ORTHOFIX INTERNATIONAL NV | 2012 ANNUAL REPORT

ORTHOFIX®

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 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 ☒ No ☐

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

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

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

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

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

Large Accelerated filer ☒	Accelerated filer ☐
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 ☒

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 February 22, 2013, 19,427,041 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's Definitive Proxy Statement to be filed with the Commission in connection with the 2013 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Form 10-K.

Forward-Looking Statements

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential" or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any such statement, or the risk factors described in Item 1A under the heading *Risk Factors*, to reflect new information, the occurrence of future events or circumstances or otherwise.

The forward-looking statements in this filing do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to the expected sales of our products, including recently launched products, 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 Form 10-K), 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 Form 10-K.

PART I

Item 1. Business

In this Form 10-K, the terms "we", "us", "our", "Orthofix" and "our Company" refer to the combined operations of all of Orthofix International N.V. and its respective consolidated subsidiaries and affiliates, unless the context requires otherwise.

Company Overview

We are a diversified, global medical device company focused on developing and delivering innovative repair and regenerative solutions to the spine and orthopedic markets. Our products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them achieve a more active and mobile lifestyle. We design, develop, manufacture, market and distribute medical 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, and Italy and manufacturing facilities in the U.S., the United Kingdom, and Italy. We directly distribute our products in the U.S., the United Kingdom, Italy, Germany, Switzerland, Austria, 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. 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.

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:

(US$ in thousands)	External Net Sales by GBU Year ended December 31,					
	2012		2011		2010	
	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	$ 147,206	32%	$ 143,775	31%	$ 133,831	29%
Spine Regenerative Stimulation	164,688	35%	160,442	34%	172,573	38%
Total Spine	311,894	67%	304,217	65%	306,404	67%
Orthopedics	150,426	33%	165,904	35%	154,225	33%
Total Net Sales	$ 462,320	100%	$ 470,121	100%	$ 460,629	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".

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 67% and 33%, respectively, of our total net sales in 2012. Marketing service fee sales is 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®Mini PTC(TM) PEEK Titanium Composite Spacer System™	A cervical interbody with porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics.
Construx ® PEEK VBR System	A modular device implanted during the replacement of degenerated or deformed spinal vertebrae to provide additional anterior support
NGage ® Surgical Mesh System	A modular metallic interbody implant placed between two vertebrae designed to restore disc space and increase stability that has been lost due to degeneration or deformity
PILLAR ™ PL & TL PEEK VBR System	Interbody devices for Posterior Lumbar Interbody Fusion ("PLIF") and 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 TM Spinal Fixation System which provides additional instrument and implant options for complex thoraco-lumbar spine procedures
Phoenix ™ Minimally Invasive Spinal Fixation System	A multi-axial extended reduction screw body used with the Firebird TM 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 ®
Eight-Plate Guided Growth System ®	Treatment for bowed legs or knock knees of children
Limb Reconstruction System ("LRS") and LRS ADVanced	External fixation for lengthenings and corrections of deformity
TrueLok ™	Ring fixation system for limb lengthening and deformity correction
TL-HEX™ TrueLok™ Hexapod System(TL-HEX)	Hexapod external fixation system for trauma and deformity correction with associated software
Galaxy Fixation ™ System	External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps.
PREFIX ™ and PREFIX ™ 2	External fixation range for temporary fixation of fractures in trauma
VeroNail ® Trochanteric Nailing System	Trochanteric titanium nailing system for hip fractures
Centronail ® Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail
Cemex ®	Bone cement
OSCAR	Ultrasonic bone cement removal
Centronail ® Ankle Compression Nailing System (ACN)	A differentiated solution for hindfoot fusions
Contours ® Lapidus Plating System (LPS)	A plate design contoured specifically for a tarsometatarsal (TMT) fusion
Contours® Proximal Humerus Plate (PHP)	An innovative plating solution for fraction fixation of the proximal humerus.

Contours® Volar 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
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

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

We have numerous trademarked products and services including but not limited to the following: Orthofix ®, Blackstone ®, Spinal-Stim ®, Cervical-Stim ®, Origen ™ DBM, 3 Degree ™, Reliant ™, Hallmark ®, Firebird ™, Ascent ®, Construx ®, Unity ®, NGage ®, Newbridge ®, Trinity Evolution ®, PILLAR ™, Alloquent ®, ProView ™, ProCallus ®, XCaliber ™, VeroNail ®, Centronail ®, PREFIX ™, Gotfried PC.C.P ®, Physio-Stim ®, TrueLok ™, 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 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 regenerative at the spinal fusion site. We have sponsored independent research at the Cleveland Clinic, New York University and University of Medicine and Dentistry of New Jersey, where scientists conducted animal and cellular studies to identify the mechanisms of action of our PEMF signals on bone and efficacy of healing. From this effort, a total of six studies have been published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength as well as proliferation and differentiation of cells involved in regenerative and healing. Furthermore, we believe that the research work with Cleveland Clinic allowing for characterization and visualization of the Orthofix PEMF waveform is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data along with additional clinical data could represent new indicator opportunities for our regenerative stimulation solutions.

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

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

Orthopedics

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

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, or patients which include 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, recent 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) should be utilized with the TL-HEX™. As with any other hexapod-type external fixator, for successful application of the TL-HEX™ an associated software is available (**www.tlhex.com**)

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

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

Internal Fixation

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

- The Centronail ® nailing system designed to stabilize fractures in the femur, tibia, supracondylar and recently the humerus. We believe that it has all the attributes of the Orthofix Nailing System, but has additional advantages, including that it is made of titanium, offers improved mechanical distal targeting and instrumentation and has a design which requires significantly reduced inventory.
- The Centronail® Ankle Compression Nail from Orthofix is an arthrodesis nailing system designed to improve upon the stability, simplicity, and flexibility of current hindfoot nails. This product was released in the US market in 2012.
- The VeroNail ® marks Orthofix's entry into the intramedullary hip nailing market. 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.

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 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

Government Regulation

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

Unless an exemption applies, each medical device 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 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 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 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 and results of operations.

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.

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 promulgated 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 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.

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 67% and 33%, respectively, of our total net sales in 2012.

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 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 hospital 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.

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., Italy, and the United Kingdom. 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 and the exhibits hereto, you should carefully consider the risks described below. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this Form 10-K.

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

On June 6, 2012, in connection with our settlement of a U.S. government investigation and related qui tam complaint related to our regenerative stimulation business, and our settlement of a U.S. government investigation and related qui tam complaint related to Blackstone Medical, Inc., 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 Annual Report on Form 10-K. 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.

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 that 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 CONSTRUX®Mini PTC(TM) PEEK Titanium Composite Spacer System, 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.

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.

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) 39%
- Third-Party Insurance..... 24%
- Independent Distributors..... 17%
- U.S. Government—Medicare, Medicaid, TriCare 12%
- 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 or results of operations. 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 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 and results of operations.

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 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.

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.

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 $9.8 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 number of our manufacturing facilities and suppliers are located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

- changes in 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 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.'s senior secured bank credit facility 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.)

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). 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities are:

Facility	Location	Approx. Square Feet	Ownership
Manufacturing, warehousing, distribution and research and development facility for Spine and Orthopedics Products and administrative facility for Corporate, Spine, and Biologics	Lewisville, TX	140,000	Leased
Research and development 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 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 Blackstone Medical, Inc. and Related Escrow Claims

In 2007, our subsidiary, Blackstone Medical, Inc. ("Blackstone") received a subpoena issued by the Office of Inspector General of the Department of Health and Human Services ("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 U.S. Department of Justice ("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 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 $1.7 million in 2012 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.

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." We believe that meritorious defenses exist to these claims and Breg is vigorously defending these cases. One of our insurance carriers previously asserted to us that certain potential losses related to this matter are not covered by our insurance coverage. We subsequently went into arbitration with this carrier, and on January 22, 2013, we obtained a binding arbitration award providing that such carrier is obligated to reimburse us for defense expenses, settlements, and judgments under certain policies. We currently estimate that we are 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.

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. We are vigorously defending this matter.

At the time of its divestiture by us, Breg was currently and had been engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court, alleging that the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units. The majority of these cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, we believe that meritorious defenses exist to these claims. In July 2012, a jury in one case related to a motorized cold therapy unit previously sold by Breg returned a verdict providing for approximately $2.1 million in compensatory damages to the plaintiff against Breg and $7 million in exemplary damages. The case remains subject to appeal. We believe that the damages are without merit, however, the ultimate outcome is uncertain. We previously established an accrual and related charge to discontinued operations of $4.2 million for both compensatory damages and exemplary damages for our indemnification obligations in connection with this July 2012 verdict; however, actual liability in this case could be higher or lower than the amount accrued.

Item X. Executive Officers of the Registrant

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

Name	Age	Position
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

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 department 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.

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

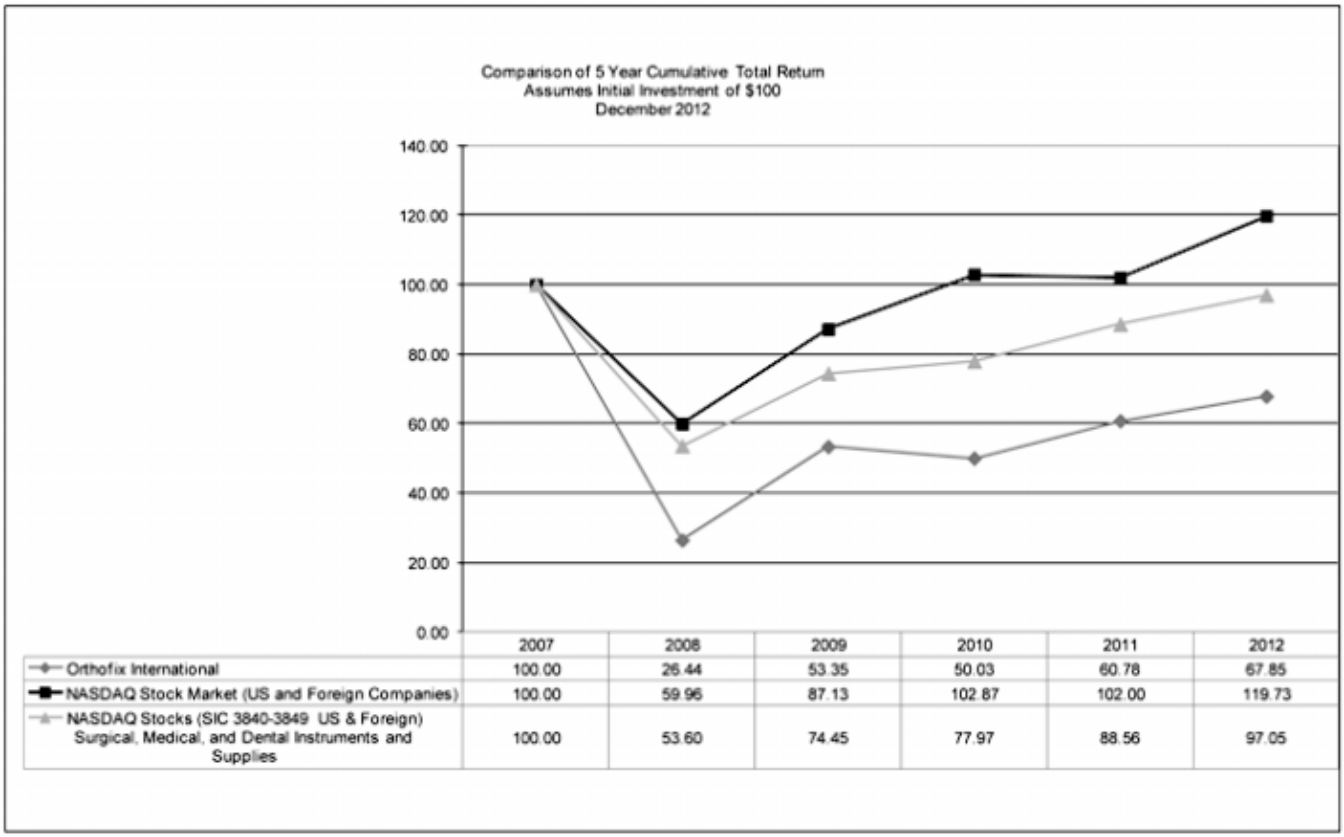
Orthofix International N.V. was organized under the laws of the Netherlands Antilles and is headquartered in Curaçao. On October 10, 2010, the Netherlands Antilles ceased to exist and Curaçao became a separate and autonomous country. As of October 10, 2010, the laws as they existed under the Netherlands 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 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.



