquisitions of other companies in a timely manner.

We have not been in compliance with Nasdaq Stock Market LLC s requirements for continued listing and, as a result, our common stock may be delisted from trading on Nasdaq, which could have a material effect on us and our shareholders.

We have been delinquent in the filing of our Quarterly Reports on Form 10-Q for the fiscal quarters ended June 30, 2013 and September 30, 2013, as a result of which we have not been in compliance with the rules of Nasdaq Stock Market LLC (Nasdaq) and are subject to having our stock delisted from trading on Nasdaq. We have been granted a stay of the delisting of our common stock until such time as a Nasdaq Hearings Panel makes a decision on the merits following a hearing, which hearing was held on March 27, 2014. We filed our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 on March 24, 2014 and filed our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013 on March 25, 2014. We also filed this Form 10-K (for the year ended

December 31, 2013), which is otherwise due under SEC rules on March 17, 2014,

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on the date hereof. As a result, we believe that we have adequately remedied our current non-compliance with Nasdaq s listing rules. However, there can be no assurance that the Nasdaq Hearings Panel will concur with our belief that we have remedied our prior non-compliance, in which case our common stock could remain subject to delisting by Nasdaq. If our common stock were delisted, there could be no assurance whether or when it would again be listed for trading on Nasdaq or any other exchange. Further, the market price of our shares might decline and become more volatile, and our shareholders may find that their ability to trade in our stock would be adversely affected. Furthermore, institutions whose charters do not allow them to hold securities in unlisted companies might sell our shares, which could have a further adverse effect on the price of our stock.

If we fail to comply with the terms of our Deferred Prosecution Agreement and 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 which 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.

On July 10, 2012, we entered into definitive agreements with the U.S. Department of Justice (DOJ) and the SEC agreeing to settle our 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 has agreed not to pursue any criminal charges against us in

connection with this 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

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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 will periodically report to the government during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, we also agreed pursuant to the Consent to certain reporting obligations to the SEC regarding the status of our remediation and implementation of compliance measures. In the event that we fail to comply with these obligations, we could be subject to criminal prosecution by the DOJ for the FCPA-related matters we self-reported. Such a criminal prosecution could subject us to penalties that could have a material adverse effect our business, financial condition, results of operations or cash flows.

We are investigating allegations involving potential improper payments with respect to our subsidiary in Brazil.

In August 2013, the Company s internal legal department was notified of certain allegations involving potential improper payments with respect to our Brazilian subsidiary, Orthofix do Brasil. The Company engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the FCPA. This review remains ongoing. The FCPA and related provisions of law provide for potential criminal and civil sanctions in connection with anti-bribery violations, including criminal fines, civil penalties, disgorgement of past profits and other kinds of remedies. We currently cannot reasonably estimate a possible loss, or range of loss, in connection with this review. In the event that such loss is substantial, it could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Consistent with the provisions of the DPA and the Consent described above, the Company contacted the DOJ and the SEC in August 2013 to voluntarily self-report the Brazil-related allegations, and the Company and its counsel remain in contact with both agencies regarding the status of the review. In the event that the DOJ and the SEC find that the matters related to our Brazilian subsidiary could give rise to a review of our obligations under the terms of the DPA and/or the Consent, we currently cannot reasonably estimate a possible loss, or range of loss, in connection with that review, including any effects it may have with respect to the DPA and the Consent. In the event such a review were to occur, any losses resulting therefrom, if substantial, could have a material adverse effect our business, financial condition, results of operations or cash flows.

The SEC Enforcement Staff s review 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, 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. Since our initial contact, we have received requests from the SEC Enforcement Staff 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. In addition to the Company, several current and former members of our senior management are named as defendants. At the present time, the allegations that the lead plaintiff ultimately intends to make in this action are unknown.

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We have incurred and/or expect to incur significant professional fees and other costs in responding to the SEC Enforcement Staff s review and in defending against the class action complaint. If we do not prevail in 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 Enforcement Staff 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 would 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 may disagree with the manner in which we have accounted for and reported these adjustments. Accordingly, there is a risk that we may have to further restate our historical consolidated financial statements, amend prior filings with the SEC or take other actions not currently contemplated. In addition, our Board of Directors, management and employees may expend a substantial amount of time on the SEC Enforcement Staff s review and the pending complaint, diverting resources and attention that would otherwise be directed toward our operations and implementation of our business strategy, all of which could materially adversely affect our business, financial condition, results of operations or cash flows.

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 Enforcement Staff s review 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 Enforcement Staff review, 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.

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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 policy holder 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

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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 United Kingdom, 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

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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 forgeoing actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations or cash flows.

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 2013, the update factor is 0.8% (reflecting a 1.7% inflation update that is partially offset by a 0.9% productivity adjustment).

The ACA establishes new disclosure requirements (Physician Payment Sunshine Act) regarding financial arrangements between medical device and supplies manufacturers and physicians, including physicians who serve as consultants. The recordkeeping requirements were effective as of August 1, 2013. Manufacturers and GPOs were required to report the data for August through December of 2013 to CMS by March 14, 2014, and the first reports will be publicly available by September 30, 2014. The regulations require us to report annually to CMS all payments and other transfers of value to physicians and teaching hospitals for products payable under federal health care programs, as well as ownership or investments held by physicians or their family members. Failure to fully and accurately disclose transfers of value to physicians 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, results of operations.

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

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

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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.

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, Extermity 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 have 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 that they are substantial, it could have a material adverse effect our business, financial condition, results of operations or cash flows.

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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.

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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 which 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 and which are used for bone reconstruction or repair and 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.

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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 2013, we continued to make improvements in revenues related to several new products we introduced to the market over the past two years, including the CONSTRUX® Mini PTC PEEK Titanium 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 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 operating results have fluctuated significantly in the past on a quarterly basis. Our operating results may fluctuate significantly from quarter to quarter in the future and we may experience losses in the future depending on a number of factors, including the extent to which our products continue to gain or maintain market

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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 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.

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 portions of Europe that have been disproportionately affected by the global recession, such as Greece and Italy, 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.

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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 2013 have had an unfavorable impact of $1.1 million on net sales from continuing operations 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, 2013, we had outstanding a currency swap to hedge a 28.7 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.

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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 subsidiary, Orthofix Holdings, Inc., is party to a senior secured bank credit facility that contains significant financial and operating restrictions, including financial covenants that we may be unable to satisfy in the future.

On August 30, 2010, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a credit agreement (the Credit Agreement) with respect to a new senior secured bank credit facility with a syndicate of financial institutions, and used these borrowings to repay all amounts owed under the prior credit facility. The Credit Agreement was further amended in May 2011. We, and certain of Orthofix Holdings direct and indirect subsidiaries, including Orthofix Inc. and Blackstone, have guaranteed the obligations of Orthofix Holdings under the senior secured bank facility. The senior secured bank facility provides for (1) a five-year term loan facility of $100 million, which was paid in full during 2012, and (2) a five-year revolving credit facility of $200 million of which we had $20 million outstanding and $180 million available to be drawn as of December 31, 2013.

The Credit Agreement contains negative covenants applicable to us and our subsidiaries, including restrictions on indebtedness, liens, dividends and mergers and sales of assets. The Credit Agreement also contains certain financial covenants and a breach of these covenants could result in an event of default under the Credit Agreement, which could permit acceleration of the debt payments under the facility. We believe that we were in compliance with the negative covenants, and there were no events of default, at December 31, 2013. Further, we believe that we should be able to meet these financial covenants in future fiscal quarters; however, there can be no assurance that we will be able to do

so, and failure to do so could result in an event of default under the Credit Agreement, which could have a material adverse effect on our financial position.

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In the event we fail to comply with the terms of a Limited Waiver we have received from our lenders, we could be in default under our senior secured credit facility.

On August 14, 2013, we and certain required lender parties (the Lenders) entered into a Limited Waiver (the Limited Waiver) pursuant to the Credit Agreement described above. Under the Limited Waiver, the Lenders collectively waived requirements under the Credit Agreement that we deliver quarterly consolidated financial statements with respect to the fiscal quarters ending on June 30, 2013 and September 30, 2013, and related financial covenant certificates, until the earlier of (i) March 31, 2014 or (ii) the date that is one day after such consolidated financial statements are publicly filed or released. In addition, the Limited Waiver provided that the restatement of our consolidated financial statements for any period ending on or before March 31, 2013 will not constitute a default or event of default provided that within one business day after the public release or filing of such restated consolidated financial statements, we deliver corrected consolidated financial statements and compliance certificates with respect to such restated periods and immediately pay any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated consolidated financial statements.

As of the date hereof, we have delivered the quarterly consolidated financial statements for the quarter ended, and are in the process of delivering our audited consolidated financial statements for the year ended, December 31, 2013, as described above. However, in the event that we do not satisfy these respective obligations under the Limited Waiver and/or the Credit Agreement, an event of default could be declared under the Credit Agreement, which could have a material adverse effect on our financial position.

The conditions of the U.S. and international capital and credit markets may adversely affect our ability to draw on our current revolving credit facility, our ability to obtain future short- or long-term lending or our interest expense under our existing credit facility.

We maintain a five-year revolving credit facility of $200 million upon which we had $180 million available to be drawn as of December 31, 2013, pursuant to the Credit Agreement described above. However, to the extent our business requires us to access the credit markets in the future and we are not able to do so, including in the event that lenders cease to lend to us, or cease to be capable of lending, for any reason, we could experience a material and adverse impact on our financial condition and ability to borrow additional funds. This might impair our ability to obtain sufficient funds for working capital, capital expenditures, acquisitions, research and development and other corporate purposes.

Borrowings under our existing credit facility bear interest at a floating rate, which will be, at our option, either the London Inter-Bank Offered Rate (LIBOR) plus an applicable margin or a base rate plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated leverage ratio with respect to the immediately preceding four fiscal quarters. Our overall effective interest rate as of December 31, 2013 on our senior secured debt was 2.7%. Our interest expense that we incur under our credit facilities could increase if there are increases in either the LIBOR rate or base rate. (See Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk in this Form 10-K.)

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.

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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 substantial 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.

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Item 2. Properties

Our principal facilities as of December 31, 2013 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 offices	Florham Park, NJ	2,700	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

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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, our Audit Committee began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in the decision to restate certain of our previously filed consolidated financial statements. As a result of this review and the restatement of certain of our previously filed consolidated financial statements, the filing of our Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2013 and September 30, 2013, and this Report, was not timely. We filed our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 on March 24, 2014, and filed our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013 on March 25, 2014. We also have filed this Annual Report on the date hereof.

SEC Enforcement Staff Review

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, through its counsel, has been in direct communication with the SEC Enforcement Staff regarding these matters, and both the Company and the Audit Committee are cooperating fully with the SEC Enforcement Staff s review of these matters. The Company has received requests from the SEC Enforcement Staff for documents and other information concerning various accounting practices, internal controls and business practices. 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 Enforcement Staff in the future. We have further provided notice concerning these matters 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. The matter is at an early stage and, at this time, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

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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. In addition to the Company, Alan W. Milinazzo, our former President and Chief Executive Officer, Robert S. Vaters, our former President and Chief Executive Officer, Brian McCollum, our former Chief Financial Officer, Bradley R. Mason, our current President and Chief Executive Officer, and Emily Buxton, our current Chief Financial Officer, are named as defendants. The operative complaint has not yet been filed in the action following the appointment by the court of a lead plaintiff. Accordingly, the allegations that the lead plaintiff ultimately intends to make in this action are unknown. The matter is at an early stage and, at this time, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

Matters Related to Promeca

On July 10, 2012, we entered into definitive agreements with the DOJ and the SEC agreeing to settle our 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). Under the terms of these agreements, we voluntarily disgorged profits to the United States government in an amount of $5.2 million, inclusive of pre-judgment interest, and agreed to pay a fine of $2.2 million. We paid $2.2 million in July 2012 and $5.2 million in September 2012. 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 has agreed not to pursue any criminal charges against us in connection with this matter if we comply with the terms of the DPA. The DPA takes note of our self-reporting of this matter to 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 will periodically report to the government during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, we also agreed pursuant to the Consent to certain reporting obligations to the SEC regarding the status of our remediation and implementation of compliance measures. In the event that we fail to comply with these obligations, we could be subject to criminal prosecution by the DOJ for the FCPA-related matters we self-reported.

Review of Potential Improper Payments Involving Brazil Subsidiary

In August 2013, our internal legal department was notified of certain allegations involving potential improper payments with respect to our Brazilian subsidiary, Orthofix do Brasil. We engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the FCPA. This review remains ongoing. The FCPA and related provisions of law provide for potential criminal and civil sanctions in connection with anti-bribery violations, including criminal fines, civil penalties, disgorgement of past profits and other kinds of remedies. We currently cannot reasonably estimate a possible loss, or range of loss, in connection with this review.

Consistent with the provisions of the DPA and the Consent described above, the Company contacted the DOJ and the SEC in August 2013 to voluntarily self-report the Brazil-related allegations, and the Company and

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its counsel remain in contact with both agencies regarding the status of the review. In the event that the DOJ and the SEC find that the matters related to our Brazilian subsidiary could give rise to a review of our obligations under the terms of the DPA and/or the Consent, we currently cannot reasonably estimate a possible loss, or range of loss, in connection with that review, including any effects it may have with respect to the DPA and the Consent.

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 Blackstone, 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 (i) the government investigation and product liability matters regarding the previously

owned infusion pump product line described below, and (ii) pre-closing sales of cold

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therapy units and certain post-closing sales of cold therapy units. We have established an accrual of $4.2 million for our indemnification obligations in connection with the July 2012 verdict described in the third paragraph below, however, actual liability in this case could be higher or lower than the amount accrued. We have not established any accrual in connection with our other indemnification obligations under the Breg SPA, and currently cannot reasonably estimate the possible loss, or range of loss, in connection with certain of such obligations (including with respect to the matters described in the three paragraphs below).

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 2013, 2012 and 2011 for $6.7 million, $6.8 million and $1.8 million, respectively. In addition, several cases remain outstanding for which the Company currently cannot reasonably estimate the possible loss, or range of loss.

On or about August 2, 2010, Breg received a HIPAA subpoena issued by the DOJ. The subpoena seeks documents from us and our subsidiaries for the period of January 1, 2000 through the date of the subpoena. We believe that document production in response to the subpoena was completed as of July 2012. We believe that this subpoena relates to an investigation by the DOJ into whether Breg s sale, marketing and labeling of local infusion pumps for pain management, prior to Breg s divestiture of this product line in 2008, complied with FDA regulations and federal law. We are currently cooperating with the U.S. Government in connection with this matter.

At the time of its divestiture by us, 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 that 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. The majority of these cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, we believe that meritorious defenses exist to these claims. In July 2012, a jury in one case related to a motorized cold therapy unit previously sold by Breg returned a verdict providing for approximately $2.1 million in compensatory damages to the plaintiff against Breg and $7 million in exemplary damages. The case remains subject to appeal. We believe that the damages are without merit; however, the ultimate outcome is uncertain. We previously established an accrual and related charge to discontinued operations of $4.2 million for both compensatory damages and exemplary damages for our indemnification obligations in connection with this July 2012 verdict; however, actual liability in this case could be higher or lower than the amount accrued.

Item X. Executive Officers of the Registrant

The following table sets forth certain information about the persons who serve as our executive officers.

Name	Age	Position
Bradley R. Mason	60	President and Chief Executive Officer and Director
Emily V. Buxton	37	Chief Financial Officer
Michael M. Finegan	50	Chief Strategy Officer
Jeffrey M. Schumm	52	Chief Administrative Officer, General Counsel and Corporate Secretary
Davide Bianchi	49	President, Global Extremity Fixation

Our officers serve at the discretion of the Board of Directors. There are no family relationships among any of our directors or executive officers. The following is a summary of the background of each executive officer.

Bradley R. Mason. Mr. Mason was appointed as the Company s President and Chief Executive Officer and as a Director in March 2013. He had previously served as the Company s Group President, North America from

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June 2008 through October 2009, and as a Strategic Advisor from November 2009 through October 2010, when he had originally retired from the Company. Prior to being appointed as Group President, North America, he had served as a Vice President of the Company since December 2003, when the Company acquired Breg, Inc. Prior to its acquisition by Orthofix, Mr. Mason had served as President and Chairman of Breg, a company he principally founded in 1989 with five other shareholders. Mr. Mason has over 30 years of experience in the medical device industry, some of which were spent with dj Orthopedics (formally DonJoy) where he held the position of Executive Vice President. After his original retirement from Orthofix in 2010, he served in a variety of part-time consulting and advisory roles, including as a consultant to Orthofix from October 2012 to March 2013. Mr. Mason is the named inventor on 38 issued patents in the orthopedic product arena. He graduated Summa Cum Laude with an Associate of Arts and Associate of Science degree from MiraCosta College

Emily V. Buxton. Ms. Buxton was named Chief Financial Officer in April 2013 after previously having served as Interim Chief Financial Officer since November 2012. She joined Orthofix s corporate finance group in 2003, advancing to the position of Vice President, Controller in December 2008. After holding the position of Vice President, Controller, Ms. Buxton served as Chief Financial Officer of Global Orthopedics for Orthofix from July 2010 to the time of her appointment as Interim Chief Financial Officer. Prior to joining Orthofix, Ms. Buxton worked for two large public companies in their Securities and Exchange Commission reporting departments and prior to that she worked in public accounting. She received her Bachelor s of Arts degree in Accounting from Columbia College, Columbia, SC.

Michael M. Finegan. Mr. Finegan joined Orthofix International N.V. in June 2006 as Vice President of Corporate Development, and became the President, Biologics in March 2009. In October 2011, he was promoted to Senior Vice President, Business Development, and President, Biologics, and in June 2013, to his current position as Chief Strategy Officer. Prior to joining Orthofix, Mr. Finegan spent sixteen years as an executive with Boston Scientific in a number of different operating and strategic roles, most recently as Vice President of Corporate Sales. Earlier in his career, Mr. Finegan held sales and marketing roles with Marion Laboratories and spent three years in banking with First Union Corporation (Wachovia). Mr. Finegan earned a BA in Economics from Wake Forest University.

Jeffrey M. Schumm. Mr. Schumm joined Orthofix International N.V. as Assistant General Counsel in January 2007, was promoted to Senior Vice President, General Counsel and Corporate Secretary in October 2010 and, in June 2013, was named as the Company s Chief Administrative Officer, General Counsel, and Corporate Secretary. From 2004 to 2006, Mr. Schumm served as Vice President and General Counsel for Regeneration Technologies, Inc. Earlier in his career, he served as an Assistant Attorney General for the State of Florida, as an associate at Holland & Knight LLP and as a Staff Attorney at the Supreme Court of Florida. Mr. Schumm received his Bachelors of Science in Electrical Engineering and Masters in Business Administration from Lehigh University, and he is a magna cum laude graduate of the Florida State University College of Law.

Davide Bianchi. Mr. Bianchi joined Orthofix International N.V. as President, International Extremity Fixation in July 2013 and was named as the Company s President, Global Extremity Fixation in December 2013. From February 2009 through June 2013, Mr. Bianchi served as President of the Heart Valve Global Business Unit at Sorin Group. Earlier in his career, he spent ten years with Edwards Lifesciences, where he served as the European Marketing Manager; the Business Director, Emerging Markets; the Managing Director, Germany; the VP, Sales; and, most recently, the VP, Marketing, EMEA. Mr. Bianchi received his M.B.A. from ISTUD Milano.

Item 4. Mine Safety Disclosure

Not applicable.

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PART II

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

Market for Our Common Stock

Our common stock is traded on the Nasdaq ® Global Select Market under the symbol OFIX. 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, 2013. As of March 24, 2014 we had 333 holders of record of our common stock. The closing price of our common stock on March 24, 2014 was $24.79.

	High	Low
2012		
First Quarter	$ 42.92	$ 34.28
Second Quarter	41.26	35.55
Third Quarter	44.90	40.25
Fourth Quarter	45.52	36.47
2013		
First Quarter	$ 39.94	$ 35.87
Second Quarter	35.76	26.19
Third Quarter	28.58	20.77
Fourth Quarter	22.90	19.64

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 credit agreement obligations and to finance 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.

Recent Sales of Unregistered Securities

There were no securities sold by us during 2013 that were not registered under the Securities Act.

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. 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

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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 return of two indexes: the Nasdaq Stock Market and Nasdaq stocks for surgical, medical, and dental instruments and supplies.

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The graph assumes that you invested $100 in Orthofix Common Stock and in each of the indexes on December 31, 2008. Points on the graph represent the performance as of the last business day of each of the years indicated.

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Item 6. Selected Financial Data

The following selected consolidated financial data for the years ended December 31, 2013, 2012, 2011, 2010 and 2009 have been derived from our audited consolidated financial statements. The audited consolidated financial statements have been restated for the fiscal years ended December 31, 2012, 2011 and 2010 and the restatement has been reflected in the information provided below. In addition, we have previously determined that errors existed in the Company s previously issued financial statements for the fiscal year ended December 31, 2009, for which the Company is including such previously restated information below. The financial data as of December 31, 2013 and 2012 and for the years ended December 31, 2013, 2012 and 2011 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. For more information about the restatement of certain of our consolidated financial statements, see Part II, Item 8, Financial Statements and Supplementary Data Note 2, Restatement of the Consolidated Financial Statements. Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (GAAP).

	Year ended December 31,				
	2013	2012 (Restated)	2011 (Restated)	2010 (Restated)	2009 (Restated)
	(U.S. Dollars in thousands, except margin and per share data)				
Consolidated operating results					
Net sales	$ 400,534	$ 447,581	$ 441,971	$ 462,571	$ 429,237
Gross profit	298,234	349,328	346,444	365,478	329,973
Gross profit margin	75%	78%	78%	79%	77%
Total operating income (loss) (3)	(5,087)	76,636	5,900	65,984	37,526
Net income (loss) from continuing operations	(14,908)	45,050	(16,218)	30,997	10,469
Net income (loss) from discontinued operations	(10,607)	(2,212)	(1,892)	13,299	12,453
Net income (loss) (1) (2) (3)	$ (25,515)	$ 42,838	$ (18,110)	$ 44,296	$ 22,922
Net income (loss) per share of common stock:					
Basic:					
Net income (loss) from continuing operations	$ (0.80)	$ 2.37	$ (0.89)	$ 1.76	$ 0.61
Net income (loss) from discontinued operations	(0.57)	(0.12)	(0.10)	0.76	0.73
Net income (loss)	$ (1.37)	$ 2.25	$ (0.99)	$ 2.52	$ 1.34
Net income (loss) per share of common stock:					
Diluted:					
Net income (loss) from continuing operations	$ (0.80)	$ 2.32	$ (0.89)	$ 1.73	$ 0.61

Net income (loss) from discontinued operations	(0.57)	(0.11)	(0.10)	0.74	0.72
Net income (loss)	$ (1.37)	$ 2.21	$ (0.99)	$ 2.47	$ 1.33

(1) The Company has not paid any dividends in any of the years presented.
(2) Includes the gain on sale of vascular operations of $8.5 million for the year ended December 31, 2010.
(3) 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.

