ORTHOFIX INTERNATIONAL N V
Form 10-K/A
March 31, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K/A

(Amendment No. 1)

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	**N/A**
(Address of principal executive offices)	**(Zip Code)**

599-9-4658525

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.10 par value	**Nasdaq Global Select Market**
(Title of Class)	**(Name of Exchange on Which Registered)**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ¨ No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No x

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 fiscal quarter ended June 28, 2013, as reported by the Nasdaq Global Select Market, was approximately $497.5 million.

As of March 27, 2015, 18,754,831 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant s Definitive Proxy Statement filed with the Commission on April 30, 2014 in connection with the 2014 Annual General Meeting of Shareholders are incorporated by reference in Part III of this report.

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Orthofix International N.V.

Form 10-K/A 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 amendment (this Amendment or Form 10-K/A) to its Annu Report on Form 10-K for the fiscal year ended December 31, 2013, which was originally filed on March 31, 2014 (the Original Form 10-K). The Original Form 10-K reflected and described 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 addition, the Original Form 10-K included restated consolidated financial information for the fiscal years ended December 31, 2010 and 2009 in Part II, Item 6, Selected Financial Data. The error corrections contained in these restated financial statements, which we refer to herein as the Original Restatement, were prepared following an independent review by the Audit Committee (the Audit Committee) of the Company s Board of Directors into certain accounting matters (the Independent Review), which is further described herein.

In connection with the Company s preparation of its consolidated interim quarterly financial statements for the fiscal quarter ended June 30, 2014, the Company determined that certain manual journal entries with respect to the previously filed financial statements contained in the Original Form 10-K were not properly accounted for under U.S. generally accepted accounting principles (U.S. GAAP). As further described below, these additional errors affect the fiscal years ended December 31, 2013, 2012 and 2011, as well as the fiscal quarter ended March 31, 2014 and other prior periods. Due to these errors, the Company determined in August 2014 to restate its consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011 (including the interim quarterly periods contained within the fiscal years ended December 31, 2013 and 2012) and the fiscal quarter ended March 31, 2014, and that the previously filed consolidated financial statements for these periods (including those contained in the Original Form 10-K) should no longer be relied upon. Contemporaneously with the filing of this Form 10-K/A, the Company is filing (i) an amendment to its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2014 (the 2014 First Quarter Form 10-Q/A), which amendment contains restated consolidated interim financial statements for the fiscal quarters ended March 31, 2014 and 2013, and (ii) its delayed Quarterly Reports on Form 10-Q for the fiscal quarters ended June 30, 2014 (the 2014 Second Quarter Form 10-Q) and September 30, 2014 (the 2014 Third Quarter Form 10-Q), which contain restated consolidated interim financial statements for the fiscal quarters ended June 30, 2013 and September 30, 2013, respectively. The corrections of the additional errors in this Form 10-K/A and the 2014 First Quarter Form 10-Q/A are referred to herein as the Further Restatement.

Description of the Further Restatement

The errors corrected by the Further Restatement are as follows:

A majority of revenue from the Company s BioStim SBU is derived from third parties, which is subject to change due to contractual adjustments related to commercial insurance carriers, and may include certain patient co-pay amounts. The Company previously recorded certain co-pay and self-pay amounts as revenue with estimated uncollectible portions being recognized as bad debt expense. Given the collectability of co-pay and self-pay amounts was not reasonably assured, the conditions for revenue recognition had not been met and revenue for those amounts should not have been recognized until collected. Adjustments to correct the foregoing reduce equally both the Company s historical net sales and its sales and marketing expense by approximately $2.2 million, $9.0 million and $6.0 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, and $1.4 million for the fiscal quarter ended March 31, 2014. Additionally, there was $1.4 million in the fiscal quarter ended March 31, 2014 related to contractual amounts from commercial insurance carriers which was incorrectly classified to bad debt expense rather than

a reduction of revenue, for a total reduction to bad debt and revenue of $2.8 million for the fiscal quarter ended March 31, 2014. These adjustments have no effect on net income from continuing operations or net income in those periods.

Certain bad debt reserves originally recorded in fiscal years 2011 and 2012 were reversed in incorrect periods in the Original Restatement in connection with the change to sell-through accounting for certain distributors. As a result, sales and marketing expense was understated by approximately $1.5 million and $1.1 million for the fiscal years ended December 31, 2013 and 2012, respectively, and overstated by approximately $2.1 million for the fiscal year ended December 31, 2011.

As part of analyzing collections experience on accounts receivable, the Company identified that it had incorrectly considered certain deferred revenue amounts included in gross accounts receivable when calculating estimated reserves. Specifically, the computation of the contractual allowances and bad debt allowances, which serves to adjust accounts receivable to the estimated collectible amount, incorrectly assumed that some percentage of deferred amounts would be collected, rather than fully deferring these amounts. Adjustments to correct this error resulted in a net decrease in operating income of $0.7 million and $0.2 million for the fiscal years ended December 31, 2013 and 2011, respectively, and a net increase in operating income of $2.1 million for the fiscal year ended December 31, 2012, as well as a net decrease in operating loss of $1.5 million for the fiscal quarter ended March 31, 2014.

As part of the Original Restatement, the Company made certain corrections to prior period excess and obsolete inventory reserves. The effect of these corrections was not considered when determining the adjustments needed to eliminate intercompany profits from inventories in the Original Restatement. Adjustments to correct this error resulted in an increase to cost of sales of $1.1 million, $0.2 million and $0.3 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $3.0 million for the fiscal quarter ended March 31, 2014.