	2007	2008	2009	2010	2011	2012
Orthofix International	100.00	26.44	53.35	50.03	60.78	67.85
NASDAQ Stock Market (US and Foreign Companies)	100.00	59.96	87.13	102.87	102.00	119.73
NASDAQ Stocks (SIC 3840-3849 US & Foreign) Surgical, Medical, and Dental Instruments and Supplies	100.00	53.60	74.45	77.97	88.56	97.05

Item 6. Selected Financial Data

The following selected consolidated financial data for the years ended December 31, 2012, 2011, 2010, 2009 and 2008 have been derived from our audited consolidated financial statements. The financial data as of December 31, 2012 and 2011 and for the 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. 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	2011	2010	2009	2008
	(US$ in thousands, except margin and per share data)				
Consolidated operating results					
Net sales	$462,320	$470,121	$460,629	$430,479	$ 407,257
Gross profit (3)	375,828	377,502	370,168	333,616	302,369
Gross profit margin (3)	81%	80%	80%	77%	74%
Total operating income (loss) (5)	89,010	31,309	66,250	42,108	(271,283)
Net income (loss) from continuing operations, net of tax (2) (5)	53,936	(1,740)	27,758	9,006	(239,075)
Net income (loss) from discontinued operations, net of tax (4)	(2,641)	667	16,450	15,466	10,521
Net income (loss) (1) (2) (4) (5)	51,295	(1,073)	44,208	24,472	(228,554)
Net (loss) income per share of common share:					
Basic:					
Net income (loss) from continuing operations, net of tax	2.84	(0.10)	1.58	0.53	(13.99)
Net income (loss) from discontinued operations, net of tax	(0.14)	0.04	0.93	0.90	0.62
Net income (loss)	2.70	(0.06)	2.51	1.43	(13.37)
Net (loss) income per share of common stock:					
Diluted:					
Net income (loss) from continuing operations, net of tax	2.78	(0.10)	1.55	0.52	(13.99)
Net income (loss) from discontinued operations, net of tax	(0.14)	0.04	0.92	0.90	0.62
Net income (loss)	$ 2.64	$ (0.06)	$ 2.47	$ 1.42	$ (13.37)

(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 $12 million for the year ended December 31, 2010.
(5) Operating income includes charges related to U.S. Government resolutions of $56.5 million for the year ended December 31, 2011.

	As of December 31,				
(at year-end)	2012	2011	2010	2009	2008
	(US$ in thousands, except share data)				
Consolidated financial position					
Total assets	$ 504,281	$ 704,472	$ 612,926	$ 601,690	$ 573,542
Total debt	20,016	210,013	220,007	254,673	282,844
Shareholders' equity	399,098	315,171	300,891	240,269	202,061
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

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

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

General

We are a diversified, global medical device company focused on 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 $7.7 million in 2012 or 3% versus 2011 led by our Spine Regenerative Biologics and Spine Regenerative Stimulation. Our Orthopedics revenue decreased 9% or $15.5 million dollars during 2012 as compared to 2011. Foreign currency accounted for 6% of the decrease with the rest due to a 2% decrease in sales in our external fixation which was partially offset by an 8% increase in revenues from Orthopedic Regenerative Biologics.
- An increase in gross profit margin from 80.3% in 2011 to 81.3% in 2012 which was primarily the result of operational efficiency initiatives and a favorable product and geographical sales mix.
- 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, and Italy and manufacturing facilities in the U.S., the United Kingdom, 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, Switzerland, Austria, 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 US 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

Revenue is generally recognized as income in the period in which title passes and the products are delivered. 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.

For stimulation that is prescribed by a physician, we recognize revenue when the product is placed on or implanted in and accepted by the patient. For domestic spinal implant and HCT/P products, revenues are recognized when the product has been utilized and a confirming purchase order has been received from the hospital. For sales to commercial customers, including hospitals and distributors, revenues are recognized at the time of shipment unless contractual agreements specify that title passes on delivery. Revenues for inventory delivered on consignment are recognized as the product is used by the consignee.

We derive a significant amount of revenues in the U.S. from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare. 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.

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 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 goods sold. If conditions or assumptions used in determining the market value change, additional inventory adjustments in the future may be necessary.

Goodwill and Other Intangible Assets

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

We generally calculate fair value of 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 reevaluate 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.

Selected Financial Data

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 (%)	2011 (%)	2010 (%)
Net sales	100	100	100
Cost of sales	19	20	20
Gross profit	81	80	80
Operating expenses			
Sales and marketing	43	43	44
General and administrative	12	14	16
Research and development	6	5	6
Amortization of intangible assets	—	—	—
Charges related to U.S. Government resolutions	—	12	—
Total operating income (loss)	19	7	14
Net income (loss) from continuing operations	12	—	6
Net income (loss) from discontinued operations	(1)	—	4
Net income (loss)	11	—	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.

GBU Revenues

Business Segments by GBU:

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

(US$ in thousands)	External Net Sales by GBU Year ended December 31,					
	2012		2011		2010	
	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	$ 147,206	32%	$ 143,775	31%	$ 133,831	29%
Spine Regenerative Stimulation	164,688	35%	160,442	34%	172,573	38%
Total Spine	311,894	67%	304,217	65%	306,404	67%
Orthopedics	150,426	33%	165,904	35%	154,225	33%
Total Net Sales	$ 462,320	100%	$ 470,121	100%	$ 460,629	100%

2012 Compared to 2011

Net sales decreased 2% to $462.3 million in 2012 compared to $470.1 million in 2011. The impact of foreign currency decreased sales by $9.8 million in 2012 when compared to 2011. Net sales includes product sales and marketing service fees which is comprised of sales of Trinity Evolution® in spine and orthopedic applications.

Sales

Net sales in our Spine global business unit increased to $311.9 million in 2012 compared to $304.2 million for 2011, an increase of 3%. The increase in Spine's net sales was primarily the result of a 2% 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. The Regenerative Stimulation products used in Spine applications increased 3% when compared with 2011. This sales increase was partially offset by a 6% decrease in sales of our Spine Repair devices in 2012 when compared to 2011. International Spine Repair device sales were down 21% and Spine Repair sales in the U.S. were flat in 2012 when compared to 2011.

Net sales in our Orthopedics global business unit decreased 9% to $150.4 million in 2012 compared to $165.9 million for 2011. Orthopedics's constant currency net sales decreased by 3%, or $5.6 million, during 2012 as compared to 2011. This decrease was primarily due to a 15% 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 8% increase in Orthopedic Regenerative Biologics.

Gross Profit—Our gross profit decreased less than 1% to $375.8 million for 2012 compared to $377.5 million for 2011. Gross profit as a percent of net sales in 2012 was 81.3% compared to 80.3% in 2011. This increase was the result of operational efficiency initiatives and a favorable product and geographical sales mix

Sales and Marketing Expense—Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increases and decreases in relation to sales. Sales and marketing expense increased $0.2 million, or less than 1%, to $200.3 million in 2012 compared to $200.1 million in 2011. As a percent of sales, sales and marketing expense was 43.3% and 42.6% for 2012 and 2011, respectively. In 2012 the increase 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 $10.6 million, or 16.5%, in 2012 to $53.8 million compared to $64.4 million in 2011. General and administrative expense as a percent of sales was 11.6% in 2012 compared to 13.7% 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 6.2% in 2012 compared to 4.9% 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 codevelopment agreement, a $3 million strategic investment with Musculoskeletal Transplant Foundation ("MTF") on the development and commercialization of the next generation cell-based bone growth technology and timing of spending related to our ongoing research, development and clinical activities.

Amortization of Intangible Assets—Amortization of intangible assets was $2.1 and $2.4 million for 2012 and 2011, respectively.

Charges Related to U.S. Government Resolutions—During 2012, we recorded a charge of $2 million 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 $4.6 million in 2012 compared to $9.5 million in 2011, primarily as the result of a lower year over year outstanding debt balance and to a lesser extent, lower interest rates.

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

Income Tax Benefit (Expense)—We recognized a $28.8 million and $21.2 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 for 2012 and 2011 was approximately 36% and 38%, respectively, excluding the impact of the charges related to the U.S. Government inquiries.

Discontinued operations—Discontinued operations in 2012 include approximately $4 million of legal settlements and legal costs, net of income taxes, related to certain specified product liability matters related to its former subsidiary, Breg. We agreed to indemnify Breg and its purchaser with respect to such matters. 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 $51.3 million, or $2.70 per basic share and $2.64 per diluted share, compared to net loss of $1.1 million, or $(0.06) 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 increased 2% to $470.1 million in 2011 compared to $460.6 million in 2010. The impact of foreign currency increased sales by $6.3 million in 2011 when compared to 2010. Net sales includes product sales and marketing service fees which is comprised of sales of Trinity Evolution® in spine and orthopedic applications.

Sales

Net sales in our Spine global business unit decreased to $304.2 million in 2011 compared to $306.4 million in 2010, a decrease of 1%. 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 the 2010, due to lower industry-wide surgical procedures and organizational changes to our sales force. This sales decrease was partially offset by a 23% increase in sales of our biologics products and an increase in our implant products of 3% when compared to 2010. The improvement in hardware products included 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.