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(at year-end)	2013	2012 (Restated)	2011 (Restated)	2010 (Restated)	2009 (Restated)
	As of December 31, (U.S. Dollars in thousands, except share data)				
Consolidated financial position					
Total assets	$ 423,182	$ 472,897	$ 685,380	$ 608,251	$ 595,722
Total debt	20,000	20,016	210,013	220,007	254,673
Shareholders equity	310,494	367,832	292,074	293,918	232,620
Weighted average number of shares of common stock outstanding (basic)	18,697,228	18,977,263	18,219,343	17,601,956	17,119,474
Weighted average number of shares of common stock outstanding (diluted)	18,697,228	19,390,413	18,219,343	17,913,545	17,202,943

The effect of the restatements of the Company s Selected Financial Data are as follows:

	Year ended December 31,					
	2012			2011		
	(U.S. Dollars, in thousands, except margin and per share data)					
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Consolidated operating results						
Net sales	$ 462,320	$ (14,739)	$ 447,581	$ 470,121	$ (28,150)	$ 441,971
Gross profit	375,828	(26,500)	349,328	377,502	(31,058)	346,444
Gross profit margin	81%	(3)%	78%	80%	(2)%	78%
Total operating income (loss)	89,010	(12,374)	76,636	31,309	(25,409)	5,900
Net income (loss) from continuing operations	53,936	(8,886)	45,050	(1,740)	(14,478)	(16,218)
Net income (loss) from discontinued operations	(2,641)	429	(2,212)	667	(2,559)	(1,892)
Net income (loss)	$ 51,295	$ (8,457)	$ 42,838	$ (1,073)	$ (17,037)	$ (18,110)
Net income (loss) per share of common stock Basic:						
Net income (loss) from continuing operations	$ 2.84	$ (0.47)	$ 2.37	$ (0.10)	$ (0.79)	$ (0.89)
Net income (loss) from discontinued operations	(0.14)	0.02	(0.12)	0.04	(0.14)	(0.10)
Net income (loss)	$ 2.70	$ (0.45)	$ 2.25	$ (0.06)	$ (0.93)	$ (0.99)

Net income (loss) per share of common stock Diluted:						
Net income (loss) from continuing operations	$ 2.78	$ (0.46)	$ 2.32	$ (0.10)	$ (0.79)	$ (0.89)
Net income (loss) from discontinued operations	(0.14)	0.03	(0.11)	0.04	(0.14)	(0.10)
Net income (loss)	$ 2.64	$ (0.43)	$ 2.21	$ (0.06)	$ (0.93)	$ (0.99)

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(at year-end)	As of December 31, 2012 Previously Reported	2012 Adjustments	2012 Restated	2011 Previously Reported	2011 Adjustments	2011 Restated
	(U.S. Dollars, in thousands, except share data)					
Consolidated financial position						
Total assets	$ 504,281	$ (31,384)	$ 472,897	$ 704,472	$ (19,092)	$ 685,380
Total debt	20,016		20,016	210,013		210,013
Shareholders equity	399,098	(31,266)	367,832	315,171	(23,097)	292,074
Weighted average number of shares of common stock outstanding (basic)	18,977,263		18,977,263	18,219,343		18,219,343
Weighted average number of shares of common stock outstanding (diluted)	19,390,413		19,390,413	18,219,343		18,219,343

	Year ended December 31, 2010 Previously Reported	2010 Adjustments	2010 Restated	2009 Previously Reported	2009 Adjustments	2009 Restated
	(U.S. Dollars, in thousands, except margin and per share data)					
Consolidated operating results						
Net sales	$ 460,629	$ 1,942	$ 462,571	$ 430,479	$ (1,242)	$ 429,237
Gross profit	370,168	(4,690)	365,478	333,616	(3,643)	329,973
Gross profit margin	80%	(1)%	79%	77%		77%
Total operating income (loss)	66,250	(266)	65,984	42,108	(4,582)	37,526
Net income (loss) from continuing operations	27,758	3,239	30,997	9,006	1,463	10,469
Net income (loss) from discontinued operations	16,450	(3,151)	13,299	15,466	(3,013)	12,453
Net income (loss)	$ 44,208	$ 88	$ 44,296	$ 24,472	$ (1,550)	$ 22,922
Net (loss) income per share of common stock:						
Basic:						
Net income (loss) from continuing operations	$ 1.58	$ 0.18	$ 1.76	$ 0.53	$ 0.08	$ 0.61
Net income (loss) from discontinued operations	0.93	(0.17)	0.76	0.90	(0.17)	0.73
Net income (loss)	$ 2.51	$ 0.01	$ 2.52	$ 1.43	$ (0.09)	$ 1.34

Net (loss) income per share of common stock:												
Diluted:												
Net income (loss) from continuing operations	$	1.55	$	0.18	$	1.73	$	0.52	$	0.09	$	0.61
Net income (loss) from discontinued operations		0.92		(0.18)		0.74		0.90		(0.18)		0.72
Net income (loss)	$	2.47	$		$	2.47	$	1.42	$	(0.09)	$	1.33

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(at year-end)	As of December 31, 2010 (U.S. Dollars, in thousands, except share data)			2009		
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Consolidated financial position						
Total assets	$ 612,926	$ (4,675)	$ 608,251	$ 601,690	$ (5,968)	$ 595,722
Total debt	220,007		220,007	254,673		254,673
Shareholders equity	300,891	(6,973)	293,918	240,269	(7,649)	232,620
Weighted average number of shares of common stock outstanding (basic)	17,601,956		17,601,956	17,119,474		17,119,474
Weighted average number of shares of common stock outstanding (diluted)	17,913,545		17,913,545	17,202,943		17,202,943

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

As discussed below and in Item 8, Financial statements and Supplementary Data Notes to the Consolidated Financial Statements Note 2 Restatement of the Consolidated Financial Statements, we have restated our previously issued audited consolidated financial statements for the fiscal years ended December 31, 2012 and 2011 and our unaudited condensed consolidated financial statements for each of the quarters within 2012 and 2011 and the first quarter of 2013. Accordingly, the Management s Discussion and Analysis of Financial Condition and Results of Operations set forth below reflects the effects of the restatement.

The following discussion and analysis addresses the results of our operations which are based upon the consolidated financial statements included herein, which have been prepared in accordance with 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.

Restatement of Previously Issued Consolidated Financial Statements

As described further below and herein, this Form 10-K reflects the restatement of our consolidated financial statements as of and for each of the years ended December 31, 2012 and December 31, 2011. The restatement of our original Form 10-K for the year ended December 31, 2012 reflected in the amended Form 10-K filed on March 24, 2014 corrected errors principally related to our accounting for revenue recognition for sales to distributors, our accounting for inventory reserves, and our accounting for royalties. This Management s Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement adjustments in the years ended December 31, 2012 and December 31, 2011. For further information regarding the matters leading to the restatement and related findings with respect to our disclosure controls and procedures and internal control over financial reporting, see Part II, Item 9A, Controls and Procedures of this Form 10-K.

In conjunction with the Audit Committee Review described in the Explanatory Note to this Form 10-K, management concluded that errors existed in the Company s previously issued consolidated financial statements with respect to the fiscal years ended December 31, 2012, 2011, 2010, 2009, 2008 and 2007, and the fiscal quarter ended March 31, 2013.

In reaching these conclusions, the Company considered information obtained in the Independent Review, including emails, data and interviews with current and former employees that indicated (i) the existence of extra-contractual terms or arrangements at the onset of the sale and concessions agreed to subsequent to the initial sale (such as extended payment terms and return and exchange rights for sales to distributors with respect to certain transactions), including some with which certain senior-level personnel were involved, (ii) that at the time of some sales collection was not reasonably assured, and (iii) that certain amounts previously characterized as commissions were paid to related parties of the applicable customer.

The Company assessed the information derived from the Independent Review in making determinations with respect to accounting adjustments reflected in the restated consolidated financial statements contained in this Form 10-K, and such determinations are consistent with the findings of the Independent Review. In addition to the matters that were the subject of the Independent Review, certain other adjustments identified by management, including revisions to inventory reserves and royalties, were made to the consolidated financial statements in connection with the restatement.

As set forth in more detail below, the restatement of the Company s consolidated financial statements included in this Form 10-K decreased net sales by $14.7 million and $28.2 million in 2012 and 2011, respectively; decreased net

income from continuing operations by $8.9 million and $14.5 million in 2012 and 2011, respectively.

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General

We are a diversified, global medical device company focused on developing and delivering innovative repair and regenerative solutions to the spine and orthopedic markets. Our products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them achieve a more active and mobile lifestyle. We design, develop, manufacture, market and distribute medical equipment used principally by musculoskeletal medical specialists for orthopedic applications. Our main products are invasive and minimally invasive spinal implant products and related human cellular and tissue based products (HCT/P products), non-invasive regenerative stimulation products used to enhance bone growth and the success rate of spinal fusions and to treat non-union fractures, external and internal fixation devices used in fracture repair, limb lengthening and bone reconstruction. Our products also include bone cement and devices for removal of bone cement used to fix artificial implants.

Our 2013 results and financial condition include the following items of significance:

- BioStim revenues decreased $34.0 million to $147.9 million, or 18.7%, when compared to 2012, which includes Spine Regenerative Stimulation that decreased $28.8 million, or 19%, in 2013, when compared to 2012 as well as Regenerative Stimulation in Orthopedics which decreased $5.2 million or 23% in 2013, when compared to 2012.

- A decrease in gross profit margin from 78.0% in 2012 to 74.5% in 2013 was primarily the result of increased costs primarily associated with inventory reserves and salaries.

- An increase in operating expenses as a percentage of net sales compared to prior period is primarily a result of significant costs incurred for legal and other professional services in connection with the Audit Committee s investigation which led to the restatement of our 2012 and 2011 consolidated financial statements, as well as an impairment of goodwill of $19.2 million in 2012.

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

Our consolidated financial statements include the financial results of our Company and our wholly owned and majority-owned subsidiaries and entities over which we have control. All intercompany accounts and transactions are eliminated in consolidation.

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 rates of exchange prevailing during the year. Gains and losses resulting from foreign currency transactions 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 not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. 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 have used derivative instruments to hedge foreign currency fluctuation exposures. See Item 7A Quantitative and Qualitative Disclosures About Market Risk.

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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 GAAP. The preparation of these statements necessarily 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, including those related to contractual allowances, doubtful accounts, inventories, potential intangible assets and goodwill impairment, income taxes, and share-based compensation. We base our estimates on historical experience and various other assumptions. Actual results may differ from these estimates. We have reviewed our critical accounting policies with the Audit Committee of the Board of Directors.

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 or implanted in and accepted by the patient. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

For distributor revenue which is primarily related to implant products, we recognize revenue either on a sell-in or sell-through basis depending on the specific circumstances of the distributor. In some cases we recognize 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 has been achieved (the sell-in method). Based on the results of the Independent Review, we determined 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. Effective April 1, 2013, all distributor revenue is recognized on the sell-through basis.

For distributors on the sell-in method prior to April 1, 2013, cost of sales are 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.

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Biologics revenue is primarily related to a collaborative arrangement with the MTF. We have exclusive global marketing rights and receives 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.

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.

Inventory Allowances

We write down our inventory for inventory excess and obsolescence by an amount equal to the difference between the cost of the inventory and the estimated net realizable value based upon the current stage of the product s life cycle and assumptions about future demand and market conditions. Inventory is analyzed to assess the adequacy of inventory excess and obsolescence provisions. Reserves for excess and obsolescence provisions are recorded as adjustments to cost of sales. As set forth in Accounting Standards Codification (ASC) Topic 330, *Inventory* (specifically ASC 330-10-35-14), 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. 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 ASC Topic 360 *Property, Plant and Equipment*, intangible assets with definite 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.

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 and certain indefinite lived trademarks at least annually for impairment. We test more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. We assess goodwill for impairment at the reporting unit level, which is

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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. Effective July 1, 2013, we re-aligned the Company s segments and consequently reallocated the carrying value of goodwill from its previous reporting units to its new reporting units based on the relative fair value of each new reporting unit to total enterprise value at July 1, 2013.

As a result of our change in reportable segments, we allocated goodwill to each reportable segment, and subsequently evaluated the Extremity Fixation and Spine Fixation reportable 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, our Spine Fixation and reportable units, totaling $19.2 million. There continue to be no indicators of impairment in our remaining reporting units which were reevaluated at year end using a qualitative assessment.

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.

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 ASC Topic 740 *Income Taxes* 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

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interpretations of tax law, effectively settled issues under audit and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision.

We 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.

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,		
	2013 (%)	2012 (%)	2011 (%)
Net sales	100	100	100
Cost of sales	25	22	22
Gross profit	75	78	78
Operating expenses			
Sales and marketing	44	42	44
General and administrative	16	12	14
Research and development	7	6	5
Amortization of intangible assets	1	1	1
Costs related to the accounting review and restatement	3		
Impairment of goodwill	5		
Charges related to U.S. Government resolutions			13
Total operating (loss) income	(1)	17	1
Net (loss) income from continuing operations	(4)	10	(3)
Net loss from discontinued operations	(2)	(1)	(1)
Net (loss) income	(6)	9	(4)

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 strategic business units (SBUs), which are comprised of BioStim, Biologics, Extremity Fixation and Spine Fixation supported by Corporate activities. These SBUs represent the segments for which our Chief Operating Decision Maker (the CODM) reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information has been prepared based on our four SBUs reporting segments. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. These four segments are discussed below.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for a portfolio of market leading devices for enhancing bone fusion that utilize Orthofix s patented pulsed electromagnetic (PEMF) technology. These Food and Drug Administration-approved Class 3 medical devices are indicated as an adjunctive treatment to enhance fusion success in cervical and lumbar spine fusion as well as a therapeutic treatment for non-healing fractures outside of the spine (non-unions). The PEMF technology is supported by a strong clinical background on mechanism of action in the scientific literature and current research and clinical studies are underway to identify potential new clinical indications.

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Biologics

The Biologics SBU provides a portfolio of regenerative products 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 distributes its tissues through a network of distributors, sales representatives and affiliates to market to hospitals, doctors, and other healthcare providers, primarily in the U.S. Our partnership with 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 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. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This SBU uses both distributors and direct sales representatives to sell orthopedics 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 and affiliates. This SBU uses distributors and direct sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Corporate

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

External Net Sales by SBU:

The table below presents external net sales for continuing operations by SBU reporting segment:

(U.S. Dollars in thousands)	External Net Sales by SBU Year ended December 31, 2013		2012 (Restated)		2011 (Restated)	
	Net Sales	Percent of Total Net Sales	Net Sales (Restated)	Percent of Total Net Sales (Restated)	Net Sales (Restated)	Percent of Total Net Sales (Restated)
BioStim	$ 147,910	37%	$ 181,959	41%	$ 188,136	43%
Biologics	53,769	13%	53,730	12%	42,919	10%
Extremity Fixation	103,385	26%	112,009	25%	119,521	27%
Spine Fixation	95,470	24%	99,883	22%	91,395	20%

Total Net Sales	$ 400,534	100%	$ 447,581	100%	$ 441,971	100%

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2013 Compared to 2012

Net sales decreased 10.5% to $400.5 million in 2013 compared to $447.6 million in 2012. The impact of foreign currency decreased sales by $0.5 million in 2013 when compared to 2012. Net sales include product sales and marketing service fees which is comprised of sales of Trinity Evolution® and Trinity Elite .

Sales

Net sales in our BioStim SBU decreased 18.7% to $147.9 million in 2013 compared to $182.0 million in 2012. The decrease in BioStim revenue was primarily attributable to a decline in sales of our stimulation products for spine and cervical application caused by distribution turnover and changes in certain payor policies. The decrease for the year ended December 31, 2013 was also negatively impacted by a reduction in third-party payor revenue driven by our transition in third quarter of 2013 to recognize revenue upon accumulation of the full billable package for third-party payors given the increased complexity in insurance billing requirements.

Net sales in our Biologics SBU increased slightly to $53.8 million in 2013 compared to $53.7 million in 2012. Net sales were positively impacted by an increase in our marketing service fee revenue from MTF related to the launch of our new tissue from Trinity Elite ; however, this increase was primarily offset by a reduction in our marketing service fee from 70% to 65% which became effective April 1, 2013.

Net sales in our Extremity Fixation SBU decreased 7.7% to $103.4 million in 2013 compared to $112.0 million for 2012, a decrease of $8.6 million. This decrease is due primarily to two factors. The first was deterioration of sales in Brazil, which accounted for 2.7% of our total decline and the second was a prospective change from a sell-in to cash accounting methodology beginning April 1, 2013 to all non-Brazil distributors, which accounted for 4.8% of the decline in sales. Historically, for most distributor transactions within our Extremity Fixation SBU, we recorded revenue on the sell-in accounting basis. However, as described more fully in Note 2 to the Consolidated Financial Statements, we have reassessed our application of distributor revenue recognition and have applied sell-through accounting for all distributor transactions within the Extremity Fixation SBU on a prospective basis beginning on April 1, 2013 which caused the majority of the decrease in net sales.

Net sales in our Spine Fixation SBU decreased to $95.5 million in 2013 compared to $99.9 million for 2012, a decrease of 4.4%. This decrease was due to a 6% drop in average selling price (ASP) due to discounting, which was somewhat offset by double-digit growth in our international business.

Gross Profit Our gross profit decreased 14.6% to $298.2 million for 2013 compared to $349.3 million for 2012. Gross profit as a percent of net sales in 2013 was 74.5% compared to 78.0% in 2012. This decrease was primarily due to the decrease of sales in our BioStim SBU which carries a higher gross margin compared to our other products as well as increased costs that do not have a strong correlation to net sales, primarily associated with inventory reserves and salaries.

Sales and Marketing Expense Sales and marketing expense, which includes commissions and the bad debt provision, generally increases and decreases in relation to sales. Sales and marketing expense decreased $10.5 million, or 5.6%, to $176.6 million in 2013 compared to $187.1 million in 2012. As a percent of net sales, sales and marketing expense was 44.1% and 41.8% for 2013 and 2012, respectively. In 2013 the decrease in sales and marketing expense was primarily due to a decrease in commission expenses due to lower sales and a decrease in bad debt expense compared to 2012.

General and Administrative Expense General and administrative expense increased $11.7 million, or 21.9%, in 2013 to $65.1 million compared to $53.4 million in 2012. General and administrative expense as a percent of sales was 16.3% in 2013 compared to 11.9% in 2012. The 2013 increase in general and administrative expense was primarily attributable to investments in people and processes to improve business structure and

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internal controls. These investments were primarily related to the departments of accounting and finance and information systems. The 2013 increase was also related to increased incentive compensation expense and medical device tax in 2013. General and administrative expense in 2012 included the impact of approximately $1.9 million in legal expenses associated with the bone growth stimulation investigation, and other costs incurred in connection with our internal investigation into the compliance with the Foreign Corrupt Practices Act with our former orthopedic distribution entity in Mexico.

Research and Development Expense Research and development expense decreased $1.8 million in 2013 to $26.8 million compared to $28.6 million in 2012. As a percent of net sales, research and development expense remained relatively flat at 6.7% in 2013 compared to 6.4% for the same period last year.

Amortization of Intangible Assets Amortization of intangible assets was $2.7 and $2.3 million for 2013 and 2012, respectively.

Costs related to the accounting review and restatement As previously discussed, our Audit Committee conducted an Independent Review, with the assistance of outside professionals, of certain accounting matters. As a result of this review and the restatement of certain of our previously filed consolidated financial statements, the Company incurred legal, accounting and other professional fees of approximately $12.9 million through the year ended December 31, 2013.

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.

Charges Related to U.S. Government Resolutions During 2012, we recorded a charge of $1.3 million representing imputed interest accrued from the respective settlement in principle dates in 2011 and 2012 through the payment dates in the fourth quarter of 2012 on the previously disclosed settlements in principle of the U.S. government investigations and related qui tam complaints related to our regenerative stimulation business and Blackstone Medical, Inc., respectively.

Interest Expense, net Interest expense, net decreased to $1.9 million in 2013 compared to $4.7 million in 2012, primarily as the result of substantial repayments of long-term debt during 2012, resulting in a lower year over year outstanding debt balance, and to a lesser extent, lower interest rates.

Other Income (Expense) Other income, net was $2.2 million in 2013 compared to other expense of $(1.7) million in 2012. The increase in other income can be mainly attributed to a gain recorded related to our receipt of $4.4 million cash related to the demutualization of a mutual insurance company in which we were an eligible member to share in such proceeds. This increase was partially offset by the positive effect of foreign exchange during 2013. 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 Tax Expense We recognized a $10.1 million and $25.1 million provision for income tax for 2013 and 2012, respectively. The income tax expense and effective tax rate for the year ended 2013 reflects a disproportionate ratio to the $25.1 million of income tax expense and effective tax rate of 35.8% for the year ended 2012. The principal factors affecting the Company s effective tax rate was the company s mix of earnings amongst various tax jurisdictions, state taxes, and the impairment of $19.2 million in non-deductable goodwill. For the year ended 2012, the Company did not record tax benefit on certain expenses associated with the Company s estimate of the charges related to U.S.

Government resolutions.

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Discontinued operations Discontinued operations in 2013 included approximately $10.6 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to its former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. Discontinued operations in 2012 included the gain on the sale of Breg of $1.3 million and the results of our Sports Medicine SBU through May 24, 2012 (the closing date of the sale of Breg), net of income taxes. Subsequent to December 31, 2012, the Company won an arbitration award against an insurance carrier relating to its denial of coverage under excess products liability policies with total limits of $30 million. As a result of the binding arbitration award, the carrier is obligated to reimburse the Company for defense expenses, settlements, and judgments associated with the underlying products liability claims at issue. The Company was entitled to reimbursement of approximately $13 million for past losses incurred, which is included in discontinued operations in 2012.

Net Income (Loss) Net loss in 2013 was $(25.5) million, or $(1.37) per basic share and diluted share, compared to net income of $42.8 million, or $2.25 per basic and $2.21 per diluted share for 2012. The weighted average number of basic common shares outstanding was 18,697,228 and 18,977,263 during the years ended December 31, 2013 and 2012, respectively. The weighted average number of diluted common shares outstanding was 18,697,228 and 19,390,413 during the years ended December 31, 2013 and 2012, respectively.

