ORTHOFIX INTERNATIONAL N V
Form 10-K/A
March 24, 2014
Table of Contents

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, 2012

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 x No ¨

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

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

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

The aggregate market value of registrant s common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the registrant s most recently completed second fiscal quarter, June 30, 2012, as reported by the Nasdaq Global Select Market, was approximately $781.5 million.

As of March 14, 2014, 18,187,194 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections called for in Part III of this Form 10-K/A have been incorporated by reference from the registrant s Definitive Proxy Statement in connection with the 2013 Annual General Meeting of Shareholders held on June 20, 2013, which Definitive Proxy Statement was filed with the Securities and Exchange Commission (the Commission) on April 30, 2013.

Table of Contents

Orthofix International N.V.

Form 10-K/A for the Year Ended December 31, 2012

Table of Contents

Table of Contents

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 Annua Report on Form 10-K for the year ended December 31, 2012, originally filed on March 1, 2013 (the Original Form 10-K) to reflect the restatement of its consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010, and related disclosures described below. The restatement of the Original Form 10-K reflected in this Amendment corrects errors principally related to our accounting for revenue recognition for sales to distributors, our accounting for inventory reserves, and our accounting for royalties. Concurrently with the filing of this Amendment, we are also filing an amendment to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013 (the 2013 First Quarter 10-Q Amendment) to reflect the restatement of our consolidated financial statements as of and for the fiscal quarter ended March 31, 2013, which reflects the correction of the same types of errors with respect to such period. This Amendment also includes restated unaudited quarterly financial information for each of the years ended December 31, 2012 and 2011 and amends certain other information in the Original Form 10-K as listed in Items Amended by this Filing below, as a result of the restatement of our financial statements.

Background of Restatement

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

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

The Independent Review focused on the periods between January 1, 2010 and March 31, 2013 and included (i) over 50 witness interviews, (ii) collection of emails and files from 70 document custodians, and (iii) quantitative analysis. The scope of the Independent Review, which was determined by the Audit Committee in consultation with outside professionals engaged by the Audit Committee, focused primarily on revenue recognition related to distributor arrangements and inventory reserve adjustments. In conjunction with the Independent Review, management concluded that errors existed in the Company s previously issued financial statements with respect to the Non-Reliance Period, as well as in the Company s previously issued consolidated financial statements for the fiscal year ended December 31, 2010. There were also similar types of errors identified as affecting the Company s previously issued consolidated financial statements for the fiscal years ended December 31, 2009, 2008 and 2007, for which the Company is including restated consolidated financial information for the fiscal years ended December 31, 2009 and 2008 in the Selected Financial Data table of this Form 10-K/A. Adjustments prior to January 1, 2010 have been

recognized as a cumulative adjustment to beginning retained earnings in the consolidated statements of changes in shareholders equity included in the consolidated financial statements included in Item 8 of this Form 10-K/A.

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

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

Table of Contents

Items Amended by this Filing

This Amendment reflects the results of the work described above and includes the restatement of our consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010, as well as the restatement of certain financial information for the fiscal years ended December 31, 2009, 2008 and 2007, as described above. For the convenience of the reader, this Amendment sets forth the Original Form 10-K, as modified and superseded where necessary to reflect the restatement and other related adjustments, internal control matters, and as otherwise specifically indicated (including in relation to legal proceedings). Specifically, the following items included in the Original Form 10-K are amended by this Amendment:

Part I, Item 1, Business

Part I, Item 1A, Risk Factors

Part I, Item 3, Legal Proceedings

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 correction of the errors described above is 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 Amendment.

Other than this Amendment and the 2013 First Quarter 10-Q Amendment, we do not intend to file any other amended Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for periods affected by the restatement, and the financial statements, related financial information, and internal controls disclosures and assessments contained in other reports for those periods should no longer be relied upon. 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 Amendment and the 2013 First Quarter 10-Q Amendment, as applicable.

The Chief Executive Officer and the Chief Financial Officer of the Company have also reissued as part of this Amendment the certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002. The reissued

certifications are included in this Amendment as Exhibits 31.1, 31.2, 32.1 and 32.2.

As noted above, for ease of reference, this Amendment sets forth the Original Form 10-K in its entirety, as updated to reflect the effects of the restatement and other related adjustments, internal control matters, and as otherwise specifically indicated (including in relation to legal proceedings). However, this Amendment does not reflect events that have occurred after March 1, 2013, 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 January 1, 2013, (ii) the 2013 First Quarter 10-Q Amendment and the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, each of which are being filed contemporaneously with this Amendment, and (iii) the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013, which we expect to file on the date immediately following the date hereof. We also currently expect to file our Annual Report on Form 10-K for the year ended December 31, 2013 by March 31, 2014.

Internal Control Considerations

In connection with the restatement and the Audit Committee s review, management has re-evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012 and the effectiveness of the Company s internal control over financial reporting as of December 31, 2012 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 has determined that the Company had material weaknesses in its internal control over financial reporting as of December 31, 2012 related to revenue recognition practices for sales to the Company s distributors, inventory reserves and foreign subsidiary oversight. As a result, management has determined that the Company s disclosure controls and procedures and internal control over financial reporting were not effective as of December 31, 2012.

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 the Company s annual or interim financial statements will not be prevented or detected on a timely basis. The existence of one or more material weaknesses precludes a conclusion by management that a corporation s internal control over financial reporting is effective. We are currently in the process of remediating the weaknesses in internal control over financial reporting referred to above by designing and implementing new procedures and controls throughout the Company and its subsidiaries.

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.

Table of Contents

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans anticipates, believes, estimates, projects, intends, predicts, potential or continue or other comparable ter 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, except with respect to statements revised or provided herein to reflect the Audit Committee review, our re-evaluation of internal control effectiveness, the restatement of our consolidated financial statements and other related matters, any forward-looking statement speaks only as of March 1, 2013, the date on which the Original Form 10-K was filed, unless they are specifically otherwise stated to be made as of a different date, and we have not updated these forward-looking statements to reflect other events occurring since March 1, 2013. We undertake no obligation to further update any such statement, or the risk factors described in Item 1A under the heading *Risk Factors*, to reflect new information, the occurrence of future events or circumstances or otherwise.

The forward-looking statements in this filing do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to the Audit Committee review and financial restatement described herein and related legal proceedings (including potential action by the Division of Enforcement of the SEC and pending securities class action litigation), the Company s review of allegations of improper payments involving the Company s Brazil-based subsidiary (which review is described in the Legal Proceedings section of this Form 10-K/A), the Company s non-compliance with certain Nasdaq Stock Market LLC (Nasdaq) 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 the *Legal Proceedings* section of this report and other reports that we have filed since March 1, 2013 and 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 Item 1A under the heading *Risk Factors* in this report, as well as in other reports that we have filed since March 1, 2013 and will file in the future.

Table of Contents

PART I

Item 1. Business

In this Form 10-K/A, the terms we , us , our , Orthofix and the 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 equipment used principally by musculoskeletal medical specialists for spine and orthopedic applications. Our main products are spinal implant products and related 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, external and internal fixation devices used in fracture repair, limb lengthening and bone reconstruction. Our products also include bone cement and devices for removal of bone cement used to fix artificial implants.

We have administrative and training facilities in the United States (U.S.), Brazil, the United Kingdom, France, Germany, Puerto Rico and Italy and manufacturing facilities in the U.S. and Italy. We directly distribute our products in the U.S., the United Kingdom, Italy, Germany, France, Belgium, Brazil 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, Annual Proxy Statement on Schedule 14A and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information on our website or connected to our website is not incorporated by reference into this Form 10-K/A. 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 Strategy

Our business strategy is to develop and deliver innovative repair and regenerative solutions to the spine and orthopedic markets in order to minimize pain and restore mobility. Our strategy for growth and profitability includes the following initiatives by global business unit:

Spine: Provide a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of spinal conditions. Our main tactics and objectives are:

Concentrate our focus on expanding our current repair and regenerative product offering;

Enhance our geographic coverage in the U.S. and internationally;

Expand breadth and depth of account-level, customer base;

Leverage integrated global business unit structure to promote cross-selling market opportunities; and

Differentiate emerging biologics offering so as to potentially promote pull-through for best in class implants.

Orthopedics: Provide a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of orthopedic conditions ranging from fracture management to deformity correction. Our main tactics and objectives are:

Expand and strengthen our leadership position internationally in fixation hardware markets with our repair solutions;

Improve our U.S. market penetration by leveraging core competency in foot and ankle products and promote pull-through of key regenerative stimulation and biologics solutions; and

Continue to develop fracture repair solutions focused on providing treatment options for the bone healing process.

Table of Contents

Other Financial and Business Initiatives:

Focus on research, development and clinical outcomes data activities to ensure an appropriate return on these investments and increase the probability of commercial success;

Continue to expand applications for our products by utilizing synergies among our core technologies;

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

Continue to strengthen contracting, reimbursement relationships and billing capabilities.

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 two global business units (GBUs), which are comprised of Spine and Orthopedics supported by Corporate activities. These GBUs represent the segments for which our Chief Operating Decision Maker (the CODM) reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information has been prepared based on our two GBUs reporting segments. These two segments are discussed below.

Spine

Spine provides a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of spinal conditions. This global business unit specializes in the design, development and marketing of the Company s spinal repair products along with regenerative stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Orthopedics

Orthopedics provides a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This global business unit specializes in the design, development and marketing of the Company s orthopedic repair products along with regeneration stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors and other healthcare providers, globally.

Corporate

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

Business Segments by GBU:

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

(U.S. Dollars, in thousands)	External Net Sales by GBU Year ended December 31, 2012 (Restated)		2011 (Restated)		2010 (Restated)	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine						
Spine Repair Implants and Regenerative Biologics	$ 142,829	32%	$ 124,415	28%	$ 132,938	29%
Spine Regenerative Stimulation	159,289	36%	160,946	37%	172,574	37%
Total Spine	302,118	68%	285,361	65%	305,512	66%
Orthopedics	145,463	32%	156,610	35%	157,059	34%
Total Net Sales	$ 447,581	100%	$ 441,971	100%	$ 462,571	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 .

Table of Contents

Our segment information is prepared on the same basis that our management reviews the financial information for operational decision making purposes.

Products

Our revenues are generally derived from the sales of products and marketing service fees in two GBU s, Spine (which is comprised of our Spine Repair Implants and Regenerative Biologics and our Spine Regenerative Stimulation) and Orthopedics, which accounted for 68% and 32%, respectively, of our total net sales in 2012. Marketing service fee sales are comprised of sales of Trinity Evolution ® in Spine and Orthopedic applications.

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

Product	Primary Application
Spinal Regenerative Solutions	
Cervical-Stim ®	Pulsed electromagnetic field (PEMF) non-invasive cervical spine regenerative stimulator used to enhance bone growth
Spinal-Stim ®	PEMF non-invasive lumbar spine regenerative stimulator used to enhance bone growth
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 Evolution ®	An allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion procedure
Collage Synthetic Osteoconductive Scaffold	A bone void filler
Spinal Repair Solutions	
3 Degree /Reliant ® Anterior Cervical Plating Systems	Plating systems implanted during anterior cervical spine fusion procedures
Hallmark ® Anterior Cervical Plate System	A cervical plating system implanted during anterior cervical spine fusion procedures
Ascent ® LE Posterior Occipital Cervico-Thoracic (POCT) System	A system of pedicle screws and rods implanted during a posterior spinal fusion procedure involving the stabilization of several degenerated or deformed cervical vertebrae
NewBridge ® Laminoplasty Fixation System	A device implanted during a posterior surgical procedure designed to expand the cervical vertebrae and relieve pressure on the spinal canal
Construx ® Mini PEEK Spacer System	Smaller, unibody versions of the Construx PEEK VBR System, implanted as a cervical interbody or partial vertebrectomy solution
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 Trans-laminar Lumbar Interbody Fusion (TLIF) procedures
FORZA Spacer System	Interbody devices for Posterior Lumbar Interbody Fusion (PLIF) and Trans-laminar Lumbar Interbody Fusion (TLIF) procedures
PILLAR ® AL PEEK Partial VBR System	An intervertebral body fusion device for Anterior Lumbar Interbody Fusion (ALIF) procedures
PILLAR ® SA PEEK Spacer System	An intervertebral body fusion device that incorporates screw fixation to optimize implant stability
Firebird ® Spinal Fixation System	A system of rods, crossbars and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure
Firebird ® Deformity Correction System	An extension to the Firebird Spinal Fixation System which provides additional instrument and implant options for complex thoraco-lumbar spine procedures

Table of Contents

Product	Primary Application
Phoenix ® Minimally Invasive Spinal Fixation System	A multi-axial extended reduction screw body used with the Firebird Spinal Fixation System designed to be implanted during a posterior 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 pedical 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
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
TDX Posterior Dynamic Stabilization	A posterior dynamic rod allowing natural movements in the treated segments of the lumbar spine (Currently only available for sale outside the U.S.)
In-Swing Interspinous Process Spacer	An implant placed between the spinous processes of the lumbar spine, designed to widen the canal and decompress the symptomatic level (Currently only available for sale outside the U.S.)
Orthopedic Repair Solutions	
Fixation	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus ®, XCaliber and Gotfried PC.C.P ®
8-Plate Guided Growth System ®	Treatment for bowed legs or knock knees of children
LRS ADVANCED LIMB RECONSTRUCTION SYSTEM ® (LRS)	External fixation for lengthenings and corrections of deformity
True-Lok	Ring fixation system for limb lengthening and deformity correction
TL-HEX TRUELOK HEXAPOD SYSTEM ® or TL-HEX	Hexapod external fixation system for trauma and deformity correction with associated software
Galaxy Fixation System	External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps
PREFIX and PREFIX 2	External fixation range for temporary fixation of fractures in trauma
VeroNail ® Trochanteric Nailing System	Trochanteric titanium nailing system for hip fractures
Centronail ® Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail
Cemex ®	Bone cement

OSCAR	Ultrasonic bone cement removal
Centronail ® Ankle Compression Nailing System (ACN)	A differentiated solution for hindfoot fusions
Contours Lapidus Plating System (LPS)	A plate design contoured specifically for a tarsometatarsal (TMT) fusion
ContoursProximal Humerus Plate ® (PHP)	An innovative plating solution for fraction fixation of the proximal humerus
ContoursVolar Plating System (VPS) III	The 3rd generation of plates to treat distal radius fractures
Collage Synthetic Osteoconductive Scaffold	A bone void filler
Orthopedic Regenerative Solutions	
Physio-Stim ®	PEMF long bone non-invasive regenerative stimulator used to enhance bone growth in non union factures

Table of Contents

Product	Primary Application
Trinity Evolution ®	An allograft with viable cells used during surgery that is designed to enhance the success of a bone fusion procedure
Collage Synthetic Osteoconductive Scaffold	A bone void filler
Versashield ®	A thin hydrophilic amniotic membrane designed to serve as a wound covering for a variety of surgical demands.

We have proprietary rights in all of the above products with the exception of TrueLok , TL-Hex TrueLok Hexapod System ®, Cemex ®, 8-Plate Guided Growth System ® and Contour VPS ®. We have the exclusive licensees and distribution rights for the True-Lok , TL-Hex TrueLok Hexapod System ®, Cemex ® in Italy and for the 8-Plate Guided Growth System ® and Contour VPS ® worldwide.

We have numerous products protected by common law and registered trademarks including but not limited to the following: Orthofix ®, Blackstone ®, Spinal-Stim ®, Cervical-Stim ®, Origen DBM, 3 Degree Reliant ® Hallmark ®, Firebird ®, Ascent ®, Construx ®, Unity ®, NGage ®, Newbridge ®, Trinity Evolution ®, PILLAR ® skyAlloquent , ProView , ProCallus , XCaliber ®VeroNail ®, Centronail ®, PREFIX , Gotfried PC.C.P ®, Physio-Stim ®, True-Lok , Galaxy Fixation System and TL-HEX .

Spine

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 that 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.

Additionally, 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.

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

Table of Contents

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.

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. Additionally, Spinal Implants and Biologics product portfolio includes a unique allograft with viable cells HCT/P bone grafting product called Trinity Evolution ®.

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

We also offer a variety of devices made of PEEK, including vertebral body replacements and interbody devices. Vertebral body replacements are designed to replace a patient s degenerated or deformed vertebrae. On the other hand, interbody devices, or cages, are designed to replace a damaged disc, restoring the space that had been lost between two vertebrae. Spinal Implants and Biologics also offers the NGage ® Surgical Mesh System made of titanium metal.

Spinal Regenerative Solutions

We are also a distributor of HCT/P products including interbody implants made of human cadaveric bone that have been harvested from donors and carved by a machine into a desired shape, and a unique allograft in Trinity Evolution ® with viable cells that is intended to enhance a patient s ability to quickly grow new bone around a spinal fusion site. This product contains live adult stem cells harvested from human cadaveric donors and is intended to be a safer, simpler alternative to an autograft, which is commonly performed in connection with a spine fusion procedure. An autograft involves a separate surgical incision in the patient s hip area in order to harvest the patient s own bone to be used during the fusion procedure. An autograft procedure adds risk of an additional surgical procedure and related patient discomfort in conjunction with the spinal fusion.

In addition to our Spinal Repair Solutions 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 bone 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 bone 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 indication opportunities for our regenerative stimulation solutions.

