ORTHOFIX INTERNATIONAL N V
Form 10-K
February 29, 2012
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

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# FORM 10-K

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

**For the fiscal year ended December 31, 2011**

**or**

**o 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**

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# ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

| **Curaçao** | **N/A** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **7 Abraham de Veerstraat** | |
| **Curaçao** | **N/A** |
| (Address of principal executive offices) | (Zip Code) |

**599-9-4658525**

(Registrant s telephone number, including area code)

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

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

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

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

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 o No x

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

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

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. o

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

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

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

The aggregate market value of registrant s common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the registrant s most recently completed second fiscal quarter, June 30, 2011, as reported by the Nasdaq Global Select Market, was approximately $774.7 million.

As of February 21, 2012, 18,700,474 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 2012 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Form 10-K.

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**Forward-Looking Statements**

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, 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, anticipat believes, estimates, projects, intends, predicts, potential or continue or other comparable terminology. These forward-looking statemer 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.

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 the government investigation and False Claims Act matters relating to our regenerative stimulation and spinal implant businesses, and the possible violations of the FCPA by our former Mexican orthopedic distribution entity, as well as certain product liability claims against our sports medicine global business unit, each as further described in the Legal Proceedings section of this Form 10-K), 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.

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**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 along with offering a portfolio of non-invasive products to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility. 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 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, and bracing products used for ligament injury prevention, pain management and protection of surgical repair to promote faster healing. Our products also include a device for cold therapy and 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. ) and Italy and manufacturing facilities in the U.S., the United Kingdom, Italy and Mexico. 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. Curacao 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 along with offering a portfolio of non-invasive products to treat a variety of sports medicine related conditions in order to minimize pain and restore

mobility. Our strategy for growth and profitability includes the following initiatives by market sector:

**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;
- 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

**Sports Medicine:** Provide a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Our main tactics and objectives are:

- Optimize distribution channels;
- Leverage strong market share in high growth areas such as Osteoarthritis knee bracing and cold therapy; and

- Launch innovative products and expand service solutions into new and existing market segments

**Other Financial and Business Initiatives:**

- Improve operating margins across all business units;

- 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

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

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**Business Segments**

The Company s segment information is prepared on the same basis that management reviews the financial information for operational decision making purposes. Beginning January 1, 2011, the Company began managing its business by its three global business units ( GBU s), which are comprised of Spine, Orthopedics and Sports Medicine supported by Corporate activities. These GBUs represent the current segments for which the Company s Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. Accordingly, the Company s segment information (as provided below) has been prepared based on the Company s three GBUs reporting segments. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new 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 comprehensive 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.

*Sports Medicine*

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives, and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

*Corporate*

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings, Inc., along with activities not necessarily identifiable within the three GBUs.

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**Business Segments by GBU:**

| | Year ended December 31, (US$ in thousands) | | | | | |
|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2009 | |
| | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Spine | $ 304,217 | 52% | $ 306,404 | 54% | $ 279,425 | 51% |
| Orthopedics | 165,904 | 29% | 154,198 | 27% | 151,054 | 28% |
| Sports Medicine | 108,867 | 19% | 103,768 | 19% | 115,156 | 21% |
| Total Net Sales | $ 578,988 | 100% | $ 564,370 | 100% | $ 545,635 | 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. Market sectors group our GBU reporting segment revenues by strategic products and divested products. Our market sectors are Spine Products that include Implants and Biologics along with Spine Stimulation, Orthopedic Products, and Sports Medicine Products.

**Market Sectors:**

| | Year ended December 31, (US$ in thousands) | | | | | |
|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2009 | |
| | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Spine Products | | | | | | |
| Implants and Biologics | $ 143,775 | 24% | $ 133,831 | 23% | $ 120,445 | 22% |
| Stimulation | 160,442 | 28% | 172,573 | 31% | 158,980 | 29% |
| Total Spine Products | 304,217 | 52% | 306,404 | 54% | 279,425 | 51% |
| Orthopedics Products | 165,904 | 29% | 149,175 | 26% | 139,304 | 25% |
| Sports Medicine Products | 103,040 | 18% | 95,514 | 18% | 96,446 | 18% |
| Total Strategic Products | 573,161 | 99% | 551,093 | 98% | 515,175 | 94% |
| Divested Products | 5,827 | 1% | 13,277 | 2% | 30,460 | 6% |
| Total Net Sales | $ 578,988 | 100% | $ 564,370 | 100% | $ 545,635 | 100% |

**Products**

Our revenues are generally derived from the sales of products in three market sectors, Spine, Orthopedics and Sports Medicine, which collectively accounted for 99% of our total net sales in 2011. Sales of our Divested Products, which accounted for 1% of our total net sales in 2011, relate to the vascular business which was divested in March 2010 (and the transition services supply agreement that commenced upon the sale of the business) and the anesthesia product line which was exited after the expiration of its distribution agreement in the United Kingdom during the second quarter of 2010.

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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 Polyetheretherketones ( PEEK ) Vertebral Body Replacement ( VBR ) System | Smaller, unibody versions of the Construx PEEK VBR System, implanted during the replacement of degenerated or deformed spinal vertebrae |
| 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 |
| 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 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.) |

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| Product | Primary Application |
|---|---|
| ***Orthopedic Repair Solutions*** | |
| Fixation | External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus ® , XCaliber , Contours VPS ® , VeroNail ® and Gotfried PC.C.P ® |
| Eight-Plate Guided Growth System ® | Treatment for bowed legs or knock knees of children |
| ISKD ® | Internal limb-lengthening device |
| 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 |
| 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 |
| ***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 spinal fusion procedure |
| Collage Synthetic Osteoconductive Scaffold | A bone void filler |
| ***Sports Medicine Products*** | |
| Breg ® Bracing | Bracing products which are designed to provide support and protection of limbs, extremities and back during healing and rehabilitation |
| Polar Care ® and KODIAK ® | Cold therapy products that are designed to reduce swelling, pain and accelerate the rehabilitation process |
| OrthoSelect services and Vision Inventory Management System | Consulting services which provide guidance and tools to improve overall practice efficiency and a web based inventory system customized to enable efficient management of orthopedic devices |

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

***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.

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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 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.

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*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 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.

According to internal sales data, more than 500,000 patients have been treated using our spine fusion stimulators since 1990.

***Orthopedics***

The medical devices offered in our Orthopedics market sector 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.

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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.

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.

Another example of external fixation devices designed for the rapid stabilization of complex fractures are PREFIX and PREFIX 2. PREFIX offers free pin placement in any desired plane to rapidly create a solid stabilization using radiolucent components and PREFIX 2 has further enhanced the clamp ease-of-use and construct stability. We believe the PREFIX and PREFIX 2 fixators provide the necessary temporary stabilization to allow the surgeon to reduce the fracture, move the patient or attend to more urgent matters.

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: made of titanium, improved mechanical distal targeting and instrumentation and a design which requires significantly reduced inventory.

- 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.

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 limb length discrepancies, 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 ® and the Intramedullary Skeletal Kinetic Distractor, or ISKD ®.

The ISKD ® system is a patented, internal limb-lengthening device that uses a magnetic sensor to monitor limb-lengthening progress on a daily basis. ISKD ® is an expandable tubular device that is completely implanted inside the bone to be lengthened. The ISKD ® system is designed to lengthen the patient s bone gradually, and, after lengthening is completed, stabilize the lengthened bone. ISKD ® is an FDA-approved intramedullary bone lengthener on the market, and we have the exclusive worldwide distribution rights for this product.

*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 spinal 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 bones found in areas other than the spine.

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. According to internal sales data, more than 150,000 patients have been treated using Physio-Stim ® for long bone non-unions since the product was introduced.

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***Sports Medicine***

We believe Breg Inc. ( Breg ), one of Orthofix s wholly-owned subsidiaries, is a market leader in the sale of orthopedic post-operative reconstruction and rehabilitative products to hospitals and orthopedic offices. Breg s products are grouped primarily into two product categories: Breg ® Bracing and Cold Therapy. Approximately 65% of Breg s net revenues were attributable to the sale of bracing products in 2011, including: (1) functional braces for treatment and prevention of ligament injuries, (2) load-shifting braces for osteoarthritic pain management, (3) post-operative braces for protecting surgical repair and (4) foot and ankle supports that provide an alternative to casting. Approximately 30% of Breg s 2011 net revenues came from the sale of cold therapy products used to minimize the pain and swelling following knee, shoulder, elbow, ankle and back injuries or surgery. Approximately 5% of Breg s 2011 net revenues came from the sale of other rehabilitative products. Breg sells its products through a network of domestic and international independent distributors, employee sales representatives and related international subsidiaries.

*Breg ® Bracing*

We design, manufacture and market a broad range of rigid knee bracing products, including ligament braces, post-operative braces and osteoarthritic braces. The rigid knee brace products are either customized braces or standard adjustable off-the-shelf braces.

Ligament braces are designed to provide durable support for moderate to severe knee ligament instabilities and help stabilize the joint so that patients may successfully complete rehabilitation and resume their daily activities. The product line includes premium custom braces and off-the-shelf braces designed for use in all activities. Select premium ligament braces are also available with a patellofemoral option to address tracking and subsequent pain of the patellofemoral joint. We market the ligament product line under the Fusion ® and X2K ® brand names.

Post-operative braces are designed to limit a patient s range of motion after knee surgery and protect the repaired ligaments and/or joints from stress and strain. These braces are designed to promote a faster and healthier healing process. The products within this line provide both immobilization and/or a protected range of motion. The Breg post-operative family of braces, featuring the patented Quick-Set hinge, offers complete range of motion control for both flexion and extension, along with a simple-to-use drop lock mechanism to lock the patient in full extension. The release lock mechanism allows for easy conversion to full range of motion. The straps, integrated through hinge bars, offer greater support and stability. This hinge bar can be broken down to accommodate later stages of rehabilitation. The Breg T-Scope ® is a premium brace in the post-operative bracing market and has every feature available offered in our post-operative knee braces, including telescoping bars, easy application, full range of motion and a drop lock feature.

Osteoarthritis ( OA ) braces are used as a non-surgical, drug free treatment options to treat patients suffering from osteoarthritis of the knee. Osteoarthritis is a disease created by the degeneration of cartilage on the surfaces of the joint resulting in chronic pain and discomfort. This line of custom and off-the-shelf braces is designed to unload the knee joint and reduce the bone on bone joint pressures that cause this discomfort and pain in OA patients. In some cases, this type of brace may serve as a cost-efficient alternative to total knee replacement. Breg s single upright Solus ® and lateral offloader, which are based on Fusion ® technology, are our newest bracing designs delivering optimal comfort and pain relief for patients suffering from OA.

*Cold Therapy*

We manufacture, market and sell a cold therapy product line, Polar Care ® . Breg entered the market for cold therapy products in 1991 when it introduced the Polar Care ® 500, a cold therapy device used to reduce swelling, minimize the need for post-operative pain medications and generally accelerate the rehabilitation process. Breg s leading cold therapy offering is the KODIAK ® cold therapy system which uses Intelliflow ® technology to customize treatment for various clinical applications. Today, we believe that cold therapy is a standard of care with physicians despite limited historical reimbursement by insurance companies over the years.

The Polar Care ® product uses a circulation system designed to provide constant fluid flow rates and effective treatment. The product consists of a cooler filled with ice and cold water connected to a pad, which is applied to the affected area of the body; the device flows cold water through the pad to provide continuous cold therapy for the relief of pain. Breg s cold therapy line consists of the Polar Care ® 500, Kodiak ® , Cube , Polar Care ® 300, Polar Cub and cold gel packs.

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***Divested Products***

Divested Product sales is comprised of sales from the vascular operations which was divested in March 2010; subsequent revenues from the transition supply agreement that commenced upon the sale of the vascular operations and sales from the anesthesia product line which was exited in the June of 2010.

*Vascular and Laryngeal Mask*

In March 2010, we sold our non-invasive post-surgical vascular therapy product, called the A-V Impulse System ® , which was designed to reduce dangerous deep vein thrombosis, or blood clots, and post-surgery pain and swelling by improving venous blood return and improving arterial blood flow. In June 2010, we terminated our distribution agreement to sell the Laryngeal Mask, a product of The Laryngeal Mask Company Limited, which is an anesthesia medical device designed to establish and maintain the patient s airway during an operation.

**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; Lewisville, Texas; and Carlsbad, California.

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 2011, 2010, and 2009 we spent $25.1 million, $30.4 million and $31.5 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 began implementation of our enhanced compliance program, which we branded the *Integrity Advantage* Program , in February 2008, at our Spinal Implants and Biologics business. In September 2011, we hired a new Chief Compliance Officer to oversee implementation of 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.

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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 agents;
- 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, agents and distributors; and
- Risk assessment 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.D10K_HTM_TOC

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.

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In addition, our Spinal Implants and Biologics business is a distributor of 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. 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

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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.

Our subsidiaries Orthofix Inc. and Breg, 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.

The Patient Protection and Affordable Health Care Act ( Act ), which was signed into law in March of 2010, contains new Sunshine Provisions that will require, among other things, pharmaceutical, medical device, biological and medical supply manufacturers to begin reporting to the federal government payments made to recipients covered under the Act, such as, physicians and teaching hospitals. The Sunshine Provisions also require manufacturers and group purchasing organizations ( GPOs ) to report ownership interests by a physician. The reporting requirements under the Act take effect in March of 2013. Similar to other state disclosure laws currently in effect, such as Massachusetts and Vermont, penalties for non-compliance with the reporting requirements under the Act may result in civil monetary penalties. While we believe our operations monitor these laws to materially comply with reporting requirements, as these laws are subject to interpretation by state and federal regulatory authorities, there can be no assurance that compliance will not be challenged.

**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.

*Market Sectors*

Our revenues are generally derived from the sales of products in three market sectors, Spine, Orthopedics and Sports Medicine, which collectively accounted for 99% of our net sales in 2011. Sales of our Divested Products, which accounted for 1% of our total net sales in 2011, relate to revenues from the transition supply agreement that commenced upon the sale of the vascular operations which was divested in March 2010.

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*Sales, Marketing and Distributor Network*

We have established a broad distribution network comprised of direct sales representatives and distributors. This established distribution network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products through a sales and marketing force of approximately 682 sales and marketing representatives. Worldwide we also have over 300 independent distributors for our products in approximately 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 market sectors. The Spine market sector is addressed primarily by a direct sales force for spinal regenerative stimulation products and a distribution network for spinal implant and HCT/P products. The Orthopedics market sector is addressed by a hybrid distribution network of predominately direct sales representatives supplemented by distributors. The Sports Medicine market sector is addressed additionally by a hybrid network of predominantly independent distributors supplemented by direct sales representatives.

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 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 the Orthofix Institute, our facility in Verona, Italy, and in various locations in Latin America. The Orthofix Institute for Research, Training and Education in the North American Operations and Training Center in Lewisville, Texas is a state of the art facility which features a lecture room, classroom, workshop and 7-station bioskills laboratory. In 2011, these product education seminars were attended by over 800 surgeons and over 300 distributor and sales representatives from 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 centers in Lewisville, Texas, our Breg training center in Vista, California 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, a division of Johnson and Johnson; Synthes AG; Stryker Corp.; Zimmer, Inc.; NuVasive; Biomet Spine; and various smaller public and private companies. For external and internal fixation devices, our principal competitors include Synthes AG; Zimmer, Inc.; Stryker Corp.; Smith & Nephew plc; and Biomet Orthopedics, a business unit of Biomet, Inc. The principal competitors for the Breg bracing and cold therapy products include DJO Incorporated; Biomet, Inc.; Ossur Lf.; Bledsoe and various smaller private companies.

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. In addition to designing, developing, assembling, testing and packaging its products, Breg also designs and subcontracts the manufacturing for a substantial portion of the component parts used in its products. Although certain of our key raw materials are obtained from a single source, we believe that alternate sources for these materials are

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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, the United Kingdom and Mexico. 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. Certain of the Breg ® bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. 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 $25.8 million, $26.4 million and $22.0 million in 2011, 2010 and 2009, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. In 2011, we invested $25.8 million in capital expenditures of which the most significant item was $12.1 million related to instrumentation and tooling. We currently plan to invest approximately $28 to $30 million in capital expenditures during 2012 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, 2011, we had 1,496 employees worldwide. Of these, 1,215 were employed in the U.S. and Mexico (which includes 582 employed at Breg), and 281 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 131 at December 31, 2011, 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 1,496 employees, 650 were employed in sales and marketing functions, 213 in general and administrative roles, 484 in production and operations and 149 in research and development.