2012 Compared to 2011

Net sales increased 1.3% to $447.6 million in 2012 compared to $442.0 million in 2011. The impact of foreign currency decreased sales by $9.4 million in 2012 when compared to 2011. Net sales include product sales and marketing service fees which are comprised of sales of Trinity Evolution® in spine and orthopedic applications.

Sales

Net sales in our BioStim SBU decreased 3.3% to $182.0 million in 2012 compared to $188.1 million in 2011. The decrease is primarily due to a 17.0% decrease in Physio-Stim Regenerative Stimulation from 2011 to 2012.

Net sales in our Biologics SBU increased to $53.7 million in 2012 compared to $42.9 million in 2011, an increase of 25.2%. Net sales were positively impacted by an increase in our marketing service fee revenue from MTF due to the adoption of Trinity Evolution® in spine and orthopedic applications.

Net sales in our Extremity Fixation SBU decreased 6.3% to $112.0 million in 2012 compared to $119.5 million for 2011, a decrease of $7.5 million. The decrease was due to a decrease in revenue from our Orthopedic Repair and Hardware products when compared to 2011.

Net sales in our Spine Fixation SBU increased to $99.9 million in 2012 compared to $91.4 million for 2011, an increase of 9.3%. The increase was primarily the result of increased sales of Spine Fixation System and KON spine implants in international markets in 2012 compared to 2011.

Gross Profit Our gross profit increased less than 1% to $349.3 million for 2012 compared to $346.4 million for 2011. Gross profit as a percent of net sales remained flat at 78% in both 2012 and 2011.

Sales and Marketing Expense Sales and marketing expense, which includes commissions and the bad debt provision, generally increases and decreases in relation to sales. Sales and marketing expense decreased $6.4 million, or 3.3%, to $187.1 million in 2012 compared to $193.5 million in 2011. As a percent of sales, sales and marketing expense was 41.8% and 43.8% for 2012 and 2011, respectively. The decrease in sales and marketing expense as percent of sales was the result of decreased incentive compensation expense for sales administration and marketing personnel in 2012.

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General and Administrative Expense General and administrative expense decreased $11.1 million, or 17.2%, in 2012 to $53.4 million compared to $64.5 million in 2011. General and administrative expense as a percent of sales was 11.9% in 2012 compared to 14.6% in 2011. General and administrative expense in 2012 and 2011 included the impact of approximately $1.9 million and $8.1 million, respectively, in legal expenses associated with the bone growth stimulation investigation, as well as costs incurred in connection with our internal investigation into the compliance with the Foreign Corrupt Practices Act with our former orthopedic distribution entity in Mexico. General and administrative expense in 2011 also included $3.2 million of senior management succession charges. The 2012 decrease is also attributable to decreased incentive compensation expense during the year.

Research and Development Expense Research and development expense increased $5.7 million in 2012 to $28.6 million compared to $22.9 million in 2011. As a percent of sales, research and development expense was 6.4% in 2012 compared to 5.2% for the same period last year. The increase in research and development expenses in 2012 compared to 2011 was due to a $3.1 million charge for an arbitration resolution related to a 2008 co-development agreement, a $3.0 million strategic investment with MTF on the development and commercialization of the next generation cell-based bone growth technology and timing of spending related to our ongoing research, development and clinical activities.

Amortization of Intangible Assets Amortization of intangible assets was $2.3 and $2.6 million for the year ended December 31, 2012 and 2011, respectively.

Charges Related to U.S. Government Resolutions For the year ended December 31, 2012 and 2011, we recorded charges related to U.S. Government resolutions of $1.3 million and $57.1 million, respectively. During 2012 and 2011, we recorded a charge of $1.3 million and $0.6 million, respectively, which represents imputed interest accrued from the respective settlement in principle dates in 2011 and 2012 through the payment dates in the fourth quarter of 2012 on the previously disclosed settlements in principle of the U.S. government investigations and related qui tam complaints related to our regenerative stimulation business and Blackstone Medical, Inc., respectively. During 2011, we reached an agreement in principle with the U.S. Government to resolve criminal and civil matters related to the previously disclosed government investigations of our regenerative stimulation business and recorded a charge of $43 million for the estimated settlement. During 2011, we recorded a charge of $7.5 million to establish an accrual in connection with the fines and penalties related to the FCPA matter involving our former distribution entity. In February 2012, we reached an agreement with the representative of the former shareholders of Blackstone resolving all outstanding escrow and indemnification claims under the Blackstone Merger Agreement. In 2011, we recorded a charge of approximately $6 million for previously incurred legal fees that were in excess of the amounts released and received from the escrow fund.

Interest Expense, net Interest expense, net was $4.7 million in 2012 compared to $5.5 million in 2011, primarily as the result of a lower year over year outstanding debt balance and to a lesser extent, lower interest rates.

Other Expense, net Other expense, net was $1.7 million in 2012 compared to $2.4 million in 2011. The decrease can be mainly attributed to the effect of foreign exchange. 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 Tax Benefit (Expense) We recognized a $25.1 million and $14.2 million provision for income tax for 2012 and 2011, respectively. During 2012, we recognized a change in the estimate of the tax deduction associated with the settlement of the U.S. Government investigation of the Company s bone growth stimulation business. The income tax expense and effective tax rate for the year ended 2011 reflects a disproportionate ratio to 2012, as we did not record tax benefit on certain expenses associated with our estimate of the charges related to U.S. Government resolutions in

2011. The effective tax rate was approximately 42.0% in 2012 and (149.1)% in 2011 excluding the impact of the charges related to the U.S. Government resolutions and the foreign rate differential.

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Discontinued operations Discontinued operations in 2012 include approximately $3.5 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to our former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. 2012 also includes the gain on the sale of Breg of $1.3 million and the results of our Sports Medicine SBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. Subsequent to year end, the Company won an arbitration award against an insurance carrier relating to its denial of coverage under excess products liability policies with total limits of $30 million. As a result of the binding arbitration award, the carrier is obligated to reimburse the Company for defense expenses, settlements, and judgments associated with the underlying products liability claims at issue. The Company estimates that it is entitled to reimbursement of approximately $13 million for past losses incurred, which is included in discontinued operations in 2012. Discontinued operations in 2011 include the results of our Sports Medicine SBU.

Net Income (Loss) Net income in 2012 was $42.8 million, or $2.25 per basic share and $2.21 per diluted share, compared to net loss of $(18.1) million, or $(0.99) per basic and diluted share for 2011. The weighted average number of basic common shares outstanding was 18,977,263 and 18,219,343 during the years ended December 31, 2012 and 2011, respectively. The weighted average number of diluted common shares outstanding was 19,390,413 and 18,219,343 during the years ended December 31, 2012 and 2011, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at December 31, 2013 were $54.2 million, of which $23.8 million is subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $52.4 million at December 31, 2012, of which $21.3 million was subject to certain restrictions under the senior secured credit agreement described below.

Net cash provided by operating activities was $66.9 million in 2013 compared to $10.2 million in 2012, an increase of $56.7 million. Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, provision for doubtful accounts, share-based compensation, impairment of goodwill, deferred taxes, and the net gain on sale of Breg, Inc.) and changes in working capital. Net income decreased $68.3 million to a net loss of $25.5 million in 2013 compared to net income of $42.8 million in 2012. Non-cash items for 2013 increased $15.4 million to $58.0 million compared to $42.6 million in 2012. The change in working capital accounts is mainly attributable to charges related to goodwill impairment. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect day s sales in receivables of 65 days at December 31, 2013 compared to 84 days at December 31, 2012 and inventory turns of 1.1 times at December 31, 2013, and 1.2 times as of December 31, 2012.

Net cash used in investing activities was $29.7 million in 2013 compared cash provided of $125.0 million in 2012 primarily driven by the net proceeds on the sale of Breg, Inc. in 2012. During 2013 and 2012, we invested $29.7 million and $28.8 million in capital expenditures, respectively.

Net cash used in financing activities was $38.4 million for 2013 compared to $137.6 million for 2012. During 2012, we repaid approximately $188.7 million against the principal on our senior secured debt compared to $0.1 million in 2013. Our restricted cash balance decreased to $23.8 million due to a use of $2.4 million compared to cash provided of $25.8 million in 2012. During the year ended December 31, 2013, we received proceeds of $3.5 million compared to $25.6 million during 2012, from the issuance of shares of our common stock related to stock purchase plan issuances and stock option exercises. In 2013, we used $39.5 million in connection with the stock repurchase program.

On August 30, 2010, the Company s wholly owned U.S. holding company, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the Credit Agreement) with certain domestic direct and indirect

subsidiaries of the Company (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto. The Credit Agreement

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provides for a five year, $200.0 million secured revolving credit facility (the Revolving Credit Facility), and a five year, $100.0 million secured term loan facility (the Term Loan Facility , and together with the Revolving Credit Facility, the Credit Facilities). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to $50.0 million upon satisfaction of certain conditions.

In May 2012, the Company used a portion of the proceeds from the sale of Breg, Inc. (see Note 16) to repay in full the remaining $87.5 million balance on the Term Loan Facility and pay down $57.5 million of amounts outstanding under the Revolving Credit Facility. This use of proceeds was required by the lenders consent dated April 23, 2012 to the Credit Agreement. As a result of the sale of Breg, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. Additionally, the Company paid $20 million in June and $20 million in September 2012 to reduce amounts outstanding under the Revolving Credit Facility. As a result, at December 31, 2012, the Term Loan Facility had been repaid in full and there was $20 million outstanding under the Revolving Credit Facility. As of December 31, 2012, the entire Revolving Credit Facility was at the London Inter-Bank Offered Rate (LIBOR) plus a margin of 2.50%. As of December 31, 2011, the entire Term Loan Facility and $100 million of the Revolving Credit Facility was at the LIBOR rate plus a margin of 3.00%. The effective interest rate on the Credit Facilities as of December 31, 2012 was 2.7%.

Outstanding principal on the Revolving Credit Facility is due on August 30, 2015.

The Credit Agreement, as amended, requires Orthofix Holdings and the Company to comply with coverage ratios on a consolidated basis and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions.

The Credit Agreement, as amended, also includes events of default customary for facilities of this type. Upon the occurrence of an event of default, all outstanding loans may be accelerated and/or the lenders commitments terminated. The Company was in compliance with the affirmative and negative covenants at December 31, 2013 and there were no events of default.

On August 14, 2013, we and certain required lender parties to the Credit Agreement entered into a Limited Waiver (the Limited Waiver). Under the Limited Waiver, the lenders under the Credit Agreement (the Lenders) collectively waived requirements under the Credit Agreement that we deliver quarterly financial statements with respect to the fiscal quarters ending on June 30, 2013 and September 30, 2013, and related financial covenant certificates, until the earlier of (i) March 31, 2014 or (ii) the date that is one day after such financial statements are publicly filed or released. In addition, the Limited Waiver provided that the restatement of our financial statements for any period ending on or before March 31, 2013 will not constitute a default or event of default provided that within one business day after the public release or filing of such restated financial statements, we deliver corrected financial statements and compliance certificates with respect to such restated periods and immediately pay any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated financial statements.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company s Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes.

Borrowings under the Revolving Credit Facility, which may be made in the future, will be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the Credit Agreement. The obligations of Orthofix

Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

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At December 31, 2013, we had no outstanding borrowings and unused available lines of credit of approximately 5.8 million ($8.0 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We have incurred substantial expenses for legal and other professional services in connection with the Audit Committee s investigation. We estimate these expenses to date to be in excess of $15 million through February 28, 2014 and expect to continue to incur significant expenses in connection with this matter.

Contractual Obligations

The following chart sets forth our contractual obligations as of December 31, 2013:

		Payments Due by Period			
Contractual Obligations					
(U.S. Dollars in thousands)	**Total**	**2014**	**2015-2017**	**2018**	**2019 and thereafter**
Revolving Credit Facility	$ 20,000	$	$ 20,000	$	$
Estimated interest on Credit Facility (1)	903	542	361		
Operating leases	21,031	4,342	10,794	2,846	3,049
Total	$ 41,934	$ 4,884	$ 31,155	$ 2,846	$ 3,049

(1) Estimated interest on credit facility assumes payments are made in accordance with the scheduled payments as defined in the agreement. Interest payments are estimated using rates in effect at December 31, 2013.

We may be required to make cash outlays related to our unrecognized tax benefits. 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 $1.2 million as of December 31, 2013 have been excluded from the contractual obligations table above. For further information on unrecognized tax benefits, see Note 14 to the consolidated financial statements included in this Form 10-K.

Off-balance Sheet Arrangements

As of December 31, 2013, 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, 2013, we had a currency swap in place to minimize foreign currency exchange risk related to a 28.7 million ($39.4 million translated at the December 31, 2013 foreign exchange rate) intercompany note. As of December 31, 2013 the fair value of the currency swap was approximately $1.0 million and is recorded in other long-term liabilities.

We are exposed to interest rate risk in connection with our Term Loan Facility and Revolving Credit Facility, which bear interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base

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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 of December 31, 2013, $20 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 2.50%. This margin is adjusted based upon the measurement of the consolidated leverage ratio of the Company and its subsidiaries with respect to the immediately preceding four fiscal quarters. As of December 31, 2013, our effective interest rate on our Credit Facilities was 2.7%. Based on the balance outstanding under the Credit Facilities as of December 31, 2013, an immediate change of one percentage point in the applicable interest rate on the Revolving Credit Facility would cause a change in interest expense of approximately $0.2 million annually.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. We are subject to cost of sales currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when our foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. As of December 31, 2013, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million ($31.9 million). We recorded a foreign currency loss during the year ended December 31, 2013 of $0.3 million related to this un-hedged long-term intercompany balance included in accumulated other comprehensive income during 2013, which resulted from the weakening of the Euro against the U.S. dollar during the period. For the year ended December 31, 2013, we recorded a foreign currency loss of $0.7 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 year ended December 31, 2013 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations during 2013 versus the same periods in 2012. The U.S. dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the year ended December 31, 2012 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against the local foreign currency versus the same periods in 2011. 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.

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.

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Item 9A. Controls and Procedures

Background of Restatement

In July 2013, members of the Company s senior management brought certain information to the attention of the chair of the Audit Committee (Audit Committee) of the Company s Board of Directors (the Board) that raised questions regarding whether the Company had properly recognized revenue under GAAP in connection with revenue from distributor sales that had been recorded in 2012 and 2011, including a significant return processed in the second quarter of 2013 relating to revenue recognized in 2012. On the recommendation of management and after discussion with the Company s independent registered public accounting firm, Ernst & Young LLP (Ernst & Young), the Audit Committee concluded, with the concurrence of the Board, that it would commence an independent review into these matters with the assistance of outside professionals engaged by the Audit Committee (the Independent Review).

On August 5, 2013, the Audit Committee concluded that certain revenues recognized during 2012 and 2011, upon further evaluation, should not have been recognized or should not have been recognized during the periods in which they were recognized. As a result of the foregoing, on August 5, 2013, the Audit Committee concluded that the Company s previously issued consolidated financial statements as of and for the fiscal years ended December 31, 2012 and December 31, 2011, as well as for the interim quarterly period ended March 31, 2013, should no longer be relied upon (the Non-Reliance Period). On August 6, 2013, the Board ratified the foregoing conclusion by the Audit Committee.

The Independent Review focused on the periods between January 1, 2010 and March 31, 2013 and included (i) over 50 witness interviews, (ii) collection of emails and files from 70 document custodians, and (iii) quantitative analysis. The scope of the Independent Review, which was determined by the Audit Committee in consultation with outside professionals engaged by the Audit Committee, focused primarily on revenue recognition related to distributor arrangements and inventory reserve adjustments. In conjunction with the Independent Review, management concluded that errors existed in the Company s previously issued financial statements with respect to the Non-Reliance Period, as well as in the Company s previously issued consolidated financial statements for the fiscal years ended December 31, 2010, 2009, 2008 and 2007.

In reaching these conclusions, the Company considered information obtained in the Independent Review, including emails, data and interviews with current and former employees that indicated (i) the existence of extra-contractual terms or arrangements at the onset of the sale and concessions agreed to subsequent to the initial sale (such as extended payment terms and return and exchange rights for sales to distributors with respect to certain transactions), including some with which certain senior-level personnel were involved, (ii) that at the time of some sales collection was not reasonably assured, and (iii) that certain amounts previously characterized as commissions were paid to related parties of the applicable customer.

The Company assessed the information derived from the Independent Review in making determinations with respect to accounting adjustments reflected in the restated consolidated financial statements contained in the Amendments and in this Form 10-K, and such determinations are consistent with the findings of the Independent Review. In addition to the matters that were the subject of the Independent Review, certain other adjustments identified by management, including revisions to inventory reserves and royalties, were made to the consolidated financial statements in connection with the restatement.

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 the effectiveness of the design and operation of our disclosure controls and procedures. As described below, management has identified material weaknesses in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. As a result of those material

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weaknesses, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2013.

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 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 generally accepted accounting principles. 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, 2013 based on the framework set forth in Internal Control Integrated Framework (September 1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company s management concluded that, because of the material weaknesses described below, the Company s internal control over financial reporting was not effective as of December 31, 2013.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with our management s evaluation of our internal control over financial reporting described above, our management has identified the following deficiencies that it believes constituted individually, and in the aggregate, material weaknesses in our internal control over financial reporting as of December 31, 2013:

Revenue recognition practices for sales to the Company s distributors. We have concluded that we recognized revenue in certain instances in advance of all revenue recognition criteria being met, and that our controls were not effective to reasonably ensure accurate recognition of revenue in accordance with GAAP for certain distributor sales transactions previously recorded by the Company s domestic and international business units. In general, we did not establish and maintain procedures throughout the Company to reasonably ensure proper communication to, and assessment by, the Company s finance and accounting department of deviations from contractually established terms, which included written or unwritten

arrangements made with, or extra-contractual terms provided to, Company distributors at the onset of the sale regarding extended payment terms, product return or exchange rights, and similar concessions agreed to subsequent to the initial sale (which were not memorialized by any formal contractual amendment). Such additional terms were not evaluated, or not evaluated correctly, and were not maintained or reflected in Company customer sales files. In addition, Company

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personnel were not adequately trained with respect to certain revenue recognition principles applicable under GAAP that may have led to appropriate consideration of the additional terms entered into outside of the written contractual terms.

Inventory reserves. Errors occurred in establishing the Company s inventory reserves due to a design deficiency in our controls over the computation and recording of such reserves. Our method of calculating inventory reserves resulted in the misapplication of GAAP, which caused us to make adjustments in the restated consolidated financial statements. Specifically, our controls were not designed to detect that increases in our forecasted demand for products resulted in reductions in subsequent fiscal years to reserves previously recorded. ASC Topic 330 Inventory (specifically ASC 330-10-35-14) states that 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, and our controls were not designed to prevent such mark ups due to increases in forecasted demand for products.

Foreign subsidiary oversight. Oversight of certain foreign subsidiaries was insufficiently designed to detect material misstatement of financial information. Specifically, while these entities were included in oversight activities similar to our other locations, we believe the design of our controls did not adequately address the additional risks associated with certain entities. These additional risks include: sales comprised of higher risk distributor revenues; no specific requirements for statutory audits that may detect inadequacies in the Company s customer and business records; and a business culture where oral agreements were more common, resulting in contract terms that were less likely to be formally documented.

Manual journal entry control procedures. In connection with the completion of the audit for the fiscal year ended December 31, 2013, we determined that our controls over manual journal entries were not effective. Specifically, we determined that some manual journal entries were not supported with sufficient documentation, and that some manual journal entries were not adequately reviewed and approved.

Some of the material weaknesses described above resulted in material misstatements in our annual and interim consolidated financial statements. Because of the foregoing matters, our management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2013.

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

Plans for Remediation

Our management has worked, and continues to work, to strengthen our disclosure controls and procedures and internal control over financial reporting in connection with the material weaknesses that have been described above. We intend to continue taking measures, including engaging outside professionals, as may be necessary and advisable, to assist us as we continue to address and rectify the foregoing material weaknesses.

We are committed to maintaining an effective control environment and making changes necessary to enhance effectiveness. This commitment has been, and will continue to be, communicated to and reinforced throughout our organization. As part of this commitment, we are implementing an internal audit program that will take into account the nature of our business and the geographies in which we conduct it. We are also updating our code of conduct, and all our employees will be required to annually acknowledge their commitment to adhering to its provisions. We also

will inform all new employees and regularly remind all existing employees of the availability of our compliance hotline, through which employees at all levels can anonymously submit information or express concerns regarding accounting, financial reporting and other irregularities they may have become aware of or observed.

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We are in the process of developing a plan for remediation of the ineffective internal control over financial reporting described above. In addition, we have designed and plan to implement, and in some cases have already implemented, the specific remediation initiatives described below:

Management s remediation plan with respect to controls over revenue recognition practices relating to the Company s distributors:

- We have enhanced our revenue recognition training materials for all sales personnel;
- We are in the process of training sales management personnel (including senior-level management) pursuant to our updated revenue recognition training materials;
- We have created and implemented an improved sales certification process to identify any sales with deviations from written sales contracts;
- We have established and hired a new Senior Manager of Revenue position in our finance department, which we believe will bring additional revenue recognition expertise to address our more complex revenue transactions to help ensure that our revenue recognition policies are correctly applied; and
- We are working to improve procedures with respect to the proper communication, approval, documentation and accounting review of deviations from written sales contracts.

Management s remediation plan with respect to controls over the computation and recording of the Company s inventory reserves:

- We have enhanced controls over our model for determining inventory reserves to ensure that, once reserves are established in a fiscal year, subsequent write-ups based on demand are not recognized; and
- We are implementing additional review of our inventory reserve analysis, including the involvement of both finance and operational executives, and more analysis of days inventory on hand at the product line level, which we expect to provide better controls to assess excess and obsolete inventory based on the current inventory on hand in relation to the demand forecast and related reserve.

Management s remediation plan with respect to controls over foreign subsidiary oversight:

- We have changed our structure so that all of our subsidiaries accounting functions now report to the VP, Controller within the corporate accounting function, which we believe will provide additional corporate-level oversight of their activities;

We have established and hired a Director of Controls and Process Improvement, whose primary duties are the design and implementation of internal control over financial reporting;

We have engaged a professional firm to perform testing and evaluation of the Company s internal controls, and to assist the Company in designing and implementing additional financial reporting controls and financial reporting control enhancements; and

We are evaluating our accounting systems to determine appropriate enhancements.