Net sales in our Orthopedics global business unit increased to $165.9 million in 2011 compared to $154.2 million for 2010, an increase of 8%. Orthopedics's constant currency net sales increased by 4%, or $5.4 million during 2011 as compared to 2010. This increase was led by fixation products and the increased use of Trinity Evolution® in orthopedic applications but was offset by the reduction in stimulation products used in long-bone applications. Sales of our fixation products and biologics products increased 21% and 23%, respectively, during 2011 when compared to 2010.

Gross Profit—Our gross profit increased 2% to $377.5 million for 2011, compared to $370.2 million for 2010. Gross profit as a percent of net sales was 80.3% in 2011 and 80.4% in 2010.

Sales and Marketing Expense—Sales and marketing expense, which includes commissions, certain royalties and the bad debt provision, generally increases and decreases in relation to sales. Sales and marketing expense increased $0.7 million, or less than 1%, to $200.1 million in 2011 compared to $200.8 million in 2010. As a percent of sales, sales and marketing expense was 42.6% and 43.6% for 2011 and 2010, respectively. In 2011 the reduction in sales and marketing expense as percent of sales was the result of various consolidation and operational efficiency initiatives we have executed on over the past several quarters.

General and Administrative Expense—General and administrative expense decreased $8.5 million, or 11.7%, in 2011 to $64.4 million compared to $72.9 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 13.7% 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 4.9% in 2011 compared to 6.1% 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 increased $0.2 million for the year ended December 31, 2011 to $2.4 million compared to $2.2 million for the year ended December 31, 2010.

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 recorded a charge for this amount.

We have 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 $9.5 million in 2011 compared to $16.2 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.

Income Tax Benefit (Expense)—Our worldwide effective tax rate was 108.9% and 44.9% at December 31, 2011 and 2010. 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 for 2011 was approximately 38%, excluding the impact of the charges related to the U.S. Government inquiries.

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

Net Income (Loss)—Net loss in 2011 was $1.1 million, or $(0.06) per basic share and diluted share, compared to net income of $44.2 million, or $2.51 per basic and $2.47 per diluted share for 2010. The weighted average number of basic common shares outstanding was 18,219,343 and 17,601,956 during the years ended December 31, 2011 and 2010, respectively. 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.

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 $11.2 million in 2012 compared to $64.8 million in 2011, a decrease of $53.6 million. Net cash provided by operating activities is comprised of net income, non-cash items (including depreciation and amortization, provision for doubtful accounts, inventory obsolescence, share-based compensation, deferred taxes, and the net gain on sale of vascular operations) and changes in working capital. Net income increased $52.4 million to a net income of $51.3 million in 2012 compared to net loss of $1.1 million in 2011. Non-cash items for 2012 decreased $8.2 million to $43.6 million compared to $51.8 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 123 days at December 31, 2012 compared to 99 days at December 31, 2011 and inventory turns of 1.0 times at December 31, 2012, and 1.1 times as of December 31, 2011.

Net cash provided by investing activities was $125 million in 2012 compared to a 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 $138.6 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 15) 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.

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.

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.

Contractual Obligations

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

	Payments Due by Period				
Contractual Obligations (US$ 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 $1.6 million as of December 31, 2012 have been excluded from the contractual obligations table above. For further information on unrecognized tax benefits, see Note 13 to the consolidated financial statements included in this Form 10-K.

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 2.50%. This margin is adjusted based upon the measurement of the consolidated leverage ratio of the Company and its subsidiaries with respect to the immediately preceding four fiscal quarters. As of December 31, 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 goods 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 foreign subsidiaries (or the Company itself) enter into transactions denominated in a currency other than 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 $0.5 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.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer and Senior Vice President of Finance, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a—15(e) or 15d—15 (e)) as of the end of the period covered by this Form 10-K. Based upon that evaluation, our President and Chief Executive Officer and Chief Financial Officer and Senior Vice President of Finance concluded that, as of the end of the period covered by this Form 10-K, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

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

ORTHOFIX INTERNATIONAL N.V.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15f under the Exchange Act). 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 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 (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

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. Internal control over financial reporting includes self-monitoring mechanisms and actions taken to correct deficiencies as they are identified. 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.

Management conducted an evaluation of the effectiveness of the Company's system of internal control over financial reporting as of December 31, 2012 based on the framework set forth in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, management concluded that, as of December 31, 2012, the Company's internal control over financial reporting is effective based on the COSO criteria.

The Company's independent registered public accounting firm, Ernst & Young, LLP, has issued an audit report on the effectiveness of our internal control over financial reporting which immediately follows this report.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Orthofix International N.V.

We have audited 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 (the COSO criteria). Orthofix International N.V.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Orthofix International N.V. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Orthofix International N.V. as of December 31, 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 of Orthofix International N.V. and our report dated March 1, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas
March 1, 2013

Item 9B. Other Information

Not applicable.

PART III

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

Item 10. Directors, Executive Officers and Corporate Governance

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

Item 11. Executive Compensation

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

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

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

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

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

Item 14. Principal Accountant Fees and Services

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

1. Financial Statements

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

2. Financial Statement Schedules

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

3. Exhibits

Exhibit Number	Description
2.1	Asset Purchase Agreement, dated as of March 8, 2010, by and between Tyco Healthcare Group LP d/b/a Covidien, Covidien AG, Mallinckrodt do BrasilLtda, Kendall de Mexico S.A. de C.V., Novamedix Limited, Novamedix Distribution Limited, Novamedix Services Limited, Promeca S.A. de C.V., Orthofix do Brasil, OrthofixS.r.l., Orthofix S.A., Intavent Orthofix Limited, Breg Mexico S. de R.I. de CV, and Implantes y Sistemas Medicos, Inc. (filed as an exhibit to the Company's current report on Form 8-K filed March 9, 2010 and incorporated herein by reference).
2.2	Stock Purchase Agreement, dated as of April 23, 2012, by and among Breg, Inc., Orthofix Holdings, Inc. and Breg Acquisition Corp. (filed as an exhibit to the Company's current report on Form 8-K filed April 24, 2012 and incorporated herein by reference).
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's Annual report on Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.1	Credit Agreement, dated as of August 30, 2010, among Orthofix Holdings, Inc., Orthofix International N.V. and certain domestic subsidiaries of Orthofix International N.V., the several banks and other financial institutions as may from time to time become parties thereunder, and JPMorgan Chase, N.A. (filed as an exhibit to the Company's current report on Form 8-K filed August 31, 2010 and incorporated herein by reference).
10.2	First Amendment to Credit Agreement, dated May 4, 2011, among Orthofix Holdings, Inc., a Delaware corporation, Orthofix International N.V. ("Orthofix International"), a Netherlands Antilles corporation, certain domestic direct and indirect subsidiaries of Orthofix International, JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto (filed as an exhibit to the Company's current report on Form 8-K filed May 5, 2011 and incorporated herein by reference).
10.3+	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).

Exhibit Number	Description
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).
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).

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).
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).

Exhibit Number	Description
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 for the year ended December 31, 2012 filed on March 1, 2013, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Consolidated Statements of Changes in Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.

* Filed herewith.

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

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

"The Exhibits to this Annual Report on Form 10-K are not contained herein. The Company will furnish a copy of any of the Exhibits to a shareholder upon written request to Investor Relations, Orthofix International N.V., 3451 Plano Parkway, Lewisville, TX 75056."

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 1, 2013

By: /s/ Robert S. Vaters
Name: **Robert S. Vaters**
Title: **President and Chief Executive Officer, Director**

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

Name	Title	Date
/s/ ROBERT S. VATERS **Robert S. Vaters**	President and Chief Executive Officer, Director (Principal Executive Officer)	March 1, 2013
/s/ EMILY V. BUXTON **Emily V. Buxton**	Interim Chief Financial Officer and Chief Financial Officer, Orthopedics Global Business Unit (Principal Financial and Accounting Officer)	March 1, 2013
/s/ JAMES F. GERO **James F. Gero**	Chairman of the Board of Directors	March 1, 2013
/s/ WALTER VON WARTBURG **Walter von Wartburg**	Director	March 1, 2013
/s/ GUY JORDAN **Guy Jordan**	Director	March 1, 2013
/s/ KENNETH R. WEISSHAAR **Kenneth R. Weisshaar**	Director	March 1, 2013
/s/ MICHAEL MAINELLI **Michael Mainelli**	Director	March 1, 2013
/s/ DAVEY S. SCOON **Davey S. Scoon**	Director	March 1, 2013
/s/ MARIA SAINZ **Maria Sainz**	Director	March 1, 2013

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.

James F. Gero
Chairman of the Board of Directors

Robert S. Vaters
President and Chief Executive Officer, Director

Emily V. Buxton
Interim Chief Financial Officer and Chief Financial Officer, Orthopedic Global Business Unit

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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.

Reports of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Orthofix International N.V.

We have audited the accompanying 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. Our audits also included the financial statement schedule 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.

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 and our report dated March 1, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas
March 1, 2013

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	2011
Assets		
Current assets:		
Cash and cash equivalents	$ 31,055	$ 33,207
Restricted cash	21,314	45,476
Trade accounts receivable, less allowances of $16,188 and $9,376 at December 31, 2012 and 2011, respectively	150,316	132,828
Inventories	88,744	82,969
Deferred income taxes	16,959	16,349
Escrow receivable	—	41,537
Prepaid expenses and other current assets	32,056	26,069
Assets held for sale	—	171,185
Total current assets	340,444	549,620
Property, plant and equipment, net	51,362	43,368
Patents and other intangible assets, net	6,880	8,236
Goodwill	74,388	73,094
Deferred income taxes	19,904	18,584
Other long-term assets	11,303	11,570
Total assets	$ 504,281	$ 704,472
Liabilities and shareholders' equity		
Current liabilities:		
Bank borrowings	$ 16	$ 1,318
Current portion of long-term debt	—	17,500
Trade accounts payable	21,812	16,488
Accrued charges related to U.S. Government resolutions	—	82,500
Other current liabilities	46,969	45,327
Liabilities held for sale	—	22,676
Total current liabilities	68,797	185,809
Long-term debt	20,000	191,195
Deferred income taxes	11,456	9,778
Other long-term liabilities	4,930	2,519
Total liabilities	105,183	389,301
Contingencies (Note 16)		
Shareholders' equity		
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	1,934	1,846
Additional paid-in capital	246,111	214,310
Retained earnings	148,549	97,254
Accumulated other comprehensive income	2,504	1,761
Total shareholders' equity	399,098	315,171
Total liabilities and shareholders' equity	$ 504,281	$ 704,472