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As part of the remediation activities that followed the Original Restatement, the Company expanded its procedures in the second quarter of 2014 to validate the existence of field inventory held by independent sales representatives and noted that, in many cases, this inventory had higher rates of missing inventory (shrinkage) than previously estimated. To determine whether these higher error rates were pervasive across its field inventory, the Company counted approximately 90% of its field inventory during the third and fourth fiscal quarters of 2014. These counts resulted in the identification of errors relating to previous estimates of shrinkage. Adjustments in the Further Restatement to correct these errors, net of the related effect on previously recorded excess and obsolete inventory reserves, resulted in an increase to cost of sales of $0.4 million, $0.3 million and $0.2 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $0.2 million for the fiscal quarter ended March 31, 2014.

In connection with its remediation efforts associated with the material weakness noted in the Original Restatement related to inventory reserves, the Company concluded that it was not appropriately calculating inventory reserves, including its consideration of demand assumptions for kits , which contain a variety of piece part components to be used during surgery as well as inventory held by third parties under inventory purchase obligations. Adjustments to correct this error resulted in an increase to cost of sales of $3.2 million, $1.5 million and $0.1 million for the fiscal years ended December 31, 2013, 2012 and 2011, respectively, as well as an increase to cost of sales of $2.4 million for the fiscal quarter ended March 31, 2014.

In addition to the adjustments described above, the Company is correcting certain other items. The impact of correcting these items results in a decrease to income tax expense of $0.5 million and $1.1 million for the fiscal years ended December 31, 2013 and 2012, respectively, to correct an income tax payable error that was recorded during the Original Restatement; these adjustments are separate from the tax effect of the errors described above.

In the aggregate, the remaining additional adjustments resulted in a decrease to loss before income taxes of $1.1 million for the fiscal year ended December 31, 2013, a decrease to income before income taxes of $0.1 million for the fiscal year ended December 31, 2012 and a increase to loss before income taxes of $0.7 million for the fiscal year ended December 31, 2011, as well as a decrease to loss before income taxes of $1.6 million for the fiscal quarter ended March 31, 2014.

In the aggregate, the cumulative effect of these adjustments on opening 2011 retained earnings was a decrease of $12.6 million. See Note 2 to the consolidated financial statements included in Part II, Item 8 of this Form 10-K/A for further details.

Items Amended by the Form 10-K/A

For the convenience of the reader, this Form 10-K/A sets forth the Original Form 10-K, as modified and superseded where necessary to reflect the Further Restatement. Specifically, the following items included in the Original Form 10-K are amended by this Form 10-K/A:

Part I, Item 1, Business

Part I, Item 1A, Risk Factors

Part II, Item 6, Selected Financial Data

Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations

Part II, Item 8, Financial Statements and Supplementary Data

Part II, Item 9A, Controls and Procedures

Part IV, Item 15, Exhibits and Financial Statement Schedules

The errors corrected by both the Original Restatement and the Further Restatement are further discussed in Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and in Note 2 to the consolidated financial statements included in Part II, Item 8 of this Form 10-K/A.

Other than this Form 10-K/A and the Amended 2014 First Quarter Form 10-Q, we do not intend to file any other amended reports in connection with the Further Restatement. All of our future Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q will reflect the restated information included in this Form 10-K/A and the Amended 2014 First Quarter Form 10-Q, as applicable.

Other than with respect to matters related to the Further Restatement (including consequences of the Company s delay in filing the 2014 Second Quarter Form 10-Q and 2014 Third Quarter Form 10-Q), this Amendment generally does not reflect events that have occurred after March 31, 2014, the filing date of the Original Form 10-K, or modify or update the disclosures presented in the Original Form 10-K, except to reflect the effects of such matters. Accordingly, this Amendment should be read in conjunction with (i) the Company s Current Reports on Form 8-K filed with the Commission since March 31, 2014, (ii) the Amended 2014 First Quarter Form 10-Q, (iii) the 2014 Second Quarter Form 10-Q and (iv) the 2014 Third Quarter Form 10-Q.

The Company s current Chief Executive Officer and the Chief Financial Officer have issued certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 in connection with this Form 10-K/A. These certifications are included in this Form 10-K/A as Exhibits 31.1, 31.2, 32.1 and 32.2.

Internal Control Considerations

In connection with the Further Restatement, management has re-evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2013 and the effectiveness of the Company s internal control over financial reporting as of December 31, 201 3 based on the framework in Internal Control- Integrated Framework (1992 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such re-evaluation, management confirmed that the material weaknesses described in the Original Form 10-K continue to be material weaknesses as of the time of the re-evaluation, and that some of these same material weaknesses contributed to the Further Restatement. In addition, the re-evaluation concluded that two additional material weaknesses existed related to (i) the calculation of our accounts receivable reserve, and (ii) the oversight of field inventory held by our independent sales representatives, which also contributed to the Further Restatement.