Management s remediation plan with respect to controls over manual journal entries:

We intend to implement a new accounting policy setting forth specific requirements regarding supporting documentation standards and review and approval procedures for manual journal entries, including specifying the types and levels of review to be performed based on specifically defined criteria associated with the nature and magnitude of manual journal entries; and

We intend to design and conduct training for the accounting group regarding manual journal entry preparation, documentation and review and approval procedures.

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We believe the remediation steps outlined above, which in some cases have already been implemented, have improved and will continue to improve the effectiveness of our internal control over financial reporting. However, we have not completed all of the corrective processes and procedures identified above. Accordingly, as we continue to monitor the effectiveness of our internal control over financial reporting in the areas affected by the material weaknesses described above, we will perform additional procedures prescribed by management, including the use of manual mitigating control procedures, and will employ any additional tools and resources deemed necessary to provide assurance that our financial statements continue to be fairly stated in all material respects. As our management continues to evaluate and work to improve our disclosure controls and procedures and internal control over financial reporting, we may determine to take additional measures to address these deficiencies or determine to modify certain of the remediation measures described above.

Changes in Internal Control over Financial Reporting

Other than as described above (including the material weakness related to controls over manual journal entries that we determined exists in connection with the completion of the audit for the fiscal year ended December 31, 2013), there have not been any changes in our internal control over financial reporting during the fourth quarter of 2013 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

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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, 2013, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management s assessment. Management has identified material weaknesses in controls related to the prevention of revenue recognition in advance of all revenue recognition criteria being met for certain distributor sales transactions entered into by the Company s domestic and international business units, controls over the computation and recording of inventory reserves, controls relating to the oversight of certain foreign subsidiaries due to the particular risks associated with such subsidiaries, and controls over the preparation and review of manual journal entries.

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, 2013 and 2012, and the related consolidated statements of operations and comprehensive income (loss), changes in shareholders equity, and cash flows for each of the three years in the period ended December 31, 2013. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audits of these consolidated financial statements, and this report does not affect our report dated March 31, 2014, which expressed an unqualified opinion on those financial statements.

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In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Orthofix International N.V. has not maintained effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

/s/ Ernst & Young LLP

Dallas, Texas

March 31, 2014

Item 9B. Other Information

Not applicable.

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PART III

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

Item 10. Directors, Executive Officers and Corporate Governance

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

Item 11. Executive Compensation

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

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

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

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

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

Item 14. Principal Accountant Fees and Services

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

possibly elsewhere therein. That information is incorporated in this Item 14 by reference.

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PART IV

Item 15. Exhibits and 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

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

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 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 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).

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Exhibit Number	Description
10.5	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.6	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company s annual report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference).
10.7	Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company s current report on Form 8-K filed July 8, 2013 and incorporated herein by reference).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).
10.8	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).
10.9	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)
10.10	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference).
10.11	Orthofix International N.V. Staff Share Option Plan, as amended through April 22, 2003 (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated herein by reference).
10.12	Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company s current report on Form 8-K filed January 7, 2009, and incorporated herein by reference).
10.13	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.14	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).
10.15	Form of Employee Restricted Stock Grant 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).
10.16	Form of Non-Employee Director Restricted Stock Grant 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).

10.17 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).

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Exhibit Number	Description
10.18	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).
10.19	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).
10.20	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).
10.21	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).
10.22	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).
10.23	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).
10.24	Inducement Grant Nonqualified Stock Option Agreement between Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the current report on Form 8-K of Orthofix International N.V dated September 10, 2008 and incorporated herein by reference).
10.25	Inducement Grant Nonqualified Stock Option Agreement, dated April 1, 2011, between Orthofix International N.V. and Vicente Trelles (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).
10.26	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).
10.27	Amended and Restated Employment Agreement, dated as of June 15, 2011 and effective as of August 1, 2011, by and between Orthofix Inc., Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the Company s quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
10.28	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of August 29, 2012, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company s current report on Form 8-K filed August 31, 2012 and incorporated herein by reference).
10.29	Letter Agreement, dated March 12, 2013, between Orthofix Inc., Orthofix International N.V. and Robert S Vaters (filed as an exhibit to the Company s current report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.30	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).

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Exhibit Number	Description
10.31	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).
10.32	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).
10.33	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).
10.34	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).
10.35	Amended and Restated Employment Agreement, dated as of October 16, 2012 and effective as of November 6, 2012, between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company s current report on Form 8-K filed October 16, 2012 and incorporated herein by reference).
10.36	Employment Agreement, entered into as of January 7, 2013, by and between Orthofix Inc. and Emily Buxton (filed as an exhibit to the Company s current report on Form 8-K filed January 11, 2013 and incorporated herein by reference).
10.37	Amendment #1 to Employment Agreement, dated as of February 27, 2014, between Orthofix and Emily Buxton (filed as an exhibit to the Company s current report on Form 8-K filed March 4, 2014 and incorporated herein by reference).
10.38	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).
10.39	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).
10.40	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).
10.41	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).
10.42	Letter Agreement, dated May 9, 2013, between Orthofix Inc. and Vicente Trelles (filed as an exhibit to the Company s current report on Form 8-K filed May 14, 2013 and incorporated herein by reference).
10.43	Letter Agreement, entered into on June 18, 2013, between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2013 and incorporated herein by reference).

10.44	Consulting Letter Agreement, dated as of November 5, 2013, between Orthofix International N.V. and James F. Gero (filed as an exhibit to the Company s current report on Form 8-K filed November 6, 2013 and incorporated herein by reference).

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Exhibit Number	Description
10.45	Settlement Agreement, entered into on June 6, 2012, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, the TRICARE Management Activity, through its General Counsel, the Office of Personnel Management , in its capacity as administrator of the Federal Employees Health Benefits Program, the United States Department of Veteran Affairs, Orthofix International N.V. and relator Jeffrey J. Bierman (filed as an exhibit to the Company s current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
10.46	Amended Plea Agreement entered into on December 14, 2012, among the United States Attorney for the District of Massachusetts, the Department of Justice and Orthofix Inc. (filed as an exhibit to the Company s current report on Form 8-K filed December 19, 2012 and incorporated herein by reference).
10.47	Corporate Integrity Agreement, entered into on June 6, 2012, between the Office of Inspector General of the Department of Health and Human Services and Orthofix International N.V. (filed as an exhibit to the Company s current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer.
32.2*	Section 1350 Certification of Chief Financial Officer.
101^	The following financial statements from Orthofix International N.V. on Form 10-K for the year ended December 31, 2013 filed on March 31, 2014, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Consolidated Statements of Changes in Shareholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.

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

^ This exhibit will not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (15 U.S.C. 78r), or otherwise subject to the liability of that Section.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORTHOFIX INTERNATIONAL N.V.

Dated: March 31, 2014

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ BRADLEY R. MASON **Bradley R. Mason**	President and Chief Executive Officer, Director (Principal Executive Officer)	March 31, 2014
/s/ EMILY V. BUXTON **Emily V. Buxton**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2014
Ronald A. Matricaria	Chairman of the Board of Directors	
/s/ KATHLEEN T. REGAN **Kathleen T. Regan**	Director	March 31, 2014
/s/ WALTER VON WARTBURG **Walter von Wartburg**	Director	March 31, 2014
/s/ GUY JORDAN **Guy Jordan**	Director	March 31, 2014
/s/ KENNETH R. WEISSHAAR **Kenneth R. Weisshaar**	Director	March 31, 2014

/s/ DAVEY S. SCOON	Director	March 31, 2014
Davey S. Scoon		
/s/ MARIA SAINZ	Director	March 31, 2014
Maria Sainz		
/s/ ANTHONY MARTIN	Director	March 31, 2014
Anthony Martin		

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ORTHOFIX INTERNATIONAL N.V.

Statement of Management s Responsibility for Financial Statements

To the Shareholders of Orthofix International N.V.:

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

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

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

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

Davey S. Scoon

Chairman of the Audit Committee

Bradley R. Mason

President and Chief Executive Officer, Director

Emily V. Buxton

Chief Financial Officer

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ORTHOFIX INTERNATIONAL N.V.

Index to Consolidated Financial Statements

All other schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Orthofix International N.V.

We have audited the accompanying consolidated balance sheets of Orthofix International N.V. (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive income (loss), changes in shareholders equity, and cash flows for each of the three years in the period ended December 31, 2013. Our audits also included the financial statement schedules listed in the index at Item 15(a). These financial statements and schedules are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedules based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Orthofix International N.V. at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Orthofix International N.V. s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 31, 2014, expressed an adverse opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas

March 31, 2014

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ORTHOFIX INTERNATIONAL N.V.

Consolidated Balance Sheets as of December 31, 2013 and 2012

(U.S. Dollars, in thousands except share and per share data)	2013	2012 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 30,486	$ 31,055
Restricted cash	23,761	21,314
Trade accounts receivable, less allowances of $11,969 and $13,543 at December 31, 2013 and 2012, respectively	75,567	107,312
Inventories	90,577	83,373
Deferred income taxes	33,947	33,450
Prepaid expenses and other current assets	25,906	34,079
Total current assets	280,244	310,583
Property, plant and equipment, net	54,606	53,835
Patents and other intangible assets, net	9,046	7,290
Goodwill	53,565	74,388
Deferred income taxes	18,336	18,881
Other long-term assets	7,385	7,920
Total assets	$ 423,182	$ 472,897
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	$	$ 16
Trade accounts payable	20,674	22,575
Other current liabilities	46,146	39,594
Total current liabilities	66,820	62,185
Long-term debt	20,000	20,000
Deferred income taxes	13,132	11,456
Other long-term liabilities	12,736	11,424
Total liabilities	112,688	105,065
Contingencies (Note 17)		
Shareholders equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,102,335 and 19,339,329 issued and outstanding as of December 31, 2013 and 2012, respectively	1,810	1,934
Additional paid-in capital	216,653	246,306
Retained earnings	89,332	114,847
Accumulated other comprehensive income	2,699	4,745
Total shareholders equity	310,494	367,832

Total liabilities and shareholders equity	$ 423,182	$ 472,897

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

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ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Operations and Comprehensive Income (Loss)

For the years ended December 31, 2013, 2012 and 2011

(U.S. Dollars, in thousands, except share and per share data)	2013	2012 (Restated)	2011 (Restated)
Product sales	$ 352,796	$ 401,039	$ 405,147
Marketing service fees	47,738	46,542	36,824
Net sales	400,534	447,581	441,971
Cost of sales	102,300	98,253	95,527
Gross profit	298,234	349,328	346,444
Operating expenses			
Sales and marketing	176,581	187,131	193,511
General and administrative	65,147	53,391	64,481
Research and development	26,768	28,577	22,861
Amortization of intangible assets	2,687	2,298	2,550
Costs related to the accounting review and restatement	12,945		
Impairment of Goodwill	19,193		
Charges related to U.S. Government resolutions (Note 17)		1,295	57,141
	303,321	272,692	340,544
Operating (loss) income	(5,087)	76,636	5,900
Other income and (expense)			
Interest expense, net	(1,925)	(4,743)	(5,541)
Other income (expense)	2,220	(1,705)	(2,412)
	295	(6,448)	(7,953)
(Loss) income before income taxes	(4,792)	70,188	(2,053)
Income tax expense	(10,116)	(25,138)	(14,165)
Net (loss) income from continuing operations	(14,908)	45,050	(16,218)
Discontinued operations (Note 16)			
Gain on sale of Breg, Inc., net of tax		1,345	
Loss from discontinued operations	(15,510)	(2,994)	(2,705)
Income tax benefit (expense)	4,903	(563)	813
Net loss from discontinued operations	(10,607)	(2,212)	(1,892)
Net (loss) income	$ (25,515)	$ 42,838	$ (18,110)

Net income (loss) per common share basic:			
Net (loss) income from continuing operations	$ (0.80)	$ 2.37	$ (0.89)
Net loss from discontinued operations	(0.57)	(0.12)	(0.10)
Net (loss) income per common share basic	$ (1.37)	$ 2.25	$ (0.99)
Net income (loss) per common share diluted:			
Net (loss) income from continuing operations	$ (0.80)	$ 2.32	$ (0.89)
Net loss from discontinued operations	(0.57)	(0.11)	(0.10)
Net (loss) income per common share diluted	$ (1.37)	$ 2.21	$ (0.99)
Weighted average number of common shares:			
Basic	18,697,228	18,977,263	18,219,343
Diluted	18,697,228	19,390,413	18,219,343
Other comprehensive income (loss), before tax:			
Translation adjustment	$ (1,768)	$ 768	$ (2,279)
Unrealized gain (loss) on derivative instrument	(442)	416	(693)
Other comprehensive income (loss), before tax	(2,210)	1,184	(2,972)
Income tax related to components of other comprehensive income	164	(153)	256
Other comprehensive income (loss), net of tax	(2,046)	1,031	(2,716)
Comprehensive (loss) income	$ (27,561)	$ 43,869	$ (20,826)

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ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Changes in Shareholders Equity

For the years ended December 31, 2013, 2012 and 2011

(U.S. Dollars, in thousands, except share data)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Shareholders Equity
At December 31, 2010 (Restated)	17,726,645	$ 1,772	$ 195,597	$ 90,119	$ 6,430	$ 293,918
Net loss				(18,110)		(18,110)
Unrealized loss on derivative instrument (net of tax benefit of $256)					(437)	(437)
Translation adjustment					(2,279)	(2,279)
Purchase of minority interest			(517)			(517)
Tax benefit on exercise of stock options			1,737			1,737
Reclassification for tax benefit on exercise of stock options			(8,999)			(8,999)
Share-based compensation expense			6,648			6,648
Common shares issued	738,799	74	20,039			20,113
At December 31, 2011 (Restated)	18,465,444	1,846	214,505	72,009	3,714	292,074
Net income				42,838		42,838
Unrealized gain on derivative instrument (net of taxes of $153)					263	263
Translation adjustment					768	768
Share-based compensation expense			6,303			6,303
Common shares issued	873,885	88	25,498			25,586
At December 31, 2012 (Restated)	19,339,329	1,934	246,306	114,847	4,745	367,832
Net loss				(25,515)		(25,515)
Unrealized loss on derivative instrument (net of tax benefit of $164)					(278)	(278)
Translation adjustment					(1,768)	(1,768)
Share-based compensation expense			6,267			6,267
Common shares issued	200,584	20	3,430			3,450
Retirement of repurchased common stock	(1,437,578)	(144)	(39,350)			(39,494)
At December 31, 2013	18,102,335	$ 1,810	$ 216,653	$ 89,332	$ 2,699	$ 310,494

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

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ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Cash Flows

For the years ended December 31, 2013, 2012 and 2011

(U.S. Dollars, in thousands)	2013	2012 (Restated)	2011 (Restated)
Cash flows from operating activities:			
Net (loss) income	$ (25,515)	$ 42,838	$ (18,110)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	22,659	20,580	23,017
Amortization of debt costs	720	1,737	1,239
Provision for doubtful accounts	6,003	10,572	12,936
Deferred income taxes	(1,986)	(1,252)	(52)
Share-based compensation	6,267	6,303	6,648
Impairment of goodwill	19,193		
Gain on sale of Breg, Inc., net of tax		(1,345)	
Excess income tax benefit on employee stock-based awards	(82)	(1,020)	(1,737)
Income tax benefit (expense) on employee stock-based awards	795	2,910	
Other	4,442	4,136	4,491
Changes in operating assets and liabilities, net of effect of dispositions:			
Trade accounts receivable	25,747	(18,438)	293
Inventories	(6,626)	(2,495)	(12,624)
Escrow receivable		41,537	(32,562)
Prepaid expenses and other current assets	6,791	(15,577)	2,829
Trade accounts payable	(2,280)	4,575	2,322
Charges related to U.S. Government resolutions		(83,178)	87,825
Other current liabilities	8,018	(5,729)	2,695
Other long-term assets	4,296	3,416	(17,307)
Other long-term liabilities	(1,561)	616	2,878
Net cash provided by operating activities	66,881	10,186	64,781
Cash flows from investing activities:			
Capital expenditures for property, plant and equipment	(24,787)	(27,994)	(24,965)
Capital expenditures for intangible assets	(4,891)	(780)	(793)
Payment made in connection with acquisition			(5,250)
Net proceeds from sale of Breg, Inc.		153,773	
Net cash (used in) provided by investing activities	(29,678)	124,999	(31,008)
Cash flows from financing activities:			
Net proceeds from issuance of common shares	3,450	25,586	20,113
Payment of refinancing fees and debt issuance costs			(758)
Repayments of long-term debt	(16)	(188,695)	(7,500)
Repayment of bank borrowings, net		(1,297)	(2,561)

Changes in restricted cash	(2,375)	25,799	(24,178)
Purchase of common stock	(39,494)		
Cash payment for purchase of minority interest in subsidiary			(517)
Excess income tax benefit on employee stock-based awards	82	1,020	1,737
Net cash used in financing activities	(38,353)	(137,587)	(13,664)
Effect of exchange rate changes on cash	581	250	(463)
Net (decrease) increase in cash and cash equivalents	(569)	(2,152)	19,646
Cash and cash equivalents at the beginning of the year	31,055	33,207	13,561
Cash and cash equivalents at the end of the year	$ 30,486	$ 31,055	$ 33,207
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 2,046	$ 4,569	$ 17,088
Income taxes	$ 8,773	$ 18,268	$ 26,227

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

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ORTHOFIX INTERNATIONAL N.V.

Notes to the Consolidated Financial Statements

Description of business

Orthofix International N.V. (the Company) is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative technologies to the spine and orthopedic markets. The Company is comprised of four reportable segments: BioStim, Biologics, Extremity Fixation and Spine Fixation supported by Corporate activities.

1. Summary of significant accounting policies

(a) Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned and majority-owned subsidiaries and entities over which the Company has control.

All intercompany accounts, transactions and profits are eliminated in the consolidated financial statements on a continuing operations basis unless otherwise noted.

(b) Reclassifications

The Company has reclassified certain line items to conform to the current year presentation. The reclassifications have no effect on previously reported net earnings or shareholders equity.

(c) Use of estimates in preparation of financial statements

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to the recoverability and useful lives of long-lived assets and the adequacy of the allowance for doubtful accounts and inventory obsolescence, and income taxes. We base our estimates on historical experience, future expectations and on other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

(d) Foreign currency translation

The financial statements for operations outside the United States are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders equity, are translated to U.S. dollars at year end exchange rates and revenue and expense items are translated at weighted average rates of exchange prevailing

during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income component of shareholders equity. Transactional foreign currency gains and (losses), including those generated from intercompany operations, are included in other expense, net and were $0.7 million loss, $0.5 million loss and $1.6 million loss for the years ended December 31, 2013, 2012 and 2011, respectively.

(e) Cash and cash equivalents

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

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(f) Restricted cash

Restricted cash consists of cash held at certain subsidiaries, the distribution or transfer of which to Orthofix International N.V. (the Parent) or other subsidiaries that are not parties to the credit facility described in Note 9 is restricted. The senior secured credit facility restricts the Parent and subsidiaries that are not parties to the facility from access to cash held by Orthofix Holdings, Inc. and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes.

(g) Market risk

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. The Company s objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, the Company seeks to balance its non-U.S. dollar denominated income and expenditures. During 2013, 2012 and 2011, the Company made use of a foreign currency swap agreement to manage cash flow exposure generated from foreign currency fluctuations.

The Company generally does not require collateral on trade receivables.

(h) Inventories

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess, obsolete or impaired items which is reviewed and updated on a periodic basis by management. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Italy, cost is determined on a weighted-average basis, which approximates the first-in, first-out (FIFO) method, due to the high turn-over rate of inventory at this location. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Texas, standard costs, which approximates actual cost on the FIFO method, is used to value inventory. Standard costs are reviewed annually by management, or more often in the event circumstances indicate a change in cost has occurred. The valuation of work-in-process, finished products, field inventory and consignment inventory includes the cost of materials, labor and other production costs. Field inventory represents immediately saleable finished products inventory that is in the possession of the Company s direct sales representatives. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals.

(i) Long-lived assets, including intangibles

Property, plant and equipment is stated at cost less accumulated depreciation. Costs include all expenditures necessary to place the asset in service, including freight and sales and use taxes. Plant and equipment also includes instrumentation held by customers and is generally used to facilitate the implantation of the Company s products, the associated cost and accumulated depreciation as of December 31, 2013 was $54.9 million and ($33.7 million), respectively. Depreciation is computed on a straight-line basis over the useful lives of the assets. Depreciation of leasehold improvements is computed over the shorter of the lease term or the useful life of the asset. The useful lives are as follows:

	Years

Buildings	25 to 33
Plant equipment and instrumentation	2 to 10
Furniture and fixtures	4 to 8

Expenditures for maintenance and repairs and minor renewals and improvements, which do not extend the lives of the respective assets, are expensed as incurred. All other expenditures for renewals and improvements are

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capitalized. The assets and related accumulated depreciation are adjusted for property retirements and disposals, with the resulting gain or loss included in operations. Fully depreciated assets remain in the accounts until retired from service.

Patents and other intangible assets are recorded at cost, or when acquired as a part of a business combination at estimated fair value. These assets primarily include patents and other technology agreements (developed technologies) and trademarks. Identifiable intangible assets which are considered definite lived are amortized over their useful lives using a method of amortization that reflects the pattern in which the economic benefit of the intangible assets is consumed. The Company s weighted average amortization period for developed technologies is 11 years.

Intangible and long-lived assets with definite lives, such as developed technologies, are tested for impairment if any adverse conditions exist or change in circumstances have occurred that would indicate impairment or a change in the remaining useful life. If an impairment indicator exists, the Company tests the intangible asset for recoverability. For purposes of the recoverability test, the Company groups its 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), the Company will write the carrying value down to the fair value in the period identified.

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

(j) Goodwill

The Company tests goodwill at least annually for impairment. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. The Company assesses goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. The Company has identified four reporting units, which are consistent with the Company s reporting segments: BioStim, Biologics, Extremity Fixation, and Spine Fixation.

In order to calculate the respective carrying values, the Company 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. Effective July 1, 2013, the Company re-aligned its reporting units and consequently reallocated the carrying value of goodwill from its previous reporting units to its new reporting units based on the relative fair value of each new reporting unit to total enterprise value at July 1, 2013.

As a result of the Company s change in reportable segments, the Company allocated goodwill to each reportable segment, and subsequently evaluated each reportable segment for possible impairment of goodwill, as there were indicators of impairment when completing a qualitative analysis. The result of this analysis was a full impairment of the goodwill allocated to our Extremity Fixation and our Spine Fixation reportable units, totaling $19.2 million.

The Company s annual goodwill impairment analysis, which was performed qualitatively during the fourth quarter of 2013, did not result in any additional impairment charge.