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

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	2011	2010
Product sales	$ 415,850	$ 432,975	$ 430,783
Marketing service fees	46,470	37,146	29,846
Net sales	462,320	470,121	460,629
Cost of sales	86,492	92,619	90,461
Gross profit	375,828	377,502	370,168
Operating expenses			
Sales and marketing	200,343	200,145	200,835
General and administrative	53,827	64,374	72,912
Research and development	28,577	22,861	27,958
Amortization of intangible assets	2,098	2,350	2,213
Charges related to U.S. Government resolutions (Note 16)	1,973	56,463	—
	286,818	346,193	303,918
Operating income	89,010	31,309	66,250
Other income and expense			
Interest expense, net	(4,577)	(9,456)	(16,217)
Other expense	(1,705)	(2,412)	331
	(6,282)	(11,868)	(15,886)
Income before income taxes	82,728	19,441	50,364
Income tax expense	(28,792)	(21,181)	(22,606)
Net income (loss) from continuing operations, net of tax	53,936	(1,740)	27,758
Discontinued operations (Note 15)			
Gain on sale of Breg, Inc., net of tax	1,345	—	—
Gain on sale of vascular operations, net of tax	—	—	12,019
Income (loss) from discontinued operations	(4,012)	1,263	10,015
Income tax benefit (expense)	26	(596)	(5,584)
Net income (loss) from discontinued operations, net of tax	(2,641)	667	16.450
Net income (loss)	$ 51,295	$ (1,073)	$ 44,208
Net income (loss) per common share—basic:			
Net income (loss) from continuing operations, net of tax	$ 2.84	$ (0.10)	$ 1.58
Net income (loss) from discontinued operations, net of tax	(0.14)	0.04	0.93
Net income (loss) per common share—basic	$ 2.70	$ (0.06)	$ 2.51
Net income (loss) per common share—diluted:			
Net income (loss) from continuing operations, net of tax	$ 2.78	$ (0.10)	$ 1.55
Net income (loss) from discontinued operations, net of tax	(0.14)	0.04	0.92
Net income (loss) per common share—diluted:	$ 2.64	$ (0.06)	$ 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	$ 480	$ (3,192)	$ (1,710)
Unrealized gain (loss) on derivative instrument	416	(693)	(126)
Other Comprehensive income (loss), before tax	896	(3,885)	(1,836)
Income tax related to components of other comprehensive income	(153)	256	36
Other Comprehensive income loss, net of tax	743	(3,629)	(1,800)
Comprehensive income (loss)	$ 52,038	$ (4,702)	$ 42,408

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
Net income	—	—	—	44,208	—	44,208
Unrealized loss on derivative instrument (net of taxes of $36)	—	—	—	—	(90)	(90)
Translation adjustment	—	—	—	—	(1,710)	(1,710)
Tax benefit on exercise of stock options	—	—	2,222	—	—	2,222
Share-based compensation expense	—	—	8,138	—	—	8,138
Common shares issued	584,935	58	7,796	—	—	7,854
At December 31, 2010	17,726,645	1,772	195,402	98,327	5,390	300,891
Net income	—	—	—	(1,073)	—	(1,073)
Unrealized loss on derivative instrument (net of taxes of $256)	—	—	—	—	(437)	(437)
Translation adjustment	—	—	—	—	(3,192)	(3,192)
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	18,465,444	1,846	214,310	97,254	1,761	315,171
Net income	—	—	—	51,295	—	51,295
Unrealized gain loss on derivative instrument (net of taxes of $153)	—	—	—	—	263	263
Translation adjustment	—	—	—	—	480	480
Share-based compensation expense	—	—	6,303	—	—	6,303
Common shares issued	873,885	88	25,498	—	—	25,586
At December 31, 2012	19,339,329	$ 1,934	$ 246,111	$ 148,549	$ 2,504	$ 399,098

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

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	2011	2010
Cash flows from operating activities:			
Net income (loss)	$ 51,295	$ (1,073)	$ 44,208
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	20,261	22,776	22,521
Amortization of debt costs	1,737	1,239	471
Provision for doubtful accounts	13,302	11,532	8,746
Deferred income taxes	871	936	178
Share-based compensation	6,303	6,648	8,138
Provision for inventory obsolescence	351	5,463	7,376
Loss on refinancing of credit facility	—	—	550
Gain on interest rate swap	—	—	(1,254)
Gain on sale of Breg, Inc.	(1,344)	—	—
Net gain on sale of vascular operations	—	—	(12,019)
Income tax benefit on employee-stock-based awards	—	(1,737)	(2,222)
Other	2,124	4,906	4,216
Changes in operating assets and liabilities, net of effect of dispositions:			
Trade accounts receivable	(31,600)	(25,818)	(14,770)
Inventories	(6,692)	(13,812)	(222)
Escrow receivable	41,537	(32,562)	(2,049)
Prepaid expenses and other current assets	(6,191)	(4,057)	(7,214)
Trade accounts payable	5,554	576	(2,863)
Charges related to U.S. Government resolutions	(82,500)	88,463	—
Other current liabilities	(2,842)	3,384	(5,289)
Long-term assets	(825)	(1,214)	(1,625)
Long-term liabilities	(135)	(869)	(4,369)
Net cash provided by operating activities	11,206	64,781	42,508
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)	—
Income tax benefit on employee stock-based awards	—	1,737	2,222
Net cash used in financing activities	(138,607)	(13,664)	(40,026)
Effect of exchange rates 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.

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 12 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 $0.7 million gain 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 8 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 9 for additional information.

The Company generally does not require collateral on trade receivables.

(g) Inventories

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess or obsolete items. 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. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Texas, standard costs, which approximates actual cost, 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 used with 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 and equipment	2 to 10
Furniture and fixtures	4 to 8
Instrumentation	3 to 4

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 12 for additional information).

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 units to total enterprise value at January 1, 2011.

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

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 ("ASC Topic 815").*

See Note 9 for a description of the types of derivative instruments the Company utilizes.

(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 9). The components of and changes in accumulated other comprehensive income are as follows:

(US$ in thousands)	Foreign Currency Translation Adjustments	Fair Value of Cross-Currency Swaps	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2010	$ 5,085	$ 305	$ 5,390
Unrealized loss on cross-currency swaps, net of tax benefit of $256	—	(437)	(437)
Foreign currency translation adjustment (1)	(3,192)	—	(3,192)
Balance at December 31, 2011	1,893	(132)	1,761
Unrealized gain on cross-currency swaps, net of tax of $153	—	263	263
Foreign currency translation adjustment (1)	480	—	480
Balance at December 31, 2012	$ 2,373	$ 131	$ 2,504

(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

Product revenue is generally recognized as income in the period in which risk of loss and title transfers, the products are delivered subject to a fixed or determinable fee and collectability is reasonably assured. To the extent these criteria are not met, the Company accounts for shipments as consigned inventory and recognizes revenue when all criteria are met. Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs are included in cost of sales.

For certain products that are prescribed by a physician, the Company recognizes revenue when the product is placed on or implanted in and accepted by the patient. For domestic spinal implant and human cellular and tissue based products ("HCT/P products"), revenues are recognized when the product has been utilized and a confirming purchase order has been received from the hospital. For sales to commercial customers, including hospitals and distributors, revenues are recognized at the time of shipment unless contractual agreements specify that title passes on delivery. Revenues for inventory delivered on consignment are recognized as the product is used by the consignee.

In 2008, the Company entered into a collaborative arrangement with the Musculoskeletal Transplant Foundation ("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, $37.1 million and $29.8 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.

The Company derives a significant amount of revenues in the U.S. from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors such as Medicare. 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.

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 estimate of the related fee is provided throughout the year 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 $0.2 million, $0.3 million and $0.5 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.

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

The Company includes imputed interest 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 19). 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 Accounting Standards Update ("ASU") No. 2011-05, *Presentation of Comprehensive Income*. This ASU eliminates the current option to present other comprehensive income and its components in the statement of changes in shareholders' equity and increases the prominence of other comprehensive income in the statements by providing an

alternative to present the components of net income and comprehensive income as either one continuous or two separate but consecutive financial statements. Companies are also required to present reclassification adjustments for items that are reclassified from other comprehensive income to net income within these statements. This standard is to be applied retrospectively and is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company adopted this ASU as of March 31, 2012 and it did not have a material impact on the Company's Consolidated financial statements.

2. Inventories

(US$ in thousands)	December 31, 2012	2011
Raw materials	$ 8,470	$ 10,081
Work-in-process	7,886	5,606
Finished products	36,675	32,697
Field inventory	29,363	28,012
Consignment inventory	6,350	6,573
	$ 88,744	$ 82,969

Field inventory represents immediately saleable finished products that are in the possession of the Company's direct sales representatives. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals.

3. Property, plant and equipment

(US$ in thousands)	December 31, 2012	2011
Cost		
Buildings	$ 3,911	$ 3,829
Plant, equipment and instrumentation	115,167	98,290
Furniture and fixtures	5,567	5,697
	124,645	107,816
Accumulated depreciation	(73,283)	(64,448)
	$ 51,362	$ 43,368

Depreciation expense for the years ended December 31, 2012, 2011 and 2010 was $15.7 million, $14.3 million and $13.6 million, respectively.

4. Patents and other intangible assets

(US$ in thousands)	December 31, 2012	2011
Cost		
Patents	$ 37,695	$ 37,683
Trademarks—definite lived	657	545
	38,352	38,228
Accumulated amortization		
Patents	(31,045)	(29,611)
Trademarks—definite lived	(427)	(381)
	(31,472)	(29,992)
Patents and other intangible assets, net	$ 6,880	$ 8,236

Amortization expense for intangible assets is estimated to be approximately $2.1 million, $1.4 million, $1.3 million, $1.2 million, $0.8 million and $0.1 million for the periods ending December 31, 2013, 2014, 2015, 2016, 2017 and 2018 and thereafter, respectively.

5. Goodwill

The following table presents the changes in the net carrying value of goodwill by reportable segment:

(US$ in thousands)	Spine	Orthopedics	Total
At December 31, 2010	$ 41,458	$ 32,140	$ 73,598
Foreign currency	(39)	(465)	(504)
At December 31, 2011	41,419	31,675	73,094
Foreign currency	145	1,149	1,294
At December 31, 2012	$ 41,564	$ 32,824	$ 74,388

6. Bank borrowings

Borrowings under the line of credit consist of borrowings in Euros used to fund international operations. The borrowings under such facility were less than $0.1 million and $1.3 million at December 31, 2012 and 2011, respectively. The weighted average interest rate on borrowings under lines of credit as of December 31, 2012 and 2011 was 3.70% and 4.02%, respectively.

The Company had an unused available line of credit of €5.8 million ($7.6 million) and €6.3 million ($8.1 million) at December 31, 2012 and 2011, respectively, in its Italian line of credit. This line of credit provides the Company the option to borrow amounts in Italy at rates which are determined at the time of borrowing. This line of credit is unsecured.