Some spine fusion patients are at greater risk of not achieving a solid fusion of new bone around the fusion site. These patients typically have one or more risk factors such as smoking, obesity or diabetes, or their surgery involves the revision of a failed fusion or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical regenerative stimulation has been shown to significantly increase the probability of fusion success. Spinal-Stim ® is a non-invasive spinal fusion stimulator system commercially available in the U.S. since 1990 and approved in Europe. Spinal-Stim ® is designed for the treatment of the lower thoracic and lumbar regions of the spine. The device uses proprietary technology and a wavelength to generate a PEMF signal. The U.S. Food and Drug Administration (the FDA) has approved Spinal-Stim ® as a spinal fusion adjunct to increase the probability of fusion success and as a non-operative treatment for salvage of failed spinal fusion at least nine months post-operatively.

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

Orthopedics

The medical devices offered in our Orthopedics global business unit include both repair and regenerative solutions.

Table of Contents

Orthopedic Repair Solutions

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

External Fixation

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

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

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

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

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

Building on the TrueLok brand, in the international markets, TL-HEX TrueLok Hexapod System, was released in 2012. TL-HEX is a hexapod-based system designed at Texas Scottish Rite Hospital for Children as a

three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. In essence, the system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings position is adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in 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) can be utilized with the TL-HEX . For successful application of the TL-HEX , an associated software is 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

Table of Contents

of bone screws to meet the demands of the market. Adding to the XCaliber bone screw product line are also cylindrical screws first released for the US market and which we expect will be following in international markets. The type of screw is geared towards the trauma applications of the Galaxy Fixation System.

Internal Fixation

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

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

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

The VeroNail ® marks Orthofix s entry into the intramedullary hip nailing market. Designed for use in hip fractures, it provides a minimally-invasive screw and nail design intended to reduce surgical trauma and allow patients to begin walking again shortly after the operation. It uses a dual screw configuration that we believe provides more stability than previous single screw designs.

The Contours LPS (Lapidus Plating System) in the US. This system is intended for the correction of moderate to severe forefoot hallus valgus (HV), accompanying bunions and associated instability. The Lapidus Plating System consists of plates, screws and instrumentation. The anatomical plates are low-profile, titanium, (left and right) designed specifically for 1st metatarsocuneiform joint arthrodesis allowing compression across the joint achieved through a delta-shaped hole and compression screws. Lapidus System screws are titanium, low-profile and self-tapping, and include locking, non-locking, and bone compression screws in a variety of lengths. Instrumentation includes a threaded drill guide, drillbits, 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 that are 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. Examples of products offered in these areas include the Eight-Plate Guided Growth System ®.

Orthopedic Regenerative Solutions

Our regenerative biologics products principally include Trinity Evolution ®, an allograft with viable cells used during surgery that is designed to enhance the success of a bone fusion procedure to facilitate bone fusion. Surgeons will use bone grafts when their patients have a large defect in the bone and it needs to be filled. Bone grafts can come directly from the patient s own bone (autograft) or from donor bone tissue that has been processed in specialized facilities or derived from a synthetic composition that resembles the components of human bone. To date, our Biologics are being offered only in the U.S. market due to restrictions in providing U.S. human donor tissue in other countries.

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.

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 done 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 Fairfield, New Jersey; Verona, Italy and Lewisville, Texas.

Table of Contents

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 Musculoskeletal Transplant Foundation (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 that our policy of accommodating such requests enhances our reputation in the medical community.

In 2012, 2011 and 2010 we spent $28.6 million, $22.9 million and $28.0 million, respectively, on research and development.

Patents, Trade Secrets, Assignments and Licenses

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

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

Corporate Compliance and Government Regulation

Corporate Compliance and Ethics Program

We have a comprehensive compliance program, which we branded the *Integrity Advantage* Program. We have a Chief Compliance Officer to oversee the *Integrity Advantage* Program 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* of this Form 10-K/A.

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,

Table of Contents

Drug, and Cosmetic Act and the Public Health Services Act as implemented and enforced by the FDA. The regulations that cover our products and facilities vary widely from country to country. The amount of time required to obtain approvals or clearances from regulatory authorities also differs from country to country.

Unless an exemption applies, each medical device that we wish to commercially distribute in the U.S. will be covered by either premarket notification (510(k)) clearance or approval of a premarket approval application (PMA) from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring approval of a PMA.

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

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

In addition, our Spinal Implants and Biologics business offers a product for bone repair and reconstruction under the brand name Trinity Evolution ® which is an allogeneic, cancellous, bone matrix containing viable stem cells. We believe that Trinity Evolution ® is 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 it is regulated under Section 361 of the Public Health Service Act and C.F.R. Part 1271. Spinal Implants and 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 products 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

that our suppliers of the Trinity Evolution ® 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 that 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 bone 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 that 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 that such approvals will be granted on a timely basis, if at all. While we believe that 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

Table of Contents

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 CFR 20.64 (d) (3), it will release a copy of the Establishment Inspection Report (EIR) to the inspected establishment. Orthofix received its EIR for the June 2011 inspection in August 2011 indicating that this inspection was closed. The corrective action associated with the one observation on the 483 was fully corrected by Orthofix and verified by the FDA in January 2012 during a routine inspection of the Lewisville facility. At the conclusion of the January inspection the FDA issued a 483 due to minor deficiencies within our quality systems. The Company replied with a formal response, and after reviewing the evidence the FDA determined our corrective action adequate and the audit was closed. In addition to the domestic FDA inspections, all manufacturing facilities of the Company are subject to annual notified body inspections. No major findings have been received and certification has been granted or maintained. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of those actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations or cash flows.

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 CE certification from a notified body in order to be able to sell products within the member states of the European Union. 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 and products.

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.

Table of Contents

Our sales and marketing practices are also subject to a number of U.S. laws regulating healthcare fraud and abuse such as the federal Anti-Kickback Statute and the federal Physician Self-Referral Law (known as the Stark Law), the Civil False Claims Act and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as numerous state laws regulating healthcare and insurance. These laws are enforced by the Office of Inspector General within the U.S. Department of Health and Human Services, the U.S. Department of Justice, and other federal, state and local agencies. Among other things, these laws and others generally: (1) prohibit the provision of anything of value in exchange for the referral of patients for, or the purchase, order, or recommendation of, any item or service reimbursed by a federal healthcare program, (including Medicare and Medicaid); (2) require that claims for payment submitted to federal healthcare programs be truthful; (3) prohibit the transmission of protected healthcare information to persons not authorized to receive that information; and (4) require the maintenance of certain government licenses and permits.

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

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) published a final rule which will make 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 will make information publicly available about physician (or immediate family members of a physician) ownership or investment interests in applicable manufacturers and group purchasing organizations (GPOs).

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

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

Sales, Marketing and Distribution

General Trends

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

Global Business Units

Our revenues are generally derived from the sales of products in two GBU s, Spine (which is comprised of our Spine Repair Implants and Regenerative Biologics and our Spine Regenerative Stimulation) and Orthopedics, which accounted for 68% and 32%, respectively, of our total net sales in 2012.

Table of Contents

Sales, Marketing and Distributor Network

We have established a broad distribution network comprised of direct sales representatives and distributors. This established distribution network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products worldwide in over 50 countries.

In our largest geographic market, the U.S., our sales, marketing and distribution network is separated between several distinct sales forces addressing different business units. The Spine global business unit is addressed primarily by a direct sales force for spinal regenerative stimulation products and an independent distribution network for spinal implant and HCT/P products. The Orthopedics global business unit is addressed by a hybrid distribution network of predominately direct sales representatives supplemented by distributors.

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

Marketing and Product Education

We seek to market our products principally to medical professionals and group purchasing organizations (GPOs), which are organizations that buy on a large scale. We believe there is a developing focus on selling 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 2012, these product education seminars were attended by over 1,265 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 compete principally with similar products marketed by Biomet Spine, a business unit of Biomet, Inc; DJO Incorporated; and the Exogen product line owned by Smith and Nephew plc. and Essex Woodland, a private equity firm. Our spinal implant, HCT/P products, and Trinity Evolution ®, an HCT/P product from which we derive marketing fees, compete with products marketed by Medtronic, Inc.; De Puy Synthes, a division of Johnson and Johnson; Stryker Corp.; Zimmer, Inc.; NuVasive; Biomet Spine; and various smaller public and private companies. For external and internal fixation devices, our principal competitors include De Puy Synthes;

Zimmer, Inc.; Stryker Corp.; Smith & Nephew plc; and Biomet Orthopedics, a business unit of Biomet, Inc.

We believe that 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 that 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/P products, 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 that alternate sources for these materials are available. Further, we believe that 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.

Table of Contents

Trinity Evolution ®, an HCT/P product for which we have exclusive marketing rights, is an allograft tissue form that is supplied to customers by MTF in accordance with orders received directly from us. MTF sources, processes and packages the tissue form and is the sole supplier of Trinity Evolution ® to our customers.

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

Our business is generally not seasonal in nature. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. In addition, we do not consider the backlog of firm orders to be material.

Capital Expenditures

We had tangible and intangible capital expenditures in the amount of $28.8 million, $25.8 million and $26.4 million in 2012, 2011 and 2010, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. In 2012, we invested $28.8 million in capital expenditures of which the most significant item was $13.9 million related to instrumentation and tooling. We currently plan to invest approximately $30 million in capital expenditures during 2013 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, 2012, we had 892 employees worldwide. Of these, 614 were employed in the U.S. and 278 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 130 at December 31, 2012, 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 that we have good relations with our employees. Of our 892 employees, 390 were employed in sales and marketing functions, 167 in general and administrative roles, 193 in production and operations and 142 in research and development.

Item 1A. Risk Factors

In addition to the other information contained in this Form 10-K/A and the exhibits hereto, you should carefully consider the risks described below and in other periodic reports that we have filed with the SEC since March 1, 2013 and will file in the future. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. This Form 10-K/A also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this Form 10-K/A.

Risks Related to the Audit Committee s Review, the Restatement of Certain of Our Financial Statements, the State of the Company s Internal Control Over Financial Reporting, Our Failure to Timely File Periodic Reports with the SEC and Related Matters

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, as further described herein. As a result of this review and the restatement, the filing of our Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2013 and September 30, 2013 were delayed until March 2014.

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 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.

Table of Contents

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 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 Amendment, 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, 2012 related to revenue recognition practices for sales to the Company s distributors, inventory reserves and foreign subsidiary oversight. Such material weaknesses resulted in material misstatements in our previously filed annual audited and interim unaudited consolidated financial statements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. 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 fiscal quarters ended June 30, 2013 and September 30, 2013. Because we have not remained current in our reporting requirements with the SEC, we are limited in our ability to access the public markets to raise debt or equity capital. Our limited ability to access the public markets could prevent us from pursuing transactions or implementing business

strategies that we might otherwise believe are beneficial to our business. Until one year after the date we regain and maintain compliance with our SEC reporting obligations, we will be ineligible to use shorter and less costly filings, such as Form S-3, to register our securities for sale. We may use Form S-1 to register a sale of our stock to raise capital or complete acquisitions, but doing so would likely increase transaction costs and adversely impact our ability to raise capital or complete acquisitions of other companies in a timely manner.

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

We have been delinquent in the filing of our Quarterly Reports on Form 10-Q for the fiscal quarters ended June 30, 2013 and September 30, 2013, as a result of which we have not been in compliance with the rules of the Nasdaq Stock Market and are subject to having our stock delisted from trading on Nasdaq. We have been granted a stay of the delisting of our common stock until such time as a Nasdaq Hearings Panel makes a decision on the merits following a hearing, which hearing has been scheduled for March 27, 2014. We are filing our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 on the date hereof, and expect to file our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013 on the date following the date hereof. We also expect to file our Annual Report on Form 10-K for the year ended December 31, 2013 (which is otherwise due under SEC rules on March 17, 2014) by March 31, 2014. As a result, we currently believe that we will adequately remedy our current non-compliance with Nasdaq s listing rules. However, there can be no assurance that the Nasdaq Hearings Panel will concur with our belief that we

Table of Contents

have remedied our prior non-compliance, in which case our common stock could remain subject to delisting by Nasdaq. If our common stock were delisted, there can 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.

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

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

As of the date hereof, we have not delivered the quarterly financial statements described above. We expect to deliver such information to the Lenders promptly following the date hereof. In addition, we expect to deliver our audited financial statements for the year ended December 31, 2013 by March 31, 2014, which is when they are required to be delivered under the Credit Agreement. However, in the event that we do not satisfy these respective obligations under the Limited Waiver and/or the Credit Agreement, an event of default could be declared under the credit agreement, which could have a material adverse effect on our financial position.

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 Foreign Corrupt Practices Act (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 and cash flows.

In 2012, the Company entered into a 3-year deferred prosecution agreement (the DPA) with the U.S. Department of Justice (DOJ), and a consent to final judgment (the Consent) with the U.S. Securities and Exchange Commission (the SEC), in connection with the Company s self-initiated and self-reported review of FCPA-related matters involving the Company s Mexican subsidiary, Promeca S.A. de C.V. Consistent with certain provisions of the DPA and the Consent, the Company voluntarily self-reported the Brazil-related allegations to the DOJ and the SEC, and the Company and its counsel remain in contact with both agencies regarding the status of the review. The DPA and the Consent collectively

require, among other things, that with respect to anti-bribery compliance matters we (i) cooperate fully with the government in matters related to corrupt payments, false books and records or inadequate internal controls, (ii) continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws, and (iii) provide certain periodic reporting to the government. In the event that the DOJ and the SEC find that the matters related to the Brazilian subsidiary described above could give rise to a review of our obligations under the terms of the DPA and/or 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 Consent. In the event such a review were to occur, any losses resulting therefrom, if substantial, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Risks Related to the SEC Enforcement Staff Review and Pending Litigation Arising Out of our Restatement

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

As further described in Part I, Item 3, Legal Proceedings of this Amendment, we initiated contact with the staff of the Division of Enforcement of the Securities and Exchange Commission (the SEC Enforcement Staff) in July 2013 to advise them of the initiation of the Audit Committee s review and the then-potential restatement of our annual and interim unaudited condensed

Table of Contents

consolidated financial statements. Since our initial contact, we have received requests from the SEC Enforcement Staff for documents and other information concerning various accounting, internal controls and business practices, and it is anticipated that we may receive additional such requests in the future. We have further provided notice concerning these matters to the Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG) pursuant to our Corporate Integrity Agreement (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 Amendment, 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 financial statements and the matters described above. In addition to the Company, several current and former members of our senior management are named as defendants. At the present time, the allegations that the lead plaintiff ultimately intends to make in this action are unknown.

We have incurred and/or expect to incur significant professional fees and other costs in responding to the SEC Enforcement Staff s review and in defending against the class action complaint. If we do not prevail in the pending complaint or any other litigation, we may be required to pay a significant amount of monetary damages that may be in excess of our insurance coverage. Further, if the SEC Enforcement Staff were to conclude that enforcement action is appropriate, or if HHS-OIG were to conclude that we violated the CIA, we could be required to pay large civil penalties and fines. The SEC also could impose other sanctions against us or certain of our current and former directors and officers. Any of these events would have a material adverse effect on our business, financial condition, results of operations or cash flows. Additionally, while we believe we have made appropriate judgments in determining the errors and correct adjustments in preparing our restated consolidated financial statements, the SEC may disagree with the manner in which we have accounted for and reported these adjustments. Accordingly, there is a risk that we may have to further restate our historical consolidated financial statements, amend prior filings with the SEC or take other actions not currently contemplated. In addition, our Board of Directors, management and employees may expend a substantial amount of time on the SEC Enforcement Staff s review and the pending complaint, diverting resources and attention that would otherwise be directed toward our operations and implementation of our business strategy, all of which could materially adversely affect our business, financial condition, results of operations or cash flows.

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

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

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

As a result of the restatement of our financial statements and related matters, the ongoing SEC Enforcement Staff review, the securities class action complaint and 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.

Risks Described in our Original Form 10-K

The following risk factors, which were also described in the Original Form 10-K, should be read in conjunction with the risk factors described above and any risk factors described in subsequent filings.

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.

Table of Contents

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., 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 and cash flows.

In connection with this settlement, on December 14, 2012, our subsidiary Orthofix Inc. plead guilty in the U.S. District Court for the District of Massachusetts to one felony count of obstruction of a federal audit (18 U.S.C. §1516) pursuant to a plea agreement with the U.S. Attorney s Office for the District of Massachusetts (the Boston USAO) and the U.S. Department of Justice. Under the terms of the sentencing order, the court has 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 Securities and Exchange Commission (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 3-year deferred prosecution agreement with DOJ. 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 provides that we shall continue to cooperate fully with DOJ 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 DOJ during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, we also agreed 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 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 and cash flows.

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 the Legal Proceedings section under Part I, Item 3 of this Form 10-K/A. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with these indemnified matters. In the event that they are substantial, it could have a material adverse effect our business, financial condition, results of operations and cash flows.

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.

Table of Contents

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.

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 2012, we continued to make improvements in revenues related to several new products we introduced to the market over the past two years, including the Phoenix® Minimally Invasive Spinal Fixation System, the Firebird ®Deformity Correction System, the FORZA Spacer System and Trinity Evolution ®, TL-HEX TrueLok Hexapod System, Galaxy Fixation ®System, Contours LPS (Lapidus Plating System, Centronail® Ankle Compression Nail, among others. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians) and obtain regulatory approvals, which can depend, among other things, on the product achieving broad clinical acceptance, the level of third-party reimbursement and the introduction of competing technologies. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

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

Acceptance of our products depends in part on our ability to (i) educate the medical community as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies, and (ii) train physicians in the proper use and implementation of our products. We support our sales force and distributors through specialized training workshops in which surgeons and sales specialists participate. We also produce marketing materials, including materials outlining surgical procedures, for our sales force and distributors in a variety of languages using printed, video and multimedia formats. To provide additional advanced training for surgeons, consistent with the AdvaMed Code and the Eucomed Code guidelines, we organize monthly multilingual teaching seminars in multiple locations, including our Orthofix Institute for Research, Training and Education in the North American Operations and Training Center in Lewisville, Texas. However, we may not be successful in our efforts to educate the medical community and properly train physicians. If physicians are not properly trained, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products.