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**Item 1A. Risk Factors**

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

**We have reached agreements in principle with the U.S. Attorney s Office for the District of Massachusetts to resolve matters related to investigations of our regenerative stimulation business and our Blackstone subsidiary, and have taken charges related to both of these matters. However, there can be no assurance that we will be able to reach a final resolution of these matters on these terms or otherwise.**

In April 2011, we reached an agreement in principle with the U.S. Attorney s Office for the District of Massachusetts (the Boston USAO ) to resolve certain criminal and civil matters related to a government investigation of our regenerative stimulation business (which we have also described in the past as our bone growth stimulation business ). We are currently finalizing definitive written agreements with the Boston USAO, the United States Department of Justice ( DOJ ), and the Office of Inspector General of the Department of Health and Human Services ( OIG ) to finally resolve this matter, including a related qui tam lawsuit pending in the U.S. District Court for the District of Massachusetts. We expect that under the terms of these agreements, we will pay $43 million, and we recorded a charge of $43 million during the first quarter of 2011 in anticipation of this agreement. We expect that (i) our subsidiary, Orthofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) Orthofix International N.V. and Orthofix Inc will enter into a five-year Corporate Integrity Agreement ( CIA ) with the OIG as part of the resolution of these matters.

In January 2012, we reached an agreement in principle with the Boston USAO to pay $32 million to resolve certain matters, including a qui tam complaint filed by Susan Hutcheson against Blackstone and the Company in the U.S. District Court for the District of Massachusetts, related to a government investigation of our Blackstone subsidiary, which we acquired in 2006. This settlement amount will be funded from proceeds we have received from the escrow fund established in connection with the agreement and plan of merger between the Company and Blackstone in 2006. We are currently in discussions with the Boston USAO, DOJ, and OIG as to the terms of definitive written agreements to finally resolve these matters, and the final settlement is subject to approval of such definitive agreements by each of these entities.

However, there can be no assurance that we will be able to enter into definitive agreements to resolve these two investigations on these or other terms. The failure to settle either of these matters on these terms or otherwise could adversely affect our business and operations. In addition to the CIA described above, a final settlement of these matters could impose other regulatory or contractual restrictions on our business. If we are unable to comply with the CIA or any other such restrictions, or otherwise fail to meet the terms of any settlement, it could adversely affect our business and operations.

**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 have reached an agreement in principle with the Department of Justice to resolve a matter we self-reported involving allegations of improper payments by local employees of one of our subsidiaries in Mexico under the Foreign Corrupt Practices Act. However, there can be no assurance that we will be able to reach a final resolution of this matter on these terms or otherwise, and discussions regarding a settlement of this matter with the U.S. Securities and Exchange Commission are still ongoing.**

To the extent that we operate outside the U.S. we are subject to the U.S. Foreign Corrupt Practices Act (the FCPA ) which prohibits people, or companies subject to U.S. jurisdiction and their intermediaries, from engaging in bribery or other prohibited payments to foreign officials for the purposes of obtaining or retaining business or gaining an unfair business advantage. It also requires proper record keeping and characterization of such payments in our reports filed with the U.S. Securities and Exchange Commission (the SEC ).

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During a second quarter 2010 management review of Promeca S.A. de C.V. ( Promeca ), one of our Mexican subsidiaries, we received allegations of improper payments, allegedly made by certain of Promeca s local employees in Mexico, to employees of a Mexican governmental healthcare entity. We engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation focusing on compliance with the FCPA and voluntarily contacted the SEC and the DOJ to advise both agencies that an internal investigation is underway. Promeca accounted for approximately one percent of our consolidated net sales and consolidated total assets.

In January 2012, we reached an agreement in principle to settle these matters with DOJ. We are currently in discussions with DOJ as to the final terms of such resolution, and are also currently engaged in discussions regarding a settlement of such matters with the SEC. We previously recorded a charge related to this matter of $3.0 million during the first quarter of 2011, and have subsequently recorded an additional charge of $4.5 million during the first quarter of 2012 to establish an additional accrual in anticipation of a future final resolution of these matters with both DOJ and SEC.

We believe based on information known to date that the likelihood of any additional loss in excess of the amount we have accrued is remote. However, there can be no assurance that we will be able to enter into a consensual resolution of these criminal and civil matters on terms consistent with our accrual or otherwise, and the failure to settle these matters on these terms or otherwise could adversely affect our business and operations. In addition, a final settlement of these matters could impose other regulatory or contractual restrictions on our business. If we are unable to comply with any such restrictions, or otherwise fail to meet the terms of any settlement, it could adversely affect our business and operations.

**We may not be able to successfully introduce new products to the market.**

During 2011, we continued to make improvements in revenues related to several new products we introduced to the market in 2009, including the Firebird Spinal Fixation System, the PILLAR SA interbody device and Trinity ® Evolution , among others. We intend to introduce several new products to the market in 2012. Despite our planning, the process of developing and introducing new products is inherently complex and uncertain and involves risks, including the ability of such new products to satisfy customer needs and gain 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.

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:

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- 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. 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 prices charged for medical products and services. Limits put on reimbursement could make it more difficult for people to buy our products and reduce, or possibly eliminate, the demand for our products. In addition, should governmental authorities enact additional 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.

Third-party payors, including private and governmental entities, may revise coverage or reimbursement policies that address whether a particular product, treatment modality, device or therapy will be subject to reimbursement and, if so, at what level of payment.

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 believe that the competitive bidding process will principally affect products sold by our Sports Medicine business. We cannot predict which products from any of our businesses will ultimately be affected or when the competitive bidding process will be extended to our businesses. While some of our products are

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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:

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|---|---|
| • Direct (hospital) | 35% |
| • Third-Party Insurance | 24% |
| • Independent Distributors | 23% |
| • U.S. Government Medicare, Medicaid, TriCare | 10% |
| • International Public Healthcare Systems | 6% |
| • Self-pay and other | 2% |

**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.

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.

The Patient Protection and Affordable Health Care Act ( Act ), which was signed into law in March of 2010, contains new Sunshine Provisions that will require, among other things, pharmaceutical, medical device, biological and medical supply manufacturers to begin reporting to the federal government payments made to recipients covered under the Act, such as, physicians and teaching hospitals. The Sunshine Provisions also require manufacturers and group purchasing organizations ( GPOs ) to report ownership interests by a physician. The reporting requirements under the Act take effect in March of 2013. Similar to other state disclosure laws currently in effect, such as Massachusetts and Vermont, penalties for non-compliance with the reporting requirements under the Act may result in civil monetary penalties. While we believe our operations monitor these laws to materially comply with reporting requirements, as these laws are subject to interpretation by state and federal regulatory authorities, there can be no assurance that compliance will not be challenged.

**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. In addition, the new law imposes a 2.3 percent excise tax on medical devices scheduled to be implemented in 2013 that we expect will apply to United States sales of a majority of the medical device products. 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

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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 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 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, Orthopedic and Sports Medicine 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.

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**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 2011 have had a favorable impact of $6.5 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we enter into currency hedges from time to time. At December 31, 2011, we had outstanding a currency swap to hedge a 33.5 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.

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**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. Net sales outside the U.S. represented approximately 25% of our total net sales in 2011. 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.**

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.

**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., Breg, 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, of which $91.3 million was outstanding at December 31, 2011, and (2) a five-year revolving credit facility of $200 million upon which we had $117.4 million outstanding and $82.6 million available to be drawn as of December 31, 2011. The principal amount of the term loan facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments are due quarterly.

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, 2011 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.

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**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 $82.6 million available to be drawn as of December 31, 2011. 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 for which $91.3 million was outstanding as of December 31, 2011, and a five-year revolving credit facility of $200 million upon which we had $117.4 million outstanding and $82.6 million available to be drawn as of December 31, 2011. 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, 2011 on our senior secured debt was 3.4%. 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.

**Goodwill and other identified intangibles could generate future asset impairments, which would be recorded as operating losses.**

The Financial Accounting Standards Board s ( FASB ) Accounting Standards Codification ( ASC ) Topic 350 Intangibles Goodwill and Other requires that goodwill, including the goodwill included in the carrying value of investments accounted for using the equity method of accounting, and other intangible assets deemed to have indefinite useful lives, such as trademarks, cease to be amortized. ASC Topic 350 requires that goodwill and intangible assets with indefinite lives be tested at least annually for impairment. If we find that the carrying value of goodwill or a certain intangible asset exceeds its fair value, we will reduce the carrying value of the goodwill or intangible asset to the fair value, and we will recognize an impairment loss. Any such impairment losses are required to be recorded as non-cash operating losses.

In addition, ASC Topic 360 Property, Plant and Equipment requires that intangible assets with definite lives, such as our developed technologies and distribution network assets, be tested for impairment if indicators of impairment, as defined in the standard, exist.

Certain of the impairment tests require us to make an estimate of the fair value of goodwill and other intangible assets, which are primarily determined using discounted cash flow methodologies, research analyst estimates, market comparisons and a review of recent transactions. Since a number of factors may influence determinations of fair value of intangible assets, we are unable to predict whether impairments of goodwill or other indefinite lived intangibles will occur in the future.

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**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 Curacao. 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.

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**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, Domestic and Spinal Implants and Biologics segments | Lewisville, TX | 140,000 | Leased |
| Research and development office for Spinal Implants and 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 offices for fixation products | Andover, England | 9,001 | Leased |
| Sales management, distribution and administrative facility for United Kingdom | Maidenhead, England | 9,000 | Leased |
| Sales management, distribution and administrative facility for Brazil | Alphaville, Brazil | 4,690 | Leased |
| Sales management, distribution and administrative facility for Brazil | São Paulo, Brazil | 18,322 | Leased |
| Sales management, distribution and administrative facility for France | Gentilly, France | 3,854 | Leased |
| Sales management, distribution and administrative facility for Germany | Ottobrunn, Germany | 16,145 | Leased |
| Sales management, distribution and administrative facility for Switzerland | Steinhausen, Switzerland | 1,180 | Leased |
| Administrative, manufacturing, warehousing, distribution and research and development facility for Breg | Carlsbad, California | 88,329 | Leased |
| Manufacturing facility for Breg products | Mexicali, Mexico | 63,000 | Leased |
| Sales management, distribution and administrative offices for Omni Motion | Apple Valley, CA | 3,000 | Leased |
| Sales management, distribution and administrative facility for Puerto Rico | Guaynabo, Puerto Rico | 4,400 | Leased |

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**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 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 discloses 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 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, 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 reasonable estimable. As of December 31, 2011, the Company has recognized an aggregate accrual of $1.2 million for such additional matters. The Company believes additional 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

On or about July 23, 2007, our subsidiary, Blackstone Medical, Inc. ( Blackstone ) received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena sought documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone s acquisition by us. We believe that the subpoena concerned the compensation of physician consultants and related matters. On September 17, 2007, we submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between us, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the Blackstone Merger Agreement ), for any losses to us resulting from this matter. We were subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement. On or about January 7, 2008, we received a federal grand jury subpoena from the U.S. Attorney s Office for the District of Massachusetts. The subpoena sought documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerned the compensation of physician consultants and related matters, and further believe that it was associated with the Department of Health and Human Services, Office of Inspector General s investigation of such matters. On September 18, 2008, we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On or about April 29, 2009, counsel received a HIPAA subpoena issued by the U.S. Department of Justice. The subpoena sought documents from us for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerned the compensation of physician consultants and related matters, and further believe that it was associated with the Department of Health and Human Services, Office of Inspector General s investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about August 26, 2010, counsel for Orthofix Inc. and Blackstone executed a

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tolling agreement with the U.S. Attorney s Office for the District of Massachusetts (the Tolling Agreement ) that extended an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including October 31, 2010. On or about February 1, 2011, the parties further extended the tolling of the statute of limitations through and including May 31, 2011 with respect to any criminal proceedings that the government might later initiate.

On or about December 5, 2008, we obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against Blackstone and the Company in the U.S. District Court for the District of Massachusetts. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the U.S. Department of Justice and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), we submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to us resulting from this matter. On November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. We understand that this lawsuit was related to the matters described above involving the U.S. Department of Health and Human Services, Office of the Inspector General, the U.S. Attorney s Office for the District of Massachusetts, and the U.S. Department of Justice. On or about March 12, 2010, the United States District Court for the District of Massachusetts granted Blackstone s motion to dismiss and, on March 15, 2010, entered judgment in favor of Blackstone. On June 1, 2011, the United States Court of Appeals for the First Circuit reversed the motion to dismiss and remanded to the district court for further proceedings. In response to a joint motion to stay the action, on August 22, 2011, the United States District Court for the District of Massachusetts entered an order administratively closing the lawsuit for a period of no more than ninety (90) days. On August 30, 2011, Blackstone filed with the United States Supreme Court a Petition for a Writ of Certiorari to review the June 1, 2011 judgment of the United States Court of Appeals for the First Circuit, which was denied on December 5, 2011.

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 the matters described in the immediately preceding two paragraphs. We are currently in discussions with the Boston USAO, the United States Department of Justice ( DOJ ), and the Office of Inspector General of the Department of Health and Human Services ( OIG ), as to the terms of definitive written agreements to finally resolve these matters. Based on information currently available, we believe that it is probable that a final written definitive settlement agreement with the U.S. Government will be entered into on these economic terms, which, as described below, would be fully funded from the escrow fund established in connection with the Blackstone Merger Agreement. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, we believe that the likelihood of any such additional material loss in excess of this amount is remote.

In 2007 and 2008, we received certain other subpoenas from state and federal entities related to Blackstone s financial relationship with physicians, which we have described in prior reports. We have fully responded to each of these subpoenas, and there are currently no pending proceedings related to any of these matters.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone agreed to indemnify us for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders were limited to a cumulative aggregate amount of $66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was $50.0 million. As of December 31, 2011, the escrow fund contained $47.5 million.

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 the Company (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. The Company received approximately $9.5 million in cash from the escrow fund after application of the (i) $32 million allocated to the settlement in principle described above with the government and (ii) approximately $1 million of other fees 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.

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Matters Related to Regenerative Stimulation Business

On or about April 10, 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 supplemental subpoenas seeking documents in this matter, dated September 21, 2009, December 16, 2009, October 13, 2010, October 14, 2010, October 18, 2010, December 3, 2010 and January 13, 2011, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. The Boston USAO also issued two supplemental subpoenas requiring testimony in this matter dated July 23, 2009 and June 3, 2010. That office excused performance with the July 23, 2009 subpoena indefinitely. The Boston USAO has provided us with grand jury subpoenas for the testimony of certain current and former employees in connection with its ongoing investigation. We have been cooperating, and intend to continue to cooperate, with the government s requests. In meetings with us and our attorneys regarding this matter, the Boston USAO informed us that it is investigating possible criminal and civil violations of federal law related to our promotion and marketing of our regenerative stimulator devices.

On or about April 14, 2009, we obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman in the U.S. District Court for the District of Massachusetts against the 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. By order entered on March 24, 2009, the court unsealed the case. We and Orthofix Inc. were served on or about September 8, 2009. With leave of the court, the relator s Second Amended Complaint was filed on June 11, 2010. The complaint alleges 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 includes 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. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. On or about December 4, 2010, the U.S. District Court for the District of Massachusetts denied our motion to dismiss.

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. We are currently finalizing definitive written agreements with the Boston USAO, the United States Department of Justice ( DOJ ), and the Office of Inspector General of the Department of Health and Human Services ( OIG ) to finally resolve these matters. We expect that under the terms of these agreements, we will pay $43 million, and we recorded a charge of $43 million during the first quarter of 2011 in anticipation of this agreement. We expect that (i) our subsidiary, Orthofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) Orthofix International N.V. and Orthofix Inc will enter into a five-year Corporate Integrity Agreement (CIA) with the OIG as part of the resolution of these matters. Based on information currently available, we believe that it is probable that a final definitive written settlement agreement with the U.S. Government will be entered into on these terms. We have therefore recognized an accrual for this amount during the first quarter of 2011. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, we believe that the likelihood of any such additional material loss in excess of this amount is remote.

Matters Related to Promeca

During the second quarter of 2010 internal management review of Promeca S.A. de C.V. ( Promeca ), one of our Mexican subsidiaries, we received allegations of improper payments, allegedly made by certain of Promeca s local employees in Mexico, to employees of a Mexican governmental healthcare entity. We engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal

investigation (the Promeca Internal Investigation ) focusing on compliance with the Foreign Corrupt Practices Act ( FCPA ) and voluntarily contacted the Securities and Exchange Commission (the SEC ) and the United States Department of Justice ( DOJ ) to advise both agencies that an internal investigation was underway. Promeca accounted for approximately one percent of our consolidated net sales and consolidated total assets. On or about November 16, 2010, we received a subpoena from the SEC and DOJ seeking documents related to this matter. We have completed our production of documents to the SEC and DOJ in connection with the subpoena.