7. Other current liabilities

	December 31,	
(US$ in thousands)	2012	2011
Accrued expenses	$ 19,297	$ 14,001
Salaries, bonuses, commissions and related taxes payable	18,337	22,742
Other payables	9,335	8,584
	$ 46,969	$ 45,327

8. Long-term debt

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

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. ("Breg") (see Note 15) 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, 2011, the Company had $91.3 million outstanding under the Term Loan Facility and $117.4 million outstanding under the Revolving Credit Facility. Borrowings under the Credit Facilities bear interest at a floating rate, which is, at Orthofix Holdings' option, either the London Inter-Bank Offered Rate ("LIBOR") plus an applicable margin or a base rate (as defined in the Credit Agreement) plus an applicable margin (in each case subject to adjustment based on financial ratios). Such applicable margin will be up to 3.25% for LIBOR borrowings and up to 2.25% for base rate borrowings depending upon a measurement of the consolidated leverage ratio with respect to the immediately preceding four fiscal quarters. As of December 31, 2012, the entire Revolving Credit Facility was at the LIBOR rate 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%. As of December 31, 2011, the remaining $17.4 million of the Revolving Credit Facility was at a base rate (as defined in the Credit Agreement) plus a margin of 2.00%. The effective interest rate on the Credit Facilities as of December 31, 2012 and 2011 was 2.7% and 3.4%, respectively.

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

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

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

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

The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of December 31, 2012 and 2011 is $247.4 million and $186.0 million, respectively. In addition, the Credit Agreement restricts the Company and subsidiaries that are not parties to the Credit Facilities from access to cash held by Orthofix Holdings, Inc. and its subsidiaries. All of the Company's subsidiaries that are parties to the Credit Agreement have access to this cash for operational and debt repayment purposes. The amount of restricted cash of the Company as of December 31, 2012 and 2011 was $21.3 million and $45.5 million, respectively.

In conjunction with obtaining the Credit Facilities and the Credit Agreement, as amended, the Company incurred debt issuance costs of $5 million which includes $0.8 million of costs related to the May 2011 amendment. These costs are being amortized using the effective interest method over the life of the Credit Facilities. In conjunction with the Term Loan Facility repayment in May 2012, the Company wrote off $0.8 million of the related debt issuance costs. As of December 31, 2012 and 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were $1.8 million and $3.5 million, respectively.

9. Derivative instruments

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

(US$ in thousands)	Fair value: favorable (unfavorable)	Balance sheet location
As of December 31, 2012		
Cross-currency swap	$ 305	Other long-term assets
As of December 31, 2011		
Cross-currency swap	$ 1,011	Other long-term assets

	For the year ended December 31,		
(US$ in thousands)	2012	2011	2010
Interest rate swap gain recognized in net income (loss)	$ —	$ —	$ 1,254
Cross-currency swap gain (loss) recorded in other comprehensive income (loss), net of taxes	263	(437)	(90)

Cross-currency swap

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

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

Interest rate swap

In June 2008, the Company entered into a three-year fully amortizable interest rate swap agreement (the "Swap") with a notional amount of $150.0 million and an expiration date of June 30, 2011. On June 29, 2010, the Company settled the Swap with the financial institution holder of the derivative instrument, which resulted in a $1.3 million gain in 2010.

10. Fair value measurements

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

Level 1 — quoted prices in active markets for identical assets and liabilities

Level 2 — observable inputs other than quoted prices in active markets for identical assets and liabilities

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

As of December 31, 2012, the Company's financial instruments included cash equivalents, restricted cash, accounts receivable, short-term bank borrowings, accounts payable, long-term secured debt, and a cross currency derivative contract. Cash equivalents consist of short-term, highly liquid, income-producing investments, all of which have original maturities of 90 days or less, including money market funds. The carrying value of restricted cash, accounts receivable, short-term bank borrowings and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's credit facilities carry a floating rate of interest, and therefore, the carrying value is considered to approximate the fair value.

The Company's cross-currency derivative instrument is the only financial instrument recorded at fair value on a recurring basis. This instrument consists of an over-the-counter contract, which is not traded on a public exchange. The fair value of the swap contract is determined based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets. Therefore, the Company has categorized the swap contract as a Level 2 derivative financial instrument. The Company also considers counterparty credit risk and its own credit risk in its determination of all estimated fair values. The Company has consistently applied these valuation techniques in all periods presented.

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

(US$ in thousands)	Balance December 31, 2012	Level 1	Level 2	Level 3
Derivative Financial Instruments (1)				
Cash Flow Hedges				
Cross currency hedge	$ 305	$ —	$ 305	$ —

(1) See Note 9, "Derivative Instruments".

(US$ in thousands)	Balance December 31, 2011	Level 1	Level 2	Level 3
Derivative Financial Instruments (1)				
Cash Flow Hedges				
Cross currency hedge	$ 1,011	$ —	$ 1,011	$ —

11. Commitments

Leases

The Company has entered into operating leases for facilities and equipment. These leases are non-cancellable and typically do not contain renewal options. Certain leases contain rent escalation clauses for which the Company recognizes the expense on a straight-line basis. Rent expense under the Company's operating leases for the years ended December 31, 2012, 2011 and 2010 was approximately $4.1 million, $4.8 million and $6.8 million, respectively. Future minimum lease payments under operating leases, net of amounts to be received under sub-leases, as of December 31, 2012 are as follows:

(US$ in thousands)	
2013	$ 3,340
2014	2,992
2015	2,816
2016	2,677
2017	2,620
Thereafter	2,624
Total	$ 17,069

12. Business segment information

The Company's segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. At this time, the Company's Chief Operating Decision Maker (the "CODM") only uses GBU reporting for Sales and Operating Income to assess operating performance. Items below operating income are not considered when measuring the profitability of a segment. Goodwill is also assigned to specific GBUs. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. On May 24, 2012 as a result of the sale of its sports medicine business, the Company began managing its business by its two GBUs, which are comprised of Spine and Orthopedics supported by Corporate activities and represent the current segments for which the Company's Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. These 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 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 within the two GBUs.

Business Segments by GBU:

The table below presents external net sales for continuing operations by GBU reporting segment. Net sales includes product sales and marketing service fees which is comprised of sales of Trinity Evolution® in spine and orthopedic applications.

(US$ in thousands)	External Net Sales by GBU Year ended December 31,					
	2012		2011		2010	
	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	$ 147,206	32%	$ 143,775	31%	$ 133,831	29%
Spine Regenerative Stimulation	164,688	35%	160,442	34%	172,573	38%
Total Spine	311,894	67%	304,217	65%	306,404	67%
Orthopedics	150,426	33%	165,904	35%	154,225	33%
Total Net Sales	$ 462,320	100%	$ 470,121	100%	$ 460,629	100%

The table below presents operating income (loss) from continuing operations by GBU reporting segment:

(US$ in thousands)	Operating Income (Loss) Year Ended December 31,		
	2012	2011	2010
Spine (1)	$ 90,771	$ 46,618	$ 80,688
Orthopedics (2)	15,280	12,368	5,878
Corporate (3)	(17,041)	(27,677)	(20,316)
Total	$ 89,010	$ 31,309	$ 66,250

(1) For 2011, the operating income for the Spine GBU included $42.5 million of expenses in connection with charges related to U.S. Government resolutions.

(2) For 2011, the operating income for the Orthopedics GBU included $6.5 million of expenses in connection with charges related to U.S. Government resolutions.

(3) For 2011, the operating loss for the Corporate GBU included $7.5 million of expenses in connection with charges related to U.S. Government inquiries and $3.2 million of senior management succession charges.

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

(US$ in thousands)	Depreciation and amortization by GBU Year Ended December 31,		
	2012	2011	2010
Spine	$ 12,152	$ 11,060	$ 9,407
Orthopedics	5,604	5,506	6,282
Corporate	70	52	126
Total	$ 17,826	$ 16,618	$ 15,815

Geographical information

Analysis of net sales by geographic destination:

(US$ in thousands)	2012	2011	2010
U.S.	$ 341,015	$ 329,625	$ 339,781
International:			
U.K.	8,628	8,240	12,509
Italy	18,242	20,700	19,831
Brazil	38,015	48,851	29,067
Other	56,420	62,705	59,441
Total international	121,305	140,496	120,848
Total net sales	$ 462,320	$ 470,121	$ 460,629

Analysis of property, plant and equipment by geographic area:

(US$ in thousands)	2012	2011
U.S.	$ 37,081	$ 30,806
Italy	7,617	7,663
U.K.	1,402	1,449
Brazil	3,421	2,532
Others	1,841	918
Total	$ 51,362	$ 43,368

13. Income taxes

Income from continuing operations before provision for income taxes consisted of:

	Year Ended December 31,		
(US$ in thousands)	2012	2011	2010
U.S.	$ 67,692	$ 16,996	$ 48,405
Non-U.S.	15,036	2,445	1,959
	$ 82,728	$ 19,441	$ 50,364

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

	Year Ended December 31,		
(US$ in thousands)	2012	2011	2010
U.S.			
Current	$ 23,149	$ 16,508	$ 18,658
Deferred	(503)	365	1,047
Total U.S.	22,646	16,873	19,705
Non-U.S.			
Current	5,800	3,208	948
Deferred	346	1,100	1,953
	6,146	4,308	2,901
Total tax expense	$ 28,792	$ 21,181	$ 22,606

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

(US$ in thousands)	2012	2011
Intangible assets and goodwill	$ 5,471	$ 5,503
Inventories and related reserves	9,259	11,650
Accrued compensation	3,603	4,428
Allowance for doubtful accounts	7,302	4,025
Accrued interest	18,230	16,123
Net operating loss carryforwards	26,827	20,396
Other, net	987	846
	71,679	62,971
Valuation allowance	(26,125)	(19,115)
Deferred tax asset	$ 45,554	$ 43,856
Withholding taxes	(11,456)	(9,778)
Property, plant and equipment	(8,691)	(8,923)
Deferred tax liability	(20,147)	(18,701)
Net deferred tax assets	$ 25,407	$ 25,155

The valuation allowance as of December 31, 2012 and 2011 was $26.1 million and $19.1 million, respectively. The net increase in the valuation allowance of $7 million during the year principally relates to certain current period foreign losses not benefitted. The valuation allowance is attributable to net operating loss carryforwards and certain temporary differences in certain foreign jurisdictions, the benefit for which is dependent upon the generation of future taxable income in those foreign jurisdictions. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not the Company will realize the benefits of these temporary differences, net of the existing valuation allowances at December 31, 2012.

The Company has state net operating loss carryforwards of approximately $21.5 million that begin to expire in 2013. The Company has net operating losses of foreign taxing jurisdictions of approximately $101.6 million with the majority of the losses related to the Company's Netherlands operations expiring in various amounts in tax years beginning in 2013. The Company has provided a valuation allowance against a significant portion of these net operating loss carryforwards since it does not believe that this deferred tax asset can be realized prior to expiration.