For a discussion of management s consideration of our disclosure controls and procedures and the material weaknesses identified, see Part II, Item 9A, Controls and Procedures of this Amendment.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans anticipates, believes, estimates, projects, intends, predicts, potential, or continue or other comparable te 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 March 31, 2014, the date on which the Original Form 10-K was filed, unless it is specifically otherwise stated to be made as of a different date, or refers to matters related to the Further Restatement (including consequences of the Company s delay in filing the 2014 Second Quarter Form 10-Q and the 2014 Third Quarter Form 10-Q). 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 restatements 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 previous and current 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 report, 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, Switzerland, Austria, 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 report. Our Internet website is located at http://www.orthofix.com. Our SEC filings are also available on the SEC Internet website at http://www.sec.gov.

Business Segments

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 Executive Officer, who is 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 SBU s reporting segments. These four segments are discussed below.

BioStim

The BioStim SBU manufactures, distributes, and provides support services for market leading devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). The devices utilize Orthofix s patented pulsed electromagnetic field (PEMF) technology which is supported by strong basic mechanism of action data in the scientific literature as well as strong level one randomized controlled clinical trials in the medical literature. Current research and clinical studies are also 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 markets its tissues through a network of distributors, sales, representatives and affiliates to supply to hospitals, doctors, and other healthcare providers, primarily in the U.S. Our partnership with Musculoskeletal Transplant Foundation (MTF) allows us to exclusively market our Trinity Evolution® and Trinity ELITE® tissue forms for musculoskeletal defects to enhance bony fusion.

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

- Invest in basic science, clinical and evidence-based research to support broader indications for our stimulation products;
- Enhance our customer service and physician interaction through automation;
- Leverage our leadership in spinal osteogenesis stimulation to increase our market share in appendicular osteogenesis stimulation; and
- Invest in product development for next generation osteogenesis technology.

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® .

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.

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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 integrated delivery networks, group purchasing organizations and regional hospital system commercial contracting team and expertise;

Invest in a reimbursement strategy and team dedicated to addressing the requirements of third party payors. This team will be supported with evidence-based clinical research and cost effectiveness studies coordinated by our research team;

Continue to enhance physician relationships through extensive product education and training programs; and

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

Corporate

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

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,					
	2013		2012		2011	
(U.S. Dollars in thousands)	Net Sales (Restated)	Percent of Total Net Sales	Net Sales (Restated)	Percent of Total Net Sales	Net Sales (Restated)	Percent of Total Net Sales
BioStim	$ 145,085	36%	$ 174,562	40%	$ 181,736	42%
Biologics	53,746	14%	53,731	12%	42,911	10%
Extremity Fixation	103,359	26%	112,011	25%	119,504	27%
Spine Fixation	95,421	24%	99,885	23%	91,368	21%

Total Net Sales	$ 397,611	100%	$ 440,189	100%	$ 435,519	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 36%, 14%, 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 .

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

Product	Primary Application
BioStim Solutions	
Cervical-Stim®	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	A thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands
Collage Synthetic Osteoconductive Scaffold	A bone void filler
Extremity Fixation Solutions	
Fixation	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus , XCaliber® and Gotfried P.C.C.P®
Eight-Plate Guided Growth System®	Treatment for bowed legs or knock knees of children
LRS Advanced Limb Reconstruction System®	External fixation for 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
Contours PHP Proximal Humerus Plate® (PHP)	An innovative plating solution for fraction fixation of the proximal humerus.
Contours VPS Volar Plating System VPS III	The 3rd generation of plates to treat distal radius fractures.

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Product	Primary Application
Spine Fixation Solutions	
3° /Reliant® Anterior Cervical Plating Systems	Plating systems implanted during anterior cervical spine fusion procedures
Hallmark® Anterior Cervical Plate System	A cervical plating system implanted during anterior cervical spine fusion procedures
Ascent® LE Posterior Occipital Cervico-Thoracic (POCT) System	A system of pedicle screws and rods implanted during a posterior spinal fusion procedure involving the stabilization of several degenerated or deformed cervical vertebrae
Tempus Cervical Plate	A cervical plating system implanted during anterior cervical spine fusion procedures
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 PEEKTI 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
SambaScrew®	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° , Reliant , Hallmark®, Firebird , Ascent®, Construx®, Unity®, NGage®, Newbridge®, Trinity ELITE®, Trinity Evolution®, PILLAR , Alloquent®, ProView , ProCallus®, XCaliber , VeroNail®, Centronail®, PREFIX , Gotfried P.C.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 regeneration 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 regeneration and healing. Furthermore, we believe that the research work with Cleveland Clinic allowing for characterization and visualization of the Orthofix PEMF waveform is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data along with additional clinical data could represent new 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.

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.

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

We receive a marketing fee through our collaboration with MTF for Trinity Evolution®, Trinity ELITE®, and VersaShield . Under our Agreements with MTF, MTF processes the tissues, maintains inventory, and invoices hospitals and surgery centers and other points of care for service fees, which are submitted by customers via purchase orders. We have exclusive worldwide rights to market our Trinity Evolution® and Trinity ELITE® technologies, 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, both for adults and pediatrics.

Extremity Repair Solutions

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

External Fixation

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

The 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 Limb Reconstruction System®.

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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, shoulder and wrist. While the rigidity and stability allows for use in definitive fixation, the design also addresses the need for rapid stabilization needed for temporary fixation in large trauma centers.

The TrueLok Ring Fixation System is a surgeon-designed, lightweight external fixation system for limb lengthening and deformity correction. In essence, a ring fixation construct consists of circular rings and semi-circular external supports centered on the patient s limb and secured to the bone by crossed, tensioned wires and half pins. The rings are connected externally to provide stable bone fixation. The main external connecting elements are threaded rods, linear distractors, or hinges and angular distractors which allow the surgeon to adjust the relative position of rings to each other. The ring positions are manipulated either acutely or gradually in 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 currently available competitor devices.