We completed the Promeca Internal Investigation in April 2011 and commenced settlement discussions with the U.S. Government regarding this matter in May 2011. In January 2012, we reached an agreement in principle to settle these matters with DOJ. We are currently in discussions with DOJ as to the final terms of such resolution, and are also currently engaged in discussions regarding a settlement of such matters with the SEC. We previously recorded a charge related to these matters of $3.0 million during the first quarter of 2011, and have subsequently recorded an additional charge of $4.5 million during the fourth quarter of 2011 to establish an additional accrual in anticipation of a future final resolution of these matters with both DOJ and the SEC. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, we believe that the likelihood of any such additional material loss in excess of this amount is remote.

Matters Related to Breg

Our subsidiary, Breg, Inc ( Breg ), was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. 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 has asserted to us that certain potential losses related to this matter are not covered by our insurance coverage, and we are currently in arbitration with this carrier. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with these matters.

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On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice ( DOJ ). The subpoena seeks documents from the Company and its subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing. We believe that this subpoena relates to an investigation by 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. 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. We currently cannot reasonably estimate a possible loss, or range of loss, in connection with these matters.

Breg is currently engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Beginning in 2010, several domestic product liability cases have been filed, 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. 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. We currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

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**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 | 51 | President and Chief Executive Officer and Director |
| Vicente Trelles | 56 | Executive Vice President of Worldwide Operations and Shared Services |
| Brian McCollum | 36 | Senior Vice President of Finance and Chief Financial Officer |
| Michael M. Finegan | 48 | Senior Vice President, Corporate Development and President, Biologics |
| Brad Lee | 46 | President, Global Sports Medicine Business Unit |
| Luigi Ferrari | 44 | President, Global Orthopedics Business |
| Bryan McMillan | 42 | President, Global Spine Business Unit |
| Jeffrey M. Schumm | 50 | 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. Mr. Vaters also serves on the Board of Reliable Biopharmaceutical Corporation, a private healthcare company.

**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.

**Brian McCollum.** Mr. McCollum has been employed by the Company since 2001, and became our Senior Vice President of Finance and Chief Financial Officer in March 2011, after previously having been promoted to Interim Chief Financial Officer in January 2011 and Senior Vice President of Finance in August 2010. From December 2008 until August 2010, he was Vice President International Finance and Group Treasurer; from July 2006 to December 2008, he was Vice President Finance, The Americas; and from May 2001 to July 2006 he held various other finance-related positions at the Company.

**Michael M. Finegan.** Mr. Finegan joined Orthofix International N.V. in June 2006 as Senior Vice President of Corporate Development, and became our 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.

**Brad Lee.** Mr. Lee became President, Global Sports Medicine Business Unit in July 2010, after previously serving since July 2008 as President, BREG, Orthofix Sports Medicine. He joined Orthofix in 2005 as Director of Business Development, and in early 2008, became Vice President and General Manager of the BREG Sports Medicine Division. Prior to joining the Orthofix team, Mr. Lee was Vice President of Marketing for LMA North America.

**Luigi Ferrari.** Mr. Ferrari became President, Global Orthopedics Business Unit in July 2010, after previously serving since November 2009 as President for International, where he managed the Orthopedics International, MedSurg and European Spine businesses. Prior to November 2009, he was President of Orthopedics International and was responsible for the development, manufacturing and sales of fixation systems in International markets. From 2006 to 2008, he was Vice President of Europe and oversaw Orthofix activities in these key geographic markets. He serves also as General Manager of Orthofix Srl, Italy. Mr. Ferrari graduated with a degree in Management Engineering from Politecnico di Milano University in 1992 and is a graduate of the Harvard Business School Advanced Management Program in October 2010.

**Bryan McMillan.** Mr. McMillan joined Orthofix in March 2010 as the Vice-President of Global Development, and was appointed President, Spine Global Business Unit in October 2011. Prior to joining Orthofix, he was an executive at Stryker Corporation, where he held the positions of Vice President, Stryker Finance from October 2007 to March 2010 and Director, Business Development from May 2005 to October 2007. In addition to his medical device industry experience, Mr. McMillan spent nine years in investment management/banking with the firms of Rauscher Pierce, Everen securities and CIBC Oppenheimer. Mr. McMillan received his degree in Political Science and Business from Arizona State University, and has successfully completed the Harvard Executive Leadership program and Strategic Marketing Curriculum at the University of Texas, Austin.

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**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.**

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**PART II**

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

**Market for Our Common Stock**

Our common stock is traded on the Nasdaq ® Global Select Market under the symbol OFIX. The following table shows the quarterly range of high and low sales prices for our common stock as reported by Nasdaq ® for each of the two most recent fiscal years ended December 31, 2011. As of February 28, 2012 we had 397 holders of record of our common stock. The closing price of our common stock on February 28, 2012 was $40.50.

| | High | Low |
|---|---|---|
| 2010 | | |
| First Quarter | $ 36.38 | $ 28.75 |
| Second Quarter | 38.35 | 28.67 |
| Third Quarter | 33.37 | 26.63 |
| Fourth Quarter | 31.61 | 26.72 |
| | | |
| 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 |

**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 2011 that were not registered under the Securities Act.

**Exchange Controls**

Although there are Curacao 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 Curacao 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, Curacao law and our Articles of Association impose no limitations on the rights of persons who are not residents in or citizens of the Curacao to hold or vote such securities.

**Taxation**

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

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became the laws of the country of Curacao. Our tax rulings and agreements as they existed under the Netherlands Antilles remain in effect. Under the laws of the country of Curacao 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 Curacao will not be subject to Curacao 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; Curacao does not impose a withholding tax on dividends paid by us. There are no gift or inheritance taxes levied by Curacao when, at the time of such gift or at the time of death, the relevant holder of common shares was not domiciled in Curacao. No reciprocal tax treaty presently exists between Curacao 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, 2006. Points on the graph represent the performance as of the last business day of each of the years indicated.

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**Item 6. Selected Financial Data**

The following selected consolidated financial data for the years ended December 31, 2011, 2010, 2009, 2008 and 2007 have been derived from our audited consolidated financial statements. The financial data as of December 31, 2011 and 2010 and for the years ended December 31, 2011, 2010 and 2009 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, | | | | |
|---|---|---|---|---|---|
| | 2011 | 2010 | 2009 | 2008 | 2007 |
| | (US$ in thousands, except margin and per share data) | | | | |
| **Consolidated operating results** | | | | | |
| Net sales | $ 578,988 | $ 564,370 | $ 545,635 | $ 519,675 | $ 490,323 |
| Gross profit (4) | 439,802 | 432,654 | 407,185 | 367,661 | 361,291 |
| Gross profit margin (4) | 76% | 77% | 75% | 71% | 74% |
| Total operating income (loss) (5) (6) | 32,519 | 88,990 | 63,875 | (256,949) | 38,057 |
| Net (loss) income (1) (2) (3) (4) (5) (6) | (1,073) | 44,208 | 24,472 | (228,554) | 10,968 |
| Net (loss) income per share of common stock (basic) | (0.06) | 2.51 | 1.43 | (13.37) | 0.66 |
| Net (loss) income per share of common stock (diluted) | (0.06) | 2.47 | 1.42 | (13.37) | 0.64 |

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

(2) Net income for 2007 includes $12.8 million after tax earnings charge related to impairment of certain intangible assets.

(3) Net loss for 2008 includes $237.7 million after tax charge related to impairment of goodwill and certain intangible assets.

(4) Gross profit includes effect of obsolescence provision representing 2% points for the year ended December 31, 2008.

(5) Operating income includes the gain on sale of vascular operations of $12 million for the year ended December 31, 2010.

(6) 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) | 2011 | 2010 | 2009 | 2008 | 2007 |
| | (US$ in thousands, except share data) | | | | |
| **Consolidated financial position** | | | | | |
| Total assets | $ 695,551 | $ 603,989 | $ 590,473 | $ 561,215 | $ 885,664 |
| Total debt | 210,013 | 220,007 | 254,673 | 282,769 | 306,635 |
| Shareholders equity | 315,171 | 300,891 | 240,269 | 202,061 | 433,940 |
| Weighted average number of shares of common stock | 18,219,343 | 17,601,956 | 17,119,474 | 17,095,416 | 16,638,873 |

| | | | | | |
|---|---|---|---|---|---|
| outstanding (basic) | | | | | |
| Weighted average number of shares of common stock outstanding (diluted) | 18,219,343 | 17,913,545 | 17,202,943 | 17,095,416 | 17,047,587 |

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**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 along with offering a portfolio of non-invasive products to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility. 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; and bracing products used for ligament injury prevention, pain management and protection of surgical repair to promote faster healing. Our products also include cold therapy, bone cement and devices for removal of bone cement used to fix artificial implants.

Our 2011 results and financial condition include the following items of significance:

- Overall our Orthopedics revenue grew 11% or $16.7 million dollars during 2011 as compared to 2010. Spine revenues, which includes Stimulation, declined $2.1 million in 2011 or 1% versus 2010. The decrease was primarily the result of a 7% decrease in sales in our spine stimulation products in 2011 partially offset by a 7% increase in revenues from Spine Implants and Biologics. Additionally, our Sports Medicine revenue increased 8% which included $4.7 million of incremental sales from an additional billing capability added in February 2011.

- A decrease in gross profit margin from 76.7% in 2010 to 76% in 2011 which was primarily a result of increased pricing pressures in the U.S. spinal implants and sports medicine markets, an unfavorable product and geographical sales mix and a negative impact of the change in foreign currency rates.

- An increase in operating expenses, as a percentage of net sales as compared to prior period is primarily the result of the resolution of three outstanding U.S. Government matters during the year. Operating expenses were lower in 2011 versus 2010, after excluding such expenses along with removing the gain associated with the vascular divesture in 2010. 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. and Italy and manufacturing facilities in the U.S., the United Kingdom, Italy and Mexico. We directly distribute our products in the U.S., the 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. Certain of the Breg ® bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. In addition, we do not believe our operations will be significantly affected by inflation. However, in the ordinary course of business, we are exposed to the impact of changes in interest rates and foreign currency fluctuations. Our objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, we seek to balance non-dollar denominated income and expenditures. During the year, we have used derivative instruments to hedge foreign currency fluctuation exposures. See Item 7A Quantitative and Qualitative Disclosures About Market Risk.

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**Critical Accounting Policies and Estimates**

Our discussion of operating results is based upon the consolidated financial statements and accompanying notes to the consolidated financial statements prepared in conformity with 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 and certain bracing products that are 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.

In 2008, we entered into an agreement with the Musculoskeletal Transplant Foundation ( MTF ) to develop and commercialize Trinity ® Evolution , a stem cell-based regenerative biologic matrix. With the development process completed in 2009, we and MTF operate under the terms of a separate commercialization agreement. Under the terms of this 10-year agreement, MTF sources the tissue, processes it to create the regenerative matrix, packages and delivers it to the customer in accordance with orders received from us. We have exclusive global marketing rights for Trinity ® Evolution and receive a marketing fee from MTF based on total sales. This marketing fee is recorded on a net basis within net sales. On January 9, 2012 we entered into 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. MTF and Orthofix also extended the initial term of their existing agreement for an additional five years.

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, such as our developed technologies and distribution network assets, 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.

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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 three reporting units, which are consistent with our reporting segments; Spine, Orthopedics, and Sports Medicine.

In 2011, we adopted Accounting Standards Update ( ASU ) No. 2011-08, Intangibles - Goodwill and Other (Topic 350): Testing Goodwill for Impairment. This guidance does not represent an accounting change, but rather an alternative approach to the existing guidance. Under the amendment, 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. ASU 2011-08 permits the Company to assess the qualitative factors while performing this 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 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 (see additional discussions below). If the carrying value exceeds the fair value, a second step is performed to measure the amount of impairment loss, if any. No impairments were recorded during 2011 and 2010.

*Carrying Value*

In order to calculate the respective carrying values, we record 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.

*Fair Value*

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.

We believe the DCF generally provides the most meaningful fair value as it appropriately measures our income producing assets. We may consider using a cost approach but generally believe it is not appropriate, given the inability to replicate the value of the specific technology-based assets within our reporting units. In circumstances when the DCF indicator of fair value is not sufficiently conclusive to support the carrying value of a reporting unit, or when other measures provide a more appropriate indicator, we may consider a market approach in our determination of the reporting unit s fair value.

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. In connection with these estimates, we consider the following:

- The determination of expected cash flows is based on our strategic plans and long-range planning forecasts which, to the extent reasonably possible, reflect anticipated changes in the economy and the industry. Revenue growth rates represent estimates based on current and forecasted market conditions. The profit margin assumptions are projected by each reporting unit based on historical margins, the current cost structure and anticipated net cost reductions.

- The terminal value growth rate is used to calculate the value of cash flows beyond the last projected period in the DCF. This rate reflects our estimates for stable, perpetual growth for each reporting unit.

- The discount rates are based on the reporting unit s risk-adjusted weighted average cost of capital, using assumptions consistent with publicly traded guideline companies operating within the medical device industry as well as our specific risk factors for each reporting unit.

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Management utilizes its operational and industry experience to address these assumptions with best estimates. To corroborate our calculations, we reconciled our total market capitalization value to the collective fair value of the four reporting units. We believe this analysis, for the current year, provided an implied control premium consistent with the current industry average.

*Spine and Orthopedics Reporting Units*

The fair value of for these three reporting units has been established entirely using a DCF method. These DCF results concluded the fair value for each reporting unit significantly exceeded the respective carrying values at December 31, 2011. The methodology used to calculate assumptions in the December 31, 2011 DCF were consistent with that in the prior year. This approach appropriately considered adjustments for changes in the economic climate.

*Sports Medicine Reporting Unit*

The estimated fair value for our Sports Medicine reporting unit, which accounts for $106.3 million of goodwill, exceeded the relating carrying value by approximately 8%. The fair value was estimated entirely using a DCF model. This compares to the prior year, in which our fair value estimate also considered indications using a market approach. Given the lack of similar circumstances and events, that provided market based indications of fair value in the prior year, we determined a DCF model most appropriately reflected the Sports Medicine GBU s fair value in the current year.

The projected cash flows assume revenue growth, which is consistent with historical activity and reflective of recent investments in the reporting unit. The DCF model further reflects, what we believe, to be appropriate discount and terminal growth rate assumptions. While management does not believe the following assumption changes are reasonably likely to apply, for sensitivity purposes we have considered the impact to Sport Medicine s fair value by increasing the discount rate and reducing the perpetual growth rate by 50 basis points each and reducing revenue growth by 20%. These sensitivity analyses noted that any individual change to one or another of these assumptions would not have the effect of reducing Sport Medicine s estimated fair value below its respective carrying value; however, any combination of these changes would reduce Sports Medicine s estimated fair value below its carrying value. As a result, if actual operating results and/or the underlying assumptions used in the analyses differ from expected, a future impairment charge may be necessary.

In the event that the future operating results of any of our reporting units do not meet our current expectations, we will consider taking other actions as necessary to maximize profitability based upon conditions at the time. Accordingly, the above sensitivity analysis, while a useful tool, should not be used as a sole predictor of potential impairment. A thorough analysis of all the facts and circumstances existing at the time of such an evaluation would need to be performed to determine if recording an impairment loss was appropriate.

*Derivatives*

We manage our exposure to fluctuations in interest rates and foreign exchange within the consolidated financial statements according to our hedging policy. Under the policy, we may engage in non-leveraged transactions involving various financial derivative instruments to manage

exposed positions. The policy requires us 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, we formally assess (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, we 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.

We record 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.

We utilize a cross currency swap to manage our foreign currency exposure related to a portion of our 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 ).

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*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 adopted the provisions of ASC Topic 740 Income Taxes , on January 1, 2007. As such, we determine whether it is more likely than not that our tax positions will be sustained based on the technical merits of each position. At December 31, 2011, we have $0.7 million of unrecognized tax benefits compared with $0.6 million of unrecognized tax benefits at December 31, 2010. We have accrued interest and penalties of $0.5 million and $0.4 million at December 31, 2011 and 2010, respectively.

*Share-based Compensation*

We recognize share-based compensation in accordance with ASC Topic 718 Compensation Stock 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 our 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 our 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.