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

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

Table of Contents

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.

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. Third-party payors, both in the United States and internationally, are increasingly challenging the prices charged for medical products and services. 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 for people to buy our products and substantially reduce, or possibly eliminate, the demand for our products. In addition, should governmental authorities continue to enact legislation or adopt regulations that affect third-party coverage and reimbursement, demand for our products and coverage by private or public insurers may be reduced with a consequential material adverse effect on our sales and profitability.

Table of Contents

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 DMEPOS items paid for by the Medicare program. The initial implementation of the program in 2008 was terminated in that same year. CMS began the Round 1 Rebid process in 2009 and the implementation of the rebid round occurred on January 1, 2011. 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 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 estimate that our revenue by payor type is:

Direct (hospital)	45%
Third-Party Insurance	24%
U.S. Government Medicare, Medicaid, TriCare	12%
Independent Distributors	11%
International Public Healthcare Systems	7%
Self-pay and other	1%

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. 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 Agency concludes that an inspection is closed under 21 CFR 20.64 (d) (3), it will release a copy of the Establishment Inspection Report (EIR) to the inspected establishment. Orthofix received its

Table of Contents

EIR for the June 2011 inspection in August 2011 indicating that this inspection was closed. The corrective action associated with the one observation on the 483 was fully corrected by Orthofix and verified by the FDA in January 2012. 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.

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) published a final rule which will make 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 will make information publicly available about physician (or immediate family members of a physician) ownership or investment interests in applicable manufacturers and group purchasing organizations (GPOs).

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

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

The impact of 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 legislation is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. 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 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 and 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, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions. If a group purchasing organization excludes 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.

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

Our Spinal Implants and Biologics business distributes a product under the brand name Trinity Evolution ®. Trinity Evolution ® is derived from human cadaveric donors, and our ability to distribute the product 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 ® is 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 would agree that this category of regulatory classification applies to Trinity Evolution ® and the

Table of Contents

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 ® product 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 ® is classified as an HCT/P product, it can from time to time be subject to recall for safety or administrative reasons.

Spinal Implants and Biologics also distribute 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 that 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 be subject to product liability claims that may not be covered by insurance and could require us to pay substantial sums.

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 is 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.

The global recession and further adverse changes in general economic or credit market conditions could adversely impact our sales and operating results.

The direction and strength of the U.S. and global economy has been uncertain due to the recent downturn in the economy and difficulties in the credit markets. If economic growth in the U.S. and other countries continues to remain low, or if the credit markets continue to be difficult to access, our distributors, suppliers and other business partners could experience significant disruptions to their businesses and operations which, in turn, could negatively impact our business operations and financial performance along with potentially causing us to be unable to collect existing accounts receivable. In addition, continued weak consumer financial strength and demand could cause a substantial reduction in the sale of our products.

Fluctuations in insurance expense could adversely affect our profitability.

We hold a number of insurance policies, including product liability insurance, 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 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.

New developments by others could make our products or technologies non-competitive or obsolete.

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.

Table of Contents

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 Spine and Orthopedic 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.

The industry in which we operate is highly competitive.

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.

We depend on our senior management team.

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

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

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

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 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.

Table of Contents

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. We have substantial activities outside of the U.S. that are subject to the impact of foreign exchange rates. The fluctuations of foreign exchange rates during 2012 have had a unfavorable impact of $9.4 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, 2012, 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 manufacturing facility and a number of our suppliers are located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

changes in foreign currency exchange rates;

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.

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

Table of Contents

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 new senior secured bank credit facility with a syndicate of financial institutions, and used these borrowings to repay all amounts owed under the old credit facility. The 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, 2012.

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 at December 31, 2012 and there were no events of default. 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.

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 or obtain future short-term or long-term lending.

Global market and economic conditions have been, and continue to be, disrupted and volatile. In particular, the cost and availability of funding for many companies has been, and may continue to be, adversely affected by illiquid credit markets and wider credit spreads. These forces reached unprecedented levels in 2008, resulting in the bankruptcy or acquisition of, or government assistance to, several major domestic and international financial institutions. These events have significantly diminished overall confidence in the financial and credit markets. There can be no assurances that recent government responses to the disruptions in the financial and credit markets will restore consumer confidence, stabilize the markets or increase liquidity and the availability of credit.

We maintain a five-year revolving credit facility of $200 million upon which we had $180 million available to be drawn as of December 31, 2012. 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.

The conditions of the U.S. and international capital and credit markets may adversely affect our interest expense under our existing credit facility.

Our senior bank facility provides for a five-year term loan facility of $100 million which was paid in full during 2012, and 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, 2012. Borrowings under the 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, 2012 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 Item 7A, Quantitative and Qualitative Disclosures About Market Risk in this Form 10-K/A.)

Table of Contents

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 results of operations (see Critical Accounting Policies and Estimates in Item 7 of this Form 10-K/A). 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 represent 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 Orthofix is now a Curaçao legal entity subject to Curaçao law. Although Curaçao has become a separate and autonomous country with its own laws and regulations, the civil and corporate Netherlands Antilles law, as they applied to Orthofix 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 Orthofix 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 Orthofix 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.

Table of Contents

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities as of December 31, 2012 were:

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 office for Spine Repair Implants and Regenerative Biologics	Fairfield, NJ	3,946	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

Table of Contents

unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where we believe a reasonable estimate of loss, or range of loss, can be made. In such instances, we believe that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

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

Matters Related to the Audit Committee s Review, the Restatement of Certain of our Consolidated Financial Statements, the State of the Company s Internal Control Over Financial Reporting and Our Failure to Timely File Periodic Reports with the SEC

Audit Committee Review

In July 2013, our Audit Committee began conducting an independent review, with the assistance of outside professionals, of certain accounting matters. This review resulted in the decision to restate certain of our previously filed consolidated financial statements. As a result of this review and the restatement of certain of our previously filed consolidated financial statements, the filing of our Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2013 and September 30, 2013 were not timely filed. We are filing our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 on the date hereof, and expect to file our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013 on the date following the date hereof. We also currently expect to file our Annual Report on Form 10-K for the year ended December 31, 2013 (which is otherwise due under SEC rules on March 17, 2014) by March 31, 2014.

SEC Enforcement Staff Review

In connection with the initiation of the audit committee review, we initiated contact with the staff of the Division of Enforcement of the Securities and Exchange Commission (the SEC Enforcement Staff) in July 2013 to advise them of these matters. The Audit Committee, through its counsel, has been in direct communication with the SEC Enforcement Staff regarding these matters, and both the Company and the Audit Committee are cooperating fully with the SEC Enforcement Staff s review of these matters. The Company has received requests from the SEC Enforcement Staff for documents and other information concerning various accounting, internal controls and business practices. Such requests cover the years ended December 31, 2011 and 2012, and in some instances, prior periods. It is anticipated that we may receive additional requests from the SEC Enforcement Staff in the future. We have further provided notice concerning these matters to the Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG) pursuant to our Corporate Integrity Agreement (CIA) with HHS-OIG (which CIA is described below in this Item 3).

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

Securities Class Action Complaint

On August 14, 2013, a securities class action complaint against the Company, currently styled Tejinder Singh v. Orthofix International N.V., et al. (No.:1:13-cv-05696-JGK), was filed in the United States District Court for the Southern District of New York arising out of the then anticipated restatement of our prior financial statements and the matters described above. In addition to the Company, Alan W. Milinazzo, our former President and Chief Executive Officer, Robert S. Vaters, our former President and Chief Executive Officer, Brian McCollum, our former Chief Financial Officer, Bradley R. Mason, our current President and Chief Executive Officer, and Emily Buxton, our current Chief Financial Officer, are named as defendants. The operative complaint has not yet been filed in the action following the appointment by the court of a lead plaintiff. Accordingly, the allegations that the lead plaintiff ultimately intends to make in this action are unknown. The matter is at an early stage and, at this time, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

Table of Contents

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 Foreign Corrupt Practices Act (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 2012, the Company entered into a 3-year deferred prosecution agreement (the DPA) with the U.S. Department of Justice (DOJ), and a consent to final judgment (the Consent) with the U.S. Securities and Exchange Commission (the SEC), in connection with the Company s self-initiated and self-reported review of FCPA-related matters involving the Company s Mexican subsidiary, Promeca S.A. de C.V. Consistent with certain provisions of the DPA and the Consent, the Company voluntarily self-reported the Brazil-related allegations to the DOJ and the SEC, and the Company and its counsel remain in contact with both agencies regarding the status of the review. The DPA and the Consent collectively require, among other things, that with respect to anti-bribery compliance matters we (i) cooperate fully with the government in matters related to corrupt payments, false books and records or inadequate internal controls, (ii) continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws, and (iii) provide certain periodic reporting to the government. In the event that the DOJ and the SEC find that the matters related to the Brazilian subsidiary described above could give rise to a review of our obligations under the terms of the DPA and/or 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 Consent.

Matters Related To Blackstone Medical, Inc. and Related Escrow Claims

In 2007, our subsidiary, Blackstone Medical, Inc. (Blackstone) received a subpoena issued by HHS-OIG, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena sought certain documents for the period January 1, 2000 through July 31, 2006, which covered a period prior to Blackstone s acquisition by us on September 22, 2006. In 2008 and 2009, respectively, we received a federal grand jury subpoena from the U.S. Attorney s Office for the District of Massachusetts (Boston USAO) and a HIPAA subpoena issued by the DOJ. These subpoenas sought certain documents from us for the period January 1, 2000 through July 15, 2007. Each of the subpoenas concerned the compensation of physician consultants and related matters.

In 2008, we obtained a copy of a qui tam complaint filed against us and Blackstone in the U.S. District Court for the District of Massachusetts. The complaint related to the matters described above involving HHS-OIG, the Boston USAO, and DOJ. The U.S. Department of Justice subsequently filed a notice of non-intervention in the case.

In January 2012, after a series of ongoing discussions and negotiations with the Boston USAO, our board of directors approved an agreement in principle to pay $32 million to resolve these matters. On October 29, 2012, we, through Blackstone, entered into a definitive settlement agreement with the U.S. government and the qui tam relator, which settlement agreement memorialized this agreement. All of the $32 million we paid pursuant to the settlement was funded by proceeds we received from an escrow fund established in connection with our acquisition of Blackstone in 2006. We also recorded a charge of $0.3 million in 2012 which represented imputed interest on the settlement accrued through the payment date in October of 2012.

Matters Related to Regenerative Stimulation Business

In 2009, we received a HIPAA subpoena (HIPAA subpoena) issued by the Boston USAO. The subpoena sought documents concerning, among other things, our promotion and marketing of our regenerative stimulator devices (which we have also described in the past as our bone growth stimulator devices). The Boston USAO issued several subsequent document and testimony subpoenas. We cooperated with these requests. We subsequently obtained a copy of a qui tam complaint filed in the U.S. District Court for the District of Massachusetts against us, Orthofix Inc. and other companies that have allegedly manufactured regenerative stimulation devices, including Orthologic Corp., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. The complaint, as subsequently amended in 2010, alleged various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of regenerative stimulation devices. The complaint also included claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-Kickback Act by providing free products to physicians, waiving patients insurance co-payments and providing inducements to independent sales agents to generate business.

On April 28, 2011, after a series of ongoing discussions and negotiations with the Boston USAO, our board of directors approved an agreement in principle proposed by the Boston USAO to resolve the criminal and civil matters described in the immediately preceding two paragraphs. On June 6, 2012, we entered into a definitive settlement agreement with the United States of America, acting through DOJ and on behalf of HHS-OIG, the TRICARE Management Activity, through its General Counsel, the

Table of Contents

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. 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) under the terms of the settlement agreement. In addition, we agreed in July 2012 to pay the qui tam relator s counsel $1.0 million in fees. These amounts were paid during the fourth quarter of 2012.

In connection with the settlement agreement, our wholly-owned subsidiary, Orthofix Inc., entered into a plea agreement with the Boston USAO and DOJ on June 7, 2012 under which Orthofix Inc. agreed to plead guilty to one felony count of obstruction of a June 2008 federal audit (§18 U.S.C. 1516). The plea agreement was amended on December 14, 2012, though all terms remained materially consistent with the earlier plea agreement we had executed. The plea was accepted and entered by the U.S. District Court for the District of Massachusetts on December 14, 2012. Consistent with the terms recommended in the plea agreement, the court imposed a criminal fine of $7.8 million and a mandatory special assessment of $400, which we subsequently paid during the fourth quarter of 2012. In addition, the court has imposed a five year term of probation, with special conditions which mandate certain non-disparagement obligations and order Orthofix Inc. to continue complying with the terms of the Company s previously-disclosed 5-year corporate integrity agreement (which is described below) through the expiration of its term.

We previously recorded a charge of $43 million during the first quarter of 2011 in anticipation of the settlement. We also recorded a charge of $0.7 million and $1.1 million in 2011 and 2012, respectively, which represented imputed interest on the settlement accrued through the payment date in December of 2012.

Corporate Integrity Agreement with HHS-OIG

On June 6, 2012, in connection with our settlement of the matters described above related to our regenerative stimulation business, and in anticipation of a final settlement of the government investigation and related qui tam complaint described above related to Blackstone Medical, Inc., 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 Food and Drug Administration (FDA) requirements. We are also required to maintain several elements of our previously existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that we conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations.

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

Matters Related to Promeca

On July 10, 2012, we entered into definitive agreements with DOJ and the Securities and Exchange Commission (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 3-year deferred prosecution agreement (DPA) with DOJ.

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 provides that we shall continue to cooperate fully with DOJ 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 DOJ during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, we also agreed 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 DOJ for the FCPA-related matters we self-reported.

Table of Contents

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 fourth 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 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 believes that meritorious defenses exist to these claims and Breg is vigorously defending these cases. One of the Company s insurance carriers previously asserted to the Company that certain potential losses related to this matter are not covered by its insurance coverage. The Company subsequently went into arbitration with this carrier, and on January 22, 2013, the Company obtained a binding arbitration award providing that such carrier is obligated to reimburse the Company for defense expenses, settlements, and judgments under certain policies. As of December 31, 2012, the Company estimated that it was entitled to reimbursement of approximately $13 million for past losses incurred, as well as up to $15 million in potential future coverage for pending products liability matters. The approximately $13 million is recorded in income (loss) from discontinued operations in 2012 and other current assets as of December 31, 2012, and was received in 2013. We have also accrued $6.1 million (all of which was accrued during the second fiscal quarter of 2013) for judgments and settlements in connection with these matters that were not covered by insurance.

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 is 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.

On January 27, 2012, we were orally notified by a U.S. Government official that a civil investigation of Breg was pending in connection with this matter. On January 18, 2013, we were served with a qui tam complaint filed in the United States District Court for the Western District of Missouri against us (as the former owner of Breg), Stryker Corporation, I-Flow Corporation and DJO Incorporated, which contains allegations relating to the marketing and promotion of Breg s former infusion pump products. In June 2013, the qui tam complaint filed in the United States District Court for the Western District of Missouri against us was dismissed by the court.

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 December 31, 2012, and their ages and biographies as of March 1, 2013, the date that the Original Form 10-K was filed. Of the executive officers listed below, Ms. Buxton and Messrs. Finegan and Schumm are the only executive officers that are employed by the Company as of the date of this Form 10-K/A.

Name	Age	Position
Robert S. Vaters	52	President and Chief Executive Officer and Director
Vicente Trelles	57	Executive Vice President of Worldwide Operations and Shared Services
Emily V. Buxton	36	Interim Chief Financial Officer and Chief Financial Officer, Orthopedic Global Business Unit
Brian McCollum	37	President, Global Spine Business Unit
Michael M. Finegan	49	Senior Vice President, Corporate Development and President, Biologics
Jeffrey M. Schumm	51	Senior Vice President, General Counsel and Corporate Secretary

Table of Contents

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.

Robert S. Vaters. Mr. Vaters became our President and Chief Executive Officer in August 2011, after serving as our Executive Vice President, Chief Operating Officer and President, Global Spine Business Unit from January 2011 through July 2011. He first joined the Company in September 2008, holding the position of Executive Vice President and Chief Financial Officer until January 2011. Mr. Vaters joined the Company after almost four years as a senior executive at Inamed Corporation, where he was Executive Vice President, Chief Financial Officer and Head of Strategy and Corporate Development. Prior to joining Orthofix, he was also the General Partner and founder of Med Opportunity Partners, a health-care private equity firm.

Vicente Trelles. Mr. Trelles joined Orthofix in April 2011 as Senior Vice President, Worldwide Operations and Shared Services, and was promoted to Executive Vice President, Worldwide Operations, Shared Services and R&D in December 2011. Mr. Trelles came to Orthofix from Med Opportunity Partners, a healthcare private equity firm, which he co-founded in 2006 and where he served as a Partner until joining Orthofix. From 2001 to 2006, Mr. Trelles was an Executive Vice President and Chief Operations Officer at Inamed Corporation, a global medical device company which was acquired by Allergan Inc. in March, 2006. Prior to Inamed, Mr. Trelles held several executive positions with Allergan, Baxter Healthcare and American Hospital Supply in Europe and the United States.