Building on the TrueLok brand, in the international markets, TL-HEX TrueLok Hexapod System®, was released in 2012. TL-HEX is a hexapod-based system designed at Texas Scottish Rite Hospital for Children as a three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. In essence, the system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings position is adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space. All 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, hip or foot. Examples of our internal fixation devices include:

The Centronail® Titanium Nailing System is designed to stabilize fractures in the femur, tibia, supracondylar and humerus. The main advantages are, 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.

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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.

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 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.

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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° , 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, of research and development expense.

Patents, Trade Secrets, Assignments and Licenses

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

employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology.

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

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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.

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.

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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 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

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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.

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 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.

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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.

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 36%, 14%, 26%, and 24%, respectively, of our total net sales in 2013.

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 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.

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Marketing and Product Education

We seek to market our products principally to medical professionals and 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 2,500 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 Woodlands, a private equity firm. Our spinal implant, HCT/P products, and Trinity Evolution® and Trinity ELITE®, HCT/Ps from which we derive marketing fees, compete with products marketed by Medtronic, Inc.; DePuy Synthes, a division of Johnson and Johnson; Stryker Corp.; Zimmer, Inc.; NuVasive, Inc.; Biomet Spine; and various smaller public and private companies. For external and internal fixation devices, our principal competitors include DePuy Synthes; Zimmer, Inc.; Stryker Corp.; Smith & Nephew plc; and Biomet Orthopedics, a business unit of Biomet, Inc.

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.

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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. As of March 31, 2014 we planned 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.

Item 1A. Risk Factors

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

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 filings 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 was delayed until March 31, 2014.

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 report, 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, accounts receivable reserves, inventory reserves, inventory existence, 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, September 30, 2013, June 30, 2014 and September 30, 2014. In addition, our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the 2014 Form 10-K) currently is delinquent, and is not expected to be filed until April 2015. 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. Even if we maintain compliance with our SEC reporting obligations prospectively, until one year from the date we regain and maintain status as a current filer, we will be ineligible to use shorter and less costly filing forms, 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.

As a result of the accounting review that led to the Original Restatement, we were delinquent in the filing of our Quarterly Reports on Form 10-Q for the fiscal quarters ended June 30, 2013 and September 30, 2013, which caused us to be out of compliance with the rules of the Nasdaq Stock Market LLC (Nasdaq) and subject to having our stock delisted from trading on Nasdaq. In connection with our completion of the Original Restatement in March 2014, a

Nasdaq Hearings Panel determined on April 1, 2014 that we had regained compliance with Nasdaq s listing rules. However, as a result of the delay of the filing of the 2014 Second Quarter Form 10-Q, the 2014 Third Quarter Form 10-Q and the 2014 Form 10-K caused by the Further Restatement, we again become non-compliant with Nasdaq s listing rules, and received a delisting determination letter on August 15, 2014. We subsequently participated in a hearing before an additional Nasdaq Hearings Panel on October 2, 2014, which granted our request that we be provided through January 15, 2015 (which date was later extended to March 31, 2015) to become a current filer without being delisted.

As of the date hereof, we will have filed the 2014 Second Quarter Form 10-Q and 2014 Third Quarter Form 10-Q. Further, we expect to file the 2014 Form 10-K in April 2015, and have requested that the Nasdaq Hearings Panel grant us relief from delisting subject to us filing the 2014 Form 10-K with the SEC on or prior to April 30, 2015. However, there can be no assurance that the Nasdaq Hearings Panel will grant this request, or that such panel will not otherwise determine to delist our common stock or put restrictions on the ability of our common stock to remain listed prospectively. 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.

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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 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

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

As further described in Part I, Item 3, Legal Proceedings of this Form 10-K/A, we initiated contact with the staff of the Division of Enforcement of the SEC (the SEC Enforcement Staff) in July 2013 to advise them of the initiation of the Audit Committee s review and the then-potential restatement of our annual audited and interim unaudited consolidated financial statements. The SEC is conducting a formal investigation of these matters, and both the Company and the Audit Committee are cooperating fully with the SEC. Since our initial contact, we have received requests from the SEC for documents and other information concerning various accounting practices, internal controls and business practices, and other related matters, 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/A, on August 14, 2013, a securities class action complaint against the Company was filed in the United States District Court for the Southern District of New York arising out of the restatement of our prior consolidated financial statements and the matters described above. The lead plaintiff s complaint, as amended, purports to bring claims on behalf of persons who purchased the Company s common stock between March 2, 2010 and July 29, 2013. The complaint asserts that the Company and four of its former executive officers, Alan W. Milinazzo, Robert S. Vaters, Brian McCollum, and Emily V. Buxton (collectively, the Individual Defendants), violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the Exchange Act), and Securities and Exchange Commission Rule 10b-5 (Rule 10b-5) by making false or misleading statements in or relating to the Company s financial statements. The complaint further asserts that the Individual Defendants were liable as control persons under Section 20(a) of the Exchange Act for any violation by the Company of Section 10(b) of the Exchange Act or Rule 10b-5. As relief, the complaint requests compensatory damages on behalf of the proposed class and lead plaintiff s attorneys fees and costs. On March 6, 2015, the court granted the defendants motion to dismiss as to Mr. Milinazzo and denied it with respect to the Company and the other Individual Defendants.