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(k) Derivative instruments

The Company manages its exposure to fluctuating cash flows resulting from changes in interest rates and foreign exchange within the consolidated financial statements according to its hedging policy. Under the policy, the Company may engage in non-leveraged transactions involving various financial derivative instruments to manage exposed positions. The policy requires the Company to formally document the relationship between the hedging instrument and hedged item, as well as its risk-management objective and strategy for undertaking the hedge transaction. For instruments designated as a cash flow hedge, the Company formally assesses (both at the hedge s inception and on an ongoing basis) whether the derivative that is used in the hedging transaction has been effective in offsetting changes in the cash flows of the hedged item and whether such derivative may be expected to remain effective in future periods. If it is determined that a derivative is not (or has ceased to be) effective as a hedge, the Company will discontinue the related hedge accounting prospectively. Such a determination would be made when (1) the derivative is no longer effective in offsetting changes in the cash flows of the hedged item; (2) the derivative expires or is sold, terminated or exercised; or (3) management determines that designating the derivative as a hedging instrument is no longer appropriate. Ineffective portions of changes in the fair value of cash flow hedges are recognized in earnings.

The Company records all derivatives as either assets or liabilities on the balance sheet at their respective fair values. For a cash flow hedge, the effective portion of the derivative s change in fair value (i.e. gains or losses) is initially reported as a component of other comprehensive income, net of related taxes, and subsequently reclassified into net earnings when the hedged exposure is no longer effective.

The Company utilizes a cross currency swap to manage its foreign currency exposure related to a portion of the Company s intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro. The cross currency swap has been accounted for as a cash flow hedge in accordance with ASC Topic 815, *Derivatives and Hedging*.

(l) Accumulated other comprehensive income

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain (loss) on the Company s cross-currency swap, which is designated and accounted for as a cash flow hedge (see Note 10). The components of and changes in accumulated other comprehensive income are as follows:

(U.S. Dollars in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross-Currency Swaps	Accumulated Other Comprehensive Income
Balance at December 31, 2011 (Restated)	$ 3,846	$ (132)	$ 3,714
Unrealized gain on cross-currency swaps, net of taxes of $153		263	263
Foreign currency translation adjustment (1)	768		768
Balance at December 31, 2012 (Restated)	4,614	131	4,745
Unrealized loss on cross-currency swaps, net of tax benefit of $164		(278)	(278)
Foreign currency translation adjustment (1)	(1,768)		(1,768)
Balance at December 31, 2013	$ 2,846	$ (147)	$ 2,699

(1) As the cash generally remains permanently invested in the non U.S. dollar denominated foreign subsidiaries, no deferred taxes are recognized on the related foreign currency translation adjustment.

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(m) Revenue recognition and accounts receivable

Commercial revenue is related to the sale of the Company s 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 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 or implanted in and accepted by the patient. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or pre-authorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

For distributor revenue, which is related primarily to implant products, the Company recognizes revenue either on a sell-in or sell-through basis depending on the specific circumstances of the distributor. In some cases the Company recognizes distributor revenue as title and risk of loss passes at either shipment from the Company s facilities or receipt at the distributor s facility, assuming all other revenue recognition criteria has been achieved (the sell-in method). Based on the results of the Independent Review, the Company determined 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 the Company 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 the Company does not have reliable information about when its distributors sell the product through to end customers, the Company uses cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company is legally entitled to the accounts receivable at the time of shipment, the Company has not recognized accounts receivables or any corresponding deferred revenues associated with distributor transactions for which revenue is recognized on the sell-through method. Effective April 1, 2013, all distributor revenue is recognized on the sell-through basis.

For distributors on the sell-in method prior to April 1, 2013, cost of sales is recognized upon shipment. For sell-through distributors, whose revenue is recognized upon cash receipt, the Company considers whether to match the related cost of sales expense with revenue or to recognize expense upon shipment. In making this assessment, the Company considers the financially viability of its 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, the Company defers the costs of sales until the revenue is recognized.

Biologics revenue is primarily related to a collaborative arrangement with MTF. In 2008, the Company entered into a collaborative arrangement with MTF to develop and commercialize Trinity Evolution ®, a stem cell-based bone growth biologic matrix. With the development process completed in 2009, the Company and MTF operated under the terms of a separate commercialization agreement. Under the terms of the 10-year agreement, MTF sourced the tissue, processed it to create the bone growth matrix, packaged and delivered it to the customer in accordance with orders received from the Company. The Company has exclusive global marketing rights for Trinity Evolution ® and receives marketing fees from MTF based on total sales. These marketing fees are recorded on a net basis within net sales and were $47.7 million, $46.5 million and $36.8 million in 2013, 2012 and 2011, respectively. On January 10, 2012, the Company announced that it had reached an agreement with MTF to both co-develop and commercialize a new technology for use in bone grafting applications and to expand MTF s Trinity Evolution ® processing capacity. The

amendment amends the term of the existing agreement until the later of (i) 15 years after the date that certain development milestones were achieved under the existing agreement (which occurred during 2010) or (ii) the date that certain licensing

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arrangements between the Company and NuVasive, Inc. expire. MTF is considered the primary obligor in these arrangements and therefore the Company recognizes 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.

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, and contractual allowances are recorded as an adjustment to revenue. These estimates are periodically tested against actual collection experience.

(n) Sale of accounts receivable

The Company will generally sell receivables from certain Italian hospitals each year. The estimated related fee for 2013 and 2012 was $0.8 million and $0.6 million, respectively, which is recorded as interest expense. Trade accounts receivables sold without recourse are removed from the balance sheet at the time of sale.

(o) 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.

(p) Advertising costs

The Company expenses all advertising costs as incurred. Advertising expense included in sales and marketing expense for the years ended December 31, 2013, 2012 and 2011 was $0.2 million, $0.3 million and $0.5 million, respectively.

(q) Research and development costs

Expenditures related to the collaborative arrangement with MTF are expensed based on the terms of the related agreement. Milestone payments made to MTF in 2013 and 2012 totaled $2.5 million and $3.0 million, respectively. There were no milestone payments made to MTF in 2011. Expenditures for other research and development are expensed as incurred.

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(r) Income taxes

The Company is subject to income taxes in both the U.S. and foreign jurisdictions, and uses estimates in determining the provision for income taxes. The Company accounts for income taxes using the asset and liability method for accounting and reporting for income taxes. Under this method, deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and income tax basis of assets and liabilities using statutory rates. This process requires that the Company project the current tax liability and estimate the deferred tax assets and liabilities, including net operating loss and tax credit carry forwards. In assessing the need for a valuation allowance, the Company has considered the recent operating results, future taxable income projections and all prudent and feasible tax planning strategies.

The Company accounts for uncertain tax positions in accordance with ASC 740, Income Taxes, 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. The Company reevaluates 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.

The Company includes imputed interest and any applicable penalties related to tax issues as part of income tax expense in our consolidated financial statements.

(s) Net income (loss) per common share

Net income (loss) per common share basic is computed using the weighted average number of common shares outstanding during each of the respective years. Net income (loss) per common share diluted is computed using the weighted average number of common and common equivalent shares outstanding during each of the respective years using the treasury stock method, if dilutive. Common equivalent shares represent the dilutive effect of the assumed exercise of outstanding share options (see Note 20). The only differences between basic and diluted shares result from the assumed exercise of certain outstanding share options.

(t) Financial instruments and concentration of credit risk

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

Net sales to our customers and distributors based in Europe were approximately $52 million in 2013 which results in a substantial portion of our trade accounts receivable balance as of December 31, 2013. It is at least reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these distributors operate, or other factors, could affect the future realization of these accounts receivable balances.

(u) Recently issued accounting standards

In July 2013, the Financial Accounting Standards Board (FASB), issued Accounting Standards Update (ASU) No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, A Similar Tax Loss, or a Tax Credit Carryforward Exists*. The authoritative guidance concludes that, under

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certain circumstances, unrecognized tax benefits should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. We adopted this guidance early, as permitted, for the fiscal year ended December 31, 2013. The adoption of this guidance did not have a material effect on our consolidated financial statements.

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* The standard requires presentation (either in a single note or parenthetically on the face of the financial statements) of the effect of significant amounts reclassified from each component of accumulated other comprehensive income based on its source and the income statement line items affected by the reclassification. If a component is not required to be reclassified to net income in its entirety, a cross reference to the related footnote for additional information is required. The amendments are effective prospectively for reporting periods beginning after December 15, 2013. The adoption of this guidance did not have a material effect on our consolidated financial statements.

On June 16, 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This ASU eliminates the current option to present other comprehensive income and its components in the statement of changes in shareholders equity and increases the prominence of other comprehensive income in the statements by providing an alternative to present the components of net income and comprehensive income as either one continuous or two separate but consecutive financial statements. Companies are also required to present reclassification adjustments for items that are reclassified from other comprehensive income to net income within these statements. This standard is to be applied retrospectively and is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company adopted this ASU as of March 31, 2012 and it did not have a material impact on the Company s consolidated financial statements.

2. Restatement of the Consolidated Financial Statements

Background

In July 2013, the Audit Committee (the Audit Committee) of the Company s Board of Directors (the Board) commenced an independent review with the assistance of outside professionals into whether the Company had properly recognized revenue under U.S. generally accepted accounting principles (GAAP) in connection with certain revenue that had been recorded in 2012 and 2011 (the Independent Review). In conjunction with the Independent Review, the Company concluded that errors existed in the Company s previously issued financial statements for the fiscal years ended December 31, 2012 and 2011, the interim quarterly period ended March 31, 2013, and certain other prior periods.

In reaching these conclusions, the Company considered information obtained in the Independent Review, including emails, data and interviews with current and former employees that indicated (i) the existence of extra-contractual terms or arrangements at the onset of the sale and concessions agreed to subsequent to the initial sale, such as extended payment terms and return and exchange rights for sales to distributors with respect to certain transactions, (ii) that at the time of some sales collection was not reasonably assured, and (iii) that certain amounts previously characterized as commissions were paid to related parties of the applicable customer.

The Company assessed the information derived from the Independent Review in making determinations with respect to accounting adjustments reflected in the restated consolidated financial statements contained in the Amendments and in its Annual Report on Form 10-K for the fiscal year ended December 31, 2013, and such determinations are consistent with the findings of the Independent Review. In addition to the matters that were the subject of the

Independent Review, certain other adjustments identified by management, including revisions to inventory reserves and royalties, were made to the consolidated financial statements in connection with the restatement.

The correction of these errors had the following impact: decreased net sales by $14.7 million and $28.2 million for the years ended December 31, 2012 and 2011, respectively; and decreased net income from continuing

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operations by $8.9 million and $14.5 million for the years ended December 31, 2012 and 2011, respectively. The following include descriptions of the significant adjustments to the Company s financial position and results of operations from the previously reported consolidated financial statements.

Distributor Revenue Recognition

The Company has determined that it previously recognized revenue with respect to certain distributor relationships before all revenue recognition criteria were met. Specifically, the Company has determined that a fixed or determinable sales price did not exist, and/or collection was not reasonably assured, with respect to certain transactions where revenue had previously been recognized at the time of shipment. Specifically, the Company s review revealed arrangements, or extra-contractual terms, with certain of the Company s distributors regarding extended payment terms, return or exchange rights, and contingent payment obligations for sales to such distributors with respect to certain transactions. There were also concessions being made subsequent to the shipment of inventory to the distributors and the related revenue recognition. Based on the results of this review, it was determined that these arrangements were not appropriately evaluated under the appropriate revenue recognition criteria applicable under GAAP. Distributor sales represented approximately 11 13% of the Company s net sales (prior to the restatement) of approximately $462 million and $470 million for the years ended December 31, 2012 and 2011, respectively.

The Company previously recognized distributor revenue as title and risk of loss passed at either shipment from the Company s facilities or receipt at the distributor s facility, assuming all other revenue recognition criteria had been achieved (the sell-in method). Based on review of all facts and circumstances related to the arrangements described above, the Company determined that in many instances the revenue recognition criteria under the sell-in method were not satisfied at the time of shipment or receipt; specifically, the existence of extra-contractual terms or arrangements caused the Company 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 the Company is unable to reasonably estimate the effects of these extra-contractual terms, it is precluded from recognizing revenue relating to distributor arrangements until the product is delivered to the end customer. This method is commonly referred to as the sell-through revenue recognition method because the vendor does not recognize revenue until the transaction consideration is fixed or determinable, which coincides with the selling of the product through the distribution channel to the end customer. Because the Company does not have reliable information about when its distributors sell the product through to end customers, the Company will use cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company is legally entitled to the accounts receivable at the time of shipment, since the revenue recognition criteria has not been met, the Company has not recognized accounts receivables or any corresponding deferred revenues associated with these transactions.

As part of the review, the Company also considered the accounting treatment for the related cost of sales when distributor revenue is recognized on a sell-through basis. Previously, cost of sales were recognized upon shipment; however, the Company believes the matching of the recognition of costs of sales with revenue is preferred and therefore considered if such costs should be deferred until revenue is recognized on a sell-through basis. In making this assessment, the Company considered the financial viability of its distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped was reasonably assured at the time of shipment to these distributors. In instances where the distributor was determined to be financially viable, the Company determined that costs of sales should be deferred until the revenue is recognized. For those distributors where the Company has concluded that collectability was not reasonably assured, the Company has expensed the related cost of sales upon shipment.

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Based on the results of the Independent Review, the Company determined that all distributor transactions should be transitioned to the sell-through method of accounting as of the dates described below:

For distributor transactions within the Company s Orthopedics division, the Company has determined that sell-through accounting should be applied within the Brazil subsidiary for all prior periods given the frequency with which the Company conducted business under extra-contractual and undocumented terms, as well as the Company s inability to fully access underlying transactional and other information that would be necessary to evaluate transactions under a sell-in basis. For distributor transactions within the division outside the Brazil subsidiary, there were also sales to four distributors that did not meet the fixed or determinable or collectability revenue recognition criteria and therefore, such sales were adjusted to sell-through accounting in the restatement.

For distributor transactions within the Company s U.S. Spine division, the Company has determined that sell-through accounting should be applied beginning January 1, 2011. Following its consideration of the information provided from the Independent Review, the Company believes that January 1, 2011 is the date extra-contractual terms became pervasive in the Company s U.S. business, and it is unaware of circumstances existing prior to that date that would require it to broadly apply sell-through accounting to all distributor transactions within the U.S. Spine division. Additionally, there were sales in 2012 and 2011 for which revenue was previously recognized that did not meet the fixed or determinable criteria and the product associated with such sales was subsequently returned in 2013 (i) under the terms of negotiated agreements whereby the Company terminated its relationships with two distributors and (ii) by an additional distributor who returned certain product sold pursuant to a contingent sales arrangement. Such sales represented approximately $3.3 million and $4.1 million for the years ended December 31, 2012 and 2011, respectively. Due to the return of the product, no revenue will be recognized for these transactions.

The Company has determined that stimulation products sold to distributors within the Company s U.S. Spine division during 2012 did not meet the fixed or determinable (and in some cases, collectability) revenue recognition criterion at the time of shipment. Therefore, the Company has determined that sell-through accounting should be applied for these sales. Management also determined that many of these distributors (or affiliates thereof) received commission payments as part of the sales transactions, which the Company previously recorded as sales and marketing expense. The Company has recorded adjustments in the restatement to net these commission expenses against revenue, as they represented product discounts.

The Company has determined that it will prospectively apply sell-through accounting for all remaining distributor arrangements (which entails arrangements within the Company s Orthopedics division outside the Brazil subsidiary) beginning April 1, 2013, the earliest date for which financial statements had not previously been issued by the Company at the time of the determination. Although the Independent Review did not provide information to indicate extra-contractual terms or that historical revenue recognition was inappropriate in these remaining instances, the Company believes the information from the Independent Review indicating that the Company has a history of extra-contractual arrangements for distributor transactions, as described above, provides additional information which should be considered in reassessing the application of sell-through accounting on a prospective basis, particularly given that the Company believes that there is a higher risk associated with distributor arrangements generally.

The effect of adjustments made to the Company s previously filed consolidated statements of operations as a result of these matters are shown in the tables below. These adjustments also had the following effects on the Company s previously filed consolidated balance sheets:

Accounts receivable decreased as of December 31, 2012 by $41.3 million related to the de-recognition of receivables for which revenue has been deferred and will now be recognized on a sell-through basis, based on cash collections.

Inventory increased as of December 31, 2012 by $11.0 million to recognize the costs of inventory shipments to distributors determined to be financially viable as discussed previously.

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Inventory Reserves

The Company also identified material errors in inventory reserves. One error related to the Company recording an increase of $1.2 million to the Company s excess and obsolete reserve in the second quarter of 2012 related to a product within the Spine business that was subsequently reversed by the Company in the fourth quarter of 2012. During the Company s review, it was determined that removing the reserve in the fourth quarter of 2012 was not correct; therefore the reserve has been reinstated.

The Company has also determined that certain inconsistencies existed with respect to how the Company previously computed and recorded inventory reserves. As a result, the Company has reviewed the methodologies used to compute and record inventory reserves and determined that errors in the application of GAAP existed in prior periods, which required adjustment in these financial statements. Based on this review, the Company has determined that it previously made reductions to previously recorded reserves based on changes in forecasted demand, which it believes was contrary to guidance set forth in ASC Topic 330, *Inventory* (specifically ASC 330-10-35-14), which states that 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. The restated consolidated financial statements contain several adjustments to reflect recomputed inventory reserves in each of the relevant periods.

These adjustments resulted in a decrease to inventory (due to an increase in reserves) as of December 31, 2012, by $14.8 million.

Royalties

The Company also reviewed the accounting for royalties and determined there were royalties classified as sales and marketing expense; however, such royalties were based on sales of products and were paid to doctors who consulted on development of those products. Given these amounts are attributable to the cost of producing the Company s products, the Company determined they are correctly classified as cost of goods sold.

Other Adjustments

In addition to the adjustments recorded to address the Company s errors in accounting for distributor revenue recognition, inventory reserves, and royalties, the Company has identified other errors that are generally not material, individually or in the aggregate, but have been recorded in connection with the restatement.

Included in Other Adjustments are adjustments to reclassify interest expense from continuing operations to discontinued operations of $3.9 million for the year ended December 31, 2011. The reclassification was necessary as the Company used a portion of the proceeds from the sale of Breg, Inc. to repay in full the remaining $87.5 million balance on the Term Loan Facility and pay down $57.5 million of amounts outstanding under the Revolving Credit Facility.

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There were no material impacts to the statements of cash flows for the items above other than to increase operating cash flows and decrease financing cash flows for $1 million for the year ended December 31, 2012. The results of the adjustments to the Company s previously filed consolidated statements of operations detailed above are summarized in the tables below. The tax effect of the adjustments is estimated based on the Company s effective tax rate.

	Year Ended December 31, 2012 Adjustments by Category						
(U.S. Dollars, in thousands)	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total Adjustments	Restated
Net sales	$ 462,320	$ (14,777)	$	$	$ 38	$ (14,739)	$ 447,581
Cost of sales	86,492	(2,032)	5,647	8,190	(44)	11,761	98,253
Gross profit	375,828	(12,745)	(5,647)	(8,190)	82	(26,500)	349,328
Operating expenses							
Sales and marketing	200,343	(6,629)		(8,190)	1,607	(13,212)	187,131
General and administrative	53,827	(2)			(434)	(436)	53,391
Research and development	28,577						28,577
Amortization of intangible assets	2,098				200	200	2,298
Charges related to U.S. Government resolutions	1,973				(678)	(678)	1,295
	286,818	(6,631)		(8,190)	695	(14,126)	272,692
Operating income	89,010	(6,114)	(5,647)		(613)	(12,374)	76,636
Other income and (expense)	(6,282)				(166)	(166)	(6,448)
Income before income taxes	82,728	(6,114)	(5,647)		(779)	(12,540)	70,188
Income tax expense	(28,792)	1,782	1,645		227	3,654	(25,138)
Net income from continuing operations	$ 53,936	$ (4,332)	$ (4,002)	$	$ (552)	$ (8,886)	$ 45,050

	Year Ended December 31, 2011 Adjustments by Category						
(U.S. Dollars, in thousands)	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total Adjustments	Restated
Net sales	$ 470,121	$ (29,135)	$	$	$ 985	$ (28,150)	$ 441,971
Cost of sales	92,619	(8,289)	3,377	7,713	107	2,908	95,527
Gross profit	377,502	(20,846)	(3,377)	(7,713)	878	(31,058)	346,444
Operating expenses							
Sales and marketing	200,145	(1,216)		(7,713)	2,295	(6,634)	193,511
General and administrative	64,374				107	107	64,481

Research and development	22,861						22,861
Amortization of intangible assets	2,350				200	200	2,550
Charges related to U.S. Government resolutions	56,463				678	678	57,141
	346,193	(1,216)		(7,713)	3,280	(5,649)	340,544
Operating income	31,309	(19,630)	(3,377)		(2,402)	(25,409)	5,900
Other income and (expense)	(11,868)				3,915	3,915	(7,953)
Income (loss) before income taxes	19,441	(19,630)	(3,377)		1,513	(21,494)	(2,053)
Income tax expense	(21,181)	6,408	1,102		(494)	7,016	(14,165)
Net loss from continuing operations	$ (1,740)	$ (13,222)	$ (2,275)	$	$ 1,019	$ (14,478)	$ (16,218)

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The effects of the restatements on the Company s consolidated balance sheet as of December 31, 2012 are as follows:

	As of December 31, 2012		
(U.S. Dollars, in thousands except share and per share data)	**Previously Reported**	**Adjustments**	**Restated**
Assets			
Current assets:			
Cash and cash equivalents	$ 31,055	$	$ 31,055
Restricted cash	21,314		21,314
Trade accounts receivable, less allowances of $13,543	150,316	(43,004)	107,312
Inventories	88,744	(5,371)	83,373
Deferred income taxes	16,959	16,491	33,450
Prepaid expenses and other current assets	32,056	2,023	34,079
Total current assets	340,444	(29,861)	310,583
Property, plant and equipment, net	51,362	2,473	53,835
Patents and other intangible assets, net	6,880	410	7,290
Goodwill	74,388		74,388
Deferred income taxes	19,904	(1,023)	18,881
Other long-term assets	11,303	(3,383)	7,920
Total assets	$ 504,281	$ (31,384)	$ 472,897
Liabilities and shareholders equity			
Current liabilities:			
Bank borrowings	$ 16	$	$ 16
Trade accounts payable	21,812	763	22,575
Other current liabilities	46,969	(7,375)	39,594
Total current liabilities	68,797	(6,612)	62,185
Long-term debt	20,000		20,000
Deferred income taxes	11,456		11,456
Other long-term liabilities	4,930	6,494	11,424
Total liabilities	105,183	(118)	105,065
Contingencies (Note 17)			
Shareholders equity			
Common shares $0.10 par value; 50,000,000 shares authorized; 19,339,329 issued and outstanding	1,934		1,934
Additional paid-in capital	246,111	195	246,306
Retained earnings	148,549	(33,702)	114,847
Accumulated other comprehensive income	2,504	2,241	4,745
Total shareholders equity	399,098	(31,266)	367,832
Total liabilities and shareholders equity	$ 504,281	$ (31,384)	$ 472,897