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

Brian McCollum. Mr. McCollum was named President of the Global Spine Business Unit in 2012, after having served as Chief Financial Officer in 2011. He joined Orthofix s corporate finance group in 2001 advancing to the position of Corporate Controller. In 2006, Mr. McCollum was named Vice President of Finance, Americas, and 2 years later became Vice President of International Finance and Group Treasurer. Prior to joining Orthofix, Mr. McCollum was a Senior Audit Associate with PriceWaterhouseCoopers. He received his Bachelors degree in Business Administration, with concentration in Accounting, from St. Andrews Presbyterian College.

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 his current position as Senior Vice President, Business Development, and President, Biologics. 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, and was promoted to Senior Vice President, General Counsel and Corporate Secretary in October 2010. 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.

Table of Contents

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, 2012. As of February 22, 2013 we had 356 holders of record of our common stock. The closing price of our common stock on February 22, 2013 was $36.95.

	High	Low
2011		
First Quarter	$ 32.91	$ 28.60
Second Quarter	42.47	32.92
Third Quarter	44.52	33.61
Fourth Quarter	36.03	30.84
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

Dividend Policy

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

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

Recent Sales of Unregistered Securities

There were no securities sold by us during 2012 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.

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

Table of Contents

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, 2007. Points on the graph represent the performance as of the last business day of each of the years indicated.

Table of Contents

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, 2012, 2011 and 2010, and the information below with respect to such fiscal years reflects the adjustments made as part of such restatement. See Note 2 to our audited consolidated financial statements, which accompany the financial statements in Item 8 of this report, for further information about the restatement. In addition, we have determined that errors existed in the Company s previously issued financial statements for the fiscal years ended December 31, 2009, 2008 and 2007, for which the Company is including restated information below as well as previously reported amounts, and the adjustments made thereto. The financial data as of December 31, 2012 and 2011 and for the fiscal years ended December 31, 2012, 2011 and 2010 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 accounting principles generally accepted in the U.S. (US GAAP).

	Year ended December 31,				
	2012 (Restated)	2011 (Restated)	2010 (Restated)	2009 (Restated)	2008 (Restated)
	(U.S. Dollars, in thousands, except margin and per share data)				
Consolidated operating results					
Net sales	$ 447,581	$ 441,971	$ 462,571	$ 429,237	$ 404,602
Gross profit (3)	349,328	346,444	365,478	329,973	299,045
Gross profit margin (3)	78%	78%	79%	77%	74%
Total operating income (loss) (5)	76,636	5,900	65,984	37,526	(273,459)
Net income (loss) from continuing operations, net of tax (2) (5)	45,050	(16,218)	30,997	10,469	(237,985)
Net income (loss) from discontinued operations, net of tax (4)	(2,212)	(1,892)	13,299	12,453	7,471
Net income (loss) (1) (2) (4) (5)	$ 42,838	$ (18,110)	$ 44,296	$ 22,922	$ (230,514)
Net (loss) income per share of common stock:					
Basic:					
Net income (loss) from continuing operations, net of tax	$ 2.37	$ (0.89)	$ 1.76	$ 0.61	$ (13.92)
Net income (loss) from discontinued operations, net of tax	(0.12)	(0.10)	0.76	0.73	0.44
Net income (loss)	$ 2.25	$ (0.99)	$ 2.52	$ 1.34	$ (13.48)
Net (loss) income per share of common stock:					
Diluted:					
Net income (loss) from continuing operations, net of tax	$ 2.32	$ (0.89)	$ 1.73	$ 0.61	$ (13.92)

Net income (loss) from discontinued operations, net of tax	(0.11)	(0.10)	0.74	0.72	0.44
Net income (loss)	$ 2.21	$ (0.99)	$ 2.47	$ 1.33	$ (13.48)

(1) The Company has not paid any dividends in any of the years presented.
(2) Net loss for 2008 includes $237.7 million after tax charge related to impairment of goodwill and certain intangible assets.
(3) Gross profit includes effect of obsolescence provision representing 2% points for the year ended December 31, 2008.
(4) Includes the gain on sale of vascular operations of $8.5 million for the year ended December 31, 2010.
(5) 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)	**2012 (Restated)**	**2011 (Restated)**	**2010 (Restated)**	**2009 (Restated)**	**2008 (Restated)**
	(U.S. Dollars, in thousands, except share data)				
Consolidated financial position					
Total assets	$ 472,897	$ 685,380	$ 608,251	$ 595,722	$ 568,056
Total debt	20,016	210,013	220,007	254,673	282,844
Shareholders equity	367,832	292,074	293,918	232,620	196,414
Weighted average number of shares of common stock outstanding (basic)	18,977,263	18,219,343	17,601,956	17,119,474	17,095,416
Weighted average number of shares of common stock outstanding (diluted)	19,390,413	18,219,343	17,913,545	17,202,943	17,095,416

Table of Contents

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

	Year ended December 31,					
	2012			2011		
	(U.S. Dollars, in thousands, except margin and per share data)					
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Consolidated operating results						
Net sales	$ 462,320	$ (14,739)	$ 447,581	$ 470,121	$ (28,150)	$ 441,971
Gross profit	375,828	(26,500)	349,328	377,502	(31,058)	346,444
Gross profit margin	81%	(3)%	78%	80%	(2)%	78%
Total operating income (loss)	89,010	(12,374)	76,636	31,309	(25,409)	5,900
Net income (loss) from continuing operations, net of tax	53,936	(8,886)	45,050	(1,740)	(14,478)	(16,218)
Net income (loss) from discontinued operations, net of tax	(2,641)	429	(2,212)	667	(2,559)	(1,892)
Net income (loss)	$ 51,295	$ (8,457)	$ 42,838	$ (1,073)	$ (17,037)	$ (18,110)
Net income (loss) per share of common stock:						
Basic:						
Net income (loss) from continuing operations, net of tax	$ 2.84	$ (0.47)	$ 2.37	$ (0.10)	$ (0.79)	$ (0.89)
Net income (loss) from discontinued operations, net of tax	(0.14)	0.02	(0.12)	0.04	(0.14)	(0.10)
Net income (loss)	$ 2.70	$ (0.45)	$ 2.25	$ (0.06)	$ (0.93)	$ (0.99)
Net income (loss) per share of common stock:						
Diluted:						
Net income (loss) from continuing operations, net of tax	$ 2.78	$ (0.46)	$ 2.32	$ (0.10)	$ (0.79)	$ (0.89)
Net income (loss) from discontinued operations, net of tax	(0.14)	0.03	(0.11)	0.04	(0.14)	(0.10)
Net income (loss)	$ 2.64	$ (0.43)	$ 2.21	$ (0.06)	$ (0.93)	$ (0.99)

	As of December 31,

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

Table of Contents

	Year ended December 31,					
	2010			2009		
	(U.S. Dollars, in thousands, except margin and per share data)					
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Consolidated operating results						
Net sales	$ 460,629	$ 1,942	$ 462,571	$ 430,479	$ (1,242)	$ 429,237
Gross profit	370,168	(4,690)	365,478	333,616	(3,643)	329,973
Gross profit margin	80%	(1)%	79%	77%		77%
Total operating income (loss)	66,250	(266)	65,984	42,108	(4,582)	37,526
Net income (loss) from continuing operations, net of tax	27,758	3,239	30,997	9,006	1,463	10,469
Net income (loss) from discontinued operations, net of tax	16,450	(3,151)	13,299	15,466	(3,013)	12,453
Net income (loss)	$ 44,208	$ 88	$ 44,296	$ 24,472	$ (1,550)	$ 22,922
Net income (loss) per share of common stock:						
Basic:						
Net income (loss) from continuing operations, net of tax	$ 1.58	$ 0.18	$ 1.76	$ 0.53	$ 0.08	$ 0.61
Net income (loss) from discontinued operations, net of tax	0.93	(0.17)	0.76	0.90	(0.17)	0.73
Net income (loss)	$ 2.51	$ 0.01	$ 2.52	$ 1.43	$ (0.09)	$ 1.34
Net income (loss) per share of common stock:						
Diluted:						
Net income (loss) from continuing operations, net of tax	$ 1.55	$ 0.18	$ 1.73	$ 0.52	$ 0.09	$ 0.61
Net income (loss) from discontinued operations, net of tax	0.92	(0.18)	0.74	0.90	(0.18)	0.72
Net income (loss)	$ 2.47	$	$ 2.47	$ 1.42	$ (0.09)	$ 1.33

(at year-end)	As of December 31,					
	2010			2009		
	(U.S. Dollars, in thousands, except share data)					
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Consolidated financial position						
Total assets	$ 612,926	$ (4,675)	$ 608,251	$ 601,690	$ (5,968)	$ 595,722
Total debt	220,007		220,007	254,673		254,673

Shareholders equity	300,891	(6,973)	293,918	240,269	(7,649)	232,620
Weighted average number of shares of common stock outstanding (basic)	17,601,956		17,601,956	17,119,474		17,119,474
Weighted average number of shares of common stock outstanding (diluted)	17,913,545		17,913,545	17,202,943		17,202,943

Table of Contents

	Year ended December 31, 2008 (U.S. Dollars, in thousands, except margin and per share data)		
	Previously Reported	Adjustments	Restated
Consolidated operating results			
Net sales	$ 407,257	$ (2,655)	$ 404,602
Gross profit	302,369	(3,324)	299,045
Gross profit margin	74%		74%
Total operating income (loss)	(271,283)	(2,176)	(273,459)
Net income (loss) from continuing operations, net of tax	(239,075)	1,090	(237,985)
Net income (loss) from discontinued operations, net of tax	10,521	(3,050)	7,471
Net income (loss)	$ (228,554)	$ (1,960)	$ (230,514)
Net income (loss) per share of common stock: Basic:			
Net income (loss) from continuing operations, net of tax	$ (13.99)	$ 0.07	$ (13.92)
Net income (loss) from discontinued operations, net of tax	0.62	(0.18)	0.44
Net income (loss)	$ (13.37)	$ (0.11)	$ (13.48)
Net income (loss) per share of common stock: Diluted:			
Net income (loss) from continuing operations, net of tax	$ (13.99)	$ 0.07	$ (13.92)
Net income (loss) from discontinued operations, net of tax	0.62	(0.18)	0.44
Net income (loss)	$ (13.37)	$ (0.11)	$ (13.48)

(at year-end)	As of December 31, 2008 (U.S. Dollars, in thousands, except share data)		
	Previously Reported	Adjustments	Restated
Consolidated financial position			
Total assets	$ 573,542	$ (5,486)	$ 568,056

Total debt	282,844		282,844
Shareholders equity	202,061	(5,647)	196,414
Weighted average number of shares of common stock outstanding (basic)	17,095,416		17,095,416
Weighted average number of shares of common stock outstanding (diluted)	17,095,416		17,095,416

Table of Contents

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

As discussed below and in Item 8. Financial Statements and Supplementary Data Notes to the Consolidated Financial Statements Note 2 Restatement of the Consolidated Financial Statements , we have restated our previously issued audited consolidated financial statements for the fiscal years ended December 31, 2012, 2011 and 2010 and our unaudited condensed consolidated financial statements for each of the quarters within 2012 and 2011. Accordingly, the Management s Discussion and Analysis of Financial Condition and Results of Operations set forth below has been revised for the effects of the restatement.

The following discussion and analysis addresses the results of our operations which are based upon the consolidated financial statements included herein, which have been prepared in accordance with GAAP. This discussion should be read in conjunction with Forward-Looking Statements and our consolidated financial statements and notes thereto appearing elsewhere in this restated Form 10-K/A. This discussion and analysis also addresses our liquidity and financial condition and other matters.

Restatement of Previously Issued Consolidated Financial Statements

As described further below and herein, this Form 10-K/A reflects the restatement of our consolidated financial statements as of and for each of the years ended December 31, 2012 and December 31, 2011. The restatement of the Original Form 10-K reflected in this Amendment corrects errors principally related to our accounting for revenue recognition for sales to distributors, our accounting for inventory reserves, and our accounting for royalties. This Management s Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement adjustments. See Note 2 to our consolidated financial statements, which accompany the financial statements in Item 8 of this Form 10-K/A, for further detail regarding the restatement adjustments. In addition, for further information regarding the matters leading to the restatement and related findings respect to our disclosure controls and procedures and internal control over financial reporting, see Part II, Item 9A, Controls and Procedures of this Amendment.

Audit Committee Review

In conjunction with the Audit Committee review described in the Explanatory Note to this Form 10-K/A, management concluded that errors existed in the Company s previously issued financial statements with respect to the fiscal years ended December 31, 2012, 2011 and 2010, and the fiscal quarter ended March 31, 2013. In addition, other errors have been identified in the Company s previously issued consolidated financial statements for the fiscal years ended December 31, 2009, 2008 and 2007, for which the Company is including restated financial information for the fiscal years ended December 31, 2009 and 2008 in the Selected Financial Data table of this Form 10-K/A. Adjustments prior to January 1, 2010 have been recognized as a cumulative adjustment to beginning retained earnings in the consolidated statements of changes in shareholders equity included in the consolidated financial statements contained herein.

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

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

As set forth in more detail below, the restatement of the Company s consolidated financial statements included in this Form 10-K/A decreased net sales by $14.7 million and $28.2 million in 2012 and 2011, respectively, and increased net sales by $1.9 million in 2010; decreased net income from continuing operations by $8.9 million and $14.5 million in 2012 and 2011, respectively, and increased net income from continuing operations by $3.2 million in 2010; and decreased opening retained earnings and total shareholders equity at January 1, 2010 by $8.3 million and $7.6 million, respectively.

Table of Contents

General

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

Our 2012 results and financial condition include the following items of significance:

Spine revenues, which includes Spine Regenerative Stimulation, increased $16.8 million in 2012 or 6% when compared to 2011, led by our Spine Regenerative Biologics and Spine Repair Implants. Our Orthopedics revenue decreased 7% or $11.1 million dollars during 2012 as compared to 2011. Foreign currency accounted for 2% of the decrease with the rest due to an 8% decrease in sales in our external fixation.

A decrease in operating expenses as a percentage of net sales as compared to prior period is primarily a result of the reduction in charges related to U.S. Government Resolutions. Please refer to the explanation provided in our Liquidity and Capital Resources section of the Management Discussion and Analysis.

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

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

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

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar denominated income and expenditures. During

the year, we have used derivative instruments to hedge foreign currency fluctuation exposures. See Item 7A Quantitative and Qualitative Disclosures About Market Risk.

Critical Accounting Policies and Estimates

Our discussion of operating results is based upon the consolidated financial statements and accompanying notes to the consolidated financial statements prepared in conformity with GAAP. The preparation of these statements necessarily requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. These estimates and assumptions form the basis for the carrying values of assets and liabilities. On an ongoing basis, we evaluate these estimates, including those related to contractual allowances, doubtful accounts, inventories, potential intangible assets and goodwill impairment, income taxes, and share-based compensation. We base our estimates on historical experience and various other assumptions. Actual results may differ from these estimates. We have reviewed our critical accounting policies with the Audit Committee of the Board of Directors.

Revenue Recognition

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

Revenue is also derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of our stimulation products. Revenue is recognized when the stimulation product is placed on or implanted in and accepted by the patient. Amounts paid by these

Table of Contents

third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or pre-authorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

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

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

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

Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs are included in cost of sales. Royalty revenues are recognized when the royalty is earned.

Allowance for Doubtful Accounts and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collection and payor reimbursement experience is an integral part of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. In the judgment of management, adequate allowances have been provided for doubtful accounts and contractual allowances. Our estimates are periodically tested against actual collection experience.

Inventory Allowances

We write down our inventory for inventory excess and obsolescence by an amount equal to the difference between the cost of the inventory and the estimated net realizable value based upon the current stage of the product s life cycle and assumptions about future demand and market conditions. Inventory is analyzed to assess the adequacy of inventory excess and obsolescence provisions. Reserves for excess and obsolescence provisions are recorded as adjustments to cost of sales. As set forth in Accounting Standards Codification (ASC) Topic 330, *Inventory* (specifically ASC 330-10-35-14), a write-down of inventory to the lower-of-cost-or-market value at the close of a fiscal year creates a new cost basis that subsequently should not be marked up based on changes in underlying circumstances. If conditions or assumptions used in determining the market value change, additional inventory adjustments in the future may be necessary.

Goodwill and Other Intangible Assets

In accordance with ASC Topic 360 Property, Plant and Equipment, intangible assets with definite lives are tested for impairment if any adverse conditions exist or change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. If an impairment indicator exists, we test the intangible asset for recoverability. For purposes of the recoverability test, we group our intangible assets with other assets and liabilities at the lowest level of identifiable cash flows if the intangible asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the intangible asset (asset group) exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset (asset group), we will write the carrying value down to the fair value in the period identified.

Table of Contents

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

We test goodwill and certain indefinite lived trademarks at least annually for impairment. We test more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. We assess goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. We have identified two reporting units, which are consistent with our reporting segments; Spine and Orthopedics.

The Company is not required to calculate the fair value of a reporting unit unless the Company determines that it is more likely than not that its fair value is less than the carrying amount. The Company assesses the qualitative factors while performing the step zero analysis.

In performing the annual impairment test, which is performed during the fourth quarter or more frequently when impairment indicators exist, after assessing the qualitative factors in step zero, we may be required to utilize the two-step approach prescribed. The first step requires a comparison of each reporting unit s carrying value to the fair value of the respective unit. If the carrying value exceeds the fair value, a second step is performed to measure the amount of impairment loss, if any. The fair value of each reporting unit is estimated, entirely or predominantly, using an income based approach. This income approach utilizes a discounted cash flow (DCF), which estimates after-tax cash flows on a debt free basis, discounted to present value using a risk-adjusted discount rate.