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

(US$ in thousands, except percentages)	2012		2011		2010	
	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ 28,955	35.0%	$ 6,804	35.0%	$ 17,627	35.0%
State taxes, net	1,946	2.4%	1,981	10.2%	2,093	4.2%
Foreign rate differential	(2,749)	(3.3)%	1,204	6.2%	280	0.6%
Valuation allowance—foreign losses	6,833	8.3%	4,254	21.9%	3,644	7.2%
SRL Intangible	(2,214)	(2.7)%	(2,421)	(12.5)%	(2,607)	(5.2)%
Domestic manufacturing deduction	(1,533)	(1.9)%	(1,316)	(6.8)%	(1,530)	(3.0)%
Settlement of U.S. Government resolutions	(1,260)	(1.5)%	9,745	50.1%	—	0.0%
Other items, net	(1,186)	(1.5)%	930	4.8%	3,099	6.1%
Income tax expense/effective rate	$ 28,792	34.8%	$ 21,181	108.9%	$ 22,606	44.9%

The effective tax rate of 34.8% for 2012 was impacted by 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 the $28.8 million of income tax expense and effective tax rate of 34.8% for 2012. The Company did not record tax benefit on certain expenses associated with the Company's estimate of the charges related to U.S. Government resolutions. The effective tax rate was approximately 36% in 2012 and 38% in 2011 excluding the impact of the charges related to the U.S. Government resolutions.

On January 2, 2013, the American Taxpayer Relief Act of 2012 ("Act") was enacted. The Act provides tax relief for businesses by reinstating certain tax benefits and credits retroactively to January 1, 2012. There are several provisions of the Act that impact the Company, most notably the extension of the Research and Development credit. Income tax accounting rules require tax law changes to be recognized in the period of enactment; as such, the associated tax benefits of the Act will be recognized in the Company's provision for income taxes in the first quarter of 2013.

The Company's gross unrecognized tax benefit was $1.0 million and $0.6 million for the years ended December 31, 2012 and 2011, respectively. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. The Company had approximately $0.6 million and $0.5 million accrued for payment of interest and penalties as of December 31, 2012 and 2011, respectively.

The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. As of December 31, 2012, the Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2012 and December 31, 2011 follows:

(US$ in thousands)	2012	2011
Balance as of January 1,	$ 610	$ 569
Additions for current year tax positions	581	86
Decreases for prior year tax positions	(106)	(17)
Expiration of statutes	(108)	(28)
Balance as of December 31,	$ 977	$ 610

The Company files a consolidated income tax return in the U.S. federal jurisdiction, the U.K., Italy and numerous consolidated and separate income tax returns in many state and other foreign jurisdictions. The statute of limitations with respect to federal tax authorities is closed for years prior to December 31, 2009. The statute of limitations for the various state tax filings is closed in most instances for the years prior to December 31, 2008. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to December 31, 2007.

The Company's intention is to reinvest the total amount of its unremitted foreign earnings (residing outside Curaçao) in the local jurisdiction, to the extent they are generated and available, or to repatriate the earnings only when tax-effective. As such, the Company has not provided tax expense on $248 million of the unremitted earnings of its foreign subsidiaries. It is not practicable to determine the amounts of net additional income tax that may be payable if such earnings were repatriated.

14. Related parties

The following related party balances and transactions as of and for the three years ended December 31, 2012, among the Company and other companies in which directors or executive officers have an interest, are reflected in the consolidated financial statements. The Company bought components related to the A-V Impulse ® System and Laryngeal Mask products from a related party in which a former board member, who retired in May 2010, had a beneficial minority interest. These products were no longer purchased by the Company in 2010. Additionally, OrthoPro, Inc. and Superior Medical Equipment, independent distributors for Breg, Inc., are owned by the son of this former board member. The following table summarizes these related party balances and transactions as of and for the years ended December 31, 2012, 2011 and 2010.

	Year Ended December 31,		
(US$ in thousands)	2012	2011	2010
Sales	$ —	$ 479	$ 3,081
Purchases	$ —	$ —	$ 4,911
Accounts payable	$ —	$ —	$ 334
Accounts receivable	$ —	$ 106	$ 676

15. Sale of Breg and Disposition of Sports Medicine GBU

On April 23, 2012, the Company's subsidiary Orthofix Holdings and Breg entered into a stock purchase agreement (the "SPA") with Breg Acquisition Corp. ("Buyer"), a newly formed affiliate of Water Street Healthcare Partners II, L.P., pursuant to which Buyer agreed to acquire from Orthofix Holdings all the outstanding shares of Breg, subject to the terms and conditions contained therein (the "Transaction"). Under the terms of the SPA, upon closing of the sale, Orthofix Holdings and the Company agreed to indemnify Buyer with respect to certain specified matters, including the government investigation and product liability matters regarding a previously owned infusion pump product line, and pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. (See "Matters Related to the Company's former Breg Subsidiary and Possible Indemnification Obligations under Note 16.) On May 24, 2012 (the "Closing Date"), Orthofix Holdings completed the sale of all of the outstanding shares of Breg for $157.5 million in cash. After adjustments for working capital and indebtedness in accordance with the terms of the SPA, Orthofix Holdings used $145 million of the net proceeds to prepay outstanding Company indebtedness, as required by a lender consent received in connection with the Company's existing Credit Agreement. As a result of the closing of this Transaction, Breg ceased to be a subsidiary of the Company and, therefore, Breg was released as a credit party under the Credit Agreement. The Company also agreed to enter into certain transition arrangements at the closing, including a transition services agreement pursuant to which the Company agreed to continue to provide administrative operational support for a period of up to twelve months. As a result of the sale of Breg, the Company completed its exit from the Sports Medicine GBU, of which Breg was a significant component.

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

Gain on Sale of Discontinued Operations

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

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

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

The Company's consolidated financial statements and related footnote disclosures reflect the Sports Medicine GBU as discontinued operations. Income (loss) associated with the Sports Medicine GBU, net of applicable income taxes is shown as income (loss) from discontinued operations for all periods presented. In addition, the assets and liabilities of the discontinued entity have been reclassified and presented as assets held for sale and liabilities held for sale in the Company's balance sheet as of December 31, 2011.

The assets and liabilities of the discontinued operations are as follows:

(US$ in thousands)	December 31, 2011
Assets Held for Sale	
Restricted cash	$ 1,629
Trade accounts receivable, less allowance	13,711
Inventories, net	8,277
Property, plant and equipment, net	8,756
Intangible assets, net	29,279
Goodwill	106,279
Deferred income taxes, prepaid expenses and other assets	3,254
Assets Held for Sale	$ 171,185
Liabilities Held for Sale	
Trade accounts payable	3,616
Deferred income taxes and other liabilities	19,060
Liabilities Held for Sale	$ 22,676

16. Contingencies

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

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

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

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

Litigation

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

In 2007, the Company's subsidiary, Blackstone Medical, Inc. ("Blackstone") received a subpoena issued by the Office of Inspector General of the Department of Health and Human Services ("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 the Company on September 22, 2006. In 2008 and 2009, respectively, the Company 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 U.S. Department of Justice ("DOJ"). These subpoena 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, the Company obtained a copy of a qui tam complaint filed against the Company 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, the Company's board of directors approved an agreement in principle to pay $32 million to resolve these matters. On October 29, 2012, the Company, 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 the Company paid pursuant to the settlement was funded by proceeds it received from an escrow fund established in connection with the Company's 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, the Company received a HIPAA subpoena ("HIPAA subpoena") issued by the Boston USAO. The subpoena sought documents concerning, among other things, the Company's promotion and marketing of its regenerative stimulator devices (which the Company has also described in the past as its "bone growth stimulator devices"). The Boston USAO issued several subsequent document and testimony subpoenas. The Company cooperated with these requests. The Company subsequently obtained a copy of a qui tam complaint filed in the U.S. District Court for the District of Massachusetts against the Company, 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, the Company's 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, the Company 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 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. The Company agreed to pay $34.2 million (plus interest at a rate of 3% from May 5, 2011 through the day before payment was made) under the terms of the settlement agreement. In addition, the Company 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, the Company's 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 the Company 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 the Company 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.

The Company previously recorded a charge of $43 million during the first quarter of 2011 in anticipation of the settlement. The Company also recorded a charge of $1.7 million in 2012 which represented imputed interest on the settlement accrued through the payment date in December 2012.

Corporate Integrity Agreement with HHS-OIG

On June 6, 2012, in connection with the Company's settlement of the matters described above related to its 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., the Company also entered into a five-year corporate integrity agreement with HHS-OIG (the "CIA"). The CIA acknowledges the existence of the Company's current compliance program, and requires that the Company 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. The Company is also required to maintain several elements of its previously existing program during the term of the CIA, including maintaining a Chief Compliance Officer, a Compliance Committee, and a Code of Conduct. The CIA requires that the Company conduct certain additional compliance-related activities during the term of the CIA, including various training and monitoring procedures, and maintaining a disciplinary process for compliance obligations.

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

Matters Related to Promeca

On July 10, 2012, the Company entered into definitive agreements with DOJ and the Securities and Exchange Commission (the "SEC") agreeing to settle its self-initiated and self-reported internal investigation of its Mexican subsidiary, Promeca S.A. de C.V. ("Promeca"), regarding non-compliance by Promeca with the Foreign Corrupt Practices Act ("the FCPA"). Under the terms of these agreements, the Company voluntarily disgorged profits to the United States government in an amount of $5.2 million, inclusive of pre-judgment interest, and agreed to pay a fine of $2.2 million. The Company paid $2.2 million in July 2012 and $5.2 million in September 2012. As part of the settlement, the Company entered into a 3-year deferred prosecution agreement ("DPA") with DOJ. DOJ has agreed not to pursue any criminal charges against the Company in connection with this matter if the Company complies with the terms of the DPA. The DPA takes note of the Company's self-reporting of this matter to DOJ and the SEC, and of remedial measures, including the implementation of an enhanced compliance program, previously undertaken by the Company. The DPA provides that the Company 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, the Company has represented that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws. The Company will periodically report to DOJ during the term of the DPA regarding such remediation and implementation of compliance measures. As part of the settlement, the Company also agreed to certain reporting obligations to the SEC regarding the status of its remediation and implementation of compliance measures. In the event that the Company fails to comply with these obligations, it could be subject to criminal prosecution by DOJ for the FCPA-related matters it self-reported.