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The effects of the restatements on the Company s consolidated statement of operations and comprehensive income for the year ended December 31, 2012 are as follows:

	Year Ended December 31, 2012		
(U.S. Dollars, in thousands, except share and per share data)	Previously Reported	Adjustments	Restated
Product sales	$ 415,850	(14,811)	$ 401,039
Marketing service fees	46,470	72	46,542
Net sales	462,320	(14,739)	447,581
Cost of sales	86,492	11,761	98,253
Gross profit	375,828	(26,500)	349,328
Operating expenses			
Sales and marketing	200,343	(13,212)	187,131
General and administrative	53,827	(436)	53,391
Research and development	28,577		28,577
Amortization of intangible assets	2,098	200	2,298
Charges related to U.S. Government resolutions (Note 17)	1,973	(678)	1,295
	286,818	(14,126)	272,692
Operating income	89,010	(12,374)	76,636
Other income and (expense)			
Interest expense, net	(4,577)	(166)	(4,743)
Other expense	(1,705)		(1,705)
	(6,282)	(166)	(6,448)
Income before income taxes	82,728	(12,540)	70,188
Income tax expense	(28,792)	3,654	(25,138)
Net income from continuing operations	53,936	(8,886)	45,050
Discontinued operations (Note 16)			
Gain on sale of Breg, Inc.,	1,345		1,345
Loss from discontinued operations	(4,012)	1,018	(2,994)
Income tax benefit (expense)	26	(589)	(563)
Net loss from discontinued operations	(2,641)	429	(2,212)
Net income	$ 51,295	(8,457)	$ 42,838
Net income (loss) per common share basic:			
Net income from continuing operations	$ 2.84	(0.47)	$ 2.37
Net loss from discontinued operations	(0.14)	0.02	(0.12)

Net income per common share basic	$	2.70	(0.45)	$	2.25
Net income (loss) per common share diluted:					
Net income from continuing operations	$	2.78	(0.46)	$	2.32
Net loss from discontinued operations		(0.14)	0.03		(0.11)
Net income per common share diluted:	$	2.64	(0.43)	$	2.21
Weighted average number of common shares:					
Basic		18,977,263			18,977,263
Diluted		19,390,413			19,390,413
Other comprehensive income, before tax:					
Translation adjustment	$	480	288	$	768
Unrealized gain on derivative instrument		416			416
Other comprehensive income, before tax		896	288		1,184
Income tax expense related to components of other comprehensive income		(153)			(153)
Other comprehensive income, net of tax		743	288		1,031
Comprehensive income	$	52,038	(8,169)	$	43,869

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The effects of the restatements on the Company s consolidated statement of operations and comprehensive loss for the year ended December 31, 2011 are as follows:

	Year Ended December 31, 2011		
(U.S. Dollars, in thousands, except share and per share data)	Previously Reported	Adjustments	Restated
Product sales	$ 432,975	(27,828)	$ 405,147
Marketing service fees	37,146	(322)	36,824
Net sales	470,121	(28,150)	441,971
Cost of sales	92,619	2,908	95,527
Gross profit	377,502	(31,058)	346,444
Operating expenses			
Sales and marketing	200,145	(6,634)	193,511
General and administrative	64,374	107	64,481
Research and development	22,861		22,861
Amortization of intangible assets	2,350	200	2,550
Charges related to U.S. Government resolutions (Note 17)	56,463	678	57,141
	346,193	(5,649)	340,544
Operating income	31,309	(25,409)	5,900
Other income and (expense)			
Interest expense, net	(9,456)	3,915	(5,541)
Other expense	(2,412)		(2,412)
	(11,868)	3,915	(7,953)
Income (loss) before income taxes	19,441	(21,494)	(2,053)
Income tax expense	(21,181)	7,016	(14,165)
Net loss from continuing operations	(1,740)	(14,478)	(16,218)
Discontinued operations (Note 16)			
Gain on sale of Breg, Inc.			
Income (loss) from discontinued operations	1,263	(3,968)	(2,705)
Income tax (expense) benefit	(596)	1,409	813
Net income (loss) from discontinued operations	667	(2,559)	(1,892)
Net loss	$ (1,073)	(17,037)	$ (18,110)
Net income (loss) per common share basic:			
Net loss from continuing operations	$ (0.10)	(0.79)	$ (0.89)
Net income (loss) from discontinued operations	0.04	(0.14)	(0.10)

Net loss per common share basic	$	(0.06)	(0.93)	$	(0.99)
Net income (loss) per common share diluted:					
Net loss from continuing operations	$	(0.10)	(0.79)	$	(0.89)
Net income (loss) from discontinued operations		0.04	(0.14)		(0.10)
Net loss per common share diluted:	$	(0.06)	(0.93)	$	(0.99)
Weighted average number of common shares:					
Basic		18,219,343			18,219,343
Diluted		18,219,343			18,219,343
Other comprehensive loss, before tax:					
Translation adjustment	$	(3,192)	913	$	(2,279)
Unrealized loss on derivative instrument		(693)			(693)
Other comprehensive loss, before tax		(3,885)	913		(2,972)
Income tax benefit related to components of other comprehensive income		256			256
Other comprehensive loss, net of tax		(3,629)	913		(2,716)
Comprehensive loss	$	(4,702)	(16,124)	$	(20,826)

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3. Inventories

(U.S. Dollars in thousands)	December 31, 2013	2012 (Restated)
Raw materials	$ 6,499	$ 7,623
Work-in-process	6,606	7,886
Finished products	31,342	28,308
Field inventory	34,932	22,629
Consignment inventory	3,916	6,155
Deferred cost of sales	7,282	10,772
	$ 90,577	$ 83,373

Field inventory represents immediately saleable finished products that are in the possession of the Company s direct sales representatives. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals. Deferred cost of sales result from transactions where the Company has shipped product or performed services for which all revenue recognition criteria have not yet been met. Once all revenue recognition criteria have been met, revenue previously recorded as deferred and associated cost of sales are recognized.

4. Property, plant and equipment

(U.S. Dollars in thousands)	December 31, 2013	2012 (Restated)
Cost		
Buildings	$ 4,075	$ 3,911
Plant, equipment and instrumentation	131,572	120,982
Furniture and fixtures	5,872	5,567
	141,519	130,460
Accumulated depreciation	(86,913)	(76,625)
	$ 54,606	$ 53,835

Depreciation expense for the years ended December 31, 2013, 2012 and 2011 was $20.0 million, $15.8 million and $14.3 million, respectively.

5. Patents and other intangible assets

(U.S. Dollars in thousands)	December 31, 2013	2012 (Restated)
Cost		
Patents	$ 42,568	$ 38,905
Trademarks definite lived	620	657
	43,188	39,562
Accumulated amortization		
Patents	(33,688)	(31,845)
Trademarks definite lived	(454)	(427)
	(34,142)	(32,272)
Patents and other intangible assets, net	$ 9,046	$ 7,290

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Amortization expense for intangible assets is estimated to be approximately $2.1 million, $1.8 million, $1.7 million, $1.4 million, $0.5 million and $1.5 million for the periods ending December 31, 2014, 2015, 2016, 2017, 2018 and 2019 and thereafter, respectively.

6. Goodwill

The following table presents the changes in the net carrying value of goodwill by reportable segment as well as the reallocation as of July 1, 2013 in conjunction with our change in reportable segments. (See Note 1 Summary of significant accounting policies):

(U.S. Dollars in thousands)	Spine	Orthopedics	BioStim	Biologics	Extremity Fixation	Spine Fixation	Total
At December 31, 2011	$ 41,419	$ 31,675	$	$	$	$	$ 73,094
Foreign currency	145	1,149					1,294
At December 31, 2012	41,564	32,824					74,388
Foreign currency	(163)	(1,467)					(1,630)
At June 30, 2013	41,401	31,357					72,758
Reallocation at July 1, 2013	(41,401)	(31,357)	42,678	10,887	9,825	9,368	
Impairment					(9,825)	(9,368)	(19,193)
At December 31, 2013	$	$	$ 42,678	$ 10,887	$	$	$ 53,565

Goodwill Impairment

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

In order to calculate the respective carrying values, the Company 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. Effective July 1, 2013, the Company re-aligned its segments, and consequently reallocated the carrying value of goodwill to its new reporting units, determined to be the Company s segments (i.e., BioStim, Biologics, Spine Fixation, and Extremity Fixation), based on the relative fair value of each new reporting unit to total enterprise value at July 1, 2013.

In the first quarter of 2012, ASU 2011-08, Testing of Goodwill for Impairment became effective. ASU 2011-08 allows entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit (i.e. the first step of the goodwill impairment test). If entities determine, on the basis

of qualitative factors, that the fair value of the reporting unit is more likely than not greater than the carrying amount, a quantitative calculation would not be needed.

As a result of the Company s change in reportable segments, the Company re-allocated goodwill to each reporting unit. We estimated the fair value of each reporting unit using a weighting of fair values derived from an income approach, a cost approach, and a market approach (all Level 3 fair value measurements). Under the income approach, we calculated the fair value of each reporting unit based on the present value of its estimated

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future cash flows. Cash flow projections are based on our estimates of revenue growth rates and operating margins, taking into consideration industry and market conditions. The discount rate used was based on the weighted average cost of capital adjusted for the risks associated with the reporting unit and the projected cash flows. The cost approach involves methods of determining a Company s value by analyzing the market value of a Company s assets. The market approach estimates fair value based on market multiples of revenue and earnings of comparable publicly traded companies that have similar operating and investment characteristics as our reporting units.

Upon estimating the fair value of the reporting units, we determined it was less than its carrying value for two of our reporting units, Extremity Fixation and Spine Fixation. As a result, we performed step two of the impairment analysis and allocated the fair value of these reporting units to the estimated fair values of each of the assets and liabilities of the reporting units (including identifiable intangible assets) with the excess fair value being the implied goodwill. Estimating the fair value of certain assets and liabilities requires significant judgment about future cash flows. The implied fair value of the reporting unit s goodwill was less than its carrying value, which we recorded as a full impairment loss of goodwill for our Spine Fixation and Extremity Fixation reporting units, totaling $19.2 million, during the third quarter of 2013. The Company s annual goodwill impairment analysis, which was performed qualitatively during the fourth quarter of 2013, did not result in any additional impairment charge.

7. Bank borrowings

Borrowings under the line of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facility were zero and $.01 million at December 31, 2013 and 2012, respectively. The weighted average interest rate on borrowings under lines of credit as of December 31, 2013 and 2012 was 3.70%.

The Company had an unused available line of credit of 5.8 million ($8.0 million) and 5.8 million ($7.6 million) at December 31, 2013 and 2012, respectively, in its Italian line of credit. This line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

8. Other current liabilities

(U.S. Dollars in thousands)	December 31, 2013	2012 (Restated)
Accrued expenses	$ 16,016	$ 9,089
Salaries, bonuses, commissions and related taxes payable	16,598	17,915
Accrued legal expenses	10,292	8,496
Other payables	3,240	4,094
	$ 46,146	$ 39,594

9. Long-term debt

On August 30, 2010, the Company s wholly owned U.S. holding company, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the Credit Agreement) with certain domestic direct and indirect subsidiaries of the Company (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto.

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The Credit Agreement provides for a five year, $200 million secured revolving credit facility (the Revolving Credit Facility), and a five year, $100 million secured term loan facility (the Term Loan Facility , and together with the Revolving Credit Facility, the Credit Facilities). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to $50 million upon satisfaction of certain conditions.

In May 2012, the Company used a portion of the proceeds from the sale of Breg, Inc. (Breg) (see Note 16) to repay in full the remaining $87.5 million balance on the Term Loan Facility and pay down $57.5 million of amounts outstanding under the Revolving Credit Facility. This use of proceeds was required by the lenders consent dated April 23, 2012 to the Credit Agreement. As a result of the sale of Breg, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. Additionally, the Company paid $20 million in June and $20 million in September 2012 to reduce amounts outstanding under the Revolving Credit Facility. As a result, at December 31, 2012, the Term Loan Facility had been repaid in full and there was $20 million outstanding under the Revolving Credit Facility both at December 31, 2013 and 2012. Borrowings under the Credit Facilities bear interest at a floating rate, which is, at Orthofix Holdings option, either the London Inter-Bank Offered Rate (LIBOR) plus an applicable margin or a base rate (as defined in the Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated leverage ratio with respect to the immediately preceding four fiscal quarters. As of December 31, 2013 and 2012, the entire Revolving Credit Facility was at the LIBOR rate plus a margin of 2.50%. The effective interest rate on the Credit Facilities as of December 31, 2013 and 2012 was 2.7%.

Outstanding principal on the Revolving Credit Facility is due on August 30, 2015.

Borrowings under the Revolving Credit Facility, which may be made in the future, will be used for working capital, capital expenditures and other general corporate purposes of Orthofix Holdings and its subsidiaries. The Guarantors have guaranteed repayment of Orthofix Holdings obligations under the Credit Agreement. The obligations of Orthofix Holdings and each of the Guarantors with respect to the Credit Facilities are secured by a pledge of substantially all of the assets of Orthofix Holdings and each of the Guarantors.

The Credit Agreement, as amended, requires Orthofix Holdings and the Company to comply with coverage ratios on a consolidated basis and contains affirmative and negative covenants, including limitations on additional debt, liens, investments and acquisitions. The Credit Agreement, as amended, also includes events of default customary for facilities of this type. Upon the occurrence of an event of default, all outstanding loans may be accelerated and/or the lenders commitments terminated. The Company was in compliance with the affirmative and negative covenants at December 31, 2012 and there were no events of default.

On August 14, 2013, the Company and certain required lender parties to the Credit Agreement entered into a Limited Waiver (the Limited Waiver). Under the Limited Waiver, the lenders under the Credit Agreement (the Lenders) collectively waived requirements under the Credit Agreement that the Company deliver quarterly financial statements with respect to the fiscal quarters ending on June 30, 2013 and September 30, 2013, and related financial covenant certificates, until the earlier of (i) March 31, 2014 or (ii) the date that is one day after such financial statements are publicly filed or released. In addition, the Limited Waiver provided that the restatement of the Company s financial statements for any period ending on or before March 31, 2013 will not constitute a default or event or default provided that within one business day after the public release or filing of such restated financial statements, the Company delivers corrected financial statements and compliance certificates with respect to such restated periods and immediately pay any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated financial statements. The Company was in compliance with the affirmative and negative covenants at December 31, 2013 and there were no events of default.

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Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company s Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Domestic subsidiaries of the Company, as parties to the credit agreement, have access to these net assets for operational purposes.

The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of December 31, 2013 and 2012 is $192.0 million and $213.4 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings, Inc. and its subsidiaries. All of the Company s subsidiaries that are parties to the Credit Agreement have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of December 31, 2013 and 2012 was $23.8 million and $21.3 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, the Company incurred debt issuance costs of $5 million which includes $0.8 million of costs related to the May 2011 amendment. These costs are being amortized using the effective interest method over the life of the Credit Facilities. In conjunction with the Term Loan Facility repayment in May 2012, the Company wrote off $0.8 million of the related debt issuance costs. As of December 31, 2013 and 2012, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were $1.1 million and $1.8 million, respectively.

10. Derivative instruments

The tables below disclose the types of derivative instruments the Company owns, the classifications and fair values of these instruments within the balance sheet, and the amount of gain (loss) recognized in other comprehensive income (loss) (OCI) or net income (loss).

(U.S. Dollars in thousands)	Fair value: favorable (unfavorable)	Balance sheet location
As of December 31, 2013		
Cross-currency swap	$ (1,036)	Other long-term liabilities
As of December 31, 2012		
Cross-currency swap	$ 305	Other long-term assets

(U.S. Dollars in thousands)	For the year ended December 31, 2013	2012	2011
Cross-currency swap gain (loss) recorded in other comprehensive income (loss), net of taxes	$ (278)	$ 263	$ (437)

Cross-currency swap

On September 30, 2010, the Company entered into a cross-currency swap agreement (the replacement swap agreement) with JPMorgan Chase Bank and Royal Bank of Scotland PLC (the counterparties) to manage its cash flows related to foreign currency exposure for a portion of the Company s intercompany receivable of a U.S. dollar functional currency subsidiary that is denominated in Euro.

Under the terms of the swap agreement, the Company pays Euros based on a 28.7 million notional value and a fixed rate of 5.00% and receives U.S. dollars based on a notional value of $39 million and a fixed rate of 4.635%. The expiration date is December 30, 2016, the date upon which the underlying intercompany debt, to which the swap agreement applies, matures. The swap agreement is designated as a cash flow hedge and therefore the Company recognized an unrealized gain (loss) on the change in fair value, net of tax, within other comprehensive income.

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11. Fair value measurements

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

Level 1	quoted prices in active markets for identical assets and liabilities
Level 2	observable inputs other than quoted prices in active markets for identical assets and liabilities
Level 3	unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

As of December 31, 2013, the Company s financial instruments included cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt, and a cross-currency derivative contract. Cash equivalents consist of short-term, highly liquid, income-producing investments, all of which have original maturities of 90 days or less, including money market funds. The carrying value of restricted cash, accounts receivable, short-term bank borrowings 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 cross-currency derivative instrument is the only financial instrument recorded at fair value on a recurring basis. This instrument consists of an over-the-counter contract, which is not traded on a public exchange. The fair value of the swap contract is determined based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets. Therefore, the Company has categorized the swap contract as a Level 2 derivative financial instrument. The Company also considers counterparty credit risk and its own credit risk in its determination of all estimated fair values. The Company has consistently applied these valuation techniques in all periods presented.

The fair value of the Company s financial assets and liabilities on a recurring basis were as follows:

(U.S. Dollars in thousands)	Balance December 31, 2013	Level 1	Level 2	Level 3
Assets				
Deferred compensation plan	$ 3,361	$ 3,361	$	$
Total	$ 3,361	$ 3,361	$	$
Liabilities				
Deferred compensation plan	$ (2,506)	$ (2,506)	$	$
Cash Flow Hedges				
Cross-currency hedge	(1,036)		(1,036)	

Total	$ (3,542)	$ (2,506)	$ (1,036)	$

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(U.S. Dollars in thousands)	Balance December 31, 2012	Level 1	Level 2	Level 3
Assets				
Deferred compensation plan	$ 3,305	$ 3,305	$	$
Cash flow hedges				
Cross-currency hedge	305		305	
Total	$ 3,610	$ 3,305	$ 305	$
Liabilities				
Deferred compensation plan	$ (2,320)	$ (2,320)	$	$
Cash flow hedges				
Cross-currency hedge				
Total	$ (2,320)	$ (2,320)	$	$

12. Commitments

Leases

The Company has entered into operating leases for facilities and equipment. These leases are non-cancellable and typically do not contain renewal options. Certain leases contain rent escalation clauses for which the Company recognizes the expense on a straight-line basis. Rent expense under the Company s operating leases for the years ended December 31, 2013, 2012 and 2011 was approximately $3.4 million, $4.1 million and $4.8 million, respectively. Future minimum lease payments under operating leases, net of amounts to be received under sub-leases, as of December 31, 2013 are as follows:

(U.S. Dollars in thousands)	
2014	$ 4,342
2015	4,107
2016	3,713
2017	2,974
2018	2,846
Thereafter	3,049
Total	$ 21,031

13. Business segment information

On July 1, 2013, we began certain organizational and executive leadership changes to align with how our Chief Operating Decision Maker (the CODM) reviews performance and makes decisions in managing the Company. We manage our business by our four strategic business units (SBUs), which are comprised of BioStim, Biologics, Extremity Fixation, and Spine Fixation supported by Corporate activities. These SBUs represent the segments for

which our CODM reviews financial information and makes resource allocation decisions among business units. The primary metric used by the Chief Operating Decision Maker in managing the Company is contribution margin, which is defined as gross profit less sales and marketing expense. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. Accordingly, our segment information has been prepared based on our four SBUs reporting segments. These four segments are discussed below.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for a portfolio of market leading devices for enhancing bone fusion that utilize Orthofix s patented pulsed electromagnetic (PEMF) technology. These Food and Drug Administration-approved Class 3 medical devices are indicated as an adjunctive treatment

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to enhance fusion success in cervical and lumbar spine fusion as well as a therapeutic treatment for non-healing fractures outside of the spine (non-unions). The PEMF technology is supported by a strong clinical background on mechanism of action in the scientific literature and current research and clinical studies are underway to identify potential new clinical indications.