We have incurred and/or expect to incur significant professional fees and other costs in responding to the SEC investigation and in defending against the class action complaint. If we do not prevail in the pending complaint or any other litigation, we may be required to pay a significant amount of monetary damages that may be in excess of our insurance coverage. Further, if the SEC were to conclude that enforcement action is appropriate, or if HHS-OIG were to conclude that we violated the CIA, we could be required to pay large civil penalties and fines. The SEC also could impose other sanctions against us or certain of our current and former directors and officers. Any of these events could have a material adverse effect on our business, financial condition, results of operations or cash flows. Additionally, while we believe we have made appropriate judgments in determining the errors and correct adjustments in preparing our restated consolidated financial statements, the SEC 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 investigation and the pending class action 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 investigation and the class action complaint described above have also exposed us to greater risks associated with litigation, regulatory proceedings and government enforcement actions. We and current and former members of our senior management may in the future be subject to additional litigation or governmental proceedings relating to such matters. Subject to certain limitations, we are obligated to indemnify our current and former officers and directors in connection with any such lawsuits or governmental proceedings and related litigation or settlement amounts. Regardless of the outcome, these lawsuits and any other litigation or governmental proceedings that may be brought against us or our current or former officers and directors, could be time-consuming, result in significant expense and divert the attention and resources of our management and other key employees. An unfavorable outcome in any of these matters could exceed coverage provided under potentially applicable insurance policies. Any such unfavorable outcome could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Further, we could be required to pay damages or additional penalties or have other remedies imposed against us, or our current or former directors or officers, which could harm our reputation, business, financial condition, results of operations or cash flows.

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

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

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

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

- the federal Health Care Programs Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing and discounting policies, and relationships with healthcare practitioners and providers, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, in exchange for or to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program (such as the Medicare or Medicaid programs);

- federal false claims laws which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal government payors that are false or fraudulent; and

- state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payors, including commercial insurers.

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

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

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

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

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The Centers for Medicare and Medicaid Services (CMS), in its ongoing implementation of the Medicare program, has obtained a related technical assessment of the medical study literature to determine how the literature addresses spinal fusion surgery in the Medicare population. The impact that this information will have on Medicare coverage policy for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. It is also possible that the government s focus on coverage of off-label uses of devices approved by the FDA could lead to changes in coverage policies regarding off-label uses by TriCare, Medicare and/or Medicaid. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Globally, our products are sold in many countries, such as the 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 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

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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 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.

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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.

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.

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 PEEKTI Composite Spacer System, Phoenix® Minimally Invasive Spinal Fixation System, the Firebird® Deformity Correction System, the FORZA® Spacer System, TL-HEX TrueLok Hexapod System®, Galaxy Fixation System, Contours LPS (Lapidus Plating System), Centronail® Ankle Compression Nail, among others. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians) and obtain regulatory approvals, which can depend, among other things, on the product achieving broad clinical acceptance, the level of third-party reimbursement and the introduction of competing technologies. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

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

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

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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 acceptance, the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks, the timing and level of reimbursement for our products by third-party payors, the extent to which we are subject to government regulation or enforcement and other factors, many of which are outside our control.

We depend on our senior management team.

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

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

In order to compete, we must attract, retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing, finance and support positions. Hiring and retaining qualified executives, engineers, technical staff and sales representatives are critical to our business, and competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified employees, we utilize stock-based incentive awards such as employee stock options. If the value of such stock awards does not

appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain and motivate our employees could be adversely impacted, which could negatively affect our results of operations and/or require us to increase the amount we expend on cash and other forms of compensation.

We are party to numerous contractual relationships.

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

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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.

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. On January 15, 2015, at the Company s request, the lenders agreed to reduce the available capacity under the revolving facility to $100 million.

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.

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 Original Limited Waiver) pursuant to the Credit Agreement described above. Under the Original Limited Waiver, the Lenders collectively waived requirements under the Credit Agreement that we deliver quarterly consolidated financial statements with respect to the fiscal quarters ended 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 Original Limited Waiver provided that the restatement of our consolidated financial statements for any period ending on or before March 31, 2013 would 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 delivered corrected consolidated financial statements and compliance certificates with respect to such restated periods and immediately paid 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. In connection with our completion of the Original Restatement, we made such required deliveries, and determined that no payments were required.

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In connection with the Further Restatement and our delay in filing the 2014 Second Quarter Form 10-Q, on August 14, 2014 the Lenders and us entered into a subsequent Limited Waiver which was extended on September 30, 2014, January 15, 2015 and February 26, 2015 (the Subsequent Limited Waivers). Under the Subsequent Limited Waivers, the Lenders collectively waived requirements under the Credit Agreement that we deliver quarterly financial statements with respect to the fiscal quarters ended June 30, 2014 and September 30, 2014, and related financial covenant certificates, until the earlier of (i) March 31, 2015 or (ii) the date that is one day after such financial statements are publicly filed or released. The Subsequent Limited Waivers also extend the date by which the Company is required to provide certain 2014 fiscal year financial statements until the earlier of (i) one business day following the date that the Company files the 2014 Form 10-K or (ii) April 30, 2015. In addition, the Subsequent Limited Waivers, provided that the Further Restatement would 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 delivered corrected financial statements and compliance certificates with respect to such restated periods and immediately paid 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.