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

On May 24, 2012, the Company sold Breg, Inc. ("Breg") to an affiliate of Water Street Healthcare Partners II, L.P. ("Water Street") pursuant to a stock purchase agreement (the "Breg SPA"). Under the terms of the Breg SPA, upon closing of the sale, the Company and its subsidiary, Orthofix Holdings, Inc., agreed to indemnify Water Street and Breg with respect to certain specified matters, including (i) the government investigation and product liability matters regarding the previously owned infusion pump product line described below, and (ii) pre-closing sales of cold therapy units and certain post-closing sales of cold therapy units. The Company has established an accrual of $4.2 million for its indemnification obligations in connection with the July 2012 verdict described in the fourth paragraph below, however, actual liability in this case could be higher or lower than the amount accrued. The Company has not established any accrual in connection with its other indemnification obligations under the Breg SPA, and currently cannot reasonably estimate the possible loss, or range of loss, in connection with 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. The Company currently estimates that it is 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.

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

On January 27, 2012, the Company was 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, the Company was served with a qui tam complaint filed in the United States District Court for the Western District of Missouri against the Company (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. The Company is vigorously defending this matter.

At the time of its divestiture by the Company, Breg was currently and had been engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases have been filed in recent years, mostly in California state court, alleging that the use of cold therapy causes skin and/or nerve injury and seeking damages on behalf of individual plaintiffs who were allegedly injured by such units. The majority of these cases are at an early stage and no conclusion can be drawn at the present time regarding their potential outcome. However, the Company believes that meritorious defenses exist to these claims. In July 2012, a jury in one case related to a motorized cold therapy unit previously sold by Breg returned a verdict providing for approximately $2.1 million in compensatory damages to the plaintiff against Breg and $7 million in exemplary damages. The case remains subject to appeal. The Company believes that the damages are without merit however, the ultimate outcome is uncertain. The Company previously established an accrual and related charge to discontinued operations of $4.2 million for both compensatory damages and exemplary damages for its indemnification obligations in connection with this July 2012 verdict; however, actual liability in this case could be higher or lower than the amount accrued.

17. Pensions and deferred compensation

Orthofix Inc. sponsors a defined contribution plan (the "Orthofix Inc. 401(k) Plan") covering substantially all full time US employees. The Orthofix Inc. 401(k) Plan allows for participants to contribute up to 15% of their pre-tax compensation, subject to certain limitations, with the Company matching 100% of the first 2% of the employee's base compensation and 50% of the next 4% of the employee's base compensation if contributed to the Orthofix Inc. 401(k) Plan. During the years ended December 31, 2012, 2011 and 2010, expenses incurred relating to 401(k) Plans, including matching contributions, were approximately $2.5 million, $2.5 million and $2.8 million, respectively.

The Company operates defined contribution pension plans for its other International employees not described above meeting minimum service requirements. The Company's expenses for such pension contributions during 2012, 2011 and 2010 were $0.7 million, $0.8 million and $0.7 million, respectively.

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

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

The Company's expense for deferred compensation during 2012, 2011 and 2010 was approximately $0.4 million, $0.1 million and $0.1 million, respectively. Deferred compensation payments of $0.8 million, $- million, and $0.2 million were made in 2012, 2011, and 2010, respectively. The balance as of December 31, 2012 and 2011 was $2.3 and $1.5 million that represents the amount which would be payable if all the employees and agents had terminated employment at that date and is included in other long-term liabilities.

18. Share-based compensation plans

At December 31, 2012, the Company had stock option and award plans, and an employee stock purchase plan which are described below.

2012 Long Term Incentive Plan

The Board of Directors adopted the Orthofix International N.V. 2012 Long-Term Incentive Plan (the "2012 LTIP") on April 13, 2012, subject to shareholder approval which was subsequently provided by shareholder ratification. The 2012 LTIP provides for the grant of options to purchase shares of the Company's common stock, stock awards (including restricted stock, unrestricted stock, and stock units), stock appreciation rights, performance-based awards and other equity-based awards. All of the Company's employees and the employees of the Company's subsidiaries and affiliates are eligible to receive awards under the 2012 LTIP. In addition, the Company's non-employee directors and consultants and advisors who perform services for the Company and the Company's

subsidiaries and affiliates may receive awards under the 2012 LTIP. Incentive share options, however, are only available to the Company's employees. The Company reserves a total of 1,600,000 shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2012, there were 156,000 options outstanding under the 2012 LTIP Plan, of which none were exercisable; in addition, there were 125,500 shares of restricted stock outstanding, none of which were vested.

2004 Long Term Incentive Plan

The 2004 Long Term Incentive Plan (the "2004 LTIP Plan") reserves 3.1 million shares for issuance (in addition to shares (i) available for future awards as of June 29, 2004 under prior plans or (ii) that become available for future issuance upon the expiration or forfeiture after June 29, 2004 of awards upon prior plans). Awards generally vest on years of service with all awards fully vesting within three years from the date of grant for employees and either three or five years from the date of grant for non-employee directors. Awards can be in the form of a stock option, restricted stock, restricted share unit, performance share unit, or other award form determined by the Board of Directors. Awards granted under the 2004 LTIP Plan expire no later than ten years after the date of the grant. The 2004 LTIP Plan provides an annual grant to non-employee directors of 5,000 shares and limits the future the number of shares that may be awarded under the plan as full value awards to 100,000 shares. At December 31, 2012, there were 1,460,355 options outstanding under the 2004 LTIP Plan, of which 1,218,693 were exercisable; in addition, there were 35,331 shares of restricted stock outstanding, none of which were vested.

Staff Share Option Plan

The Staff Share Stock Option Plan (the "Staff Share Plan") is a fixed stock option plan which was adopted in April 1992. Under the Staff Share Plan, the Company granted options to its employees at the estimated fair market value of such options at the date of grant. Options generally vest based on years of service with all options to be fully vested within five years from date of grant. Options granted under the Staff Share Plan expire ten years after the date of grant. There are no options left to be granted under the Staff Plan. At December 31, 2012, there were 29,600 options outstanding and exercisable under the Staff Share Plan.

Employee Stock Purchase Plan

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

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

Due to the compensatory nature of such plan, the Company has recorded the related share based compensation in the consolidated statement of operations. The aggregate number of shares reserved for issuance under the Employee Stock Purchase Plan is 1,850,000 shares. As of December 31, 2012, 1,362,808 shares had been issued under the Stock Purchase Plan.

Share-Based Compensation:

As of December 31, 2012, the unamortized compensation expense relating to options granted and expected to be recognized was $3.9 million. This amount is expected to be recognized through August 2016. The following table shows the detail of share-based compensation by line item in the consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010 and the assumptions for each of these years in which grants were awarded:

(US$ in thousands, except assumptions)	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010 (1)
Cost of sales	$ 592	$ 153	$ 210
Sales and marketing	1,550	2,031	3,505
General and administrative	4,023	4,322	4,105
Research and development	138	142	318
Total	$ 6,303	$ 6,648	$ 8,138
Assumptions:			
Expected term	4.50 years	4.58 years	—
Expected volatility	50.9% – 51.8%	49.6% – 49.9%	—
Risk free interest rate	0.76% – 0.84%	0.90% – 2.26%	—
Dividend rate	—	—	—
Weighted average fair value of options granted during the year	$ 16.99	$ 14.21	$ —

(1) The Company did not grant any options during 2010.

Stock Option Activity:

Summaries of the status of the Company's stock option plans as of December 31, 2012 and 2011 and changes during the year ended December 31, 2012 are presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2011	2,559,272	$ 33.41	
Granted	347,250	$ 40.46	
Exercised	(716,564)	$ 31.50	
Forfeited	(244,003)	$ 40.50	
Outstanding at December 31, 2012	1,945,955	$ 34.50	5.39
Vested and expected to vest at December 31, 2012	1,903,616	$ 34.42	5.31
Options exercisable at December 31, 2012	1,448,293		4.20

Outstanding and exercisable by price range as of December 31, 2012

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$10.42 – $25.01	253,661	5.09	$ 23.40	253,661	$ 23.40
$25.05 – $28.95	326,383	5.30	$ 26.96	314,383	$ 26.97
$29.23 – $33.01	314,433	6.84	$ 31.60	167,102	$ 31.44
$33.08 – $38.11	347,859	3.50	$ 37.49	307,194	$ 37.51
$38.40 – $39.94	282,687	6.61	$ 39.68	126,687	$ 39.69
$40.27 – $41.37	210,000	7.05	$ 41.22	68,334	$ 41.20
$43.04 – $45.84	188,932	3.47	$ 44.63	188,932	$ 44.63
$50.15 – $50.15	12,500	4.29	$ 50.15	12,500	$ 50.15
$50.50 – $50.50	2,000	4.01	$ 50.50	2,000	$ 50.50
$50.99 – $50.99	7,500	4.04	$ 50.99	7,500	$ 50.99
$10.42 – $50.99	1,945,955	5.39	$ 34.50	1,448,293	$ 33.54

The weighted average remaining contractual life of exercisable options was 4.2 years at December 31, 2012. The total intrinsic value of options exercised was $7.2 million, $4.2 million and $3.0 million for the years ended December 31, 2012, 2011 and 2010, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2012 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the shares that had exercise prices that were lower than the $39.33 closing price of the Company's stock on December 31, 2012. The aggregate intrinsic value of options outstanding was $11.2 million, $10.8 million and $4.8 million for the years ended December 31, 2012, 2011, and 2010, respectively. The aggregate intrinsic value of options exercisable was $9.8 million, $8.4 million and $2.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Restricted Stock:

During the year ended December 31, 2012, the Company granted to employees and non-employee directors 149,500 shares of restricted stock, which vest at various dates through November 2015. During the year ended December 31, 2011, the Company granted to employees 94,000 shares of restricted stock, which vest at various dates through February 2014. The compensation expense, which represents the fair value of the stock measured at the market price at the date of grant, less estimated forfeitures, is recognized on a straight-line basis over the vesting period. Unamortized compensation expense related to restricted stock amounted to $4.8 million at December 31, 2012.

A summary of the status of our restricted stock as of December 31, 2012 and 2011 and changes during the year ended December 31, 2012 are presented below:

	Shares	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2011	69,000	$ 29.23
Granted	149,500	$ 40.93
Vested	(28,336)	$ 29.23
Cancelled	(29,333)	$ 38.87
Non-vested as of December 31, 2012	160,831	$ 38.34

19. Earnings per share

For each of the three years ended December 31, 2011, there were no adjustments to net income (loss) for purposes of calculating basic and diluted net income (loss) available to common shareholders. The following is a reconciliation of the weighted average shares used in the basic and diluted net income (loss) per common share computations.

	Year Ended December 31,		
	2012	2011	2010
Weighted average common shares-basic	18,977,263	18,219,343	17,601,956
Effect of diluted securities:			
Unexercised stock options net of treasury share repurchase	413,150	—	311,589
Weighted average common share-diluted	19,390,413	18,219,343	17,913,545

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

Options to purchase shares of common stock with exercise prices in excess of the average market price of common shares are not included in the computation of diluted earnings per share. There were 789,650 and 1,487,809 outstanding options not included in the diluted earnings per share computation for the fiscal years ended December 31, 2012 and 2011, respectively, because the inclusion of these options was anti-dilutive.