Biologics

The Biologics SBU provides a portfolio of regenerative products 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 distributes its tissues through a network of distributors, sales, representatives and affiliates to market to hospitals, doctors, and other healthcare providers, primarily in the U.S. Our partnership with 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 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. Extremity Fixation distributes its products through a network of distributors, sales representatives, and affiliates. This SBU uses both distributors and direct sales representatives to sell orthopedics 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 and affiliates. This SBU uses distributors and direct sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Corporate

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

External Net Sales by SBU:

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

	External Net Sales by SBU Year ended December 31,					
(U.S. Dollars in thousands)	**2013**		**2012**		**2011**	
	Net Sales	**Percent of Total Net Sales**	**Net Sales**	**Percent of Total Net Sales**	**Net Sales**	**Percent of Total Net Sales**

			(Restated)	(Restated)	(Restated)	(Restated)
BioStim	$ 147,910	37%	$ 181,959	41%	$ 188,136	43%
Biologics	53,769	13%	53,730	12%	42,919	10%
Extremity Fixation	103,385	26%	112,009	25%	119,521	27%
Spine Fixation	95,470	24%	99,883	22%	91,395	20%
Total Net Sales	$ 400,534	100%	$ 447,581	100%	$ 441,971	100%

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The table below presents net margin, defined as gross profit less sales and marketing expenses from continuing operations by SBU reporting segment:

Net Margin by SBU	Year Ended December 31,		
(U.S. Dollars in thousands)	2013	2012 (Restated)	2011 (Restated)
Net Margin			
BioStim	$ 64,930	$ 86,654	$ 93,056
Biologics	24,532	23,559	18,979
Extremity Fixation	26,389	34,337	29,530
Spine Fixation	7,245	19,142	13,068
Corporate	(1,443)	(1,495)	(1,700)
Total net margin	$ 121,653	$ 162,197	$ 152,933
General & administrative	65,147	53,391	64,481
Research and development	26,768	28,577	22,861
Amortization of intangible assets	2,687	2,298	2,550
Costs related to the accounting review and restatement	12,945		
Impairment of goodwill	19,193		
Charges related to U.S. Government resolutions		1,295	57,141
Operating (loss) income	$ (5,087)	$ 76,636	$ 5,900

The following table presents depreciation and amortization for continuing operations by SBU reporting segment:

	Depreciation and amortization by SBU Year Ended December 31,		
(U.S. Dollars in thousands)	2013	2012 (Restated)	2011 (Restated)
BioStim	$ 1,946	$ 1,584	$ 2,033
Biologics	628	543	415
Extremity Fixation	7,195	5,196	5,148
Spine Fixation	12,794	10,752	9,211
Corporate	96	70	53
Total	$ 22,659	$ 18,145	$ 16,860

Geographical information

The following geographic data includes net sales by geographic destination:

(U.S. Dollars in thousands)	2013	2012 (Restated)	2011 (Restated)
U.S.	$ 295,857	$ 334,624	$ 328,585
International:			
U.K.	10,002	8,431	8,206
Italy	16,755	18,742	17,447
Brazil	26,786	31,166	34,424
Other	51,134	54,618	53,309
Total international	104,677	112,957	113,386
Total net sales	$ 400,534	$ 447,581	$ 441,971

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Analysis of property, plant and equipment by geographic area:

(U.S. Dollars in thousands)	2013	2012 (Restated)
U.S.	$ 39,858	$ 39,554
Italy	7,813	7,617
U.K.	1,871	1,402
Brazil	3,210	3,421
Others	1,854	1,841
Total	$ 54,606	$ 53,835

14. Income taxes

The provision for (benefit from) income taxes on continuing operations in the accompanying consolidated statements of operations consists of the following:

(US$ in thousands)	Year Ended December 31, 2013	2012 (Restated)	2011 (Restated)
U.S.			
Current	$ 2,914	$ 17,897	$ 25,148
Deferred	5,716	1,788	(12,657)
Total U.S	8,630	19,685	12,491
Non-U.S.			
Current	2,355	4,609	2,735
Deferred	(869)	844	(1,061)
	1,486	5,453	1,674
Total tax expense	$ 10,116	$ 25,138	$ 14,165

The tax effects of the significant temporary differences, which comprise the deferred tax assets and liabilities and assets, are as follows:

(US$ in thousands)	2013	2012 (Restated)
Intangible assets and goodwill	$ 4,978	$ 5,346
Inventories and related reserves	14,678	14,020

Deferred revenue and cost of sales	9,669	11,682
Other accruals and reserves	3,200	3,868
Accrued compensation	3,880	3,817
Allowance for doubtful accounts	4,429	3,718
Accrued interest	17,775	18,229
Net operating loss carryforwards	34,215	27,231
Other, net	621	539
	93,445	88,450
Valuation allowance	(31,472)	(26,361)
Deferred tax asset	$ 61,973	$ 62,089
Withholding taxes	(13,132)	(11,456)
Property, plant and equipment	(9,690)	(9,758)
Deferred tax liability	(22,822)	(21,214)
Net deferred tax assets	$ 39,151	$ 40,875

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The valuation allowance as of December 31, 2013 and 2012 was $31.5 million and $26.4 million, respectively. The net increase in the valuation allowance of $5.1 million during the year principally relates to certain current period foreign losses not benefitted and certain state net operating losses and tax credits. The valuation allowance is attributable to net operating loss carryforwards and certain temporary differences in certain foreign jurisdictions, the benefit for which is dependent upon the generation of future taxable income in those foreign jurisdictions. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not the Company will realize the benefits of these temporary differences, net of the existing valuation allowances at December 31, 2013.

The Company has state net operating loss carryforwards of approximately $22.8 million, a portion of which began to expire in 2013. The Company has net operating losses of foreign taxing jurisdictions of approximately $121.7 million. The majority of the foreign losses relates to the Company s Netherlands operations, a portion of which began to expire in 2013. The Company has provided a valuation allowance against a significant portion of these state and foreign net operating loss carryforwards since it does not believe that this deferred tax asset can be realized prior to expiration.

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

(U.S. Dollars in thousands, except percentages)	2013		2012		2011	
	Amount	Percent	Amount (Restated)	Percent (Restated)	Amount (Restated)	Percent (Restated)
Statutory U.S. federal income tax rate	$ (1,677)	35.0 %	$ 24,565	35.0 %	$ (719)	35.0 %
State taxes, net	2,744	(57.3)	1,708	2.4	1,896	(92.4)
Foreign rate differential	(626)	13.1	(3,115)	(4.4)	1,585	(77.2)
Valuation allowance foreign losses	3,913	(81.7)	6,183	8.8	4,882	(237.8)
SRL intangible	(2,288)	47.8	(2,214)	(3.2)	(2,421)	117.9
Goodwill impairment	6,452	(134.7)				
Domestic manufacturing deduction	(233)	4.9	(1,694)	(2.4)	(1,703)	82.9
Withholding taxes	1,679	(35.0)	1,679	2.4	1,676	(81.6)
Settlement of U.S. Government resolutions			(1,260)	(1.8)	9,520	(463.7)
Other items, net	152	(3.2)	(714)	(1.0)	(551)	26.9
Income tax expense/effective rate	$ 10,116	(211.1)%	$ 25,138	35.8 %	$ 14,165	(690.0)%

The income tax expense and effective tax rate for the year ended 2013 reflects a disproportionate ratio to the $25.1 million of income tax expense and effective tax rate of 35.8% for the year ended 2012. The principal factors affecting the Company s effective tax rate was the company s mix of earnings amongst various tax jurisdictions, state taxes, and the impairment of $19.2 million in non-deductable goodwill. For the years ended 2012 and 2011, the Company did not record tax benefit on certain expenses associated with the Company s estimate of the charges related to U.S. Government resolutions.

On January 2, 2013, the American Taxpayer Relief Act of 2012 (Act) was enacted. The Act provides tax relief for businesses by reinstating certain tax benefits and credits retroactively to January 1, 2012. There are several provisions of the Act that impact the Company, most notably the extension of the Research and

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Development credit. Income tax accounting rules require tax law changes to be recognized in the period of enactment; as such, the Company recognized a tax benefit of $0.3 million in its provision for income taxes in the first quarter of 2013.

The Company s unrecognized tax benefit was $0.7 million and $1.2 million for the years ended December 31, 2013 and 2012, respectively. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company had approximately $0.5 million and $0.8 million accrued for payment of interest and penalties as of December 31, 2013 and 2012, respectively.

The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company s effective tax rate if recognized. As of December 31, 2013, the Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2013 and December 31, 2012 follows:

(US$ in thousands)	2013	2012 (Restated)
Balance as of January 1,	$ 1,189	$ 610
Additions for current year tax positions	183	793
Decreases for prior year tax positions	(12)	(106)
Settlements of prior year tax positions	(560)	
Expiration of statutes	(77)	(108)
Balance as of December 31,	$ 723	$ 1,189

The Company files a consolidated income tax return in the U.S. federal jurisdiction, the U.K., Italy and numerous consolidated and separate income tax returns in many state and other foreign jurisdictions. The statute of limitations with respect to federal tax authorities is closed for years prior to December 31, 2010. The statute of limitations for the various state tax filings is closed in most instances for the years prior to December 31, 2009. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to December 31, 2008.

The Company s intention is to reinvest the total amount of its unremitted foreign earnings (residing outside Curaçao) in the local jurisdiction, to the extent they are generated and available, or to repatriate the earnings only when tax-effective. 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 $292.0 million at December 31, 2012 to $345.2 million at December 31, 2013. The $345.2 million at December 31, 2013 includes $354.8 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. The Company does not anticipate any impact on income tax liabilities since earnings are permanently reinvested for both U.S and non-U.S. subsidiaries.

Total cash and cash equivalents at December 31, 2013 were $54.2 million, of which $23.7 million is restricted under the senior secured credit agreement for use in the U.S. and is therefore classified as restricted cash on the balance sheet. The Company s U.S. business generates sufficient cash flow and has borrowing capacity in the United States to fund its U.S. operations. Cash and cash equivalents of $30.5 million at December 31, 2013 was held by non-U.S. subsidiaries and is permanently reinvested for use in non-U.S. operations.

15. Related parties

In 2011, we sold $0.5 million in products to OrthoPro, Inc. and Superior Medical Equipment, who were independent distributors for Breg, Inc., and were owned by the son of a former board member.

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16. Sale of Breg and Disposition of Sports Medicine SBU

On April 23, 2012, the Company s subsidiary Orthofix Holdings and Breg entered into a stock purchase agreement (the SPA) with Breg Acquisition Corp. (Buyer), a newly formed affiliate of Water Street Healthcare Partners II, L.P., pursuant to which Buyer agreed to acquire from Orthofix Holdings all the outstanding shares of Breg, subject to the terms and conditions contained therein (the Transaction). Under the terms of the SPA, upon closing of the sale, Orthofix Holdings and the Company agreed to indemnify Buyer with respect to certain specified matters, including the government investigation and product liability matters regarding a previously owned infusion pump product line, and pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. (See Matters Related to the Company s former Breg Subsidiary and Possible Indemnification Obligations under Note 17.) On May 24, 2012 (the Closing Date), Orthofix Holdings completed the sale of all of the outstanding shares of Breg for $157.5 million in cash. After adjustments for working capital and indebtedness in accordance with the terms of the SPA, Orthofix Holdings used $145 million of the net proceeds to prepay outstanding Company indebtedness, as required by a lender consent received in connection with the Company s existing Credit Agreement. As a result of the closing of this Transaction, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. The Company also agreed to enter into certain transition arrangements at the closing, including a transition services agreement pursuant to which the Company agreed to continue to provide administrative operational support for a period of up to twelve months. As a result of the sale of Breg, the Company completed its exit from the Sports Medicine SBU, of which Breg was a significant component.

The portion of indemnification related to post closing claims related to post-closing sales of cold therapy has created a guarantee under ASC 460 Guarantees and the fair value of the liability has been recorded under the initial recognition criteria in the amount of $2 million at the Closing Date of the transaction. The Company amortizes the fair value of the noncontingent liability ratably over the period of indemnification which is three years. The Company s obligations under this guarantee were approximately $0.9 million and $1.6 million as of December 31, 2013 and December 31, 2012, respectively.

Gain on Sale of Discontinued Operations

The following table presents the value of the asset disposition, proceeds received, net of various working capital adjustments and indebtedness and net gain on sale of Breg as shown in the condensed consolidated statement of operations for the year ended December 31, 2012.

(U.S. Dollars in thousands)	Total
Cash proceeds	$ 157,500
Less:	
Working Capital	(7,093)
Transaction related expenses	(4,276)
Fair value of indemnification	(2,000)
Tangible assets	(8,309)
Intangible assets	(28,164)
Goodwill	(106,200)
Gain on sale of Breg	1,458
Income tax expense	(113)
Gain on sale of Breg, net of taxes	$ 1,345

The Sports Medicine SBU contributed $44 million and $108.9 million of net sales in the years ended December 31, 2012 and 2011, respectively. The Sports Medicine SBU had $2.9 million of operating losses and $1.2 million of operating income in the years ended December 31, 2012 and 2011, respectively. The financial information above includes the financial results of Breg operations up to the date of sale.

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The Company s consolidated financial statements and related footnote disclosures reflect the Sports Medicine SBU as discontinued operations. Income (loss) associated with the Sports Medicine SBU, net of applicable income taxes is shown as income (loss) from discontinued operations for all periods presented.

17. Contingencies

The Company is party to outstanding legal proceedings, investigations and claims as described below. The Company believes that it is unlikely that the outcome of each of these matters, including the matters discussed below, will have a material adverse effect on it and its subsidiaries as a whole, notwithstanding that the unfavorable resolution of any matter may have a material effect on the Company s net earnings (if any) in any particular quarter. However, the Company 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 it 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 the Company s consolidated financial position, results of operations, or cash flows.

The Company records 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. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

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 the Company considers 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, the Company s experience in similar matters and the experience of other companies, the facts available to the Company at the time of assessment, and how the Company intends to respond, or has responded, to the proceeding, investigation or claim. The Company s assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where the Company is not currently able to reasonably estimate the range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where the Company believes a reasonable estimate of loss, or range of loss, can be made. In such instances, the Company believes 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 its business, the Company is 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, the Company accrues appropriate amounts

in the accompanying financial statements and provides disclosures as to the possible range of loss in excess of the amount accrued, if such range is reasonably estimable. The Company believes losses are individually and collectively immaterial as to a possible loss and range of loss.

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Matters Related to the Audit Committee s Review and the Restatement of Certain of the Company s Consolidated Financial Statements

Audit Committee Review

In July 2013, the Audit Committee began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in the decision to restate certain of the Company s previously filed consolidated financial statements. As a result of this review and the restatement of certain of the Company s previously filed consolidated financial statements, the filing of the Company s Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2013 and September 30, 2013, and the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2013, were not timely. The Company filed its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 on March 24, 2014, and filed its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013 on March 25, 2014. The Company also has filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2013 on the date hereof.

SEC Enforcement Staff Review

In connection with the initiation of the Audit Committee s independent review, the Company initiated contact with the staff of the Division of Enforcement of the Securities and Exchange Commission (the SEC Enforcement Staff) in July 2013 to advise them of these matters. The Audit Committee, through its counsel, has been in direct communication with the SEC Enforcement Staff regarding these matters, and both the Company and the Audit Committee are cooperating fully with the SEC Enforcement Staff s review of these matters. The Company has received requests from the SEC Enforcement Staff for documents and other information concerning various accounting practices, internal controls and business practices. Such requests cover the years ended December 31, 2011 and 2012, and in some instances, prior periods. It is anticipated that the Company may receive additional requests from the SEC Enforcement Staff in the future. The Company has further provided notice concerning these matters to the Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG) pursuant to the Company s corporate integrity agreement with HHS-OIG (which agreement is described below in this Note 17).

The Company cannot predict if, when or how this matter will be resolved or what, if any, actions it 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 the Company and/or certain of its current and former officers, directors and employees. The matter is at an early stage and, at this time, the Company 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. In addition to the Company, Alan W. Milinazzo, the Company s former President and Chief Executive Officer, Robert S. Vaters, the Company s former President and Chief Executive Officer, Brian McCollum, the Company s former Chief Financial Officer, Bradley R. Mason, the Company s current President and Chief Executive Officer, and Emily Buxton, the Company s current Chief Financial Officer, are named as defendants. The operative complaint has not yet been filed in the action following the appointment by the court of a lead plaintiff. Accordingly, the allegations that the lead plaintiff ultimately intends to make in this action are unknown. The matter is at an early stage and, at this time, the Company cannot reasonably estimate the possible loss, or range of loss, in connection with it.

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Matters Related to Promeca

On July 10, 2012, the Company entered into definitive agreements with the DOJ and the SEC agreeing to settle its 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). Under the terms of these agreements, the Company voluntarily disgorged profits to the United States government in an amount of $5.2 million, inclusive of pre-judgment interest, and agreed to pay a fine of $2.2 million. The Company paid $2.2 million in July 2012 and $5.2 million in September 2012. As part of the settlement, the Company 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 has agreed not to pursue any criminal charges against the Company in connection with this matter if the Company complied with the terms of the DPA. The DPA takes note of the Company s self-reporting of this matter to DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by the Company. The DPA and the Consent collectively require, among other things, that with respect to anti-bribery compliance matters the Company 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, the Company has represented that it has 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. The Company will periodically report to the government during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, the Company also agreed pursuant to the Consent to certain reporting obligations to the SEC regarding the status of the Company s remediation and implementation of compliance measures. In the event that the Company fails to comply with these obligations, it could be subject to criminal prosecution by the DOJ for the FCPA-related matters we self-reported.

Review of Potential Improper Payments Involving Brazil Subsidiary

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. The Company engaged outside counsel to assist in the review of these matters, focusing on compliance with applicable anti-bribery laws, including the FCPA. This review remains ongoing. The FCPA and related provisions of law provide for potential criminal and civil sanctions in connection with anti-bribery violations, including criminal fines, civil penalties, disgorgement of past profits and other kinds of remedies. The Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this review.

Consistent with the provisions of the DPA and the Consent described above, the Company contacted the DOJ and the SEC in August 2013 to voluntarily self-report the Brazil-related allegations, and the Company and its counsel remain in contact with both agencies regarding the status of the review. In the event that the DOJ and the SEC find that the matters related to the Company s Brazilian subsidiary could give rise to a review of the Company s obligations under the terms of the DPA and/or the Consent, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with that review, including any effects it may have with respect to the DPA and the Consent.

Corporate Integrity Agreement with HHS-OIG

As previously disclosed, on June 6, 2012, the Company 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 the Company 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 the Company s regenerative stimulator devices (which the Company has also

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described in the past as its bone growth stimulator devices). In connection with such settlement agreement, Orthofix Inc., the Company s 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, the Company, through Blackstone, entered into a definitive settlement agreement with the U.S. government and the qui tam relator, pursuant to which the Company paid $32 million to settle claims (covering a period prior to Blackstone s acquisition by the Company) concerning the compensation of physician consultants and related matters. All of the $32 million we paid pursuant to such settlement was funded by proceeds the Company received from an escrow fund established in connection with its acquisition of Blackstone in 2006.

On June 6, 2012, in connection with these settlements, the Company also entered into a five-year corporate integrity agreement with HHS-OIG (the CIA). The CIA acknowledges the existence of the Company s current compliance program and requires that the Company continues to maintain during the term of the CIA a compliance program designed to promote compliance with federal healthcare and FDA requirements. The Company also is required to maintain several elements of its 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, the Company is 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. The Company is 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, the Company could be excluded from participation in federal healthcare programs and/or subject to monetary penalties.

Matters Related to the Company s Former Breg Subsidiary and Possible Indemnification Obligations

On May 24, 2012, the Company sold Breg to an affiliate of Water Street Healthcare Partners II, L.P. (Water Street) 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 (i) the government investigation and product liability matters regarding the previously owned infusion pump product line described below, and (ii) pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. The Company has established an accrual of $4.2 million for its indemnification obligations in connection with the July 2012 verdict described in the third paragraph below; however, actual liability in this case could be higher or lower than the amount accrued. The Company has not established any accrual in connection with its other indemnification obligations under the Breg SPA, and currently cannot reasonably estimate the possible loss, or range of loss, in connection with certain of such obligations (including with respect to the matters described in the three paragraphs below).

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 2011, 2012 and 2013

for $1.8 million, $6.8 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.

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On or about August 2, 2010, Breg received a HIPAA subpoena issued by the DOJ. The subpoena seeks documents from the Company and its subsidiaries for the period of January 1, 2000 through the date of the subpoena. The Company believes that document production in response to the subpoena was completed as of July 2012. It believes that this subpoena relates to an investigation by the DOJ into whether Breg s sale, marketing and labeling of local infusion pumps for pain management, prior to Breg s divestiture of this product line in 2008, complied with FDA regulations and federal law. The Company is currently cooperating with the U.S. government in connection with this matter.

At the time of its divestiture by the Company, 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 that 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. The majority of these cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, the Company believes that meritorious defenses exist to these claims. In July 2012, a jury in one case related to a motorized cold therapy unit previously sold by Breg returned a verdict providing for approximately $2.1 million in compensatory damages to the plaintiff against Breg and $7 million in exemplary damages. The case remains subject to appeal. The Company believes that the damages are without merit; however, the ultimate outcome is uncertain. The Company previously established an accrual and related charge to discontinued operations of $4.2 million for both compensatory damages and exemplary damages for its indemnification obligations in connection with this July 2012 verdict; however, actual liability in this case could be higher or lower than the amount accrued.

18. Pensions and deferred compensation

Orthofix Inc. sponsors a defined contribution plan (the Orthofix Inc. 401(k) Plan) covering substantially all full time US employees. The Orthofix Inc. 401(k) Plan allows for participants to contribute up to 15% of their pre-tax compensation, subject to certain limitations, with the Company matching 100% of the first 2% of the employee s base compensation and 50% of the next 4% of the employee s base compensation if contributed to the Orthofix Inc. 401(k) Plan. During the years ended December 31, 2013, 2012 and 2011, expenses incurred relating to 401(k) Plans, including matching contributions, were approximately $2.4 million, $2.5 million and $2.5 million, respectively.

The Company operates defined contribution pension plans for its other International employees not described above meeting minimum service requirements. The Company s expenses for such pension contributions during 2013, 2012 and 2011 were $0.7 million, $0.7 million and $0.8 million, respectively.

Under Italian Law, Orthofix S.r.l. accrues, on behalf of its employees, deferred compensation, which is paid on termination of employment. Each year s provision for deferred compensation is based on a percentage of the employee s current annual remuneration plus an annual charge. Deferred compensation is also accrued for the leaving indemnity payable to agents in case of dismissal which is regulated by a national contract and is equal to approximately 3.5% of total commissions earned from the Company.

The Orthofix Deferred Compensation Plan (the Plan), administered by the Board of Directors of the Company, effective January 1, 2007, and as amended and restated effective January 1, 2009, is a plan intended to allow a select group of key management and highly compensated employees of the Company to defer the receipt of compensation that would otherwise be payable to them. The terms of this plan are intended to comply in all respects with the provisions of Code Section 409A and Code Section 457A. As of January 1, 2011 the Company disallowed further contributions into the plan and any new plan participants. Distributions are made in accordance with the requirements

of Code Section 409A.

The Company s expense for deferred compensation during 2013, 2012 and 2011 was approximately $0.3 million, $0.4 million and $0.1 million, respectively. Deferred compensation payments of $0.1 million and $0.8 million were made in 2013 and 2012, respectively, and no deferred compensation payments were made in 2011.

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The balance as of December 31, 2013 and 2012 was $2.5 and $2.3 million that represents the amount which would be payable if all the employees and agents had terminated employment at that date and is included in other long-term liabilities.

19. Share-based compensation plans

At December 31, 2013, the Company had stock option and award plans, and an employee stock purchase plan which are described below.

2012 Long Term Incentive Plan

The Board of Directors adopted the Orthofix International N.V. 2012 Long-Term Incentive Plan (the 2012 LTIP) on April 13, 2012, subject to shareholder approval which was subsequently provided by shareholder ratification. The 2012 LTIP provides for the grant of options to purchase shares of the Company s common stock, stock awards (including restricted stock, unrestricted stock, and stock units), stock appreciation rights, performance-based awards and other equity-based awards. All of the Company s employees and the employees of the Company s subsidiaries and affiliates are eligible to receive awards under the 2012 LTIP. In addition, the Company s non-employee directors and consultants and advisors who perform services for the Company and the Company s subsidiaries and affiliates may receive awards under the 2012 LTIP. Incentive share options, however, are only available to the Company s employees. The Company reserves a total of 1,600,000 shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2013, there were 515,917 options outstanding under the 2012 LTIP Plan, of which 22,668 were exercisable; in addition, there were 279,039 shares of restricted stock outstanding, none of which were vested.