As of the date hereof, we have delivered the quarterly consolidated financial statements for the fiscal quarters ended June 30, 2014 and September 30, 2014, and we do not believe that the Further Restatement triggers any such additional interest or fees with respect to such prior periods. However, in the event that we do not satisfy these respective obligations under the Original Limited Waiver, the Subsequent 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.

As of December 31, 2013, we maintain a five-year revolving credit facility of $200 million upon which we had $180 million available to be drawn on 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 report.)

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

The methods, estimates and judgments we use in applying our accounting policies have a significant impact on our consolidated results of operations (see Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk

under the subheading Critical Accounting Policies and Estimates). Such methods, estimates and judgments are, by their nature, subject to substantial risks, uncertainties and assumptions, and factors may arise over time that leads us to change our methods, estimates and judgments. Changes in those methods, estimates and judgments could significantly affect our results of operations.

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

A 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

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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 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.

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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 reflected in the Original Restatement. As a result of this review and the Original Restatement, the filing of our Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2013 and September 30, 2013, and the Original Form 10-K, 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 filed the Original Form 10-K on March 31, 2014. As further described in the explanatory note to this Form 10-K/A, this report also reflects a further restatement of our consolidated financial statements, which we refer to herein as the Further Restatement.

SEC Investigation

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

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

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

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

Securities Class Action Complaint

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

The lead plaintiff s complaint, as amended, purports to bring claims on behalf of persons who purchased the Company s common stock between March 2, 2010 and July 29, 2013. The complaint asserts that the Company and four of its former executive officers, Alan W. Milinazzo, Robert S. Vaters, Brian McCollum, and Emily V. Buxton (collectively,

the Individual Defendants), violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the Exchange Act), and Securities and Exchange Commission Rule 10b-5 (Rule 10b-5) by making false or misleading statements in or relating to the Company s financial statements. The complaint further asserts that the Individual Defendants were liable as control persons under Section 20(a) of the Exchange Act for any violation by the Company of Section 10(b) of the Exchange Act or Rule 10b-5. As relief, the complaint requests compensatory damages on behalf of the proposed class and lead plaintiff s attorneys fees and costs. On March 6, 2015, the court granted the defendants motion to dismiss as to Mr. Milinazzo and denied it with respect to the Company and the other Individual Defendants. This matter remains at an early stage and, as of the date of this Form 10-K/A, 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.

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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 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.

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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 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 served as our executive officers as of the date of this Form 10-K/A.

Name	Age	Position
Bradley R. Mason	61	President and Chief Executive Officer and Director
Doug Rice	49	Interim Chief Financial Officer, Chief Accounting Officer
Davide Bianchi	50	President, Global Extremity Fixation
Michael M. Finegan	51	Chief Strategy Officer
Jeffrey M. Schumm	53	Chief Administrative Officer, General Counsel and Corporate Secretary

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 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

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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

Doug Rice. Mr. Rice joined Orthofix as Chief Accounting Officer on September 4, 2014 and was appointed to the position of Interim Chief Financial Officer on October 3, 2014. Mr. Rice joined the Company from Vision Source and Smile Source, a private equity-backed optometric and dental network provider, where he had served since 2012 as Senior Vice President and Chief Financial Officer. Mr. Rice served as the Vice President Finance, Treasurer of McAfee, a security technology company, from 2007 to 2012, when it was acquired by Intel. From 2000 to 2007, he served as the Senior Vice President, Corporate Controller of Concentra, Inc., a national healthcare service provider. Mr. Rice was the Vice President, Finance of la Madeleine French Bakery and Café, a restaurant chain with locations in multiple metropolitan areas, from 1996 to 1999. From 1994 to 1996, he was Director of Finance at Allied Marketing Group, an international direct mail marketer. Mr. Rice also served as an Audit Manager at PricewaterhouseCoopers (formerly Coopers & Lybrand) between 1988 and 1993. He is a certified public accountant, and received both an MBA and BBA from Southern Methodist University.

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 Master in Business Management from ISTUD Milano.

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.

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. Certain subsidiaries of the Company have restrictions on their ability to pay dividends in certain circumstances pursuant to the Credit Agreement. 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 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.

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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.

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

As discussed in the Explanatory Note to this Form 10-K/A, we are restating our audited consolidated financial statements for the fiscal years ended December 31, 2013, 2012 and 2011. The information below reflects both the Original Restatement (which included a restatement of the fiscal years ended December 31, 2012, 2011, 2010, and 2009) and the Further Restatement (which consists of the restatement of the fiscal year ended December 31, 2013 and the further restatement of the fiscal years ended December 31, 2012, 2011, 2010 and 2009. See Part II, Item 8, Financial Statements and Supplementary Data Note 2, Restatement of the Consolidated Financial Statements for further information about the restatement of certain of our consolidated financial statements. 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/A. Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP).