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**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, | | |
|---|---|---|---|
| | 2011 (%) | 2010 (%) | 2009 (%) |
| Net sales | 100 | 100 | 100 |
| Cost of sales | 24 | 23 | 25 |
| Gross profit | 76 | 77 | 75 |
| Operating expenses | | | |
| Sales and marketing | 40 | 41 | 40 |
| General and administrative | 15 | 16 | 16 |
| Research and development | 4 | 5 | 6 |
| Amortization of intangible assets | 1 | 1 | 1 |
| Charges related to U.S. Government resolutions | 10 | | |
| Net gain on sale of vascular operations | | (2) | |
| Total operating income (loss) | 6 | 16 | 12 |
| Net (loss) income | 0 | 8 | 4 |

Through December 31, 2010, we managed our operations as five reportable segments: Domestic, Spinal Implants and Biologics, Breg, International and Group. Beginning January 1, 2011, we began managing our business by our three global business units ( GBU s ), which are comprised of Spine, Orthopedics and Sports Medicine, 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 three GBU reporting segments. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new segments are discussed below. Corporate activities not necessarily identifiable within the three GBUs are recorded as part of Corporate. We have designated Presidents (or GBU leaders) to lead the various segments.

*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 comprehensive 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.

*Sports Medicine*

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

*Corporate*

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings, Inc., along with activities not necessarily identifiable with the three GBUs.

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**Segment and Market Sector Revenue**

The following tables display net sales by business segment and net sales by market sector. We maintain our books and records and account for net sales, costs of sales and expenses by business segment. We provide net sales by market sector for information purposes only.

**Business Segments by GBU:**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Spine | $ | 304,217 | 52% | $ | 306,404 | 54% | $ | 279,425 | 51% |
| Orthopedics | | 165,904 | 29% | | 154,198 | 27% | | 151,054 | 28% |
| Sports Medicine | | 108,867 | 19% | | 103,768 | 19% | | 115,156 | 21% |
| Total Net Sales | $ | 578,988 | 100% | $ | 564,370 | 100% | $ | 545,635 | 100% |

Our market sectors are Spine that includes implants, biologics, and also stimulation products, Orthopedics, and Sports Medicine.

**Market Sectors:**

| | | | | | | |
|---|---|---|---|---|---|---|
| Spine Products | | | | | | |
| Stimulation | 160,442 | 28% | 172,573 | 31% | 158,980 | 29% |
| Orthopedics Products | 165,904 | 29% | 149,175 | 26% | 139,304 | 25% |
| Total Strategic Products | 573,161 | 99% | 551,093 | 98% | 515,175 | 94% |

(1) Divested Products sales for 2011 include $5.8 million related to the vascular business which was divested in March 2010. Divested Products sales for 2010 and 2009 include $8.3 million and $18.7 million, respectively, related to the vascular business which was divested in

March 2010. This revenue represents amounts recognized in 2010 and 2009 prior to the March 2010 sale date as well as revenue generated in 2010 and 2011 from the transition services supply agreement that commenced upon the sale of the business. In addition, Divested Products sales for 2010 and 2009 also include $5 million and $11.8 million, respectively, related to the anesthesia product line. The Company exited its anesthesia product line after the expiration of its distribution agreement in the United Kingdom during the second quarter of 2010.

**2011 Compared to 2010**

Net sales increased 3% to $579 million in 2011 compared to $564.4 million in 2010. The impact of foreign currency increased sales by $6.5 million in 2011 when compared to 2010.

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*Sales*

Net sales in our Spine market sector decreased to $304.2 million in 2011 compared to $306.4 million for 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 market sector increased to $165.9 million in 2011 compared to $149.2 million for 2010, an increase of 11%. Orthopedics s constant currency net sales increased by 7%, or $10.5 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.

Net sales in our Sports Medicine market sector increased to $103 million in 2011 compared to $95.5 million for the same period in the prior year, an increase of 8%. We had increased billing capacity and revenues of $4.7 million resulting from the acquisition of a billing capability in February 2011.

Net sales of our Divested Products decreased in 2011 from $13.3 million to $5.8 million. This revenue represents amounts recognized in 2010 and in 2011 from the vascular business which we divested in March 2010 and the transition services supply agreement that commenced upon the sale of the business. In addition, sales for the year ended December 31, 2010 also include $5 million related to the anesthesia product line. We exited the anesthesia product line after the expiration of our distribution agreement in the United Kingdom during the second quarter of 2010.

*Gross Profit* Our gross profit increased 2% to $439.8 million for 2011 compared to $432.7 million for 2010. Gross profit as a percent of net sales in 2011 was 76.0% compared to 76.7% in 2010. This decrease was primarily a result of increased pricing pressures in the U.S. spinal implants and sports medicine markets, an unfavorable product and geographical sales mix and a negative impact of the change in foreign currency rates.

*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 $2.7 million, or 1%, to $233.6 million in 2011 compared to $230.9 million in 2010. As a percent of sales, sales and marketing expense was 40.3% and 40.9% 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 $2.1 million, or 2%, in 2011 to $86.5 million compared to $88.6 million in 2010. General and administrative expense as a percent of sales was 14.9% in 2011 compared to 15.7% 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 $5 million of litigation and settlement costs for certain product liability matters

related to our Sports Medicine GBU and $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 $2.0 million related to employee termination benefits associated with our internal reorganization which streamlined operations and is expected to lower future operating costs.

*Research and Development Expense* Research and development expense decreased $5.3 million in 2011 to $25.1 million compared to $30.4 million in 2010. As a percent of sales, research and development expense was 4.3% in 2011 compared to 5.4% for the same period last year. The decrease in research and development expenses in 2011 compared to 2010 was due to timing of spending related to our ongoing research, development and clinical activities, our focus to eliminate activities that are not directly related to developing and bringing our products to market, and certain improvements in our operational efficiencies. In addition 2010 included costs associated with the cancellation of the cervical disc clinical trial.

*Amortization of Intangible Assets* Amortization of intangible assets was $5.6 and $5.8 million for 2011 and 2010, respectively.

*Net gain on sale of vascular operations* Represents the gain on the sale of our vascular operations related to the A-V IMPULSE SYSTEM ® and related accessories on March 8, 2010. No such gain was recorded in 2011.

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*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. The Company is finalizing definitive agreements with the U.S. Attorney s Office, the DOJ, and the OIG to resolve these matters which includes resolution of a qui tam lawsuit pending in the U.S. District Court for the District of Massachusetts. We expect that under the terms of these agreements, the Company will pay $43 million to resolve these matters, and we have recorded a charge of $43 million in anticipation of these agreements. We expect that (i) our subsidiary, Othofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) Orthofix International N.V. and Orthofix Inc will enter into a five-year Corporate Integrity Agreement (CIA) with the OIG as part of the resolution of these matters.

We have recorded a charge of $7.5 million to establish an accrual in connection with the potential fines and penalties related to the FCPA matter involving our Promeca subsidiary, and are in discussions with the SEC and DOJ regarding a resolution of this matter (as further described in Part I, Item 3 Legal Proceedings ). Final resolution is subject to the negotiation and execution of definitive agreements with the DOJ and SEC.

Although neither of these matters has concluded, we believe that the costs for which the charges have been recognized during 2011 are probable of being incurred and paid during 2012. We have recorded these charges associated with the potential settlement costs as charges related to U.S. Government resolutions in our consolidated statements of operations.

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* Interest expense was $9.8 million in 2011 compared to $17.2 million in 2010. The decrease was primarily as the result of a lower rate of effective interest due to refinancing in August 2010, and a lower year over year outstanding debt balance.

*Loss on Refinancing of Credit Facility* In 2010, we incurred $0.6 million of expense related to the write-off of the remaining capitalized debt placement costs associated with the former credit facility agreement. There are no comparable costs in 2011.

*Gain (Loss) on Interest Rate Swap* In June 2008, we 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. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in our former credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, we settled the Swap with the financial institution holder of the derivative instrument resulting in a gain of $1.3 million. There are no comparable gains in 2011.

*Other Expense, net* Other expense, net was $2.3 million in 2011 compared to $0.4 million in 2010. The increase 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 $21.8 million provision for income tax for 2011. This reflects a disproportionate ratio to the $20.7 million of income before tax, as we did not record tax benefit on certain expenses associated with our estimate of the charges related to U.S. Government resolutions. The effective tax rate for 2011 was 38.1% excluding the impact of the charges related to the U.S. Government inquiries. The effective tax rate was 38.9% for 2010.

*Net Income (Loss)* Net loss in 2011 was $1.1 million, or $(0.06) per basic share and $(0.06) per 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.

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**2010 Compared to 2009**

Net sales increased 3% to $564.4 million in 2010 compared to $545.6 million in 2009. The impact of foreign currency increased sales by $0.3 million in 2010 when compared to 2009.

*Sales*

Net sales in our Spine market sector increased to $306.4 million in 2010 compared to $279.4 million in 2009, an increase of 10%. The increase in Spine s net sales was primarily the result of a 9% increase in sales of our spine stimulation products in 2010 when compared to the 2009. The improvement in hardware products included improved sales in our thorocolumbar devices during 2010 compared to 2009 due to increased sales of our Firebird platform products including Phoenix MIS and Deformity Correction.

Net sales in our Orthopedics market sector decreased to $149.2 million in 2010 compared to $139.3 million for 2009, an increase of 7%. This increase was led by hardware products and the increased use of Trinity ® Evolution in orthopedic applications and our external fixation products. Sales of our hardware products increased 10% during the 2010 when compared with 2009.

Net sales in our Sports Medicine market sector decreased 1% to $95.5 million in 2010 from $96.4 million for 2009.

Net sales of our Divested Products decreased in 2010 from $30.5 million to $13.2 million. This revenue represents amounts recognized in 2010 and in 2011 from the vascular business which we divested in March 2010 and the transition services supply agreement that commenced upon the sale of the business. In addition, sales for 2010 and 2009 also include $5 million and $11.8 million, respectively, related to the anesthesia product line. We exited the anesthesia product line after the expiration of our distribution agreement in the United Kingdom during the second quarter of 2010.

*Gross Profit* Our gross profit increased 6% to $432.7 million for 2010, compared to $407.2 million for 2009. Gross profit as a percent of net sales in 2010 was 76.7% compared to 74.6% in 2009. The increase in the gross profit is primarily due to the increased sales of our higher margin stimulation products and Spinal Implants and Biologics products. While we record 70% of the sales price of Trinity ® Evolution allograft versus recording 100% of the sales price of the previous Trinity ® product, we recognize a 100% gross profit margin from the marketing fees earned from the sales of this allograft, compared to an approximately 50% gross profit margin on our previous Trinity ® product. This is due to the fact that we are not required to purchase inventory of Trinity ® Evolution whereas, previously, we were required to purchase inventory of the previous Trinity ® product and record the associated cost of sales.

*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 $15 million, or 7%, to $230.9 million in 2010 compared to $215.9 million in 2009. As a percent of sales, sales and marketing expense was 40.9% and 39.6% for 2010 and 2009, respectively. In 2010 sales and marketing expense included $1.6 million related to employee termination benefits associated with our internal reorganization which will streamline operations and lower future operating costs. Sales and marketing expense in 2010 also included $2 million related to a patent dispute

settlement charge concerning the Trinity ® Evolution allograft product.

*General and Administrative Expense* General and administrative expense decreased $0.3 million, or 1%, in 2010 to $88.6 million compared to $88.9 million in 2009. In 2010 general and administrative expense included $2.0 million related to employee termination benefits associated with our internal reorganization which will streamline operations and is expected to lower future operating costs. In 2010 we recorded $9.2 million of legal expenses associated with the DOJ investigation of the bone growth stimulation industry and our internal investigation into compliance with the Foreign Corrupt Practices Act at our distribution subsidiary in Mexico. In 2010, we experienced a lower than normal share-based compensation expense related to stock options and awards, as we did not grant any in 2010. In 2009, we recorded a $3.6 million restructuring charge to consolidate substantially all of Spinal Implants and Biologics operations previously conducted in Wayne, NJ and Springfield, MA into the same facility housing our spine stimulation and U.S. orthopedics business in the Dallas, TX area. In addition, during the first quarter of 2009, we incurred $0.7 million of costs incurred in connection with a proxy contest. We also recorded an $0.8 million accrual during 2009 for potential royalties payable in connection with litigation. Legal expenses, that are unrelated to the matters above, totaled $8.3 million in 2010 compared to $12.1 million in 2009. General and administrative expense as a percent of sales was 15.7% in 2010 compared to 16.3% in 2009.

*Research and Development Expense* Research and development expense decreased $1.1 million in 2010 to $30.4 million compared to $31.5 million in 2009. During 2010, we incurred $4.6 million in expenses related to research and development projects associated with our orthopedics business. During 2009, we incurred $3.9 million and $1.8 million in expenses primarily related to collaborative arrangements with the Musculoskeletal Transplant Foundation ( MTF ) and Intelligent Implant Systems, LLC ( IIS ), respectively. As a percent of sales, research and development expense was 5.4% in 2010 compared to 5.8% for the same period last year.

*Amortization of Intangible Assets* Amortization of intangible assets decreased $1.2 million for the year ended December 31, 2010 to $5.8 million compared to $7.0 million for the year ended December 31, 2009.

*Net gain on sale of vascular operations* Represents the gain on the sale of our vascular operations related to the A-V IMPULSE SYSTEM ® and related accessories on March 8, 2010. No such gain was recorded in 2009.

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*Interest Expense* Interest expense was $17.2 million in 2010 compared to $24.8 million in 2009. The decrease was primarily the result of a lower year-over-year outstanding debt balance, a lower interest rate resulting from the payoff of the interest rate swap in June 2010 and the refinancing of our outstanding long-term debt facility in August 2010.

*Loss on Refinancing of Senior Secured Term Loan* For the year ended December 31, 2010, we incurred $0.6 million of expense related to the write-off of the remaining capitalized debt placement costs associated with the former credit facility agreement.

*Gain (Loss) on Interest Rate Swap* In June 2008, we 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. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in our former credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, we settled the Swap with the financial institution holder of the derivative instrument. For 2010 and 2009, the Company recorded a gain of $1.3 million and $1.9 million, respectively, related to the change in the fair value of the Swap.

*Other Expense, net* Other expense, net was $0.4 million in 2010 compared to $1.1 million in 2009. 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)* Our worldwide effective tax rate was 38.9% at December 31, 2010 and 2009. The 2010 effective tax rate was impacted primarily by the sale of vascular assets, losses in certain foreign jurisdictions, for which we receive no tax benefit and the mix of earnings among tax jurisdictions. The effective tax rate for 2009 was impacted by a mix of earnings among tax jurisdictions, state taxes and other items. We also incur losses in a number of foreign jurisdictions for which we do not currently recognize a tax benefit. We do not believe that it is more likely than not that we will generate sufficient future income in these jurisdictions to allow for the utilization of these losses before their expiration.

*Net Income (Loss)* Net income in 2010 was $44.2 million, or $2.51 per basic share and $2.47 per diluted share, compared to net income of $24.5 million, or $1.43 per basic and $1.42 per diluted share for 2009. The weighted average number of basic common shares outstanding was 17,601,956 and 17,119,474 during the years ended December 31, 2010 and 2009, respectively. The weighted average number of diluted common shares outstanding was 17,913,545 and 17,202,943 during the years ended December 31, 2010 and 2009, respectively.

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**Liquidity and Capital Resources**

Cash and cash equivalents at December 31, 2011 were $80.3 million, of which $47.1 million is subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $36.5 million at December 31, 2010, of which $22.9 million was subject to certain restrictions under the senior secured credit agreement described below.

Net cash provided by operating activities was $64.8 million in 2011 compared to $42.5 million in 2010, an increase of $22.3 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 decreased $45.3 million to a net loss of $1.1 million in 2011 compared to net income of $44.2 million in 2010. Non-cash items for 2011 increased $19 million to $49.7 million compared to $30.7 million in 2010 primarily as a result of the net gain on the sale of vascular operations of $12 million and an increase in the tax benefit on non-qualified stock options of $2.2 million. Working capital accounts provided $16.1 million of cash in 2011 as compared to consuming $32.4 million in 2010. Working capital impacts in the 2011 period can be attributed to charges related to U.S. Government resolutions of $88.5 million partially offset by the change in escrow receivable of $30.5 million. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory reflect days sales in receivables of 89 days at December 31, 2011 compared to 86 days at December 31, 2010 and inventory turns of 1.5 times at December 31, 2011 and 2010.