2004 Long Term Incentive Plan

The 2004 Long Term Incentive Plan (the 2004 LTIP Plan) reserves 3.1 million shares for issuance (in addition to shares (i) available for future awards as of June 29, 2004 under prior plans or (ii) that become available for future issuance upon the expiration or forfeiture after June 29, 2004 of awards upon prior plans). Awards generally vest on years of service with all awards fully vesting within three years from the date of grant for employees and either three or five years from the date of grant for non-employee directors. Awards can be in the form of a stock option, restricted stock, restricted share unit, performance share unit, or other award form determined by the Board of Directors. Awards granted under the 2004 LTIP Plan expire no later than ten years after the date of the grant. The 2004 LTIP Plan provides an annual grant to non-employee directors of 5,000 shares and limits the future the number of shares that may be awarded under the plan as full value awards to 100,000 shares. At December 31, 2013, there were 1,243,262 options outstanding under the 2004 LTIP Plan, of which 1,179,601 were exercisable; in addition, there were 7,665 shares of restricted stock outstanding, none of which were vested.

Staff Share Option Plan

The Staff Share Stock Option Plan (the Staff Share Plan) is a fixed stock option plan which was adopted in April 1992. Under the Staff Share Plan, the Company granted options to its employees at the estimated fair market value of such options at the date of grant. Options generally vest based on years of service with all options to be fully vested within five years from date of grant. Options granted under the Staff Share Plan expire ten years after the date of grant. There are no options left to be granted under the Staff Plan. At December 31, 2013, there were 15,000 options outstanding and exercisable under the Staff Share Plan.

Stock Purchase Plan

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

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During each purchase period, eligible employees may designate between 1% and 25% of their compensation to be deducted for the purchase of common stock under the plan (up to 25% for employees working in North America, South America and Asia, and up to 15% for employees working in Europe). For eligible directors, the designated percentage will be an amount equal to his or her annual or other director compensation paid in cash for the current plan year. The purchase price of the shares under the plan is equal to 85% of the fair market value on the first day of the plan year (which is a calendar year, running from January 1 to December 31) or, if lower, on the last day of the plan year.

Due to the compensatory nature of such plan, the Company has recorded the related share based compensation in the consolidated statement of operations. The aggregate number of shares reserved for issuance under the Employee Stock Purchase Plan is 1,850,000 shares. As of December 31, 2013, 1,437,519 shares had been issued under the Stock Purchase Plan.

Share-Based Compensation:

As of December 31, 2013, the unamortized compensation expense relating to options granted and expected to be recognized was $2.8 million. This amount is expected to be recognized through January 2018. The following table shows the detail of share-based compensation by line item in the consolidated statements of operations for the years ended December 31, 2013, 2012 and 2011 and the assumptions for each of these years in which grants were awarded:

(U.S. Dollars in thousands, except assumptions)	**Year Ended December 31, 2013**	**Year Ended December 31, 2012**	**Year Ended December 31, 2011**
Cost of sales	$ 104	$ 592	$ 153
Sales and marketing	1,444	1,550	2,031
General and administrative	4,483	4,023	4,322
Research and development	236	138	142
Total	$ 6,267	$ 6,303	$ 6,648
Assumptions:			
Expected term	5.00 years	4.50 years	4.58 years
Expected volatility	32.1% 50.8%	50.9% 51.8%	49.6% 49.9%
Risk free interest rate	0.58% 1.52%	0.76% 0.84%	.90% 2.26%
Dividend rate			
Weighted average fair value of options granted during the year	$ 10.83	$ 16.99	$ 14.21

Stock Option Activity:

Summaries of the status of the Company s stock option plans as of December 31, 2013 and 2012 and changes during the year ended December 31, 2013 are presented below:

	Options	**Weighted Average Exercise Price**	**Weighted Average**

				Remaining Contractual Term
Outstanding at December 31, 2012	1,945,955	$	34.50	
Granted	466,250	$	28.51	
Exercised	(79,949)	$	23.25	
Forfeited	(408,077)	$	36.33	
Outstanding at December 31, 2013	1,924,179	$	33.12	4.41
Vested and expected to vest at December 31, 2013	1,839,383	$	33.50	4.17
Options exercisable at December 31, 2013	1,367,269	$	34.35	2.89

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Outstanding and exercisable by price range as of December 31, 2013

Range of Exercise Prices		Options Outstanding Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Options Exercisable Number Exercisable	Weighted Average Exercise Price
$10.42	$21.78	232,250	9.31	$ 20.79	16,000	$ 13.31
$22.75	$25.05	326,166	4.10	$ 24.73	306,166	$ 24.84
$26.79	$28.95	230,000	4.79	$ 28.45	170,000	$ 28.65
$29.23	$37.36	225,168	5.10	$ 33.14	169,839	$ 32.41
$37.76	$38.11	230,975	1.69	$ 37.99	230,975	$ 37.99
$38.40	$40.27	351,354	3.17	$ 39.76	174,355	$ 39.77
$41.33	$43.04	178,633	2.84	$ 41.66	150,301	$ 41.72
$44.87	$45.84	140,133	3.05	$ 45.02	140,133	$ 45.02
$50.50	$50.50	2,000	3.01	$ 50.50	2,000	$ 50.50
$50.99	$50.99	7,500	3.04	$ 50.99	7,500	$ 50.99
$10.42	$50.99	1,924,179	4.41	$ 33.12	1,367,269	$ 34.35

The weighted average remaining contractual life of exercisable options was 2.89 years at December 31, 2013. The total intrinsic value of options exercised was $0.4 million, $7.2 million and $4.2 million for the years ended December 31, 2013, 2012 and 2011, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2013 is calculated as the difference between the exercise price of the underlying options and the market price of the Company s common stock for the shares that had exercise prices that were lower than the $22.82 closing price of the Company s stock on December 31, 2013. The aggregate intrinsic value of options outstanding was $0.5 million, $11.2 million and $10.8 million for the years ended December 31, 2013, 2012, and 2011, respectively. The aggregate intrinsic value of options exercisable was $0.2 million, $9.8 million and $8.4 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Restricted Stock:

During the year ended December 31, 2013, the Company granted to employees and non-employee directors 269,791 shares of restricted stock, which vest at various dates through October 2017. During the year ended December 31, 2012, the Company granted to employees and non-employee directors 149,500 shares of restricted stock, which vest at various dates through November 2015. The compensation expense, which represents the fair value of the stock measured at the market price at the date of grant, less estimated forfeitures, is recognized on a straight-line basis over the vesting period. Unamortized compensation expense related to restricted stock amounted to $6.7 million at December 31, 2013.

A summary of the status of our restricted stock as of December 31, 2013 and 2012 and changes during the year ended December 31, 2013 are presented below:

	Shares	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2012	160,831	$ 38.34
Granted	269,791	$ 27.09
Vested	(62,948)	$ 36.58
Cancelled	(80,970)	$ 38.80
Non-vested as of December 31, 2013	286,704	$ 28.01

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20. Earnings per share

For each of the three years ended December 31, 2013, there were no adjustments to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net income (loss) per common share computations.

	Year Ended December 31,		
	2013	2012	2011
Weighted average common shares-basic	18,697,228	18,977,263	18,219,343
Effect of diluted securities:			
Unexercised stock options net of treasury share repurchase		413,150	
Weighted average common shares-diluted	18,697,228	19,390,413	18,219,343

No adjustment has been made in 2013 or 2011 for any common stock equivalents because their effects would be anti-dilutive. For 2013 and 2011, potentially dilutive shares totaled 101,672 and 344,168, respectively.

Options to purchase shares of common stock with exercise prices in excess of the average market price of common shares are not included in the computation of diluted earnings per share. There were 1,186,259 and 789,650 outstanding options not included in the diluted earnings per share computation for the fiscal year ended December 31, 2013 and 2012, respectively, because the inclusion of these options was anti-dilutive.

21. Stock Repurchase Program

On May 8, 2013, the Company announced that the Board of Directors had authorized a share repurchase program in an amount up to $50 million. Repurchases began on May 10, 2013 consisting 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. Repurchases are being made from cash on hand, cash generated from operations and additional borrowings. The timing of the transactions and the aggregate number of shares of common stock that will be ultimately repurchased under the repurchase program will depend on a variety of factors, including market conditions and the prices at which the securities are repurchased. The Company may discontinue repurchases without prior notice at any time if the Company determines additional repurchases are not warranted. The Company made total repurchases in 2013 of $39.5 million.

22. Quarterly financial data (unaudited)

We have restated all quarterly periods of 2012 as well as the first quarter of 2013, to reflect the restatement described herein. See Note 2 Restatement of the Consolidated Financial Statements. The following tables summarize the impacts of the restatement on our previously reported condensed consolidated statements of operations and balance sheets included in our Quarterly Reports on Form 10-Q for each respective period.

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Condensed Consolidated Statement of Operations

As Restated or Currently Reported

(U.S. Dollars, in thousands, except per share data)

	1st Quarter (Restated)	2nd Quarter	3rd Quarter	4th Quarter	Year
2013					
Net sales	$ 103,373	$ 98,280	$ 92,738	$ 106,143	$ 400,534
Cost of sales	25,617	20,246	23,920	32,517	102,300
Gross profit	77,756	78,034	68,818	73,626	298,234
Operating Expense	69,669	69,230	84,418	80,004	303,321
Operating Income (loss)	8,087	8,804	(15,600)	(6,378)	(5,087)
Net income (loss) from continuing operations	7,610	4,130	(18,084)	(8,564)	(14,908)
Net income (loss)	$ 4,500	$ (2,317)	$ (19,822)	$ (7,876)	$ (25,515)
Net income (loss) per common share:					
Basic:					
Net income (loss) from continuing operations	$ 0.39	$ 0.22	$ (1.00)	$ (0.47)	$ (0.80)
Net income (loss)	$ 0.23	$ (0.12)	$ (1.10)	$ (0.43)	$ (1.37)
Diluted:					
Net income (loss) from continuing operations	$ 0.39	$ 0.21	$ (1.00)	$ (0.47)	$ (0.80)
Net income (loss)	$ 0.23	$ (0.12)	$ (1.10)	$ (0.43)	$ (1.37)

	(Restated)	(Restated)	(Restated)	(Restated)	(Restated)
2012					
Net sales	$ 108,936	$ 113,423	$ 107,857	$ 117,365	$ 447,581
Cost of sales	21,378	27,547	24,384	24,944	98,253
Gross profit	87,558	85,876	83,473	92,421	349,328
Operating Expense	69,638	71,578	64,668	66,808	272,692
Operating Income	17,920	14,298	18,805	25,613	76,636
Net income from continuing operations	8,597	9,870	10,574	16,009	45,050
Net income	$ 9,407	$ 7,254	$ 5,016	$ 21,161	$ 42,838
Net income (loss) per common share:					
Basic:					
Net income from continuing operations	$ 0.46	$ 0.52	$ 0.55	$ 0.83	$ 2.37

Net income	$ 0.50	$ 0.38	$ 0.26	$ 1.10	$ 2.25
Diluted:					
Net income from continuing operations	$ 0.45	$ 0.51	$ 0.54	$ 0.81	$ 2.32
Net income	$ 0.49	$ 0.37	$ 0.25	$ 1.07	$ 2.21

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Condensed Consolidated Statement of Operations

As Previously Reported

(U.S. Dollars, in thousands, except per share data)

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
2013 (1)					
Net sales	$ 100,254				
Cost of sales	22,699				
Gross profit	77,555				
Operating Expense	73,531				
Operating Income	4,024				
Net income from continuing operations	4,908				
Net income	$ 2,116				
Net income (loss) per common share:					
Basic:					
Net income from continuing operations	$ 0.25				
Net income	$ 0.11				
Diluted:					
Net income from continuing operations	$ 0.25				
Net income	$ 0.11				
2012					
Net sales	$ 116,041	$ 119,492	$ 114,752	$ 112,035	$ 462,320
Cost of sales	21,939	23,676	22,373	18,504	86,492
Gross profit	94,102	95,816	92,379	93,531	375,828
Operating Expense	71,671	75,251	70,846	69,050	286,818
Operating Income	22,431	20,565	21,533	24,481	89,010
Net income from continuing operations	12,215	13,967	13,118	14,636	53,936
Net income	$ 12,016	$ 11,205	$ 7,560	$ 20,514	$ 51,295
Net income (loss) per common share:					
Basic:					
Net income from continuing operations	$ 0.65	$ 0.74	$ 0.69	$ 0.76	$ 2.84
Net income	$ 0.64	$ 0.59	$ 0.40	$ 1.06	$ 2.70
Diluted:					

Net income from continuing operations	$ 0.64	$ 0.73	$ 0.67	$ 0.74	$ 2.78
Net income	$ 0.63	$ 0.58	$ 0.39	$ 1.04	$ 2.64

(1) Q2-Q4 2013 was not previously reported.

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Condensed Consolidated Statement of Operations

Restatement Adjustments

(U.S. Dollars, in thousands, except per share data)

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
2013 (1)					
Net sales	$ 3,119				
Cost of sales	2,918				
Gross profit	201				
Operating Expense	(3,862)				
Operating Income	4,063				
Net income from continuing operations	2,702				
Net income	$ 2,384				
Net income (loss) per common share:					
Basic:					
Net income from continuing operations	$ 0.14				
Net income	$ 0.12				
Diluted:					
Net income from continuing operations	$ 0.14				
Net income	$ 0.12				
2012					
Net sales	$ (7,105)	$ (6,069)	$ (6,895)	$ 5,330	$ (14,739)
Cost of sales	(561)	3,871	2,011	6,440	11,761
Gross profit	(6,544)	(9,940)	(8,906)	(1,110)	(26,500)
Operating Expense	(2,033)	(3,673)	(6,178)	(2,242)	(14,126)
Operating Income	(4,511)	(6,267)	(2,728)	1,132	(12,374)
Net income (loss) from continuing operations	(3,618)	(4,097)	(2,544)	1,373	(8,886)
Net (loss) income	$ (2,609)	$ (3,951)	$ (2,544)	$ 647	$ (8,457)
Net income (loss) per common share:					
Basic:					
Net income (loss) from continuing operations	$ (0.19)	$ (0.22)	$ (0.14)	$ 0.07	$ (0.47)
Net income (loss)	$ (0.14)	$ (0.21)	$ (0.14)	$ 0.04	$ (0.45)
Diluted:					

Net income (loss) from continuing operations	$ (0.19)	$ (0.22)	$ (0.13)	$ 0.07	$ (0.46)
Net income (loss)	$ (0.14)	$ (0.21)	$ (0.14)	$ 0.03	$ (0.43)

(1) Q2-Q4 2013 was not previously reported and therefore does not have restatement adjustments.

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Condensed Consolidated Balance Sheets

As Restated or Currently Reported

(U.S. Dollars, in thousands, except share and per share data)	1st Quarter (Restated)	2nd Quarter	3rd Quarter	4th Quarter
2013				
Total assets	$ 475,758	$ 459,450	$ 430,058	$ 423,182
Total liabilities	102,366	114,223	111,001	112,688
Total shareholders equity	373,392	345,227	319,057	310,494
Total liabilities and shareholders equity	$ 475,758	$ 459,450	$ 430,058	$ 423,182
2012	**(Restated)**	**(Restated)**	**(Restated)**	**(Restated)**
Total assets	$ 694,106	$ 530,395	$ 539,566	$ 472,897
Total liabilities	381,734	205,196	193,599	105,065
Total shareholders equity	312,372	325,199	345,967	367,832
Total liabilities and shareholders equity	$ 694,106	$ 530,395	$ 539,566	$ 472,897

Condensed Consolidated Balance Sheets

As Previously Reported

(U.S. Dollars, in thousands, except share and per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2013 (1)				
Total assets	$ 503,380			
Total liabilities	101,212			
Total shareholders equity	402,168			
Total liabilities and shareholders equity	$ 503,380			
2012				
Total assets	$ 707,586	$ 553,320	$ 565,073	$ 504,281

Total liabilities	369,178	199,104	187,463	105,183
Total shareholders equity	338,408	354,216	377,610	399,098
Total liabilities and shareholders equity	$ 707,586	$ 553,320	$ 565,073	$ 504,281

(1) Q2-Q4 2013 was not previously reported.

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Condensed Consolidated Balance Sheets

Restatement Adjustments

(U.S. Dollars, in thousands, except share and per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2013 (1)				
Total assets	$ (27,622)			
Total liabilities	1,154			
Total shareholders equity	(28,776)			
Total liabilities and shareholders equity	$ (27,622)			
2012				
Total assets	$ (13,480)	$ (22,925)	$ (25,507)	$ (31,384)
Total liabilities	12,556	6,092	6,136	(118)
Total shareholders equity	(26,036)	(29,017)	(31,643)	(31,266)
Total liabilities and shareholders equity	$ (13,480)	$ (22,925)	$ (25,507)	$ (31,384)

(1) Q2-Q4 2013 was not previously reported and therefore does not have restatement adjustments.

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Orthofix International N.V.

Schedule 1 Condensed Financial Information of Registrant Orthofix International N.V.

Condensed Balance Sheets (unaudited)

(U.S. Dollars in thousands)	December 31, 2013	December 31, 2012 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 1,426	$ 7,392
Prepaid expenses and other current assets	670	534
Total current assets	2,096	7,926
Other long term assets		15
Investments in and amounts due from subsidiaries and affiliates	322,804	369,204
Total assets	$ 324,900	$ 377,145
Liabilities and shareholder s equity		
Current liabilities	$ 6,295	$ 1,202
Long-term liabilities	8,111	8,111
Shareholder s equity:		
Common stock	1,810	1,934
Additional paid in capital	216,653	246,306
Accumulated earnings	89,332	114,847
Accumulated other comprehensive income	2,699	4,745
	310,494	367,832
Total liabilities and shareholder s equity	$ 324,900	$ 377,145

See accompanying notes to condensed financial statements.

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Orthofix International N.V.

Schedule 1 Condensed Financial Information of Registrant Orthofix International N.V.

Condensed Statements of Operations (unaudited)

(U.S. Dollars in thousands)	Year Ended December 31, 2013	Year Ended December 31, 2012 (Restated)	Year Ended December 31, 2011 (Restated)
(Expenses) income:			
General and administrative	$ (16,641)	$ (7,700)	$ (11,134)
Equity in earnings of investments in subsidiaries and affiliates	(9,197)	50,317	(6,296)
Other, net	323	24	7
(Loss) income before income taxes	(25,515)	42,641	(17,423)
Income tax benefit (expense)		197	(687)
Net (loss) income	$ (25,515)	$ 42,838	$ (18,110)

See accompanying notes to condensed financial statements.

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Orthofix International N.V.

Schedule 1 Condensed Financial Information of Registrant Orthofix International N.V.

Condensed Statement of Cash Flows (unaudited)

(U.S. Dollars in thousands)	Year Ended December 31, 2013	Year Ended December 31, 2012 (Restated)	Year Ended December 31, 2011 (Restated)
Net income (loss)	$ (25,515)	$ 42,838	$ (18,110)
Equity in earnings of (loss) investments in subsidiaries and affiliates	9,197	(50,317)	6,296
Cash used in provided by other operating activities	468	(6,811)	3,429
Net cash used in operating activities	(15,850)	(14,290)	(8,385)
Cash flows from investing activities:			
Distributions and amounts received from subsidiaries	53,389	12,564	5,875
Capital expenditures			
Net cash used in provided by investing activities	53,389	12,564	5,875
Cash flows from financing activities:			
Net proceeds from issuance of common stock	3,450	25,586	20,113
Repurchase of treasury shares	(39,494)		
Contributions to subsidiaries and affiliates	(7,543)	(36,921)	(2,789)
Tax benefit on exercise of stock options	82	1,020	1,737
Net cash provided by financing activities	(43,505)	(10,315)	19,061
Net increase (decrease) in cash and cash equivalents	(5,966)	(12,041)	16,551
Cash and cash equivalents at the beginning of the year	7,392	19,433	2,882
Cash and cash equivalents at the end of the year	$ 1,426	$ 7,392	$ 19,433

See accompanying notes to condensed financial statements.

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Orthofix International N.V.

Schedule 1 Condensed Financial Information of Registrant Orthofix International N.V.

Notes to Condensed Financial Statements (unaudited)

1. Background and basis of presentation

These condensed parent company financial statements have been prepared in accordance with Rule 12-04, Schedule 1 of Regulation S-X, as the restricted net assets of Orthofix Holdings, Inc. and its subsidiaries exceed 25% of the consolidated net assets of Orthofix International N.V. and its subsidiaries (the Company). This information should be read in conjunction with the Company s consolidated financial statements included elsewhere in this filing.

2. Restricted net assets of subsidiaries

Certain of the Company s subsidiaries have restrictions on their ability to pay dividends or make intercompany loans and advances pursuant to their financing arrangements. The amount of restricted net assets the Company s subsidiaries held at December 31, 2013 and 2012 was approximately $192.0 million and $213.4 million, respectively. Such restrictions are on net assets of Orthofix Holdings, Inc. and its subsidiaries.

3. Commitments, contingencies and long-term obligations

For a discussion of the Company s commitments, contingencies and long term obligations under its senior secured credit facility, see Note 9, Note 12 and Note 17 of the Company s consolidated financial statements.

4. Dividends from subsidiaries

Orthofix International N.V. did not receive cash dividends in 2013 or 2012.

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Orthofix International N.V.

Schedule 2 Valuation and Qualifying Accounts

For the years ended December 31, 2013, 2012 and 2011:

(U.S. Dollars in thousands) Provisions from assets to which they apply:	Balance at beginning of year	Additions Charged to cost and expenses	Additions Charged (credited) to other accounts	Deductions/ Other	Balance at end of year
2013					
Allowance for doubtful accounts receivable	$ 13,543	$ 6,003		$ (7,577)	$ 11,969
Deferred tax valuation allowance	26,361	5,111			31,472
2012 (Restated)					
Allowance for doubtful accounts receivable	$ 9,341	$ 10,387	$ (13)	$ (6,172)	$ 13,543
Deferred tax valuation allowance	19,124	7,237			26,361
2011 (Restated)					
Allowance for doubtful accounts receivable	$ 6,542	$ 12,879	$ (501)	$ (9,579)	$ 9,341
Deferred tax valuation allowance	21,023	(1,899)			19,124