In performing a DCF calculation, we are required to make assumptions about the amount and timing of future expected cash flows, terminal value growth rates and appropriate discount rates and no impairments were recorded during 2012 and 2011. Since December 31, 2011, there has been no event or adverse business trend that would suggest that goodwill or our indefinite lived intangibles have been impaired or that an interim test should be performed. Subsequent to the sale of Breg, the Company had no indefinite lived intangibles.

Litigation and Contingent Liabilities

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

Tax Matters

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

We account for uncertain tax positions in accordance with ASC 740 *Income Taxes* which contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We re-evaluate our income tax positions periodically to consider factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues under audit and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision.

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

Table of Contents

Results of Operations

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

	Year ended December 31,		
	2012 (%) (Restated)	2011 (%) (Restated)	2010 (%) (Restated)
Net sales	100	100	100
Cost of sales	22	22	21
Gross profit	78	78	79
Operating expenses			
Sales and marketing	42	44	42
General and administrative	12	14	16
Research and development	6	5	6
Amortization of intangible assets	1	1	1
Charges related to U.S. Government resolutions		13	
Total operating income (loss)	17	1	14
Net income (loss) from continuing operations	10	(3)	7
Net income (loss) from discontinued operations	(1)	(1)	3
Net income (loss)	9	(4)	10

We manage our business by our two global business units (GBU s), which are comprised of Spine and Orthopedics, supported by our Corporate activities. These GBUs represent the current segments in which our Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. Accordingly, our segment information (as provided below) has been prepared based on our two GBU reporting segments. Corporate activities not necessarily identifiable within the two GBUs are recorded as part of Corporate.

Spine

Spine provides a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of spinal conditions. This global business unit specializes in the design, development and marketing of our spine repair products along with regenerative stimulation and biologics products used in spine applications. Spine distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell spine products to hospitals, doctors and other healthcare providers, globally.

Orthopedics

Orthopedics provides a portfolio of repair and regenerative products that allow physicians to successfully treat a variety of orthopedic conditions unrelated to spine. This global business unit specializes in the design, development and marketing of our orthopedic repair products along with regenerative stimulation and biologics products used in orthopedic applications. Orthopedics distributes its products through a network of distributors, sales representatives and affiliates. This global business unit uses both direct and distributor sales representatives to sell orthopedics products to hospitals, doctors and other healthcare providers, globally.

Corporate

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

Table of Contents

GBU Revenues

Business Segments by GBU:

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

(U.S. Dollars, in thousands)	External Net Sales by GBU Year ended December 31, 2012		2011		2010	
	Net Sales (Restated)	Percent of Total Net Sales (Restated)	Net Sales (Restated)	Percent of Total Net Sales (Restated)	Net Sales (Restated)	Percent of Total Net Sales (Restated)
Spine						
Spine Repair Implants and Regenerative Biologics	$ 142,829	32%	$ 124,415	28%	$ 132,938	29%
Spine Regenerative Stimulation	159,289	36%	160,946	37%	172,574	37%
Total Spine	302,118	68%	285,361	65%	305,512	66%
Orthopedics	145,463	32%	156,610	35%	157,059	34%
Total Net Sales	$ 447,581	100%	$ 441,971	100%	$ 462,571	100%

2012 Compared to 2011

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

Sales

Net sales in our Spine global business unit increased to $302.1 million in 2012 compared to $285.4 million for 2011, an increase of 6%. The increase in Spine s net sales was primarily the result of a 14.8% increase in sales of our Spine Repair and Regenerative Biologics in 2012 when compared to 2011, due to increased adoption of Trinity Evolution® in Spine applications which led to a 30% increase in sales of Regenerative Biologics in 2012. Sales of Spine Repair devices increased 9% in 2012 when compared to 2011. This sales increase was partially offset by a decrease in sales of Regenerative Stimulation products used in Spine applications of 1% when compared with 2011.

Net sales in our Orthopedics global business unit decreased 7% to $145.5 million in 2012 compared to $156.6 million for 2011. Orthopedics s constant currency net sales decreased by 1%, or $1.6 million, during 2012 as compared to 2011. This decrease was primarily due to a 17% decrease in Physio-Stim Regenerative Stimulation sales which were was partially offset by increased sales of Trinity Evolution® in orthopedic applications which resulted in a 9% increase in Orthopedic Regenerative Biologics.

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

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

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

Research and Development Expense Research and development expense increased $5.7 million in 2012 to $28.6 million compared to $22.9 million in 2011. As a percent of sales, research and development expense was 6.4% in 2012 compared to 5.2% for the same period last year. The increase in research and development expenses in 2012 compared to 2011 was due to a $3.1 million charge for an arbitration resolution related to a 2008 co-development agreement, a $3 million strategic investment with MTF on the development and commercialization of the next generation cell-based bone growth technology and timing of spending related to our ongoing research, development and clinical activities.

Table of Contents

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

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

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

Other Expense, net Other expense, net was $1.7 million in 2012 compared to $2.4 million in 2011. The decrease can be mainly attributed to the effect of foreign exchange. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

Income Tax Benefit (Expense) We recognized a $25.1 million and $14.2 million provision for income tax for 2012 and 2011, respectively. During 2012, we recognized a change in the estimate of the tax deduction associated with the settlement of the U.S. Government investigation of the Company s bone growth stimulation business. The income tax expense and effective tax rate for the year ended 2011 reflects a disproportionate ratio to 2012, as we did not record tax benefit on certain expenses associated with our estimate of the charges related to U.S. Government resolutions in 2011. The effective tax rate was approximately 42.0% in 2012 and 149.1% in 2011 excluding the impact of the charges related to the U.S. Government resolutions and the foreign rate differential.

Discontinued operations Discontinued operations in 2012 include approximately $4.0 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to our former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. 2012 also includes the gain on the sale of Breg of $1.3 million and the results of our Sports Medicine GBU up to May 24, 2012 (the closing date of the sale of Breg), net of income taxes. Subsequent to year end, the Company won an arbitration award against an insurance carrier relating to its denial of coverage under excess products liability policies with total limits of $30 million. As a result of the binding arbitration award, the carrier is obligated to reimburse the Company for defense expenses, settlements, and judgments associated with the underlying products liability claims at issue. The Company estimates that it is entitled to reimbursement of approximately $13 million for past losses incurred, which is included in discontinued operations in 2012. Discontinued operations in 2011 includes the results of our Sports Medicine GBU.

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

2011 Compared to 2010

Net sales decreased 4.5% to $442.0 million in 2011 compared to $462.6 million in 2010. The impact of foreign currency increased sales by $5.6 million in 2011 when compared to 2010. Net sales includes product sales and marketing service fees which are comprised of sales of Trinity Evolution® in spine and orthopedic applications.

Sales

Net sales in our Spine global business unit decreased to $285.4 million in 2011 compared to $305.5 million in 2010, a decrease of 7%. The decrease in Spine s net sales was primarily the result of a 7% decrease in sales of our spine stimulation products in 2011 when compared to 2010, due to lower industry-wide surgical procedures and organizational changes to our sales force. This sales decrease was exacerbated by a 14% decrease in sales of our implant products, and partially offset by a 23% increase in sales of our biologics products when compared to 2010. The decline in hardware products was due to a decline in spine fixation products in 2011 compared to 2010, and was partially offset by improved sales in our thorocolumbar devices in 2011 compared to 2010 due to increased sales of our Firebird® platform products including Phoenix MIS and Deformity Correction.

Table of Contents

Net sales in our Orthopedics global business unit decreased to $156.6 million in 2011 compared to $157.1 million for 2010, a decrease of less than 1%. Orthopedics s constant currency net sales decreased by 1%, or $1.0 million during 2011 as compared to 2010. This decrease was due to a reduction in stimulation products used in long-bone applications but was offset by an increase in sales of fixation products and the increased use of Trinity Evolution® in orthopedic applications. Sales of our fixation products and biologics products increased 11% and 22%, respectively, during 2011 when compared to 2010.

Gross Profit Gross profit decreased 5% to $346.4 million for 2011, compared to $365.5 million for 2010. Gross profit as a percent of net sales was 78.4% in 2011 and 79.0% in 2010.

Sales and Marketing Expense Sales and marketing expense, which includes commissions and the bad debt provision, generally increases and decreases in relation to sales. Sales and marketing expense decreased $2.6 million, or 1.3%, to $193.5 million in 2011 compared to $196.1 million in 2010. As a percent of sales, sales and marketing expense was 43.8% and 42.4% for 2011 and 2010, respectively.

General and Administrative Expense General and administrative expense decreased $8.5 million, or 11.7%, in 2011 to $64.5 million compared to $73.0 million in 2010, 2011 and 2010 included the impact of approximately $8.1 million and $9.2 million, respectively, in legal expenses associated with the bone growth stimulation investigation as well as costs incurred in connection with our internal investigation into the compliance with the Foreign Corrupt Practices Act with our orthopedic distribution entity in Mexico. 2011 included $3.2 million of senior management succession charges. These expenses were offset by the various consolidation and operational efficiency initiatives we have executed on over the past several quarters. Also in 2010 general and administrative expense included $2 million related to employee termination benefits associated with our internal reorganization which streamlined operations and is expected to lower future operating costs. General and administrative expense as a percent of sales was 14.6% in 2011 compared to 15.8% in 2010.

Research and Development Expense Research and development expense decreased $5.1 million in 2011 to $22.9 million compared to $28.0 million in 2010. As a percent of sales, research and development expense was 5.2% in 2011 compared to 6.0% for 2010. The decrease in research and development expenses in 2011 compared to 2010 was due to timing of spending related to our ongoing research, development and clinical activities, our focus to eliminate activities that are not directly related to developing and bringing our products to market, and certain improvements in our operational efficiencies. In addition 2010 included costs associated with the cancellation of the cervical disc clinical trial.

Amortization of Intangible Assets Amortization of intangible assets was $2.6 and $2.4 million for the year ended December 31, 2011 and 2010, respectively.

Charges Related to U.S. Government Resolutions During 2011, we reached an agreement in principle with the U.S. Government to resolve criminal and civil matters related to the previously disclosed government investigations of our regenerative stimulation business. We expect that the Company will pay $43 million to resolve these matters, and $0.6 million representing imputed interest accrued for the settlement, and recorded a charge for this amount.

During the fiscal year ended December 31, 2011, we recorded a charge of $7.5 million to establish an accrual in connection with the fines and penalties related to the FCPA matter involving our Promeca subsidiary.

In February 2012, we reached an agreement with the representative of the former shareholders of Blackstone resolving all outstanding escrow and indemnification claims under the Blackstone Merger Agreement. Under this agreement, approximately $42.5 million was distributed from the escrow fund to us (which will be used, among other things, to

fund the proposed $32 million settlement in principle described above). Each of the Company and the former shareholders also mutually released each other from all further claims against each other related to these matters. As of September 30, 2011, we had recognized $15.5 million as an escrow receivable on our balance sheet, reflecting previously incurred expenses that we believed were reasonably assured of collection. In 2012 we received approximately $9.5 million in cash from the escrow fund after application of (i) the $32 million allocated to the settlement in principle described above with the government and (ii) approximately $1 million of other fees recently incurred with respect to this matter since September 30, 2011. As a result, we have recorded a charge of approximately $6 million during the fourth quarter of 2011 for previously incurred legal fees that were reflected in this escrow receivable balance as of September 30, 2011.

Interest Expense, net Interest expense, net was $5.5 million in 2011 compared to $11.3 million in 2010. The decrease was primarily the result of a lower rate of effective interest due to refinancing in 2010 and a lower year-over-year outstanding debt balance.

Other Expense, net Other expense, net was $2.4 million in 2011 compared to other income, net of $0.3 million in 2010. The change can be mainly attributed to the effect of foreign exchange. Several of our foreign subsidiaries hold trade payables or receivables in currencies (most notably the U.S. Dollar) other than their functional (local) currency which results in foreign exchange gains or losses when there is relative movement between those currencies.

Table of Contents

Income Tax Benefit (Expense) We recognized a $14.2 million and $24.0 million provision for income tax for 2011 and 2010, respectively. The income tax expense and effective tax rate for the year ended 2011 reflects a disproportionate ratio to 2010, as we did not record tax benefit on certain expenses associated with our estimate of the charges related to U.S. Government resolutions in 2011. The effective tax rate for 2010 was mainly impacted by the sale of the vascular assets along with losses in certain jurisdictions for which we receive no tax benefit and the mix of earnings among tax jurisdictions. The effective tax rate was approximately 149.1% in 2011 and 43.2% in 2010 excluding the impact of the charges related to the U.S. Government resolutions and the foreign rate differential.

Discontinued operations Discontinued operations in 2011 and 2010 includes the results of our Sports Medicine GBU.

Net Income (Loss) Net loss in 2011 was $(18.1) million, or $(0.99) per diluted share, compared to net income of $44.3 million, or $2.47 per diluted share for 2010. The weighted average number of diluted common shares outstanding was 18,219,343 and 17,913,545 during the years ended December 31, 2011 and 2010, respectively.

Restatement of Interim Financial Statements

We have restated all interim quarterly periods of 2012 and 2011 to correct errors noted principally in the Company s accounting for revenue recognition on sales to distributors, inventory reserves and royalties, and recorded other adjustments to correct previously identified errors affecting operating income. The following paragraphs update the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations for the interim periods ended March 31, June 30 and September 30, 2012 and 2011.

For the three months ended March 31, 2012, gross profit increased $6.3 million to $87.6 million in the first quarter of 2012, compared to $81.3 million for the same period of 2011. Gross profit as a percent of net sales in the first quarter of 2012 increased to 80.4% compared to 78.4% for the same period last year.

For the three months ended June 30, 2012, our gross profit increased $0.4 million to $85.9 million in the second quarter of 2012 compared to $85.5 million for the same period last year. Gross profit as a percent of net sales in the second quarter of 2012 was 75.7% for the second quarter of 2012 and 79.0% for 2011 during the same period.

For the six months ended June 30, 2012, our gross profit increased $6.7 million to $173.4 million in the first six months of 2012, compared to $166.7 million for the same period last year. Gross profit as a percent of net sales in the first six months of 2012 was 78.0% for the first six months of 2012 and 78.7% in 2011 during the same period.

For the three months ended September 30, 2012, our gross profit decreased $4.9 million to $83.5 million in the third quarter of 2012 compared to $88.4 million for the same period last year. Gross profit as a percent of net sales in the third quarter of 2012 was 77.4% for the third quarter of 2012 and 79.3% for 2011 during the same period.

For the nine months ended September 30, 2012, our gross profit increased $1.8 million to $256.9 million in the first nine months of 2012, compared to $255.1 million for the same period last year. Gross profit as a percent of net sales in the first nine months of 2012 was 77.8% for the first nine months of 2012 and 78.9% in 2011 during the same period.

Liquidity and Capital Resources

Cash and cash equivalents at December 31, 2012 were $52.4 million, of which $21.3 million is subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $78.7 million at December 31, 2011, of which $45.5 million was subject to certain restrictions under the senior secured credit agreement described below.

Net cash provided by operating activities was $10.2 million in 2012 compared to $64.8 million in 2011, a decrease of $54.6 million. Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, provision for doubtful accounts, share-based compensation, deferred taxes, and the net gain on sale of vascular operations) and changes in working capital. Net income increased $60.9 million to a net income of $42.8 million in 2012 compared to net loss of $18.1 million in 2011. Non-cash items for 2012 decreased $3.9 million to $42.6 million compared to $46.5 million in 2011. The change in working capital accounts is mainly attributable to charges related to U.S. Government resolutions and the escrow receivable. During 2011, we incurred charges related to the U.S. Government resolutions and fully paid these settlements during 2012. During 2011, the escrow receivable balance increased $32.6 million. The full escrow receivable was received in cash in 2012. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect day s sales in receivables of 84 days at December 31, 2012 compared to 77 days at December 31, 2011 and inventory turns of 1.2 times at December 31, 2012 and December 31, 2011.

Table of Contents

Net cash provided by investing activities was $125 million in 2012 compared to net cash use of $31 million in 2011 primarily driven by the net proceeds on the sale of Breg Inc. During 2012 and 2011, we invested $28.8 million and $25.8 million in capital expenditures, respectively.

Net cash used in financing activities was $137.6 million for 2012 compared to $13.7 million for 2011. During 2012, we repaid approximately $188.7 million against the principal on our senior secured debt compared to $7.5 million in 2011. Our restricted cash balance decreased $25.8 million compared to an increase of $24.2 million in 2011. During the year ended December 31, 2012, we received proceeds of $25.6 million compared to $20.1 million during 2011, from the issuance of shares of our common stock related to stock purchase plan issuances and stock option exercises.

On August 30, 2010, the Company s wholly-owned U.S. holding company, Orthofix Holdings, Inc. (Orthofix Holdings) entered into a Credit Agreement (the Credit Agreement) with certain domestic direct and indirect subsidiaries of the Company (the Guarantors), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto. The Credit Agreement provides for a five year, $200.0 million secured revolving credit facility (the Revolving Credit Facility), and a five year, $100.0 million secured term loan facility (the Term Loan Facility , and together with the Revolving Credit Facility, the Credit Facilities). Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to $50.0 million upon satisfaction of certain conditions.

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

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

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

The Credit Agreement, as amended, also includes events of default customary for facilities of this type. Upon the occurrence of an event of default, all outstanding loans may be accelerated and/or the lenders commitments terminated. The Company was in compliance with the affirmative and negative covenants at December 31, 2012 and there were no events of default.