Net cash used in investing activities was $31 million in 2011 compared to $2.1 million in 2010. During the first quarter of 2010, we sold our vascular operations with cash proceeds, net of litigation settlement costs, for $24.2 million. During the first quarter of 2011, we acquired 100% of the stock of Omni Motion, Inc. for a cash purchase price of $5.3 million plus acquisition costs. During 2011 and 2010, we invested $25.8 million and $26.4 million in capital expenditures, respectively.

Net cash used in financing activities was $13.7 million for 2011 compared to $40 million for 2010. During 2011, we repaid approximately $7.5 million against the principal on our senior secured term loan compared to $36.3 million in 2010. Our restricted cash balance increased $24.2 million compared to $11.3 million in 2010. During the year ended December 31, 2011, we received proceeds of $20.1 million from the issuance of shares of our common stock related to stock purchase plan issuances and stock option exercises.

On August 30, 2010, our wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. ( Orthofix Holdings ) entered into a Credit Agreement (the Credit Agreement ) with certain of our domestic direct and indirect subsidiaries (the Guarantors ), JPMorgan Chase Bank, N.A., as Administrative Agent, RBS Citizens, N.A., as Syndication Agent, and certain lender parties thereto. In connection with the execution by Orthofix Holdings and the Guarantors of the Credit Agreement, the previously existing credit agreement, dated as of September 22, 2006 and as subsequently amended on September 29, 2008 and February 24, 2010, among Orthofix Holdings, the Company, and certain subsidiaries, the several banks and other financial institutions parties, and Wachovia Bank, National Association, was terminated and all term loan obligations existing were repaid in full using proceeds of the Credit Agreement.

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 ). The full $100.0 million Term Loan Facility and approximately $132.4 million of the Revolving Credit Facility were drawn on August 30, 2010. These proceeds were used to repay amounts owed in connection with the termination of the previous credit agreement, as well as certain fees related to the establishment of the Credit Agreement. Orthofix Holdings has the ability to increase the amount of the Credit Facilities by an aggregate amount of up to $50 million upon satisfaction of certain conditions. These increased borrowings may be provided either by one or more existing

lenders upon Orthofix Holdings obtaining the agreement of such lenders to increase commitments or by new lenders being added to the Credit Facilities.

As of December 31, 2011, we 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. The principal amount of the Term Loan Facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments are due quarterly and began with the quarter ended December 31, 2010.

The aggregate maturities of long-term debt after December 31, 2011 are as follows: 2012 $17.5 million, 2013 $25.0 million, 2014 $26.3 million, and 2015 $139.9 million.

As of December 31, 2011, the entire Term Loan Facility of $91.3 million is at the LIBOR rate plus a margin of 3.00%. In addition, as of December 31, 2011, $100 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining $17.4 million of the Revolving Credit Facility is 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, 2011 and 2010 was 3.4%.

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

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Certain of our subsidiaries have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to our Credit Facilities. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company. Our domestic subsidiaries, 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, 2011 is $186 million compared to $178.5 million at December 31, 2010. In addition, the Credit Agreement restricts us and our subsidiaries that are not parties to the credit facility from access to cash held by Orthofix Holdings and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes. The amount of our restricted cash as of December 31, 2011 is $47.1 million compared to $22.9 million at December 31, 2010.

In conjunction with obtaining the Credit Facilities and the Amended Credit Agreement, the Company incurred debt issuance costs of $5.0 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. As of December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were $3.5 million.

At December 31, 2011, we had outstanding borrowings of 1.0 million ($1.3 million) and unused available lines of credit of approximately 6.3 million ($8.1 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.

In the fourth quarter of 2008, as part of our strategic plan to strengthen the business, we 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. We 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, we initiated a reorganization plan to further align and streamline operations and lower operating costs within its Spine, Orthopedics and Sports Medicine global business units. Employee severance payments will extend through the third quarter of 2011. During the year ended December 31, 2010, we recorded restructuring charges of $3.6 million, which were related to employee severance costs. Final cash payments were made in the third quarter of 2011 and no further charges are anticipated.

The following table presents changes in the restructuring liability, which is included within Other Current Liabilities in our 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 | $ | |

On March 8, 2010, we entered into an asset purchase agreement (the APA ) in which we agreed to sell substantially all of the assets of our vascular operations related to the A-V IMPULSE SYSTEM ® and related accessories (including finished goods inventory and tangible assets).

At the closing, we 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, we agreed to enter into certain transition arrangements at the closing, including (i) a transition services agreement pursuant to which, among other things, we 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 pursuant to which, among other things, we would provide manufacturing and logistics services with respect to 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, we 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. We also agreed to enter into a five-year noncompetition agreement at closing with respect to the business of the assets being transferred. Due to the continuing contractual involvement of these agreements, the transaction has not been presented in discontinued operations.

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The following table presents the value of the asset disposition, 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.

*Contractual Obligations*

The following chart sets forth our contractual obligations as of December 31, 2011:

| | | **Payments Due by Period** | | | |
|---|---|---|---|---|---|
| **Contractual Obligations (US$ in thousands)** | **Total** | **2012** | **2013-2015** | **2016** | **2017 and thereafter** |
| Senior secured term loan | $ 208,695 | $ 17,500 | $ 191,195 | $ | $ |
| Estimated interest on senior secured term loan (1) | 22,200 | 6,967 | 15,233 | | |
| Purchase obligations (2) | 417 | 417 | | | |
| Operating leases | 23,011 | 4,197 | 9,330 | 2,759 | 6,725 |
| | | | | | |
| Total | $ 254,323 | $ 29,081 | $ 215,758 | $ 2,759 | $ 6,725 |

(1) Estimated interest on senior secured term loan 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, 2011.

(2) In addition to the unconditional purchase obligations stated above, we also have inventory purchase agreements that, if terminated, would require us to purchase an additional $1.8 million of inventory.

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 of $0.7 million as of December 31, 2011 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, 2011, 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.

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**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, 2011, we had a currency swap in place to minimize foreign currency exchange risk related to a 38.3 million intercompany note.

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, 2011, the entire Term Loan Facility of $91.3 million is at the LIBOR rate plus a margin of 3.00%. As of December 31, 2011, $100 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining $17.4 million of the Revolving Credit Facility is at a base rate (as defined in the Credit Agreement) plus a margin of 2.00%. These margins are 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, 2011, our effective interest rate on our Credit Facilities was 3.4%. Based on the balance outstanding under the Credit Facilities as of December 31, 2011, an immediate change of one percentage point in the applicable interest rate on the Term Loan Facility and Revolving Credit Facility would cause a change in interest expense of approximately $2.1 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, 2011, we had an un-hedged intercompany receivable denominated in Euro of approximately 23.2 million ($30 million). We recorded a foreign currency loss during the year ended December 31, 2011 of $3.2 million related to this un-hedged long-term intercompany balance in accumulated other comprehensive income during 2011, which resulted from the weakening of the Euro against the U.S. dollar during the period. For the year ended December 31, 2011, we recorded a foreign currency loss of $1.6 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 favorably impacted during the year ended December 31, 2011 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations during 2011 versus the same periods in 2010. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the year ended December 31, 2010 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against the local foreign currency versus the same periods in 2009 in certain countries outside of Europe, partially offset by the effect of the fluctuations of the U.S. dollar against the Euro. 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.

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**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 year ended December 31, 2011 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Our management s assessment regarding the Company s internal control over financial reporting can be found immediately prior to the financial statements in a section entitled Management s Report on Internal Control over Financial Reporting in this Form 10-K.

**Item 9B. Other Information**

Not applicable.

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## PART III

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

### Item 10. Directors, Executive Officers and Corporate Governance

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

### Item 11. Executive Compensation

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

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

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

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

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

**Item 14. Principal Accountant Fees and Services**

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

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## PART IV

**Item 15. Exhibits and Financial Statement Schedules**

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

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

1. Financial Statements

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

2. Financial Statement Schedules

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

3. Exhibits

| Exhibit Number | Description |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of August 4, 2006, among Orthofix International N.V., Orthofix Holdings, Inc., New Era Medical Limited, Blackstone Medical, Inc. and William G. Lyons, III, as Equityholders Representative (filed as an exhibit to the Company s current report on Form 8-K filed August 7, 2006 and incorporated herein by reference). |
| 2.2 | 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). |
| 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). |

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|---|---|
| 3.2* | Articles of Association of the Company as amended. |
| 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. |

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| 10.6 | Orthofix International N.V. Amended and Restated Stock Purchase Plan, as amended (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference). |
| 10.7 | Orthofix International N.V. 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). |
| 10.8 | 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). |
| 10.9 | 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). |
| 10.10 | Form of Employee Non-Qualified Stock Option Agreement (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). |
| 10.11 | Form of Non-Employee Director Non-Qualified Stock Option Agreement (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). |
| 10.12 | 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). |
| 10.13 | Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (pre-2009 grants 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). |
| 10.14 | 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). |
| 10.15 | 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). |
| 10.16 | 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). |
| 10.17 | 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). |
| 10.18 | 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). |
| 10.19 | Second Amended and Restated Performance Accelerated Stock Options Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company s current report on Form 8-K filed October 15, 2008 and incorporated herein by reference). |
| 10.20 | Nonqualified Stock Option Agreement between Orthofix International N.V. and Bradley R. Mason dated October 14, 2008 (filed as an exhibit to the Company s current report on Form 8-K filed October 15, 2008 and incorporated herein by reference). |
| 10.21 | 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). |

| | |
|---|---|
| 10.22 | Description of Director Compensation Policy (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). |
| 10.23 | 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). |

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|---|---|
| 10.24 | 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). |
| 10.25 | 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). |
| 10.26 | 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). |
| 10.27 | Amended and Restated Employment Agreement, entered into and effective as of July 28, 2010, 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 3, 2010 and incorporated herein by reference). |
| 10.28 | Addendum to Amended and Restated Employment Agreement, entered into as of March 9, 2011, by and between Orthofix Inc. and Robert S. Vaters (filed as an exhibit to the Company s quarterly report on current report on Form 8-K filed March 15, 2011 and incorporated herein by reference). |
| 10.29 | 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). |
| 10.30 | Amended and Restated Employment Agreement, entered into and effective as of July 1, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 and incorporated herein by reference). |
| 10.31 | Amendment No. 1 to Amended and Restated Employment Agreement, dated August 4, 2009, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended September 30, 2009 and incorporated herein by reference). |
| 10.32 | Amendment No. 2 to Amended and Restated Employment Agreement, dated as of October 1, 2011, by and between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company s current report on Form 8-K filed October 4, 2011 and incorporated herein by reference). |
| 10.33 | Amended and Restate Employment Agreement, entered into on February 11, 2011, by and between Breg, Inc. and Brad Lee (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). |
| 10.34 | Employment Agreement, entered into on December 9, 2010, by and between Orthofix Inc. and Jeffrey M. Schumm (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference). |
| 10.35 | 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). |
| 10.36 | 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). |
| 10.37 | Employment Agreement, entered into as of October 1, 2011, by and between Orthofix Inc. and Bryan McMillan (filed as an exhibit to the Company s quarterly report on Form 10-Q for the quarter ended September 30, 2011 and incorporated herein by reference). |
| 10.38 | Amended and Restated Employment Agreement, entered into on July 28, 2010, by and between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company s current report on Form 8-K filed August 3, 2010 and incorporated herein by |

reference).

10.39 Separation Letter Agreement, dated February 7, 2011, between Orthofix Inc. and Michael Simpson (filed as an exhibit to the Company s current report on Form 8-K filed on February 10, 2011 and incorporated herein by reference).

10.40 Amended and Restated Employment Agreement, entered into on July 1, 2009, by and between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company s annual report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).

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|---|---|
| 10.41 | Separation Letter Agreement, dated January 10, 2011, between Orthofix Inc. and Eric Brown (filed as an exhibit to the Company s current report on Form 8-K filed January 14, 2011 and incorporated herein by reference). |
| 10.42 | Form of Amendment to Stock Option Agreements (for Alan W. Milinazzo, Robert S. Vaters, Bradley R. Mason, Michael M. Finegan and Michael Simpson) (filed as an exhibit to the Company s current report on Form 8-K filed July 7, 2009 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, 2011 filed on February 29, 2012, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Changes in Shareholders Equity and Comprehensive Income (Loss), (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements. |

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* Filed herewith.

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

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

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**SIGNATURES**

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

ORTHOFIX INTERNATIONAL N.V.

Dated: February 29, 2012

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

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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 | President and Chief Executive Officer, | February 29, 2012 |
| **Robert S. Vaters** | Director (Principal Executive Officer) | |
| /s/ BRIAN MCCOLLUM | Senior Vice President of Finance and Chief | February 29, 2012 |
| **Brian McCollum** | Financial Officer (Principal Financial and Accounting Officer) | |
| /s/ JAMES F. GERO | Chairman of the Board of Directors | February 29, 2012 |
| **James F. Gero** | | |
| /s/ WALTER VON WARTBURG | Director | February 29, 2012 |
| **Walter von Wartburg** | | |
| /s/ GUY JORDAN | Director | February 29, 2012 |
| **Guy Jordan** | | |
| /s/ KENNETH R. WEISSHAAR | Director | February 29, 2012 |
| **Kenneth R. Weisshaar** | | |
| /s/ MICHAEL MAINELLI | Director | February 29, 2012 |
| **Michael Mainelli** | | |
| /s/ ALAN W. MILINAZZO | Director | February 29, 2012 |
| **Alan W. Milinazzo** | | |
| /s/ DAVEY S. SCOON | Director | February 29, 2012 |
| **Davey S. Scoon** | | |

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**ORTHOFIX INTERNATIONAL N.V.**

**Index to Consolidated Financial Statements**


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

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**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

**Brian McCollum**

Senior Vice President of Finance and Chief Financial Officer

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**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, 2011 based on the framework set forth in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation, management concluded that, as of December 31, 2011, the Company s internal control over financial reporting is effective based on the specified criteria.

The Company s internal control over financial reporting has been audited by the Company s Independent Registered Public Accounting Firm, Ernst & Young LLP, as stated in their reports at pages F-4 and F-5 herein.