20. Restructuring charges

In the fourth quarter of 2008, as part of the Company's strategic plan to strengthen the business, the Company initiated a restructuring plan to improve operations and reduce costs at Blackstone. The plan involved the consolidation of substantially all of Blackstone's operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing its spine stimulation and U.S. orthopedics business in the Dallas, TX area. The Company completed the restructuring and consolidation in the second quarter of 2010 and recognized a total restructuring expense of $3.6 million.

In the fourth quarter of 2010, the Company initiated a reorganization plan to further streamline operations and lower operating costs within its Spine, Orthopedics and Sports Medicine GBU. During the fourth quarter of 2010, the Company recorded restructuring charges of $0.4 million in Spine and $3.2 million in Orthopedics which were related to employee severance costs. Final cash payments were made during the third quarter of 2011 and no further charges are anticipated.

These restructuring costs were recorded in the year ended December 31, 2010 consolidated statements of operations with $1.6 million in selling and marketing and $2.0 million in general and administrative expense.

The following table presents changes in the restructuring liability, which is included within Other Current Liabilities in the Company's consolidated balance sheets as of December 31, 2011 and December 31, 2010:

(US$ in thousands)	Severance
Balance at December 31, 2009	$ 1,826
Charges under 2010 plan	3,550
Cash payments	(3,738)
Balance at December 31, 2010	1,638
Cash payments	(1,638)
Balance at December 31, 2011	$ —

21. Net gain on sale of vascular operations

On March 8, 2010, the Company entered into an asset purchase agreement (the "APA") in which the Company agreed to sell substantially all of the assets of its vascular operations related to the A-V IMPULSE SYSTEM ® and related accessories (including finished goods inventory and tangible assets). At the closing, the Company received payment of approximately $27.7 million, which amount includes the estimated value of certain finished goods inventory conveyed at the closing, and remains subject to post-closing verification.

Pursuant to the APA, the Company agreed to enter into certain transition arrangements at the closing, including (i) a transition services agreement pursuant to which, among other things, the Company would continue to provide operational support with respect to the transferred assets in certain jurisdictions for a period of up to five months, and (ii) two separate supply agreements for certain Impads for a period of two years and provide other products for a period of 90 days. During the second and third quarters of 2010, the Company completed the transition services agreement and one of the supply agreements (which supplies the other products). In September 2011, the Company completed an amendment to the supply agreement to supply certain Impads until March 2014. The Company also agreed to enter into a 5-year noncompetition agreement at closing with respect to the business of the assets being transferred.

The following table presents the value of the asset disposition, cash proceeds received, net of litigation settlement costs and the net gain on sale of vascular operations as shown in the consolidated statements of operations for the year ended December 31, 2010.

(US$ in thousands)	Total
Cash proceeds, net of litigation (1)	$ 24,215
Less:	
Transaction related expenses	2,253
Inventory and property, plant and equipment	2,369
Goodwill and intangible assets	7,574
Net gain on sale of vascular operations	12,019
Income tax expense	(3,498)
Net gain on sale of vascular operations, net of taxes	$ 8,521

(1) In conjunction with the sale of the vascular operations, the Company settled an outstanding litigation claim by the former patent holders for $3.5 million.

22. Quarterly financial data (unaudited)

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

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
2012					
Net sales	$ 116,041	$ 119,492	$ 114,752	$ 112,035	$ 462,320
Gross profit	$ 94,102	$ 95,816	$ 92,379	$ 93,531	$ 375,828
Net income (loss) from continuing operations, net of tax	$ 12,215	$ 13,967	$ 13,118	$ 14,636	$ 53,936
Net income (loss) from discontinued operations, net of tax	$ (199)	$ (2,762)	$ (5,558)	$ 5,878	$ (2,641)
Net income (loss)	$ 12,016	$ 11,205	$ 7,560	$ 20,514	$ 51,295
Net income (loss) per common share:					
Basic:					
Net income (loss) from continuing operations, net of tax	$ 0.65	$ 0.74	$ 0.69	$ 0.76	$ 2.84
Net income (loss) from discontinued operations, net of tax	$ (0.01)	$ (0.15)	$ (0.29)	$ 0.30	$ (0.14)
Net income (loss)	$ 0.64	$ 0.59	$ 0.40	$ 1.06	$ 2.70
Diluted:					
Net income (loss) from continuing operations, net of tax	$ 0.64	$ 0.73	$ 0.67	$ 0.74	$ 2.78
Net income (loss) from discontinued operations, net of tax	$ (0.01)	$ (0.15)	$ (0.28)	$ 0.30	$ (0.14)
Net income (loss)	$ 0.63	$ 0.58	$ 0.39	$ 1.04	$ 2.64
2011					
Net sales	$ 113,060	$ 116,670	$ 117,306	$ 123,085	$ 470,121
Gross profit	$ 90,720	$ 93,484	$ 93,452	$ 99,846	$ 377,502
Net income (loss) from continuing operations, net of tax	$ (36,740)	$ 10,519	$ 12,951	$ 11,530	$ (1,740)
Net income (loss) from discontinued operations, net of tax	$ 939	$ (561)	$ (573)	$ 862	$ 667
Net income (loss)	$ (35,801) (1)	$ 9,958	$ 12,378	$ 12,392 (2)	$ (1,073)
Net income (loss) per common share:					
Basic:					
Net income (loss) from continuing operations, net of tax	$ (2.05)	$ 0.58	$ 0.70	$ 0.62	$ (0.10)
Net income (loss) from discontinued operations, net of tax	$ 0.05	$ (0.03)	$ (0.03)	$ 0.05	$ 0.04
Net income (loss)	$ (2.00)	$ 0.55	$ 0.67	$ 0.67	$ (0.06)
Diluted:					
Net income (loss) from continuing operations, net of tax	$ (2.05)	$ 0.57	$ 0.69	$ 0.62	$ (0.10)
Net income (loss) from discontinued operations, net of tax	$ 0.05	$ (0.03)	$ (0.03)	$ 0.04	$ 0.04
Net income (loss)	$ (2.00)	$ 0.54	$ 0.66	$ 0.66	$ (0.06)

(1) Includes $46 million of charges related to U.S. Government resolutions
(2) Includes $10.5 million of charges related to U.S. Government resolutions

Orthofix International N.V.

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

Condensed Balance Sheets (unaudited)

(US$ in thousands)	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 7,392	$ 19,433
Prepaid expenses and other current assets	534	487
Total current assets	7,926	19,920
Other long term assets	15	61
Investments in and amounts due from subsidiaries and affiliates	400,471	307,202
Total assets	$ 408,412	$ 327,183
Liabilities and shareholder's equity		
Current liabilities	$ 1,203	$ 3,900
Long-term liabilities	8,111	8,112
Shareholder's equity:		
Common stock	1,934	1,846
Additional paid in capital	246,111	214,310
Accumulated earnings	148,549	97,254
Accumulated other comprehensive income	2,504	1,761
	399,098	315,171
Total liabilities and shareholder's equity	$ 408,412	$ 327,183

See accompanying notes to condensed financial statements.

Orthofix International N.V.

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

Condensed Statements of Operations (unaudited)

(US$ in thousands)	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010
(Expenses) income:			
General and administrative	$ (7,700)	$ (11,503)	$ (13,146)
Equity in earnings of investments in subsidiaries and affiliates	59,264	11,111	59,620
Other, net	24	7	(390)
Income (loss) before income taxes	51,588	(385)	46,084
Income tax benefit (expense)	(293)	(688)	(1,876)
Net income (loss)	$ 51,295	$ (1,073)	$ 44,208

See accompanying notes to condensed financial statements.

Orthofix International N.V.

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

Condensed Statement of Cash Flows

(US$ in thousands)	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010
Net income (loss)	$ 51,295	$ (1,073)	$ 44,208
Equity in earnings of investments in subsidiaries and affiliates	(59,264)	(11,111)	(59,620)
Cash used in other operating activities	(5,312)	3,799	7,497
Net cash used in operating activities	(13,281)	(8,385)	(7,915)
Cash flows from investing activities:			
Distributions and amounts received from subsidiaries	12,564	5,875	21,597
Capital expenditures	—	—	(5)
Net cash provided by investing activities	12,564	5,875	21,592
Cash flows from financing activities:			
Net proceeds from issuance of common stock	25,586	20,113	7,854
Contributions to subsidiaries and affiliates	(36,921)	(2,789)	(21,274)
Tax benefit on exercise of stock options	—	1,737	2,222
Net cash provided by financing activities	(11,335)	19,061	(11,198)
Net increase (decrease) in cash and cash equivalents	(12,041)	16,551	2,479
Cash and cash equivalents at the beginning of the year	19,433	2,882	403
Cash and cash equivalents at the end of the year	$ 7,392	$ 19,433	$ 2,882

See accompanying notes to condensed financial statements.

Orthofix International N.V.

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

Notes to Condensed Financial Statements (unaudited)

1. Background and basis of presentation

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

2. Restricted net assets of subsidiaries

Certain of the Company's subsidiaries have restrictions on their ability to pay dividends or make intercompany loans and advances pursuant to their financing arrangements. The amount of restricted net assets the Company's subsidiaries held at December 31, 2012 and 2011 was approximately $247.4 million and $186.0 million, respectively. Such restrictions are on net assets of Orthofix Holdings, Inc. and its subsidiaries.

3. Commitments, contingencies and long-term obligations

For a discussion of the Company's commitments, contingencies and long term obligations under its senior secured credit facility, see Note 8, Note 11 and Note 16 of the Company's consolidated financial statements.

4. Dividends from subsidiaries

Cash dividends received by Orthofix International N.V. from its consolidated subsidiaries accounted for by the equity method were $5.9 million and $21.6 million for the years ended December 31, 2011 and 2010, respectively. Orthofix International N.V. did not receive cash dividends in 2012.

Orthofix International N.V.

Schedule 2—Valuation and Qualifying Accounts

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

(US$ in thousands) Provisions from assets to which they apply:	Balance at beginning of year	Additions: Charged to cost and expenses	Additions: Charged (credited) to other accounts	Deductions/ Other	Balance at end of year
2012					
Allowance for doubtful accounts receivable	$ 9,376	$ 13,117	$ (201)	$ (6,104)	$ 16,188
Deferred tax valuation allowance	19,115	7,010	—	—	26,125
2011					
Allowance for doubtful accounts receivable	$ 6,676	$ 11,475	$ (520)	$ (8,255)	$ 9,376
Deferred tax valuation allowance	21,023	(1,908)	—	—	19,115
2010					
Allowance for doubtful accounts receivable	$ 6,584	$ 8,757	$ —	$ (8,665)	$ 6,676
Deferred tax valuation allowance	17,239	3,784	—	—	21,023

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