On August 14, 2013, we and certain required lender parties to the Credit Agreement entered into a Limited Waiver (the Limited Waiver). Under the Limited Waiver, the lenders under the Credit Agreement (the Lenders) collectively waived requirements under the Credit Agreement that we deliver quarterly financial statements with respect to the fiscal quarters ending on June 30, 2013 and September 30, 2013, and related financial covenant certificates, until the earlier of (i) March 31, 2014 or (ii) the date that is one day after such financial statements are publicly filed or released. In addition, the Limited Waiver provided that the restatement of our financial statements for any period

ending on or before March 31, 2013 will not constitute a default or event of default provided that within one business day after the public release or filing of such restated financial statements, we deliver corrected financial statements and compliance certificates with respect to such restated periods and immediately pay any additional interest and other fees that would have been owed had applicable interest and fees originally been calculated based on the restated financial statements.

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

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

Table of Contents

At December 31, 2012, we had outstanding borrowings of less than $1 million and unused available lines of credit of approximately 5.8 million ($7.6 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

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

Contractual Obligations

The following chart sets forth our contractual obligations as of December 31, 2012:

		Payments Due by Period			
Contractual Obligations (U.S. Dollars, in thousands)	**Total**	**2013**	**2014-2016**	**2017**	**2018 and thereafter**
Revolving Credit Facility	$ 20,000	$	$ 20,000	$	$
Estimated interest on Credit Facility (1)	1,445	542	903		
Operating leases	17,069	3,340	8,485	2,620	2,624
Total	$ 38,514	$ 3,882	$ 29,388	$ 2,620	$ 2,624

(1) Estimated interest on credit facility assumes payments are made in accordance with the scheduled payments as defined in the agreement. Interest payments are estimated using rates in effect at December 31, 2012.

We may be required to make cash outlays related to our unrecognized tax benefits. However, due to the uncertainty of the timing of future cash flows associated with our unrecognized tax benefits, we are unable to make reasonably reliable estimates of the period of cash settlement, if any, with the respective taxing authorities. Accordingly, unrecognized tax benefits, inclusive of interest and penalties, of $1.9 million as of December 31, 2012 have been excluded from the contractual obligations table above. For further information on unrecognized tax benefits, see Note 14 to the consolidated financial statements included in this Form 10-K/A.

Off-balance Sheet Arrangements

As of December 31, 2012, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We use derivative financial instruments,

where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes. As of December 31, 2012, we had a currency swap in place to minimize foreign currency exchange risk related to a 28.7 million ($37.9 million translated at the December 31, 2012 foreign exchange rate) intercompany note. As of December 31, 2012 the fair value of the currency swap was approximately $0.3 million and is recorded in other long-term assets.

We are exposed to interest rate risk in connection with our Term Loan Facility and Revolving Credit Facility, which bear interest at floating rates based on LIBOR plus an applicable borrowing margin or at a base rate (as defined in the Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant.

As of December 31, 2012, $20 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 2.5%. This margin is adjusted based upon the measurement of the consolidated leverage ratio of the Company and its subsidiaries with respect to the immediately preceding four fiscal quarters. As of December 31, 2012, our effective interest rate on our Credit Facilities was 2.7%. Based on the balance outstanding under the Credit Facilities as of December 31, 2012, an immediate change of one percentage point in the applicable interest rate on the Revolving Credit Facility would cause a change in interest expense of approximately $0.2 million annually.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Great Britain Pound, Mexican Peso and Brazilian Real. We are subject to cost of sales currency exposure when we produce products in foreign currencies such as the Euro or Great Britain Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when our foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than

Table of Contents

their functional currency. As of December 31, 2012, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million ($30.6 million). We recorded a foreign currency gain during the year ended December 31, 2012 of $0.8 million related to this un-hedged long-term intercompany balance in accumulated other comprehensive income during 2012, which resulted from the weakening of the Euro against the U.S. dollar during the period. For the year ended December 31, 2012, we recorded a foreign currency loss of $0.5 million on the statement of operations resulting from gains and losses in foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that fluctuate during the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the year ended December 31, 2012 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations during 2012 versus the same periods in 2011. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the year ended December 31, 2011 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against the local foreign currency versus the same periods in 2010. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results.

Item 8. Financial Statements and Supplementary Data

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

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Table of Contents

Item 9A. Controls and Procedures

Background of Restatement

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

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

The Independent Review focused on the periods between January 1, 2010 and March 31, 2013 and included (i) over 50 witness interviews, (ii) collection of emails and files from 70 document custodians, and (iii) quantitative analysis. The scope of the Independent Review, which was determined by the Audit Committee in consultation with outside professionals engaged by the Audit Committee, focused primarily on revenue recognition related to distributor arrangements and inventory reserve adjustments. In conjunction with the Independent Review, management concluded that errors existed in the Company s previously issued financial statements with respect to the Non-Reliance Period, as well as in the Company s previously issued consolidated financial statements for the fiscal year ended December 31, 2010. There were also similar types of errors identified as affecting the Company s previously issued consolidated financial statements for the fiscal years ended December 31, 2009, 2008 and 2007, for which the Company is including restated consolidated financial information for the fiscal years ended December 31, 2009 and 2008 in the Selected Financial Data table of this Form 10-K/A. Adjustments prior to January 1, 2010 have been recognized as a cumulative adjustment to beginning retained earnings in the consolidated statements of changes in shareholders equity included in the consolidated financial statements included in Item 8 of this Form 10-K/A.

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

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

restatement.

Evaluation of Disclosure Controls and Procedures

In connection with the filing of the Original Form 10-K in March 2013, under the supervision and with the participation of our management, including our then-President and Chief Executive Officer (who has subsequently departed the Company) and our then-Interim Chief Financial Officer (who is currently our Chief Financial Officer), we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2012. Based upon that evaluation, our then-President and Chief Executive Officer and then-Interim Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Subsequent to the evaluation made in connection with the filing of the Original Form 10-K in March 2013 and in connection with the preparation and filing of the above-described restatement and this Form 10-K/A, our management, with the participation of our current President and Chief Executive Officer (who was not employed by the Company at the time of the filing of the Original

Table of Contents

Form 10-K) and our current Chief Financial Officer (who was our Interim Chief Financial Officer at the time of the filing of the Original Form 10-K), re-evaluated the effectiveness of the design and operation of our disclosure controls and procedures. As described below, management has identified material weaknesses in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. As a result of those material weaknesses, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2012.

Management s Report on Internal Control over Financial Reporting

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

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

In connection with the preparation and filing of the Original Form 10-K in March 2013, the Company s management, including our then President and Chief Executive Officer (who has subsequently departed the Company) and our then Interim Chief Financial Officer (who is currently our Chief Financial Officer), conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012 based on the framework set forth in Internal Control Integrated Framework (September 1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company s management concluded at that time that, as of December 31, 2012, the Company s internal control over financial reporting was effective based on the COSO criteria.

In connection with the preparation and filing of the above-described restatement and this Form 10-K/A, the Company s management, including our current President and Chief Executive Officer (who was not employed by the Company at the time of the filing of the Original Form 10-K) and our Chief Financial Officer (who was our Interim Chief Financial Officer at the time of the filing of the Original Form 10-K), has re-evaluated the effectiveness of our internal control over financial reporting as of December 31, 2012 and concluded that, because of the material weaknesses described below, our internal control over financial reporting was not effective as of December 31, 2012.

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

constituted individually, and in the aggregate, material weaknesses in our internal control over financial reporting as of December 31, 2012:

Revenue recognition practices for sales to the Company s distributors. We have concluded that we recognized revenue in certain instances in advance of all revenue recognition criteria being met, and that our controls were not effective to reasonably ensure accurate recognition of revenue in accordance with GAAP for certain distributor sales transactions previously recorded by the Company s domestic and international business units. In general, we did not establish and maintain procedures throughout the Company to reasonably ensure proper communication to, and assessment by, the Company s finance and accounting department of deviations from contractually established terms, which included written or unwritten arrangements made with, or extra-contractual terms provided to, Company distributors at the onset of the sale regarding extended payment terms, product return or exchange rights, and similar concessions agreed to subsequent to the initial sale (which were not memorialized by any formal contractual amendment). Such additional terms were not evaluated, or not evaluated correctly, and were not maintained or reflected in Company customer sales files. In addition, Company personnel were not adequately trained with respect to certain revenue recognition principles applicable under GAAP that may have led to appropriate consideration of the additional terms entered into outside of the written contractual terms.

Table of Contents

Inventory reserves. Errors occurred in establishing the Company s inventory reserves due to a design deficiency in our controls over the computation and recording of such reserves. Our method of calculating inventory reserves resulted in the misapplication of GAAP, which caused us to make adjustments in the restated consolidated financial statements. Specifically, our controls were not designed to detect that increases in our forecasted demand for products resulted in reductions in subsequent fiscal years to reserves previously recorded. ASC Topic 330 *Inventory* (specifically ASC 330-10-35-14) states that a write-down of inventory to the lower-of-cost-or-market value at the close of a fiscal year creates a new cost basis that subsequently should not be marked up based on changes in underlying circumstances, and our controls were not designed to prevent such mark ups due to increases in forecasted demand.

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

Some or all of the material weaknesses described above resulted in material misstatements in our annual and interim consolidated financial statements. Because of the foregoing matters, our management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2012.

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

Plans for Remediation

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

We are committed to maintaining an effective control environment and making changes necessary to enhance effectiveness. This commitment has been, and will continue to be, communicated to and reinforced throughout our organization. As part of this commitment, we are implementing an internal audit program that will take into account the nature of our business and the geographies in which we conduct it. We are also updating our code of conduct, and all our employees will be required to annually acknowledge their commitment to adhering to its provisions. We also will inform all new employees and regularly remind all existing employees of the availability of our compliance hotline, through which employees at all levels can anonymously submit information or express concerns regarding accounting, financial reporting and other irregularities they may have become aware of or observed.

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

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

We have enhanced our revenue recognition training materials for all sales personnel;

We are in the process of training sales management personnel (including senior-level management) pursuant to our updated revenue recognition training materials;

We have created and implemented an improved sales certification process to identify any sales with deviations from written sales contracts;

We have established and hired a new Senior Manager of Revenue position in our finance department, which we believe will bring additional revenue recognition expertise to address our more complex revenue transactions to help ensure that our revenue recognition policies are correctly applied; and

We are working to improve procedures with respect to the proper communication, approval, documentation and accounting review of deviations from written sales contracts.

Table of Contents

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

- We have enhanced controls over our model for determining inventory reserves to ensure that, once reserves are established in a fiscal year, subsequent write-ups based on demand are not recognized; and

- We are implementing additional review of our inventory reserve analysis, including the involvement of both finance and operational executives, and more analysis of days inventory on hand at the product line level, which we expect to provide better controls to assess excess and obsolete inventory based on the current inventory on hand in relation to the demand forecast and related reserve.

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

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

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

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

- We are evaluating our accounting systems to determine appropriate enhancements.

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

Changes in Internal Control over Financial Reporting

Other than as described above, there have not been any changes in our internal control over financial reporting during the fourth quarter of 2012 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

60

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Orthofix International N.V.

We have audited Orthofix International N.V. s (the Company) internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (the COSO criteria). Orthofix International N.V. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

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

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

In our report dated March 1, 2013, we expressed an unqualified opinion that Orthofix International N.V. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria. Management has subsequently determined that deficiencies in controls related to revenue recognition practices for sales to the Company s distributors, the methodology applied for establishing inventory reserves, and oversight associated with certain foreign subsidiaries existed as of the previous assessment date, and has further concluded that such deficiencies represented material weaknesses as of December 31, 2012. As a result, management has revised its assessment, as presented in the accompanying Management s Report on Internal Control Over Financial Reporting, to conclude that Orthofix International N.V. s internal control over financial reporting was not effective as of December 31, 2012. Accordingly, our present opinion on the effectiveness of Orthofix International N.V. s internal control over financial reporting as of December 31, 2012, as expressed herein, is different from that expressed in our

previous report.

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

These material weaknesses resulted in the restatement of the Company s consolidated financial statements as of December 31, 2012 and 2011 and for each of the three years in the period ended December 31, 2012. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Orthofix International N.V. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive income (loss), changes in shareholders equity, and cash flows for each of the three years in the period ended December 31, 2012. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audits of these consolidated financial statements, and this report does not affect our report dated March 1, 2013, except for Notes 2, 17, and 24 as to which the date is March 24, 2014, which expressed an unqualified opinion on those financial statements.

Table of Contents

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Orthofix International N.V. has not maintained effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

/s/ Ernst & Young LLP

Dallas, Texas
March 1, 2013, except for the effect of the
material weaknesses described in the sixth
paragraph above, as to which the date is
March 24, 2014

Item 9B. Other Information

Not applicable.

Table of Contents

PART III

Information required by Items 10, 11, 12, 13 and 14 of Form 10-K has been omitted from this report and is incorporated by reference to information appearing in our definitive proxy statement for our annual general meeting of shareholders held on June 20, 2013, as filed with the Commission on April 30, 2013, which information appears under the captions entitled Security Ownership of Certain Beneficial Owners and Management and Related Stockholders, Section 16(a) Beneficial Ownership Reporting Compliance, Information about Directors, and Proposal 1 Election of Directors .

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to information appearing in our definitive proxy statement for our annual general meeting of shareholders held on June 20, 2013, which information appears under the captions Section 16(a) Beneficial Ownership Reporting Compliance, Information about Directors and Proposal 1: Election of Directors. The proxy statement was filed on April 30, 2013.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to information appearing in our definitive proxy statement for our annual general meeting of shareholders held on June 20, 2013, which information appears under the captions Compensation Discussion and Analysis, Report of the Compensation Committee, Summary Compensation Table, Grants of Plan-Based Awards, Outstanding Equity Awards at Fiscal Year-End, Option Exercises and Stock Vested, Deferred Compensation, Agreements with Named Executive Officers, Potential Payments upon Termination or Change of Control and Director Compensation. The proxy statement was filed on April 30, 2013.

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

The information required by this Item is incorporated herein by reference to information appearing in our definitive proxy statement for our annual general meeting of shareholders held on June 20, 2013, which information appears under the captions Security Ownership of Certain Beneficial Owners and Management and Related Stockholders and Equity Compensation Plan Information. The proxy statement was filed on April 30, 2013.

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

The information required by this Item is incorporated herein by reference to information appearing in our definitive proxy statement for our annual general meeting of shareholders held on June 20, 2013, which information appears under the captions Information about Directors and Certain Relationships and Related Transactions. The proxy statement was filed on April 30, 2013.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated herein by reference to information appearing in our definitive proxy statement for our annual general meeting of shareholders held on June 20, 2013, which information appears under the captions Proposal 3: Ratification of the Selection of Ernst & Young LLP as Independent Registered Public Accounting Firm for 2013. The proxy statement was filed on April 30, 2013.

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

1. Financial Statements

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

2. Financial Statement Schedules

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

3. Exhibits

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

10.2	First Amendment to Credit Agreement, dated May 4, 2011, among Orthofix Holdings, Inc., a Delaware corporation, Orthofix International N.V. (Orthofix International), a Netherlands Antilles corporation, certain domestic direct and indirect subsidiaries of Orthofix International, JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto (filed as an exhibit to the Company s current report on Form 8-K filed May 5, 2011 and incorporated herein by reference).
10.3+	Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
10.4	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.5+	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company s annual report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference).
10.6	Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.7	Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference)
10.8	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference).

Table of Contents

Exhibit Number	Description
10.9	Orthofix International N.V. Staff Share Option Plan, as amended through April 22, 2003 (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2007 and incorporated herein by reference).
10.10	Amended and Restated Orthofix Deferred Compensation Plan (filed as an exhibit to the Company s current report on Form 8-K filed January 7, 2009, and incorporated herein by reference).
10.11**	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan.
10.12**	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan.
10.13**	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan.
10.14**	Form of Non-Employee Director Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan.
10.15	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants) (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.16	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants) (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.17	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants vesting over 3 years) (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.18	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants year cliff vesting) (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.19	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2011 grants vesting over 3 years) (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.20	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (post-2010 grants vesting over 3 years) (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.21	Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (3 year cliff vesting) (filed as an exhibit to the Company s current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.22	Inducement Grant Nonqualified Stock Option Agreement between Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the current report on Form 8-K of Orthofix International N.V dated September 10, 2008 and incorporated herein by reference).

10.23	Inducement Grant Nonqualified Stock Option Agreement, dated April 1, 2011, between Orthofix International N.V. and Vicente Trelles (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.24	Form of Award Letter Regarding Special Retention Cash Bonus Award (filed as an exhibit to the Company s current report on Form 8-K/A filed on February 23, 2011 and incorporated herein by reference).

Table of Contents

Exhibit Number	Description
10.25	Description of Director Compensation Policy (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended June 30, 2012 and incorporated herein by reference).
10.26	Form of Indemnity Agreement (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2008 and incorporated herein by reference).
10.27	Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.28	Amendment No. 1 to Amended and Restated Employment Agreement, dated July 30, 2009, by and between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
10.29	Letter Agreement, dated June 15, 2011, between Orthofix Inc., Orthofix International N.V. and Alan W. Milinazzo (filed as an exhibit to the Company s quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
10.30	Amended and Restated Employment Agreement, dated as of June 15, 2011 and effective as of August 1, 2011, by and between Orthofix Inc., Orthofix International N.V. and Robert S. Vaters (filed as an exhibit to the Company s quarterly report on current report on Form 8-K filed June 16, 2011 and incorporated herein by reference).
10.31	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of August 29, 2012, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company s current report on Form 8-K filed August 31, 2012 and incorporated herein by reference).
10.32	Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.33	Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference).
10.34	Amendment No. 2 to Amended and Restated Employment Agreement, dated as of October 1, 2011, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company s current report on Form 8-K filed October 4, 2011 and incorporated herein by reference).
10.35	Amendment No. 3 to Amended and Restated Employment Agreement, dated as of August 29, 2012, by and between Orthofix Inc. and Michael Finegan (filed as an exhibit to the Company s current report on Form 8-K filed August 31, 2012 and incorporated herein by reference).
10.36	Employment Agreement, entered into on December 9, 2010, by and between Orthofix Inc. and Jeffrey M. Schumm (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.37	Employment Agreement, entered into as of March 2, 2011, by and between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company s current report on Form 8-K filed March 7, 2011 and incorporated herein by reference).
10.38	

Amended and Restated Employment Agreement, dated as of October 16, 2012 and effective as of November 6, 2012, between Orthofix Inc. and Brian McCollum (filed as an exhibit to the Company s current report on Form 8-K filed October 16, 2012 and incorporated herein by reference).