**James F. Gero**

Chairman of the Board of Directors

**Robert S. Vaters**

President and Chief Executive Officer, Director

**Brian McCollum**

Senior Vice President of Finance and Chief Financial Officer

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**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, 2011 and 2010, and the related consolidated statements of operations, changes in shareholders equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2011. Our audits also included the financial statement schedules listed in the index at Item 15(a). These financial statements and schedules are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedules based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Orthofix International N.V. at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas
February 29, 2012

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**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, 2011, 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, 2011, 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, 2011 and 2010, and the related consolidated statements of operations, changes in shareholders equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2011 of Orthofix International N.V. and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Dallas, Texas
February 29, 2012

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**ORTHOFIX INTERNATIONAL N.V.**

**Consolidated Balance Sheets as of December 31, 2011 and 2010**

| (U.S. Dollars, in thousands except share and per share data) | 2011 | 2010 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 33,207 | $ 13,561 |
| Restricted cash | 47,105 | 22,944 |
| Trade accounts receivable, less allowances of $10,045 and $7,250 at December 31, 2011 and 2010, respectively | 146,538 | 134,184 |
| Inventories, net | 91,247 | 84,589 |
| Deferred income taxes | 16,867 | 17,422 |
| Escrow receivable | 41,537 | 14,937 |
| Prepaid expenses and other current assets | 28,089 | 24,123 |
| Total current assets | 404,590 | 311,760 |
| Property, plant and equipment, net | 52,124 | 45,535 |
| Patents and other intangible assets, net | 37,515 | 41,457 |
| Goodwill | 179,373 | 176,497 |
| Deferred income taxes | 9,662 | 16,175 |
| Other long-term assets | 12,287 | 12,565 |
| Total assets | $ 695,551 | $ 603,989 |
| **Liabilities and shareholders equity** | | |
| Current liabilities: | | |
| Bank borrowings | $ 1,318 | $ 3,812 |
| Current portion of long-term debt | 17,500 | 7,500 |
| Trade accounts payable | 20,105 | 19,796 |
| Accrued charges related to U.S. Government resolutions | 82,500 | |
| Other current liabilities | 53,989 | 52,418 |
| Total current liabilities | 175,412 | 83,526 |
| Long-term debt | 191,195 | 208,695 |
| Deferred income taxes | 9,777 | 8,102 |
| Other long-term liabilities | 3,996 | 2,775 |
| Total liabilities | 380,380 | 303,098 |
| Contingencies (Note 15) | | |
| Shareholders equity | | |
| Common shares $0.10 par value; 50,000,000 shares authorized; 18,465,444 and 17,726,645 issued and outstanding as of December 31, 2011 and 2010, respectively | 1,846 | 1,772 |
| Additional paid-in capital | 214,310 | 195,402 |
| Retained earnings | 97,254 | 98,327 |
| Accumulated other comprehensive income | 1,761 | 5,390 |
| Total shareholders equity | 315,171 | 300,891 |
| Total liabilities and shareholders equity | $ 695,551 | $ 603,989 |

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Consolidated Statements of Operations**

**For the years ended December 31, 2011, 2010 and 2009**

| (U.S. Dollars, in thousands, except share and per share data) | 2011 | 2010 | 2009 |
|---|---|---|---|
| Net sales | $ 578,988 | $ 564,370 | $ 545,635 |
| Cost of sales | 139,186 | 131,716 | 138,450 |
| Gross profit | 439,802 | 432,654 | 407,185 |
| Operating expenses | | | |
| Sales and marketing | 233,609 | 230,942 | 215,943 |
| General and administrative | 86,468 | 88,628 | 88,866 |
| Research and development | 25,148 | 30,350 | 31,460 |
| Amortization of intangible assets | 5,595 | 5,763 | 7,041 |
| Net gain on sale of vascular operations (Note 20) | | (12,019) | |
| Charges related to U.S. Government resolutions (Note 15) | 56,463 | | |
| | 407,283 | 343,664 | 343,310 |
| Operating income | 32,519 | 88,990 | 63,875 |
| Other income (expense) | | | |
| Interest income | 326 | 330 | 193 |
| Interest expense | (9,789) | (17,228) | (24,820) |
| Loss on refinancing of credit facility | | (550) | |
| Gain on interest rate swap | | 1,254 | 1,852 |
| Other expense, net | (2,353) | (398) | (1,079) |
| | (11,816) | (16,592) | (23,854) |
| Income before income taxes | 20,703 | 72,398 | 40,021 |
| Income tax expense | (21,776) | (28,190) | (15,549) |
| Net income (loss) | $ (1,073) | $ 44,208 | $ 24,472 |
| Net income (loss) per common share basic | $ (0.06) | $ 2.51 | $ 1.43 |
| Net income (loss) per common share diluted | $ (0.06) | $ 2.47 | $ 1.42 |
| Weighted average number of common shares basic | 18,219,343 | 17,601,956 | 17,119,474 |
| Weighted average number of common shares diluted | 18,219,343 | 17,913,545 | 17,202,943 |

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Consolidated Statements of Changes in Shareholders Equity and Comprehensive Income (Loss)**

**For the years ended December 31, 2011, 2010 and 2009**

| (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, 2008 | 17,103,142 | $ 1,710 | $ 167,818 | $ 29,647 | $ 2,886 | $ 202,061 |
| Net income | | | | 24,472 | | 24,472 |
| Other comprehensive income (loss): | | | | | | |
| Unrealized loss on derivative instrument (net of taxes of $1,050) | | | | | (2,702) | (2,702) |
| Translation adjustment | | | | | 7,006 | 7,006 |
| Total comprehensive income | | | | | | 28,776 |
| Purchase of minority interest in subsidiary | | | (1,143) | | | (1,143) |
| Repurchase of equity | | | (220) | | | (220) |
| Tax benefit on exercise of stock options | | | 25 | | | 25 |
| Share-based compensation expense | | | 10,752 | | | 10,752 |
| Common shares issued | 38,568 | 4 | 14 | | | 18 |
| At December 31, 2009 | 17,141,710 | 1,714 | 177,246 | 54,119 | 7,190 | 240,269 |
| Net income | | | | 44,208 | | 44,208 |
| Other comprehensive income: | | | | | | |
| Unrealized loss on derivative instrument (net of taxes of $36) | | | | | (90) | (90) |
| Translation adjustment | | | | | (1,710) | (1,710) |
| Total comprehensive income | | | | | | 42,408 |
| 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) |
| Other comprehensive loss: | | | | | | |
| Unrealized loss on derivative instrument (net of taxes of $256) | | | | | (437) | (437) |
| Translation adjustment | | | | | (3,192) | (3,192) |
| Total comprehensive loss | | | | | | (4,702) |
| 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 |

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Consolidated Statements of Cash Flows**

**For the years ended December 31, 2011, 2010 and 2009**

| (U.S. Dollars, in thousands) | 2011 | 2010 | 2009 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income (loss) | $ (1,073) | $ 44,208 | $ 24,472 |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: | | | |
| Depreciation and amortization | 22,776 | 22,521 | 22,344 |
| Amortization of debt costs | 1,239 | 471 | 248 |
| Provision for doubtful accounts | 11,532 | 8,746 | 7,335 |
| Deferred income taxes | 936 | 178 | (4,409) |
| Share-based compensation | 6,648 | 8,138 | 10,752 |
| Provision for inventory obsolescence | 5,463 | 7,376 | 8,760 |
| Loss on refinancing of credit facility | | 550 | |
| Gain on interest rate swap | | (1,254) | (1,852) |
| Net gain on sale of vascular operations | | (12,019) | |
| Tax benefit on non-qualified stock options | (1,737) | (2,222) | (25) |
| Other | 2,823 | (1,778) | 2,541 |
| Changes in operating assets and liabilities, net of effect of sale of vascular operations and acquisitions: | | | |
| Trade accounts receivable | (25,818) | (14,770) | (23,858) |
| Inventories | (13,812) | (222) | (8,941) |
| Escrow receivable | (32,562) | (2,049) | |
| Prepaid expenses and other current assets | (4,057) | (7,214) | (12) |
| Trade accounts payable | 576 | (2,863) | (1,310) |
| Charges related to U.S. Government resolutions | 88,463 | | |
| Other current liabilities | 3,384 | (5,289) | 14,537 |
| | | | |
| Net cash provided by operating activities | 64,781 | 42,508 | 50,582 |
| Cash flows from investing activities: | | | |
| Capital expenditures for property, plant and equipment | (24,965) | (25,844) | (20,915) |
| Capital expenditures for intangible assets | (793) | (517) | (1,083) |
| Payment made in connection with acquisition | (5,250) | | |
| Investment related to collaborative arrangement | | | (2,000) |
| Proceeds from sale of investments held at cost | | | 1,711 |
| Net proceeds from the sale of vascular operations | | 24,215 | |
| | | | |
| Net cash used in investing activities | (31,008) | (2,146) | (22,287) |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of common shares | 20,113 | 7,854 | 70 |
| Payment of refinancing fees and debt issuance costs | (758) | (4,266) | |
| Repayments of long-term debt | (7,500) | (36,269) | (28,323) |
| Proceeds from (repayment of) bank borrowings, net | (2,561) | 1,723 | 248 |
| Changes in restricted cash | (24,178) | (11,290) | (612) |
| Cash payment for purchase of minority interest in subsidiary | (517) | | (1,143) |
| Tax benefit on non-qualified stock options | 1,737 | 2,222 | 25 |
| Repurchase of equity | | | (220) |
| | | | |
| Net cash used in financing activities | (13,664) | (40,026) | (29,955) |

| | | | |
|---|---|---|---|
| Effect of exchange rates changes on cash | (463) | (103) | 394 |
| | | | |
| Net increase (decrease) in cash and cash equivalents | 19,646 | 233 | (1,266) |
| Cash and cash equivalents at the beginning of the year | 13,561 | 13,328 | 14,594 |
| | | | |
| Cash and cash equivalents at the end of the year | $ 33,207 | $ 13,561 | $ 13,328 |
| | | | |
| **Supplemental disclosure of cash flow information:** | | | |
| Cash paid during the year for: | | | |
| Interest | $ 17,088 | $ 16,032 | $ 26,724 |
| | | | |
| Income taxes | $ 26,227 | $ 29,743 | $ 17,665 |

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements**

**Description of business**

Orthofix International N.V. (the Company ) is a diversified, global medical device company focused on developing and delivering innovative repair and regenerative technologies to the spine and orthopedic markets. The Company is comprised of three reportable segments: Spine, Orthopedics, and Sports Medicine 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.

**(b) Use of estimates in preparation of financial statements**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ( U.S. ) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates including those related to resolution of U.S. government matters, contractual allowances, doubtful accounts, inventories, taxes, shared-based compensation and potential goodwill and intangible asset impairment. Actual results could differ from these estimates.

**(c) Foreign currency translation**

All foreign currency denominated 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 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 $1.6 million loss, $0.1 million loss and $0.5 million loss for the years ended December 31, 2011, 2010 and 2009, respectively.

**(d) Reporting currency**

The reporting currency is the U.S. Dollar.

**(e) Cash and cash equivalents**

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

**(f) Restricted cash**

Restricted cash consists of cash held at certain subsidiaries, the distribution or transfer of which to Orthofix International N.V. (the Parent ) or other subsidiaries that are not parties to the credit facility described in Note 8 is restricted. The senior secured credit facility restricts the Parent and subsidiaries that are not parties to the facilities from access to cash held by Orthofix Holdings, Inc. and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes.

**(g) Market risk**

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. The Company s objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective the Company seeks to balance its non-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 2011, 2010, and 2009, 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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements**

**(h) Inventories**

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess or obsolete items. Cost is determined on a weighted-average basis, which approximates the first-in, first-out ( FIFO ) method. The valuation of work-in-process, finished products, field inventory and consignment inventory includes the cost of materials, labor and production. Field inventory represents immediately saleable finished products inventory that is in the possession of the Company s direct sales representatives. Consignment inventory represents immediately saleable finished products located at third party customers, such as distributors and hospitals.

**(i) Long-lived assets, including intangibles 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, except for land, which is not depreciated. 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. 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 ), trademarks and distribution networks. 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 and distribution networks is 11 and 10 years, respectively.

Intangible and long-lived assets with definite lives, such as Orthofix s developed technologies and distribution network assets, 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 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 and certain indefinite lived trademarks 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 three reporting units, which are consistent with the Company s reporting segments; Spine, Orthopedics, and Sports Medicine (see Note 12 for additional information).

During 2011 the Company elected to perform the optional Step Zero qualitative assessment to support the fair value of its spine reporting unit whereby if an entity concludes that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, it would not be required to perform the two-step impairment test for that reporting unit. During 2011 the Company performed the Step Zero qualitative assessment for its spine reporting unit and noted no impairments were to be recorded.

In performing the annual impairment test during 2011, 2010 and 2009, which is performed during the fourth quarter or more frequently when impairment indicators exist, the Company utilized the two-step approach prescribed for its orthopedics and sports medicine reporting units in 2011 and all reporting units in 2010 and 2009. The first step requires a comparison of each reporting unit s carrying value to the fair value of the respective unit (see additional discussions below). If the carrying value exceeds the fair value, a second step is performed to measure the amount of impairment loss, if any. No impairments were recorded in 2010 and 2009.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

*Carrying Value*

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.

*Fair Value*

The fair value of each reporting unit was estimated, entirely or predominantly, using an income based approach based on the Company s new reporting units as realigned effective January 1, 2011. 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.

The Company believes the DCF generally provides the most meaningful fair value as it appropriately measures the Company s income producing assets. The Company may consider using a cost approach but generally believes it is not appropriate, given the inability to replicate the value of the specific technology-based assets within the reporting units. In circumstances when the DCF indicator of fair value is not sufficiently conclusive to support the carrying value of a reporting unit, or when other measures provide a more appropriate indicator, the Company may use a market approach in its determination of the reporting unit s fair value.

In performing a DCF calculation, the Company is required to make assumptions about the amount and timing of future expected cash flows, terminal value growth rates and appropriate discount rates. In connection with these estimates, the Company considers the following:

- The determination of expected cash flows is based on the Company s strategic plans and long-range planning forecasts which, to the extent reasonably possible, reflect anticipated changes in the economy and the industry. Revenue growth rates represent estimates based on current and forecasted market conditions. The profit margin assumptions are projected by each reporting unit based on historical margins, the current cost structure and anticipated net cost reductions.

- The terminal value growth rate is used to calculate the value of cash flows beyond the last projected period in the DCF. This rate reflects the Company s estimates for stable, perpetual growth for each reporting unit.

- The discount rates are based on the reporting unit s risk-adjusted weighted average cost of capital, using assumptions consistent with publicly traded guideline companies operating within the medical device industry as well as Company specific risk factors for each reporting unit.

- When a market approach is considered in the determination of a reporting unit s fair value, the Company considers market participant multiples of earnings measures, primarily earnings before interest, taxes, depreciation, and amortization (EBIDTA) and other market based indicators of fair value.

**(j) Investments**

The Company had total investments held at cost of $0.3 million as of December 31, 2010 which represented its minority interest ownership in Biowave Corporation, a pain therapy company. In 2011, the Company assessed the cost investment and noted impairment in the carrying value and recorded a charge to write down its investment in Biowave to zero.

**(k) Derivative instruments**

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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.

**(l) Accumulated other comprehensive income**

Accumulated other comprehensive income is comprised of foreign currency translation adjustments and the effective portion of the gain (loss) on the Company s cross-currency swaps, which are 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, 2009 | $ 6,795 | $ 395 | $ 7,190 |
| Unrealized loss on cross-currency swaps, net of tax of $(36) | | (90) | (90) |
| Foreign currency translation adjustment (1) | (1,710) | | (1,710) |
| Balance at December 31, 2010 | 5,085 | 305 | 5,390 |
| Unrealized loss on cross-currency swaps, net of tax of $256 | | (437) | (437) |
| Foreign currency translation adjustment (1) | (3,192) | | (3,192) |
| | | | |
| Balance at December 31, 2011 | $ 1,893 | $ (132) | $ 1,761 |

(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.

**(m) Revenue recognition and accounts receivable**

Revenue is generally recognized as income in the period in which title passes, 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. Royalty revenues are recognized when the royalty is earned.

For stimulation and certain bracing 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 an agreement 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 a marketing fee from MTF based on total sales. This marketing fee is recorded on a net basis within net sales. 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. MTF and the Company also extended the initial term of their existing agreement for an additional five years.

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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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. These estimates are periodically tested against actual collection experience.

**(n) Sale of accounts receivable**

The Company will generally sell receivables from certain Italian hospitals during the fourth quarter of each year. The estimate of 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.

**(o) Share-based compensation**

The Company recognizes share-based compensation in accordance with ASC Topic 718, *Compensation Stock Compensation ( ASC Topic 718 ).* 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.

**(p) Advertising costs**

The Company expenses all advertising costs as incurred. Advertising expense for the years ended December 31, 2011, 2010 and 2009 was $0.5 million, $0.6 million and $0.7 million, respectively.

**(q) Research and development costs**

Expenditures for research and development are expensed as incurred. Expenditures related to collaborative arrangements with MTF are expensed based on the terms of the related agreements.

**(r) Income taxes**

The Company is subject to income taxes in both the U.S. and foreign jurisdictions, and uses estimates in determining the provision for income taxes. The Company accounts for income taxes using the asset and liability method for accounting and reporting for income taxes. Under this method, deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and income tax basis of assets and liabilities using statutory rates. This process requires that the Company project the current tax liability and estimate the deferred tax assets and liabilities, including net operating loss and tax credit 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 also recognizes a tax benefit from an uncertain tax position if it is more likely than not that the position is sustainable based solely on its technical merits. As of December 31, 2011 and 2010, the Company had $1.2 million and $1.0 million, respectively, inclusive of interest and penalties, of unrecognized tax benefits.

**(s) Net income (loss) per common share**

Net income (loss) per common share basic is computed using the weighted average number of common shares outstanding during each of the respective years. Net income (loss) per common share diluted is computed using the weighted average number of common and common equivalent shares outstanding during each of the respective years using the treasury stock method, if dilutive. Common equivalent shares represent the dilutive effect of the assumed exercise of outstanding share options (see Note 18). The only differences between basic and diluted shares result from the assumed exercise of certain outstanding share options.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

**(t) Recently Issued Accounting Standards**

In June 2011, the FASB issued Accounting Standards Update ( ASU ) No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income.* The update was intended to increase the prominence of other comprehensive income in financial statements and help financial statement users better understand the cause of a company s change in financial position and results of operations. Stakeholders, however, raised concerns that new presentation requirements about the reclassification of items out of accumulated other comprehensive income would be costly for preparers and add unnecessary complexity to financial statements. As a result of these concerns, the FASB decided to reconsider whether it was necessary to require companies to present reclassification adjustments by component in both the statement where net income is presented and the statement where other comprehensive income is presented for both interim and annual financial statements. The result was the issuance of the ASU 2011-12.