	Year ended December 31,				
	2013 (Restated)	2012 (Restated)	2011 (Restated)	2010 (Restated)	2009 (Restated)
	(U.S. Dollars in thousands, except margin and per share data)				
Consolidated operating results					
Net sales	$ 397,611	$ 440,189	$ 435,519	$ 461,919	$ 429,665
Gross profit	290,699	339,463	339,104	367,324	328,546
Gross profit margin	73%	77%	78%	80%	76%
Total operating (loss) income(3)	(11,192)	74,872	6,611	67,626	36,186
Net (loss) income from continuing operations	(18,205)	45,121	(15,806)	31,058	9,664
Net (loss) income from discontinued operations	(10,607)	(2,269)	(1,892)	13,299	12,453
Net (loss) income (1) (2) (3)	$ (28,812)	$ 42,852	$ (17,698)	$ 44,357	$ 22,117
Net (loss) income per share of common stock:					
Basic:					
Net (loss) income from continuing operations	$ (0.97)	$ 2.38	$ (0.87)	$ 1.76	$ 0.56
Net (loss) income from discontinued operations	(0.57)	(0.12)	(0.10)	0.76	0.73
Net (loss) income	$ (1.54)	$ 2.26	$ (0.97)	$ 2.52	$ 1.29
Net (loss) income per share of common stock:					
Diluted:					
Net (loss) income from continuing operations	$ (0.97)	$ 2.33	$ (0.87)	$ 1.73	$ 0.56
Net (loss) income from discontinued operations	(0.57)	(0.12)	(0.10)	0.74	0.72
Net (loss) income	$ (1.54)	$ 2.21	$ (0.97)	$ 2.47	$ 1.28

(1) The Company has not paid 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.

	As of December 31,				
(at year-end)	**2013 (Restated)**	**2012 (Restated)**	**2011 (Restated)**	**2010 (Restated)**	**2009 (Restated)**
	(U.S. Dollars in thousands, except share data)				
Consolidated financial position					
Total assets	$ 411,975	$ 464,546	$ 676,160	$ 596,352	$ 583,297
Total debt	20,000	20,016	210,013	220,007	254,673
Shareholders equity	295,863	356,439	280,304	281,354	219,995
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

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

	Year ended December 31, 2013 (U.S. Dollars, in thousands, except margin and per share data)		
	Originally Reported in 2013 Form 10-K	Further Restatement Adjustments	Restated
Consolidated operating results			
Net sales	$ 400,534	$ (2,923)	$ 397,611
Gross profit	298,234	(7,535)	290,699
Gross profit margin	75%	(2)%	73%
Total operating loss	(5,087)	(6,105)	(11,192)
Net loss from continuing operations	(14,908)	(3,297)	(18,205)
Net loss from discontinued operations	(10,607)		(10,607)
Net loss	$ (25,515)	$ (3,297)	$ (28,812)
Net loss per share of common stock Basic:			
Net loss from continuing operations	$ (0.80)	$ (0.17)	$ (0.97)
Net loss from discontinued operations	(0.57)		(0.57)
Net loss	$ (1.37)	$ (0.17)	$ (1.54)
Net loss per share of common stock Diluted:			
Net loss from continuing operations	$ (0.80)	$ (0.17)	$ (0.97)
Net loss from discontinued operations	(0.57)		(0.57)
Net loss	$ (1.37)	$ (0.17)	$ (1.54)

(at year-end)	As of December 31, 2013 (U.S. Dollars, in thousands, except share data)		
	Originally Reported in 2013	Further Restatement Adjustments	Restated

Form 10-K

Consolidated financial position			
Total assets	$ 423,182	$ (11,207)	$ 411,975
Total debt	20,000		$ 20,000
Shareholders equity	310,494	$ (14,631)	$ 295,863
Weighted average number of shares of common stock outstanding (basic)	18,697,228		18,697,228
Weighted average number of shares of common stock outstanding (diluted)	18,697,228		18,697,228

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	Year ended December 31, 2012 (U.S. Dollars, in thousands, except margin and per share data)				
	As Reported in the 2012 Form 10-K Prior to Original Restatement	Original Restatement Adjustments	As Originally Restated in 2012 Form 10-K/A	Further Restatement Adjustments	Restated
Consolidated operating results					
Net sales	$ 462,320	$ (14,739)	$ 447,581	$ (7,392)	$ 440,189
Gross profit	375,828	(26,500)	349,328	(9,865)	339,463
Gross profit margin	81%	(3)%	78%	(1)%	77%
Total operating income	89,010	(12,374)	76,636	(1,764)	74,872
Net income from continuing operations	53,936	(8,886)	45,050	71	45,121
Net loss from discontinued operations	(2,641)	429	(2,212)	(57)	(2,269)
Net income	$ 51,295	$ (8,457)	$ 42,838	$ 14	$ 42,852
Net income (loss) per share of common stock Basic:					
Net income from continuing operations	$ 2.84	$ (0.47)	$ 2.37	$ 0.01	$ 2.38
Net loss from discontinued operations	(0.14)	0.02	(0.12)		(0.12)
Net income	$ 2.70	$ (0.45)	$ 2.25	$ 0.01	$ 2.26
Net income (loss) per share of common stock Diluted:					
Net income from continuing operations	$ 2.78	$ (0.46)	$ 2.32	$ 0.01	$ 2.33
Net loss from discontinued operations	(0.14)	0.03	(0.11)	(0.01)	(0.12)
Net income	$ 2.64	$ (0.43)	$ 2.21	$	$ 2.21