10.39 Employment Agreement, entered into as of April 1, 2011, by and between Orthofix Inc. and Vicente Trelles (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).

10.40 Employment Agreement, entered into as of January 7, 2013, by and between Orthofix Inc. and Emily Buxton (filed as an exhibit to the Company s current report on Form 8-K filed January 11, 2013 and incorporated herein by reference).

Table of Contents

Exhibit Number	Description
10.41	Employment Agreement, entered into as of October 1, 2011, by and between Orthofix Inc. and Bryan McMillan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended September 30, 2011 and incorporated herein by reference).
10.42	Form of Amendment to Stock Option Agreements (for Robert S. Vaters and Michael M. Finegan) (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.43	Settlement Agreement, entered into on June 6, 2012, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, the TRICARE Management Activity, through its General Counsel, the Office of Personnel Management, in its capacity as administrator of the Federal Employees Health Benefits Program, the United States Department of Veteran Affairs, Orthofix International N.V. and relator Jeffrey J. Bierman (filed as an exhibit to the Company s current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
10.44	Amended Plea Agreement, entered into on December 14, 2012, among the United States Attorney for the District of Massachusetts, the Department of Justice and Orthofix Inc. (filed as an exhibit to the Company s current report on Form 8-K filed December 19, 2012 and incorporated herein by reference).
10.45	Corporate Integrity Agreement, entered into on June 6, 2012, between the Office of Inspector General of the Department of Health and Human Services and Orthofix International N.V. (filed as an exhibit to the Company s current report on Form 8-K/A filed June 7, 2012 and incorporated herein by reference).
21.1**	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer.
32.2*	Section 1350 Certification of Chief Financial Officer.
101	The following financial statements from Orthofix International N.V. on Form 10-K/A for the year ended December 31, 2012 filed on March 24, 2014, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Consolidated Statements of Changes in Shareholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.

* Filed herewith.
** Previously filed with the Original Form 10-K.
+ Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. This exhibit has been filed separately with the Secretary of the Commission without redactions pursuant to our Application Requesting Confidential Treatment under the Securities Exchange Act of 1934.

Table of Contents

SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Dated: March 24, 2014

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

Dated: March 24, 2014

By: /s/ EMILY V. BUXTON
Name: **Emily V. Buxton**
Title: **Chief Finacial Officer**

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Statement of Management s Responsibility for Financial Statements

To the Shareholders of Orthofix International N.V.:

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

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

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

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

Davey S. Scoon

Chairman of the Audit Committee

Bradley R. Mason

President and Chief Executive Officer, Director

Emily V. Buxton

Chief Financial Officer

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Index to Consolidated Financial Statements

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

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Orthofix International N.V.

We have audited the accompanying consolidated balance sheets of Orthofix International N.V. (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive income (loss), changes in shareholders equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedules listed in the index at Item 15(a). These financial statements and schedules are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedules based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Orthofix International N.V. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

As discussed in Note 2, the consolidated financial statements have been restated to correct the Company s revenue recognition practices for sales to the Company s distributors, the methodology applied for establishing inventory reserves, and for certain other matters.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Orthofix International N.V. s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 1, 2013, except for the effects of the material weaknesses described in the sixth paragraph as to which the date is March 24, 2014, expressed an adverse opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas
March 1, 2013, except for Notes 2, 17, and 24
as to which the date is March 24, 2014

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Consolidated Balance Sheets as of December 31, 2012 and 2011

(U.S. Dollars, in thousands except share and per share data)	2012 (Restated)	2011 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 31,055	$ 33,207
Restricted cash	21,314	45,476
Trade accounts receivable, less allowances of $13,543 and $9,341 at December 31, 2012 and 2011, respectively	107,312	99,888
Inventories	83,373	81,528
Deferred income taxes	33,450	36,313
Escrow receivable		41,537
Prepaid expenses and other current assets	34,079	21,999
Assets held for sale		171,185
Total current assets	310,583	531,133
Property, plant and equipment, net	53,835	46,137
Patents and other intangible assets, net	7,290	8,846
Goodwill	74,388	73,094
Deferred income taxes	18,881	16,741
Other long-term assets	7,920	9,429
Total assets	$ 472,897	$ 685,380
Liabilities and shareholders equity		
Current liabilities:		
Bank borrowings	$ 16	$ 1,318
Current portion of long-term debt		17,500
Trade accounts payable	22,575	18,231
Accrued charges related to U.S. Government resolutions		83,138
Other current liabilities	39,594	40,836
Liabilities held for sale		22,676
Total current liabilities	62,185	183,699
Long-term debt	20,000	191,195
Deferred income taxes	11,456	9,778
Other long-term liabilities	11,424	8,634
Total liabilities	105,065	393,306
Contingencies (Note 17)		
Shareholders equity		
	1,934	1,846

Common shares $0.10 par value; 50,000,000 shares authorized; 19,339,329 and 18,465,444 issued and outstanding as of December 31, 2012 and 2011, respectively		
Additional paid-in capital	246,306	214,505
Retained earnings	114,847	72,009
Accumulated other comprehensive income	4,745	3,714
Total shareholders equity	367,832	292,074
Total liabilities and shareholders equity	$ 472,897	$ 685,380

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Operations and Comprehensive Income (Loss)

For the years ended December 31, 2012, 2011 and 2010

(U.S. Dollars, in thousands, except share and per share data)	2012 (Restated)	2011 (Restated)	2010 (Restated)
Product sales	$ 401,039	$ 405,147	$ 432,845
Marketing service fees	46,542	36,824	29,726
Net sales	447,581	441,971	462,571
Cost of sales	98,253	95,527	97,093
Gross profit	349,328	346,444	365,478
Operating expenses			
Sales and marketing	187,131	193,511	196,113
General and administrative	53,391	64,481	73,010
Research and development	28,577	22,861	27,958
Amortization of intangible assets	2,298	2,550	2,413
Charges related to U.S. Government resolutions (Note 17)	1,295	57,141	
	272,692	340,544	299,494
Operating income	76,636	5,900	65,984
Other income and (expense)			
Interest expense, net	(4,743)	(5,541)	(11,287)
Other income (expense)	(1,705)	(2,412)	331
	(6,448)	(7,953)	(10,956)
Income (loss) before income taxes	70,188	(2,053)	55,028
Income tax expense	(25,138)	(14,165)	(24,031)
Net income (loss) from continuing operations, net of tax	45,050	(16,218)	30,997
Discontinued operations (Note 16)			
Gain on sale of Breg, Inc., net of tax	1,345		
Gain on sale of vascular operations, net of tax (Note 22)			8,521
Income (loss) from discontinued operations	(2,994)	(2,705)	5,089
Income tax benefit (expense)	(563)	813	(311)

Net income (loss) from discontinued operations, net of tax	(2,212)	(1,892)	13,299
Net income (loss)	$ 42,838	$ (18,110)	$ 44,296
Net income (loss) per common share basic:			
Net income (loss) from continuing operations, net of tax	$ 2.37	$ (0.89)	$ 1.76
Net income (loss) from discontinued operations, net of tax	(0.12)	(0.10)	0.76
Net income (loss) per common share basic	$ 2.25	$ (0.99)	$ 2.52
Net income (loss) per common share diluted:			
Net income (loss) from continuing operations, net of tax	$ 2.32	$ (0.89)	$ 1.73
Net income (loss) from discontinued operations, net of tax	(0.11)	(0.10)	0.74
Net income (loss) per common share diluted:	$ 2.21	$ (0.99)	$ 2.47
Weighted average number of common shares:			
Basic	18,977,263	18,219,343	17,601,956
Diluted	19,390,413	18,219,343	17,913,545
Other comprehensive income (loss), before tax:			
Translation adjustment	$ 768	$ (2,279)	$ (1,317)
Unrealized gain (loss) on derivative instrument	416	(693)	(126)
Other comprehensive income (loss), before tax	1,184	(2,972)	(1,443)
Income tax (expense) benefit related to components of other comprehensive income	(153)	256	36
Other comprehensive income (loss), net of tax	1,031	(2,716)	(1,407)
Comprehensive income (loss)	$ 43,869	$ (20,826)	$ 42,889

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Changes in Shareholders Equity

For the years ended December 31, 2012, 2011 and 2010

(U.S. Dollars, in thousands, except share data)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Shareholders Equity
At December 31, 2009	17,141,710	$ 1,714	$ 177,246	$ 54,119	$ 7,190	$ 240,269
Cumulative effect of adjustment on opening balance				(8,296)	647	(7,649)
Net income				44,296		44,296
Unrealized loss on derivative instrument (net of taxes of $36)					(90)	(90)
Translation adjustment					(1,317)	(1,317)
Tax benefit on exercise of stock options			2,417			2,417
Share-based compensation expense			8,138			8,138
Common shares issued	584,935	58	7,796			7,854
At December 31, 2010 (Restated)	17,726,645	1,772	195,597	90,119	6,430	293,918
Net loss				(18,110)		(18,110)
Unrealized loss on derivative instrument (net of taxes of $256)					(437)	(437)
Translation adjustment					(2,279)	(2,279)
Purchase of minority interest			(517)			(517)
Tax benefit on exercise of stock options			1,737			1,737
Reclassification for tax benefit on exercise of stock options			(8,999)			(8,999)
Share-based compensation expense			6,648			6,648
Common shares issued	738,799	74	20,039			20,113
At December 31, 2011 (Restated)	18,465,444	1,846	214,505	72,009	3,714	292,074
Net income				42,838		42,838
Unrealized gain on derivative instrument (net of taxes of $153)					263	263
Translation adjustment					768	768

Share-based compensation expense			6,303			6,303
Common shares issued	873,885	88	25,498			25,586
At December 31, 2012 (Restated)	19,339,329	$ 1,934	$ 246,306	$ 114,847	$ 4,745	$ 367,832

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Consolidated Statements of Cash Flows

For the years ended December 31, 2012, 2011 and 2010

(U.S. Dollars, in thousands)	2012 (Restated)	2011 (Restated)	2010 (Restated)
Cash flows from operating activities:			
Net income (loss)	$ 42,838	$ (18,110)	$ 44,296
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	20,580	23,017	22,087
Amortization of debt costs	1,737	1,239	471
Provision for doubtful accounts	10,572	12,936	8,616
Deferred income taxes	(1,252)	(52)	591
Share-based compensation	6,303	6,648	8,138
Loss on refinancing of credit facility			550
Gain on interest rate swap			(1,254)
Gain on sale of Breg, Inc, net of tax	(1,345)		
Net gain on sale of vascular operations, net of tax			(8,521)
Excess income tax benefit on employee stock-based awards	(1,020)	(1,737)	(2,417)
Income tax benefit on employee stock-based awards	2,910		
Other	4,136	4,491	4,439
Changes in operating assets and liabilities, net of effect of dispositions:			
Trade accounts receivable	(18,438)	293	(16,645)
Inventories	(2,495)	(12,624)	9,767
Escrow receivable	41,537	(32,562)	(2,049)
Prepaid expenses and other current assets	(15,577)	2,829	(4,378)
Trade accounts payable	4,575	2,322	(2,866)
Charges related to U.S. Government resolutions	(83,178)	89,101	
Other current liabilities	(5,729)	1,419	(9,695)
Other long-term assets	3,416	(17,307)	(744)
Other long-term liabilities	616	2,878	(8,073)
Net cash provided by operating activities	10,186	64,781	42,313
Cash flows from investing activities:			
Capital expenditures for property, plant and equipment	(27,994)	(24,965)	(25,844)
Capital expenditures for intangible assets	(780)	(793)	(517)
Payment made in connection with acquisition		(5,250)	
Net proceeds from sale of Breg Inc.	153,773		
Net proceeds from the sale of vascular operations			24,215
Net cash provided by (used in) investing activities	124,999	(31,008)	(2,146)
Cash flows from financing activities:			

Net proceeds from issuance of common shares	25,586	20,113	7,854
Payment of refinancing fees and debt issuance costs		(758)	(4,266)
Repayments of long-term debt	(188,695)	(7,500)	(36,269)
Proceeds from (repayment of) bank borrowings, net	(1,297)	(2,561)	1,723
Changes in restricted cash	25,799	(24,178)	(11,290)
Cash payment for purchase of minority interest in subsidiary		(517)	
Excess income tax benefit on employee stock-based awards	1,020	1,737	2,417
Net cash used in financing activities	(137,587)	(13,664)	(39,831)
Effect of exchange rate changes on cash	250	(463)	(103)
Net increase (decrease) in cash and cash equivalents	(2,152)	19,646	233
Cash and cash equivalents at the beginning of the year	33,207	13,561	13,328
Cash and cash equivalents at the end of the year	$ 31,055	$ 33,207	$ 13,561
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 4,569	$ 17,088	$ 16,032
Income taxes	$ 18,268	$ 26,227	$ 29,743

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

Table of Contents

ORTHOFIX INTERNATIONAL N.V.

Notes to the Consolidated Financial Statements

Description of business

Orthofix International N.V. (the Company) is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative technologies to the spine and orthopedic markets. The Company is comprised of two reportable segments: Spine and Orthopedics supported by Corporate activities. See Note 13 for a description of each segment.

1. Summary of significant accounting policies

(a) Basis of consolidation

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

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

(b) Use of estimates in preparation of financial statements

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

(c) Foreign currency translation

The financial statements for operations outside the United States are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders equity, are translated to U.S. dollars at year end exchange rates and revenue and expense items are translated at weighted average rates of exchange prevailing during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income component of shareholders equity. Transactional foreign currency gains and (losses), including those generated from intercompany operations, are included in other expense, net and were $0.5 million loss, $1.6 million loss and $0.1 million loss for the years ended December 31, 2012, 2011 and 2010, respectively.

(d) Cash and cash equivalents

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

(e) Restricted cash

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

(f) Market risk

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. The Company s objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, the Company seeks to balance its non-dollar denominated income and expenditures. During 2008, the Company executed an interest rate swap agreement to manage the cash flow exposure generated from interest rate fluctuations. On June 29, 2010, the Company settled the interest rate swap. During 2012, 2011 and 2010, the Company made use of a foreign currency swap agreement to manage cash flow exposure generated from foreign currency fluctuations. See Note 10 for additional information.

The Company generally does not require collateral on trade receivables.

Table of Contents

(g) Inventories

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

(h) Long-lived assets, including intangibles and goodwill

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

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

Expenditures for maintenance and repairs and minor renewals and improvements, which do not extend the lives of the respective assets, are expensed as incurred. All other expenditures for renewals and improvements are capitalized. The assets and related accumulated depreciation are adjusted for property retirements and disposals, with the resulting gain or loss included in operations. Fully depreciated assets remain in the accounts until retired from service.

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

Intangible and long-lived assets with definite lives, such as developed technologies, are tested for impairment if any adverse conditions exist or change in circumstances have occurred that would indicate impairment or a change in the remaining useful life. If an impairment indicator exists, the Company tests the intangible asset for recoverability. For purposes of the recoverability test, the Company groups its intangible assets with other assets and liabilities at the lowest level of identifiable cash flows if the intangible asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the intangible asset (asset group) exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset (asset group), the Company will write the

carrying value down to the fair value in the period identified.

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

The Company tests goodwill at least annually for impairment. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. The Company assesses goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. The Company has identified two reporting units, which are consistent with the Company s reporting segments; Spine and Orthopedics (see Note 13 for additional information).

Table of Contents

Goodwill

In order to calculate the respective carrying values, the Company initially recorded goodwill based on the purchase price allocation performed at the time of acquisition. Corporate assets and liabilities that directly relate to a reporting unit s operations are ascribed directly to that reporting unit. Corporate assets and liabilities that are not directly related to a specific reporting unit, but from which the reporting unit benefits, are allocated based on the respective contribution measure of each reporting unit. Effective January 1, 2011, the Company re-aligned its reporting units and consequently reallocated the carrying value of goodwill from its previous reporting units to its new reporting units based on the relative fair value of each new reporting unit to total enterprise value at January 1, 2011.

In the first quarter of 2012, Accounting Standards Update (ASU) 2011-08, Testing of Goodwill for Impairment became effective. ASU 2011-08 allows entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit (i.e. the first step of the goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not greater than the carrying amount, a quantitative calculation would not be needed.

The Company s annual goodwill impairment analysis, which was performed qualitatively during the fourth quarter of 2012, did not result in impairment charge.

(i) Derivative instruments

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

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

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

See Note 10 for a description of the types of derivative instruments the Company utilizes.