In December 2011, the FASB issued Accounting Standards Update ( ASU ) No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income* in ASU No. 2011-05. The update defers the effective date of the requirement to present separate line items on the income statement for reclassification adjustments of items out of accumulated other comprehensive income into net income. The deferral is temporary until the FASB reconsiders the operational concerns and needs of financial statement users. The FASB has not yet established a timetable for its reconsideration. The disclosure requirements of this standard will not have a material effect on the Company s results of operations or financial position as the amendment impacts presentation only.

In September 2011, the FASB issued ASU No. 2011-08, *Testing Goodwill for Impairment (the revised standard).* The revised standard is intended to reduce the cost and complexity of the annual goodwill impairment test by providing both public and nonpublic entities with the option of performing a qualitative assessment to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment test required under current accounting standards. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted for certain companies. The Company adopted the revised standard in 2011. The disclosure requirements of this standard did not have a material effect on the Company s results of operations or financial position.

**2. Inventories**

| | December 31, | |
|---|---|---|
| **(US$ in thousands)** | **2011** | **2010** |
| Raw materials | $ 13,192 | $ 12,186 |
| Work-in-process | 6,150 | 5,855 |
| Finished products | 53,526 | 54,049 |
| Field inventory | 34,565 | 32,915 |
| Consignment inventory | 13,254 | 9,009 |

| | | | | |
|---|---|---|---|---|
| | | 120,687 | | 114,014 |
| Less reserve for obsolescence | | (29,440) | | (29,425) |
| | $ | 91,247 | $ | 84,589 |

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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

**3. Property, plant and equipment**

| (US$ in thousands) | December 31, 2011 | 2010 |
|---|---|---|
| **Cost** | | |
| Buildings | $ 3,829 | $ 3,707 |
| Plant, equipment and instrumentation | 125,823 | 107,379 |
| Furniture and fixtures | 9,140 | 8,629 |
| | | |
| | 138,792 | 119,715 |
| Accumulated depreciation | (86,668) | (74,180) |
| | | |
| | $ 52,124 | $ 45,535 |

Depreciation expense for the years ended December 31, 2011, 2010 and 2009 was $17.2 million, $16.8 million and $15.3 million, respectively.

**4. Patents and other intangible assets**

| (US$ in thousands) | December 31, 2011 | 2010 |
|---|---|---|
| **Cost** | | |
| Patents and developed technologies | $ 29,065 | $ 26,226 |
| Trademarks definite lived (subject to amortization) | 646 | 543 |
| Trademarks indefinite lived (not subject to amortization) | 23,057 | 23,104 |
| Distribution networks | 44,586 | 44,586 |
| | | |
| | 97,354 | 94,459 |
| **Accumulated amortization** | | |
| Patents and developed technologies | (22,073) | (18,267) |
| Trademarks definite lived (subject to amortization) | (416) | (337) |
| Distribution networks | (37,350) | (34,398) |
| | | |
| **Patents and other intangible assets, net** | $ 37,515 | $ 41,457 |

Amortization expense for intangible assets is estimated to be approximately $5.1 million, $4.5 million, $1.5 million, $1.4 million, $0.9 million and $1.1 million for the periods ending December 31, 2012, 2013, 2014, 2015, 2016 and 2017 and thereafter, respectively.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

**5. Goodwill**

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

| (US$ in thousands) | Spine | Orthopedics | Sports Medicine | Total |
|---|---|---|---|---|
| At December 31, 2009 | $ 41,573 | $ 33,507 | $ 110,095 | $ 185,175 |
| Disposals (1) | | | (7,031) | (7,031) |
| Foreign currency | (115) | (1,367) | (165) | (1,647) |
| At December 31, 2010 | 41,458 | 32,140 | 102,899 | 176,497 |
| Acquisitions (2) | | | 3,435 | 3,435 |
| Foreign currency | (39) | (465) | (55) | (559) |
| At December 31, 2011 | $ 41,419 | $ 31,675 | $ 106,279 | $ 179,373 |

(1) In connection with the sale of vascular operations (see Note 20), the Company disposed of goodwill amounting to $7.0 million.
(2) In connection with the acquisition of Omni Motion Inc. on February 17, 2011.

**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 $1.3 million and $3.8 million at December 31, 2011 and 2010, respectively. The weighted average interest rate on borrowings under lines of credit as of December 31, 2011 and 2010 was 4.02% and 3.57%, respectively.

The Company had an unused available line of credit of 6.3 million ($8.1 million) and 4.4 million ($5.9 million) at December 31, 2011 and 2010, 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**

| (US$ in thousands) | December 31, 2011 | 2010 |
|---|---|---|
| Accrued expenses | $ 16,057 | $ 17,916 |
| Salaries, bonuses, commissions and related taxes payable | 28,178 | 24,855 |
| Other payables | 9,754 | 9,647 |
| | $ 53,989 | $ 52,418 |

**8. Long-term debt**

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

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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.

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, 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%. In addition, as of December 31, 2011, $100 million of the Revolving Credit Facility is at the LIBOR rate plus a margin of 3.00% and the remaining $17.4 million of the Revolving Credit Facility is 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, 2011 and 2010 was 3.4%.

The principal amount of the Term Loan Facility amortizes at the rate of 5%, 15%, 25%, 25% and 30% in year 1, 2, 3, 4 and 5, respectively. Amortization payments began on December 31, 2010 and end on December 31, 2015. The aggregate maturities of long-term debt under contractual obligations after December 31, 2011 are as follows: 2012 $17.5 million, 2013 $25.0 million, 2014 $26.3 million and 2015 $139.9 million. Outstanding principal on the Revolving Credit Facility is due on December 31, 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.

In May 2011, the Company obtained an amendment to the Credit Agreement to provide additional capacity under the various restrictive negative covenants for the payment by the Company of the Specified Settlement Amounts (as defined in the Credit Agreement, as amended) associated with each of the potential settlements (See Note 15). The amendment updates the definition of Consolidated EBITDA to exclude Specified Settlement Amounts of up to $50 million in the aggregate. The Company expects to be in compliance with its covenants prospectively.

The Credit Agreement, as amended requires Orthofix Holdings and the Company to comply with coverage ratios 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. Management believes the Company was in compliance with the affirmative and negative covenants at December 31, 2011 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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

The amount of restricted net assets of Orthofix Holdings and its subsidiaries as of December 31, 2011 is $186.0 million compared to $178.5 million at December 31, 2010. 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, 2011 was $47.1 million compared to $22.9 million at December 31, 2010.

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. As of December 31, 2011, debt issuance costs, net of accumulated amortization, related to the Credit Agreement were $3.5 million.

## 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, 2011** | | |
| Cross-currency swap | $ 1,011 | Other long-term assets |
| | | |
| **As of December 31, 2010** | | |
| Cross-currency swap | $ (262) | Other long-term liabilities |

| (US$ in thousands) | For the year ended December 31, 2011 | 2010 | 2009 |
|---|---|---|---|
| Interest rate swap gain recognized in net income (loss) | $ | $ 1,254 | $ 1,852 |
| Cross-currency swap loss recorded in other comprehensive income (loss), net of taxes of $256 | (437) | (90) | (2,702) |

*Cross-currency swap*

In 2006, the Company entered into a cross-currency swap agreement with Wells Fargo 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. The derivative instrument, a ten-year fully amortizable agreement with an initial notional amount of $63.0 million, was scheduled to expire on December 30, 2016. Upon executing the Company s Credit Agreement (see Note 8), the Company terminated this cross-currency swap agreement on September 30, 2010. Also on September 30, 2010, the Company entered into a new cross-currency swap agreement (the replacement swap agreement ) with JPMorgan Chase Bank and Royal Bank of Scotland PLC (the counterparties ).

Upon the termination of the cross-currency swap agreement with Wells Fargo on September 30, 2010, the amount representing the current fair value of the terminated cross-currency swap was $450,000 (the cash settlement amount ). The cash settlement amount was recorded in other long-term assets on the consolidated balance sheets and is being amortized over the remaining life of the underlying transaction, assuming such payments remain probable.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

Under the terms of the replacement swap agreement, the Company pays Euros based on a 33.5 million notional value and a fixed rate of 5.00% and receives U.S. dollars based on a notional value of $45.5 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 replacement swap agreement applies, matures. The replacement 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. During the fourth quarter of 2008, as a result of declining interest rates and a LIBOR floor in the Company s former credit facility, the Swap was no longer deemed highly effective. Special hedge accounting was no longer applied and fair value adjustments were reported in current earnings. On June 29, 2010, the Company settled the Swap with the financial institution holder of the derivative instrument. As part of the terms of the buyout of the Swap, the Company paid $4.8 million to the financial institution holder. As the instrument had a fair value of $6.1 million at December 31, 2009, the transaction 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, 2011, 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

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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, 2011 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Derivative Financial Instruments (1) | | | | |
| Cash Flow Hedges | | | | |
| Cross currency hedge | $ 1,011 | $ | $ 1,011 | $ |

(1) See Note 9, Derivative Instruments .

| (US$ in thousands) | Balance December 31, 2010 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Derivative Financial Instruments (1) | | | | |
| Cash Flow Hedges | | | | |
| Cross currency hedge | $ (262) | $ | $ (262) | $ |

**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, 2011, 2010 and 2009 was approximately $4.8 million, $6.8 million and $6.2 million, respectively. Future minimum lease payments under operating leases, net of amounts to be received under sub-leases, as of December 31, 2011 are as follows:

| (US$ in thousands) | | |
|---|---|---|
| 2012 | $ | 4,197 |
| 2013 | | 3,396 |
| 2014 | | 3,010 |
| 2015 | | 2,924 |
| 2016 | | 2,759 |
| Thereafter | | 6,725 |
| | | |
| Total | $ | 23,011 |

**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. In the future, the CODM may decide to review other financial metrics by GBU. 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. Beginning January 1, 2011, the Company began managing its business by its three GBUs, which are comprised of Spine, Orthopedics and Sports Medicine supported by Corporate activities. These GBUs represent the current segments for which the Company s Chief Operating Decision Maker reviews financial information and makes resource allocation decisions among business units. Accordingly, the Company s segment information (as provided below) has been prepared based on the Company s three GBUs reporting segments. Prior year disclosures have been revised to conform to these new GBU reporting segments. These new 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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

*Orthopedics*

Orthopedics provides a comprehensive 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.

*Sports Medicine*

Sports Medicine designs, manufactures and distributes a portfolio of non-invasive products that allow physicians and clinicians to treat a variety of sports medicine related conditions in order to minimize pain and restore mobility to their patients. Sports Medicine distributes products through a network of domestic and international distributors, sales representatives, and affiliates to hospitals, doctors and other healthcare providers, primarily in the U.S.

*Corporate*

Corporate activities are comprised of the operating expenses of Orthofix International N.V. and its U.S. holding company subsidiary, Orthofix Holdings, Inc., along with activities not necessarily identifiable within the three GBUs.

**Business Segments by GBU:**

| | Year ended December 31, (US$ in thousands) | | | | | |
|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2009 | |
| | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Spine | $ 304,217 | 52% | $ 306,404 | 54% | $ 279,425 | 51% |
| Orthopedics | 165,904 | 29% | 154,198 | 27% | 151,054 | 28% |
| Sports Medicine | 108,867 | 19% | 103,768 | 19% | 115,156 | 21% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Total Net Sales | $ | 578,988 | 100% | $ | 564,370 | 100% | $ | 545,635 | 100% |

Our market sectors are Spine that includes implants, biologics, and also stimulation products, Orthopedics, and Sports Medicine.

**Market Sectors:**

| | Year ended December 31, (US$ in thousands) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | | 2010 | | | 2009 | |
| | Net Sales | | Percent of Total Net Sales | Net Sales | | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Spine Products | | | | | | | | |
| Implants and Biologics | $ | 143,775 | 24% | $ | 133,831 | 23% | $ 120,445 | 22% |
| Stimulation | | 160,442 | 28% | | 172,573 | 31% | 158,980 | 29% |
| Total Spine Products | | 304,217 | 52% | | 306,404 | 54% | 279,425 | 51% |
| Orthopedics Products | | 165,904 | 29% | | 149,175 | 26% | 139,304 | 25% |
| Sports Medicine Products | | 103,040 | 18% | | 95,514 | 18% | 96,446 | 18% |
| Total Strategic Products | | 573,161 | 99% | | 551,093 | 98% | 515,175 | 94% |
| Divested Products | | 5,827 | 1% | | 13,277 | 2% | 30,460 | 6% |
| | | | | | | | | |
| Total Net Sales | $ | 578,988 | 100% | $ | 564,370 | 100% | $ 545,635 | 100% |

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

| Operating Income (Loss) (US$ in thousands) | Year Ended December 31, 2011 | 2010 | 2009 |
|---|---|---|---|
| Spine (1) | $ 46,618 | $ 80,688 | $ 60,830 |
| Orthopedics (2) | 12,368 | 5,879 | 5,781 |
| Sports Medicine (3) | 1,166 | 22,586 | 21,347 |
| Corporate (4) | (27,633) | (20,163) | (24,083) |
| Total | $ 32,519 | $ 88,990 | $ 63,875 |

(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 income for the Sports Medicine GBU included $5 million of litigation and settlement costs for certain product liability matters related to our Sports Medicine GBU. For 2011, the operating income for the Sports Medicine GBU included $2 million of insurance expense to cover additional product liability claims related to our Sports Medicine GBU. For 2010, the operating income for the Sports Medicine GBU included $12 million from the net gain on sale of vascular operations. For 2010, the operating income for the Sports Medicine GBU included $1.7 million of insurance expense to cover new product liability claims from its former pain management operations sold in 2008.

(4) 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 by segment:

| (US$ in thousands) | Depreciation and amortization 2011 | 2010 | 2009 |
|---|---|---|---|
| Spine | $ 11,060 | $ 9,407 | $ 9,154 |
| Orthopedics | 5,506 | 6,282 | 5,733 |
| Sports Medicine | 6,158 | 6,706 | 7,348 |
| Corporate | 52 | 126 | 109 |
| Total | $ 22,776 | $ 22,521 | $ 22,344 |

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

Analysis of property, plant and equipment by geographic area:

| (US$ in thousands) | 2011 | 2010 |
|---|---|---|
| U.S. | $ 39,563 | $ 32,718 |
| Italy | 7,663 | 7,614 |
| U.K. | 1,449 | 1,618 |
| Brazil | 2,532 | 2,400 |
| Others | 917 | 1,185 |
| Total | $ 52,124 | $ 45,535 |

**13. Income taxes**

Income before provision for income taxes consisted of:

| (US$ in thousands) | Year Ended December 31, 2011 | 2010 | 2009 |
|---|---|---|---|
| U.S. | $ 18,762 | $ 57,849 | $ 28,542 |
| Non-U.S. | 1,941 | 14,549 | 11,479 |
| | $ 20,703 | $ 72,398 | $ 40,021 |

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

| (US$ in thousands) | Year Ended December 31, 2011 | 2010 | 2009 |
|---|---|---|---|
| U.S. | | | |
| Current | $ 17,351 | $ 23,208 | $ 17,929 |
| Deferred | (169) | (1,533) | (6,698) |
| Non-U.S. | | | |
| Current | 3,489 | 4,804 | 2,029 |
| Deferred | 1,105 | 1,711 | 2,289 |
| Total tax expense | $ 21,776 | $ 28,190 | $ 15,549 |

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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

| (US$ in thousands) | 2011 | 2010 |
|---|---|---|
| Patents, trademarks, other intangible assets and goodwill | $ (5,144) | $ (6,048) |
| Property, plant and equipment | (9,767) | (6,672) |
| Withholding taxes | (9,777) | (8,102) |
| Inventories and related reserves | 11,920 | 11,576 |
| Accrued compensation | 6,833 | 15,484 |
| Allowance for doubtful accounts | 4,278 | 4,163 |
| Interest | 16,123 | 12,471 |
| Net operating loss carryforwards | 20,161 | 21,790 |
| Other, net | 1,241 | 1,856 |
| Valuation allowance | (19,116) | (21,023) |
| | | |
| Net deferred tax asset | $ 16,752 | $ 25,495 |

In 2011 the Company made a reclassification adjustment of approximately $9 million from deferred tax assets to additional paid-in-capital. The reduction in the deffered tax asset related to a benefit taken for the exercise of stock options through December 31, 2011.