(at year-end)	As of December 31, 2012 (U.S. Dollars, in thousands, except share data)				
	As Reported in the 2012 Form 10-K Prior	Original Restatement Adjustments	As Originally Restated in 2012 Form	Further Restatement Adjustments	Restated

	to Original Restatement		10-K/A		
Consolidated financial position					
Total assets	$ 504,281	$ (31,384)	$ 472,897	$ (8,351)	$ 464,546
Total debt	20,016		20,016	$	$ 20,016
Shareholders equity	399,098	(31,266)	367,832	$ (11,393)	$ 356,439
Weighted average number of shares of common stock outstanding (basic)	18,977,263		18,997,263		18,977,263
Weighted average number of shares of common stock outstanding (diluted)	19,390,413		19,390,413		19,390,413

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	Year ended December 31, 2011 (U.S. Dollars, in thousands, except margin and per share data)				
	As Reported in the 2012 Form 10-K Prior to Original Restatement	Original Restatement Adjustments	As Originally Restated in 2012 Form 10-K/A	Further Restatement Adjustments	Restated
Consolidated operating results					
Net sales	$ 470,121	$ (28,150)	$ 441,971	$ (6,452)	$ 435,519
Gross profit	377,502	(31,058)	346,444	(7,340)	339,104
Gross profit margin	80%	(2)%	78%	%	78%
Total operating income	31,309	(25,409)	5,900	711	6,611
Net loss from continuing operations	(1,740)	(14,478)	(16,218)	412	(15,806)
Net income (loss) from discontinued operations	667	(2,559)	(1,892)		(1,892)
Net loss	$ (1,073)	$ (17,037)	$ (18,110)	$ 412	$ (17,698)
Net (loss) income per share of common stock:					
Basic:					
Net loss from continuing operations	$ (0.10)	$ (0.79)	$ (0.89)	$ 0.02	$ (0.87)
Net income (loss) from discontinued operations	0.04	(0.14)	(0.10)		(0.10)
Net loss	$ (0.06)	$ (0.93)	$ (0.99)	$ 0.02	$ (0.97)
Net (loss) income per share of common stock:					
Diluted:					
Net loss from continuing operations	$ (0.10)	$ (0.79)	$ (0.89)	$ 0.02	$ (0.87)
Net income (loss) from discontinued operations	0.04	(0.14)	(0.10)		(0.10)
Net loss	$ (0.06)	$ (0.93)	$ (0.99)	$ 0.02	$ (0.97)

(at year-end)	As of December 31, 2011 (U.S. Dollars, in thousands, except share data)				
	As Reported in	Original Restatement	As Originally	Further Restatement	Restated

	the 2012 Form 10-K Prior to Original Restatement	Adjustments	Restated in 2012 Form 10-K/A	Adjustments	
Consolidated financial position					
Total assets	$ 704,472	$ (19,092)	$ 685,380	$ (9,220)	$ 676,160
Total debt	210,013		210,013	$	$ 210,013
Shareholders equity	315,171	(23,097)	292,074	$ (11,770)	$ 280,304
Weighted average number of shares of common stock outstanding (basic)	18,219,343		18,219,343		18,219,343
Weighted average number of shares of common stock outstanding (diluted)	18,219,343		18,219,343		18,219,343

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	Year ended December 31, 2010 (U.S. Dollars, in thousands, except margin and per share data)				
	As Reported in the 2012 Form 10-K Prior to Original Restatement	Original Restatement Adjustments	As Originally Restated in 2012 Form 10-K/A	Further Restatement Adjustments	Restated
Consolidated operating results					
Net sales	$ 460,629	$ 1,942	$ 462,571	$ (652)	$ 461,919
Gross profit	370,168	(4,690)	365,478	1,846	367,324
Gross profit margin	80%	(1)%	79%	1%	80%
Total operating income	66,250	(266)	65,984	1,642	67,626
Net income from continuing operations	27,758	3,239	30,997	61	31,058
Net income from discontinued operations	16,450	(3,151)	13,299		13,299
Net income	$ 44,208	$ 88	$ 44,296	$ 61	$ 44,357
Net income per share of common stock:					
Basic:					
Net income from continuing operations	$ 1.58	$ 0.18	$ 1.76	$	$ 1.76
Net income from discontinued operations	0.93	(0.17)	0.76		0.76
Net income	$ 2.51	$ 0.01	$ 2.52	$	$ 2.52
Net income per share of common stock:					
Diluted:					
Net income from continuing operations	$ 1.55	$ 0.18	$ 1.73	$	$ 1.73
Net income from discontinued operations	0.92	(0.18)	0.74		0.74
Net income	$ 2.47	$	$ 2.47	$	$ 2.47

(at year-end)	As of December 31, 2010 (U.S. Dollars, in thousands, except share data)				
	As Reported in	Original Restatement	As Originally	Further Restatement	Restated

	the 2012 Form 10-K Prior to Original Restatement	Adjustments	Restated in 2012 Form 10-K/A	Adjustments	
Consolidated financial position					
Total assets	$ 612,926	$ (4,675)	$ 608,251	$ (11,899)	$ 596,352
Total debt	220,007		220,007		220,007
Shareholders equity	300,891	(6,973)	293,918	(12,564)	281,354
Weighted average number of shares of common stock outstanding (basic)	17,601,956		17,601,956		17,601,956
Weighted average number of shares of common stock outstanding (diluted)	17,913,545		17,913,545		17,913,545

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	Year ended December 31, 2009 (U.S. Dollars, in thousands, except margin and per share data)				
	As Reported in the 2012 Form 10-K Prior to Original Restatement	Original Restatement Adjustments	As Originally Restated in 2012 Form 10-K/A	Further Restatement Adjustments	Restated
Consolidated operating results					