Table of Contents

(j) Accumulated other comprehensive income

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

(U.S. Dollars, in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross-Currency Swaps	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2010 (Restated)	$ 6,125	$ 305	$ 6,430
Unrealized loss on cross-currency swaps, net of tax benefit of $256		(437)	(437)
Foreign currency translation adjustment (1)	(2,279)		(2,279)
Balance at December 31, 2011 (Restated)	3,846	(132)	3,714
Unrealized gain on cross-currency swaps, net of tax of $153		263	263
Foreign currency translation adjustment (1)	768		768
Balance at December 31, 2012 (Restated)	$ 4,614	$ 131	$ 4,745

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

(k) Revenue recognition and accounts receivable

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

Revenue is derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare, in connection with the sale of our stimulation products. Revenue is recognized when the stimulation product is placed on or implanted in and accepted by the patient. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or pre-authorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

For distributor revenue which is related primarily to spine and orthopedic implant products, the Company recognizes revenue either on a sell-in or sell-through basis depending on the specific circumstances of the distributor. In some cases the Company recognizes distributor revenue as title and risk of loss passes at either shipment from the Company s facilities or receipt at the distributor s facility, assuming all other revenue recognition criteria has been achieved (the sell-in method). Based on the results of the Independent Review, the Company determined in some cases the revenue recognition criteria for distributor sales were not satisfied at the time of shipment or receipt;

specifically, the existence of extra-contractual terms or arrangements caused the Company not to meet the fixed or determinable criteria for revenue recognition in some cases, and in others collectability had not been established. In situations where we are unable to satisfy the requirements to recognize revenue on the sell-in method, we recognize revenue relating to distributor arrangements once the product is delivered to the end customer (the sell-through method). Because the Company does not have reliable information about when its distributors sell the product through to end customers, the Company uses cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company is legally entitled to the accounts receivable at the time of shipment, the Company has not recognized accounts receivables or any corresponding deferred revenues associated with distributor transactions for which revenue is recognized on the sell-through method. Effective April 1, 2013, all distributor revenue is recognized on the sell-through basis.

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

Biologics revenue is primarily related to a collaborative arrangement with MTF. In 2008, the Company entered into a collaborative arrangement with MTF to develop and commercialize Trinity Evolution ®, a stem cell-based bone growth biologic matrix. With the development process completed in 2009, the Company and MTF operated under the terms of a separate commercialization agreement. Under the terms of the 10-year agreement, MTF sourced the tissue, processed it to create the bone growth matrix, packaged and delivered it to the customer in accordance with orders received from the Company. The Company has exclusive global marketing rights for Trinity Evolution ® and receives marketing fees from MTF based on total sales. These marketing fees are recorded on a net basis within net sales and were $46.5 million, $36.8 million and $29.7 million in 2012, 2011 and 2010, respectively. On January 10, 2012, the Company announced that it had reached an agreement with MTF to both co-develop and commercialize a new technology for use in bone grafting applications and to expand MTF s Trinity Evolution ® processing capacity. The amendment amends the term of the existing agreement until the later of (i) 15 years after the date that certain development milestones were achieved under the existing agreement (which occurred during 2010) or (ii) the date that certain licensing arrangements between the Company and NuVasive, Inc. expire. MTF is considered the primary obligor in these arrangements and therefore the Company recognizes these marketing service fees on a net basis upon shipment of the product to the customer.

Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs are included in cost of sales. Royalty revenues are recognized when the royalty is earned.

Table of Contents

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collection and payor reimbursement experience is an integral part of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses, and contractual allowances are recorded as an adjustment to revenue. In the judgment of management, adequate allowances have been provided for doubtful accounts and contractual allowances. These estimates are periodically tested against actual collection experience.

(l) Sale of accounts receivable

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

(m) Share-based compensation

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

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

(n) Advertising costs

The Company expenses all advertising costs as incurred. Advertising expense included in sales and marketing expense for the years ended December 31, 2012, 2011 and 2010 was $0.3 million, $0.5 million and $0.6 million, respectively.

(o) Research and development costs

Expenditures for research and development are expensed as incurred. Expenditures related to the collaborative arrangement with MTF are expensed based on the terms of the related agreement. Milestone payments made to MTF in 2012 totaled $3 million.

Table of Contents

(p) Income taxes

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

The Company accounts for uncertain tax positions in accordance with ASC Topic 740, *Income Taxes,* which contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. The Company re-evaluates income tax positions periodically to consider factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues under audit, and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision.

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

(q) Net income (loss) per common share

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

(r) Financial Instruments and Concentration of Credit Risk

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

Net sales to our customers and distributors based in Europe were approximately $55 million in 2012 which results in a substantial portion of our trade accounts receivable balance as of December 31, 2012. It is at least reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these distributors operate, or other factors, could affect the future realization of these accounts receivable balances.

(s) Recently Issued Accounting Standards

In July 2012, the FASB issued ASU No. 2012-02, *Intangibles Goodwill and Other (Topic 350).* The standard is intended to reduce the cost and complexity of performing an impairment test for indefinite-lived intangible assets by simplifying how an entity tests those assets for impairment and to improve consistency in impairment testing guidance among long-lived asset categories. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test in accordance with Subtopic 350-30, Intangibles Goodwill and Other General Intangibles Other than Goodwill. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company adopted this ASU as of December 31, 2012 and it did not have a material impact on the Company s consolidated financial statements.

On June 16, 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This ASU eliminates the current option to present other comprehensive income and its components in the statement of changes in shareholders equity and increases the prominence of other comprehensive income in the statements by providing an alternative to present the components of net income and comprehensive income as either one continuous or two separate but consecutive financial statements. Companies are also required to present reclassification adjustments for items that are reclassified

Table of Contents

from other comprehensive income to net income within these statements. This standard is to be applied retrospectively and is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company adopted this ASU as of March 31, 2012 and it did not have a material impact on the Company s consolidated financial statements.

2. Restatement of the Consolidated Financial Statements

Background

In July 2013, the Audit Committee (the Audit Committee) of the Company s Board of Directors (the Board) commenced an independent review with the assistance of outside professionals into whether the Company had properly recognized revenue under U.S. generally accepted accounting principles (GAAP) in connection with certain revenue that had been recorded in 2012 and 2011 (the Independent Review). In conjunction with the Independent Review, the Company concluded that errors existed in the Company s previously issued financial statements for the fiscal years ended December 31, 2012, 2011 and 2010 (as well as the interim quarterly periods within such years), as well as for the interim quarterly period ended March 31, 2013. In addition, the Company has identified and corrected errors occurring prior to January 1, 2010 by recognizing a cumulative adjustment to beginning retained earnings in the consolidated statements of changes in shareholders equity included in these consolidated financial statements.

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

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

The correction of these errors had the following impact: decreased net sales by $14.7 million and $28.2 million for the years ended December 31, 2012 and 2011, respectively, and increased net sales by $1.9 million for the year ended December 31, 2010; decreased net income from continuing operations by $8.9 million and $14.5 million for the years ended December 31, 2012 and 2011, respectively, and increased net income from continuing operations by $3.2 million for the year ended December 31, 2010; and decreased opening retained earnings and total shareholders equity at January 1, 2010 by $8.3 million and $7.6 million, respectively. The following include descriptions of the significant adjustments to the Company s financial position and results of operations from the previously reported consolidated financial statements.

Distributor Revenue Recognition

The Company has determined that it previously recognized revenue with respect to certain distributor relationships before all revenue recognition criteria were met. Specifically, the Company has determined that a fixed or determinable sales price did not exist, and/or collection was not reasonably assured, with respect to certain transactions where revenue had previously been recognized at the time of shipment. Specifically, the Company s

review revealed arrangements, or extra-contractual terms, with certain of the Company s distributors regarding extended payment terms, return or exchange rights, and contingent payment obligations for sales to such distributors with respect to certain transactions. There were also concessions being made subsequent to the shipment of inventory to the distributors and the related revenue recognition. Based on the results of this review, it was determined that these arrangements were not appropriately evaluated under the appropriate revenue recognition criteria applicable under GAAP. Distributor sales represented approximately 11 13% of the Company s net sales (prior to the restatement) of approximately $462 million, $470 million, and $461 million for the years ended December 31, 2012, 2011, and 2010, respectively.

The Company previously recognized distributor revenue as title and risk of loss passed at either shipment from the Company s facilities or receipt at the distributor s facility, assuming all other revenue recognition criteria had been achieved (the sell-in method). Based on review of all facts and circumstances related to the arrangements described above, the Company determined that in many instances the revenue recognition criteria under the sell-in method were not satisfied at the time of shipment or receipt; specifically, the existence of extra-contractual terms or arrangements caused the Company not to meet the fixed or determinable criteria for revenue recognition in some cases, and in others collectability had not been established. In situations where the Company is unable to reasonably estimate the effects of these extra-contractual terms, it is precluded from recognizing revenue relating to distributor arrangements until the product is delivered to the end customer. This method is commonly referred to as the sell-through

Table of Contents

revenue recognition method because the vendor does not recognize revenue until the transaction consideration is fixed or determinable, which coincides with the selling of the product through the distribution channel to the end customer. Because the Company does not have reliable information about when its distributors sell the product through to end customers, the Company will use cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the Company is legally entitled to the accounts receivable at the time of shipment, since the revenue recognition criteria has not been met, the Company has not recognized accounts receivables or any corresponding deferred revenues associated with these transactions.

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

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

For distributor transactions within the Company s Orthopedics division, the Company has determined that sell-through accounting should be applied within the Brazil subsidiary for all prior periods given the frequency with which the Company conducted business under extra-contractual and undocumented terms, as well as the Company s inability to fully access underlying transactional and other information that would be necessary to evaluate transactions under a sell-in basis. Adjustments from periods ending prior to January 1, 2010 are presented by recording a cumulative effect in opening retained earnings and total shareholders equity at January 1, 2010. For distributor transactions within the division outside the Brazil subsidiary, there were also sales to four distributors that did not meet the fixed or determinable or collectability revenue recognition criteria and therefore, such sales were adjusted to sell-through accounting in the restatement.

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

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

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

Table of Contents

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

Accounts receivable decreased as of December 31, 2012 and December 31, 2011, by $41.3 million and $33.8 million, respectively, related to the de-recognition of receivables for which revenue has been deferred and will now be recognized on a sell-through basis, based on cash collections.

Inventory increased as of December 31, 2012 and December 31, 2011 by $11.0 million and $8.8 million, respectively, to recognize the costs of inventory shipments to distributors determined to be financially viable as discussed previously.

Inventory Reserves

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

The Company has also determined that certain inconsistencies existed with respect to how the Company previously computed and recorded inventory reserves. As a result, the Company has reviewed the methodologies used to compute and record inventory reserves and determined that errors in the application of GAAP existed in prior periods, which required adjustment in these financial statements. Based on this review, the Company has determined that it previously made reductions to previously recorded reserves based on changes in forecasted demand, which it believes was contrary to guidance set forth in ASC Topic 330, *Inventory* (specifically ASC 330-10-35-14), which states that a write-down of inventory to the lower-of-cost-or-market value at the close of a fiscal year creates a new cost basis that subsequently should not be marked up based on changes in underlying circumstances. The restated consolidated financial statements contain several adjustments to reflect recomputed inventory reserves in each of the relevant periods.

These adjustments resulted in a decrease to inventory (due to an increase in reserves) as of December 31, 2012 and December 31, 2011, by $14.8 million and $8.8 million, respectively.

Royalties

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

Other Adjustments

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

Included in Other Adjustments are adjustments to reclassify interest expense from continuing operations to discontinued operations of $3.9 million, and $4.9 million for the years ended December 31, 2011 and 2010, respectively. The reclassification was necessary as the Company used a portion of the proceeds from the sale of Breg, Inc. to repay in full the remaining $87.5 million balance on the Term Loan Facility and pay down $57.5 million of amounts outstanding under the Revolving Credit Facility.

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

Table of Contents

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

	Year Ended December 31, 2011						
		Adjustments by Category					
(U.S. Dollars, in thousands)	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total Adjustments	Restated
Net sales	$ 470,121	$ (29,135)	$	$	$ 985	$ (28,150)	$ 441,971
Cost of sales	92,619	(8,289)	3,377	7,713	107	2,908	95,527
Gross profit	377,502	(20,846)	(3,377)	(7,713)	878	(31,058)	346,444
Operating expenses							
Sales and marketing	200,145	(1,216)		(7,713)	2,295	(6,634)	193,511
General and administrative	64,374				107	107	64,481
Research and development	22,861						22,861
Amortization of intangibles assets	2,350				200	200	2,550
Charges related to U.S. Government resolutions	56,463				678	678	57,141
	346,193	(1,216)		(7,713)	3,280	(5,649)	340,544

Operating income	31,309	(19,630)	(3,377)	(2,402)	(25,409)	5,900
Other income and (expense)	(11,868)			3,915	3,915	(7,953)
Income (loss) before income taxes	19,441	(19,630)	(3,377)	1,513	(21,494)	(2,053)
Income tax expense	(21,181)	6,408	1,102	(494)	7,016	(14,165)
Net loss from continuing operations, net of tax	$ (1,740)	$ (13,222)	$ (2,275)	$ 1,019	$ (14,478)	$ (16,218)

	Year Ended December 31, 2010						
		Adjustments by Category					
(U.S. Dollars, in thousands)	Previously Reported	Distributor Revenue	Inventory Reserves	Royalties	Other	Total Adjustments	Restated
Net sales	$ 460,629	$ 2,088	$	$	$ (146)	$ 1,942	$ 462,571
Cost of sales	90,461	(323)	2,281	5,386	(712)	6,632	97,093
Gross profit	370,168	2,411	(2,281)	(5,386)	566	(4,690)	365,478
Operating expenses							
Sales and marketing	200,835	(275)		(5,386)	939	(4,722)	196,113
General and administrative	72,912				98	98	73,010
Research and development	27,958						27,958
Amortization of intangibles assets	2,213				200	200	2,413
Charges related to U.S. Government resolutions							
	303,918	(275)		(5,386)	1,237	(4,424)	299,494
Operating income	66,250	2,686	(2,281)		(671)	(266)	65,984
Other income and (expense)	(15,886)				4,930	4,930	(10,956)
Income before income taxes	50,364	2,686	(2,281)		4,259	4,664	55,028
Income tax expense	(22,606)	(821)	697		(1,301)	(1,425)	(24,031)
Net income from continuing operations, net of tax	$ 27,758	$ 1,865	$ (1,584)	$	$ 2,958	$ 3,239	$ 30,997

Table of Contents

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

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

Retained earnings	148,549	(33,702)	114,847
Accumulated other comprehensive income	2,504	2,241	4,745
Total shareholders equity	399,098	(31,266)	367,832
Total liabilities and shareholders equity	$ 504,281	$ (31,384)	$ 472,897

Table of Contents

The effects of the restatements on the Company s consolidated balance sheet as of December 31, 2011 are as follows:

	As of December 31, 2011		
(U.S. Dollars, in thousands except share and per share data)	**Previously Reported**	**Adjustments**	**Restated**
Assets			
Current assets:			
Cash and cash equivalents	$ 33,207	$	$ 33,207
Restricted cash	45,476		45,476
Trade accounts receivable, less allowances of $9,341	132,828	(32,940)	99,888
Inventories	82,969	(1,441)	81,528
Deferred income taxes	16,349	19,964	36,313
Escrow receivable	41,537		41,537
Prepaid expenses and other current assets	26,069	(4,070)	21,999
Assets held for sale	171,185		171,185
Total current assets	549,620	(18,487)	531,133
Property, plant and equipment, net	43,368	2,769	46,137
Patents and other intangible assets, net	8,236	610	8,846
Goodwill	73,094		73,094
Deferred income taxes	18,584	(1,843)	16,741
Other long-term assets	11,570	(2,141)	9,429
Total assets	$ 704,472	$ (19,092)	$ 685,380
Liabilities and shareholders equity			
Current liabilities:			
Bank borrowings	$ 1,318	$	$ 1,318
Current portion of long-term debt	17,500		17,500
Trade accounts payable	16,488	1,743	18,231
Accrued charges related to U.S. Government resolutions	82,500	638	83,138
Other current liabilities	45,327	(4,491)	40,836
Liabilities held for sale	22,676		22,676
Total current liabilities	185,809	(2,110)	183,699
Long-term debt	191,195		191,195
Deferred income taxes	9,778		9,778
Other long-term liabilities	2,519	6,115	8,634
Total liabilities	389,301	4,005	393,306
Contingencies (Note 17)			
Shareholders equity			
Common shares $0.10 par value; 50,000,000 shares authorized; 18,465,444 issued and outstanding	1,846		1,846
Additional paid-in capital	214,310	195	214,505

Retained earnings	97,254	(25,245)	72,009
Accumulated other comprehensive income	1,761	1,953	3,714
Total shareholders equity	315,171	(23,097)	292,074
Total liabilities and shareholders equity	$ 704,472	$ (19,092)	$ 685,380

Table of Contents

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

	Year Ended December 31, 2012		
(U.S. Dollars, in thousands, except share and per share data)	**Previously Reported**	**Adjustments**	**Restated**
Product sales	$ 415,850	(14,811)	$ 401,039
Marketing service fees	46,470	72	46,542
Net sales	462,320	(14,739)	447,581
Cost of sales	86,492	11,761	98,253
Gross profit	375,828	(26,500)	349,328
Operating expenses			
Sales and marketing	200,343	(13,212)	187,131
General and administrative	53,827	(436)	53,391
Research and development	28,577		28,577
Amortization of intangible assets	2,098	200	2,298
Charges related to U.S. Government resolutions (Note 17)	1,973	(678)	1,295
	286,818	(14,126)	272,692
Operating income	89,010	(12,374)	76,636
Other income and (expense)			
Interest expense, net	(4,577)	(166)	(4,743)
Other expense	(1,705)		(1,705)
	(6,282)	(166)	(6,448)
Income before income taxes	82,728	(12,540)	70,188
Income tax expense	(28,792)	3,654	(25,138)