The valuation allowance as of December 31, 2011 and 2010 was $19.1 million and $21.0 million, respectively. The net decrease in the valuation allowance of $1.9 million during the year principally relates to the reduction of net operating losses due to the expiration of carryforward periods, partially offset by 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 that location. 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 deductible differences, net of the existing valuation allowances at December 31, 2011.

The Company has state net operating loss carryforwards of approximately $23.7 million that begin to expire in 2012. The Company has net operating losses of foreign taxing jurisdictions of approximately $74.1 million with the majority of the losses related to the Company s Netherlands operations expiring in various amounts in tax years beginning in 2012. 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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

The rate reconciliation 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) | 2011 | | 2010 | | 2009 | |
|---|---|---|---|---|---|---|
| | Amount | Percent | Amount | Percent | Amount | Percent |
| Statutory U.S. federal income tax rate | $ 7,246 | 35% | $ 25,339 | 35% | $ 14,007 | 35% |
| State taxes, net | 1,682 | 8.1% | 2,903 | 4.0% | 1,574 | 3.9% |
| Foreign rate differential | 1,489 | 7.2% | (1,299) | (1.8)% | (1,401) | (3.5)% |
| Valuation allowance foreign losses | 4,418 | 21.3% | 3,874 | 5.4% | 2,861 | 7.2% |
| Italy step-up amortization | (2,421) | (11.7)% | (2,607) | (3.6)% | (2,573) | (6.4)% |
| Domestic manufacturing deduction | (1,416) | (6.8)% | (1,944) | (2.7)% | (839) | (2.1)% |
| Settlement of U.S. Government resolutions | 9,745 | 47.1% | | 0.0% | | 0.0% |
| Other items, net | 1,033 | 5.0% | 1,924 | 2.6% | 1,920 | 4.8% |
| | | | | | | |
| Income tax expense/effective rate | $ 21,776 | 105.2% | $ 28,190 | 38.9% | $ 15,549 | 38.9% |

The income tax expense and effective tax rate for the year ended 2011 reflects a disproportionate ratio to the $28.2 million of income tax expense and effective tax rate of 38.9%. 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 for 2011 was 38.1% excluding the impact of the charges related to the U.S. Government resolutions. The effective tax rate of 38.9% for 2010 was impacted by the $12 million net gain on the sale of vascular operations.

The Company s gross unrecognized tax benefit was $0.7 million and $0.6 million for the years ended December 31, 2011 and 2010, 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 $0.5 million and $0.4 million accrued for payment of interest and penalties as of December 31, 2011 and 2010, 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, 2011, 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) for the years ended December 31, 2011 and December 31, 2010 follows:

| (US$ in thousands) | 2011 | 2010 |
|---|---|---|
| Balance as of January 1, | $ 569 | $ 442 |
| Additions for current year tax positions | 162 | 70 |
| Decreases (increases) for prior year tax positions | (17) | 57 |
| Expiration of statutes | (28) | |
| | | |
| Balance as of December 31, | $ 686 | $ 569 |

The Company files a consolidated income tax return in the U.S. federal jurisdiction and numerous consolidated and separate income tax returns in many state and foreign jurisdictions. The statute of limitations with respect to federal tax authorities is closed for years prior to December 31, 2008. The statute of limitations for the various state tax filings is closed in most instances for the years prior to December 31, 2007. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to December 31, 2006.

The Company s intention is to reinvest the total amount of its unremitted foreign earnings (residing outside the Netherland Antilles) in the local jurisdiction, to the extent they are generated and available, or to repatriate

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

the earnings only when tax-effective. As such, the Company has not provided tax expense on $301.8 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, 2011, 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 Company has sold bracing products to OrthoRx, an entity in which the Company has a minority interest equity ownership, in the three years ended December 31, 2011. The following table summarizes these related party balances and transactions as of and for the years ended December 31, 2011, 2010 and 2009.

| | Year Ended December 31, | | |
|---|---|---|---|
| **(US$ in thousands)** | **2011** | **2010** | **2009** |
| Sales | $ 479 | $ 3,081 | $ 4,043 |
| Purchases | $ | $ 4,911 | $ 11,901 |
| Accounts payable | $ | $ 334 | $ 1,481 |
| Accounts receivable | $ 106 | $ 676 | $ 563 |

**15. 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 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 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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

In addition to the matters described in the paragraphs below, in the normal course of our 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 reasonable estimable. As of December 31, 2011, the Company has recognized an aggregate accrual of $1.2 million for such additional matters. The Company believes additional 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

On or about July 23, 2007, the Company s subsidiary, Blackstone Medical, Inc. ( Blackstone ) received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena sought documents for the period January 1, 2000 through July 31, 2006, which is prior to Blackstone s acquisition by the Company. The Company believes that the subpoena concerned the compensation of physician consultants and related matters. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the agreement and plan of merger between the Company, New Era Medical Corp. and Blackstone, dated as of August 4, 2006 (the Blackstone Merger Agreement ), for any losses to the Company resulting from this matter. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement.

On or about January 7, 2008, the Company received a federal grand jury subpoena from the U.S. Attorney s Office for the District of Massachusetts. The subpoena sought documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerned the compensation of physician consultants and related matters, and further believes that it was associated with the Department of Health and Human Services, Office of Inspector General s investigation of such matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On or about April 29, 2009, counsel received a HIPAA subpoena issued by the U.S. Department of Justice. The subpoena sought documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerned the compensation of physician consultants and related matters, and further believes that it was associated with the Department of Health and Human Services, Office of Inspector General s investigation of such matters, as well as the January 7, 2008 federal grand jury subpoena. On or about August 26, 2010, counsel for Orthofix Inc. and Blackstone executed a tolling agreement with the U.S. Attorney s Office for the District of Massachusetts (the Tolling Agreement ) that extended an agreement tolling the statute of limitations applicable to any criminal, civil, or administrative proceedings that the government might later initiate to include the period from December 1, 2008 through and including October 31, 2010. On or about February 1, 2011, the parties further extended the tolling of the statute of limitations through and including May 31, 2011 with respect to any criminal proceedings that the government might later initiate.

On or about December 5, 2008, the Company obtained a copy of a qui tam complaint filed by Susan Hutcheson and Philip Brown against Blackstone and the Company in the U.S. District Court for the District of Massachusetts. A qui tam action is a civil lawsuit brought by an individual for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. On September 18, 2008, after being informed of the existence of the lawsuit by representatives of the U.S. Department of Justice and prior to the unsealing of the complaint (which was unsealed by the court on or about November 24, 2008), the Company submitted a claim for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for any losses to the Company resulting from this matter. On November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. The complaint was served on Blackstone on or about March 24, 2009. Counsel for the plaintiffs filed an amended complaint on June 4, 2009. The amended complaint sets forth a cause of action against Blackstone under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants; Orthofix is not named as a defendant in the amended complaint. The Company understands that this lawsuit was related to the matters described above involving the U.S. Department of Health and Human Services, Office of the Inspector General, the U.S. Attorney s Office for the District of Massachusetts, and the U.S. Department of Justice. On or about March 12, 2010, the United States District Court for the District of Massachusetts granted Blackstone s motion to dismiss and, on March 15, 2010, entered judgment in favor of Blackstone. On June 1, 2011, the United States Court of Appeals for the First Circuit reversed the motion to dismiss and remanded to the district court for further proceedings. In response to a joint motion to stay the action, on August 22, 2011, the United States District Court for the District of Massachusetts entered an order administratively closing the lawsuit for a period of no more than ninety (90) days. On August 30, 2011, Blackstone filed with the United States Supreme Court a Petition for a Writ of Certiorari to review the June 1, 2011 judgment of the United States Court of Appeals for the First Circuit, which was denied on December 5, 2011.

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**Notes to the consolidated financial statements (cont.)**

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 the matters described in the immediately preceding two paragraphs. The Company is currently in discussions with the Boston USAO, the United States Department of Justice ( DOJ ), and the Office of Inspector General of the Department of Health and Human Services ( OIG ), as to the terms of definitive written agreements to finally resolve these matters. Based on information currently available, the Company believes that it is probable that a final written definitive settlement agreement with the U.S. Government will be entered into on these economic terms, which, as described below, would be fully funded from the escrow fund established in connection with the Blackstone Merger Agreement. There can be no assurance that we will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, the Company believes that the likelihood of any such additional material loss in excess of this amount is remote.

In 2007 and 2008, the Company received certain other subpoenas from state and federal entities related to Blackstone s financial relationship with physicians, which the Company has described in prior reports. The Company has fully responded to each of these subpoenas, and there are currently no pending proceedings related to any of these matters.

Under the Blackstone Merger Agreement, the former shareholders of Blackstone agreed to indemnify the Company for breaches of representations and warranties under the agreement as well as certain other specified matters. These post-closing indemnification obligations of the former Blackstone shareholders were limited to a cumulative aggregate amount of $66.6 million. At closing, an escrow fund was established pursuant to the terms of the Blackstone Merger Agreement to fund timely submitted indemnification claims. The initial amount of the escrow fund was $50.0 million. As of December 31, 2011, the escrow fund, contained $47.5 million.

In February 2012, the Company 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 the Company (which will be used, among other things, to fund the proposed $32.0 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, the Company had recognized $15.5 million as escrow receivables on the consolidated balance sheet, reflecting previously incurred expenses that the Company believed were reasonably assured of collection.

The Company received approximately $9.5 million in cash from the escrow fund after application of (i) the $32.0 million allocated to the settlement in principle described above with the government and (ii) approximately $1 million of other fees incurred with respect to this matter since September 30, 2011. As a result, the Company has 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.

Matters Related to Regenerative Stimulation Business

On or about April 10, 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. The Boston USAO issued supplemental subpoenas seeking documents in this matter, dated September 21, 2009, December 16, 2009, October 13, 2010, October 14, 2010, October 18, 2010, December 3, 2010 and January 13, 2011, respectively. The subpoenas seek documents for the period January 1, 1995 through the date of the respective subpoenas. The Boston USAO also issued two supplemental subpoenas requiring testimony in this matter dated July 23, 2009 and June 3, 2010. That office excused performance with the July 23, 2009 subpoena indefinitely. The Boston USAO has provided the Company with grand jury subpoenas for the testimony of certain current and former employees in connection with its ongoing investigation. The Company has been cooperating, and intends to continue to cooperate, with the government s requests. In meetings with the Company and its attorneys regarding this matter, the Boston USAO informed the Company that it is investigating possible criminal and civil violations of federal law related to the Company s promotion and marketing of its regenerative stimulator devices.

On or about April 14, 2009, the Company obtained a copy of a qui tam complaint filed by Jeffrey J. Bierman 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. By order entered on March 24, 2009, the court unsealed the case. The Company and Orthofix Inc. were served on or about September 8, 2009. With leave of the court, the relator s Second Amended Complaint was filed on June 11, 2010. The complaint alleges various causes of action under the federal False Claims

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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 includes 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. The Company believes that this lawsuit is related to the matter described above involving the HIPAA subpoena. On or about December 4, 2010, the U.S. District Court for the District of Massachusetts denied the Company s motion to dismiss.

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. The Company is currently finalizing definitive written agreements with the Boston USAO, the United States Department of Justice ( DOJ ), and the Office of Inspector General of the Department of Health and Human Services ( OIG ) to finally resolve these matters. The Company expects that under the terms of these agreements, it will pay $43 million, and the Company has recorded a charge of $43 million during the first quarter of 2011 in anticipation of this agreement. The Company expect that (i) its subsidiary, Orthofix Inc., will plead to a violation of 18 U.S.C. 1516 (obstruction of federal audit) related to a June 2008 federal audit, and (ii) Orthofix International N.V. and Orthofix Inc will enter into a five-year Corporate Integrity Agreement (CIA) with the OIG as part of the resolution of these matters. Based on information currently available, the Company believes that it is probable that a final definitive written settlement agreement with the U.S. Government will be entered into on these terms. The Company has therefore recognized an accrual for $43 million during the first quarter of 2011. There can be no assurance that the Company will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, the Company believes that the likelihood of any such additional material loss in excess of this amount is remote.

Matters Related to Promeca

During the second quarter of 2010 internal management review of Promeca S.A. de C.V. ( Promeca ), one of the Company s Mexican subsidiaries, the Company received allegations of improper payments, allegedly made by certain of Promeca s local employees in Mexico, to employees of a Mexican governmental healthcare entity. The Company engaged Hogan Lovells US LLP and Deloitte Financial Advisory Services LLP to conduct an internal investigation (the Promeca Internal Investigation ) focusing on compliance with the Foreign Corrupt Practices Act ( FCPA ) and voluntarily contacted the Securities and Exchange Commission (the SEC ) and the United States Department of Justice ( DOJ ) to advise both agencies that an internal investigation was underway. Promeca accounted for approximately one percent of the Company s consolidated net sales and consolidated total assets. On or about November 16, 2010, the Company received a subpoena from the SEC and DOJ seeking documents related to this matter. The Company has completed its production of documents to the SEC and DOJ in connection with the subpoena.

The Company completed the Promeca Internal Investigation in April 2011 and commenced settlement discussions with the U.S. Government regarding this matter in May 2011. In January 2012, the Company reached an agreement in principle to settle these matters with DOJ. We are currently in discussions with DOJ as to the final terms of such resolution, and are also currently engaged in discussions regarding a settlement of such matters with the SEC. The Company previously recorded a charge related to these matters of $3 million during the first quarter of 2011, and have subsequently recorded an additional charge of $4.5 million during the fourth quarter of 2011 to establish an additional accrual in anticipation of a future final resolution of these matters with both DOJ and the SEC. There can be no assurance that the Company will enter into a consensual resolution of these matters, or what the final terms of any such resolution might be; however, the Company believes based on

information known to date that the likelihood of any such additional material loss in excess of this amount is remote.

Matters Related to Breg

The Company s subsidiary, Breg, Inc ( Breg ), was engaged in the manufacturing and sale of local infusion pumps for pain management from 1999 to 2008, when the product line was divested. 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 our insurance carriers has asserted to us that certain potential losses related to this matter are not covered by our insurance coverage, and we are currently in arbitration with this carrier. We currently cannot reasonably estimate any further possible loss, or range of loss, in connection with these matters.

On or about August 2, 2010, Breg received a HIPAA subpoena issued by the U.S. Department of Justice ( DOJ ). The subpoena seeks documents from the Company and its subsidiaries for the period January 1, 2000 through the date of the subpoena. Document production in response to the subpoena is ongoing. The Company believes that this subpoena relates to an investigation by 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. 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. The Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with these matters.

Breg is currently engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Beginning in 2010, several domestic product liability cases have been filed, 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. 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. The Company currently cannot reasonably estimate the possible loss, or range of loss, in connection with this matter.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

**16. 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. Breg also sponsors a 401(k) plan (the Breg 401(k) plan ). The Breg 401(k) Plan allows for participants to contribute up to 100% of their compensation, subject to certain limitations, with the Company matching 100% of the first $1,000 deferred. Blackstone also sponsors a 401(k) plan (the Blackstone 401(k) Plan ). The Blackstone 401(k) Plan allows for participants to contribute up to 75% of their compensation, subject to certain limitations, with the Company matching 50% of the first 6% of the employee s deferred compensation. The Blackstone 401(k) Plan merged into the Orthofix Inc. 401(k) Plan at the beginning of 2010. During the years ended December 31, 2011, 2010 and 2009, expenses incurred relating to 401(k) Plans, including matching contributions, were approximately $2.6 million, $2.8 million and $1.9 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 2011, 2010 and 2009 were $0.8 million, $0.7 million and $1.0 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 Company s expense for deferred compensation during 2011, 2010 and 2009 was approximately $0.1 million, $0.1 million and $0.6 million, respectively. Deferred compensation payments of $0.2 million and $0.6 million were made in 2010 and 2009, respectively. There were no payments made during 2011. The balance as of December 31, 2011 and 2010 was $1.5 million and 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.

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. Under the Plan, employees of the Company and its subsidiaries are eligible to participate if the employee is in management or a highly compensated employee and is named by the Board of Directors to be a participant in the Plan. All directors were eligible to participate in the Plan, but effective January 1, 2009, they were prohibited from further participation, unless a director performs services as an employee attributable, for tax purposes, to any U.S. subsidiary of the Company. An eligible employee may elect to enter into a salary deferral commitment and/or a director s fees deferral commitment with respect to any plan year by submitting a participation agreement to the plan administrator by December 31 of the calendar year immediately preceding the plan year. Further, an eligible employee may elect to enter into a bonus deferral commitment with respect to bonus compensation earned during any plan year by submitting a participation agreement to the plan administrator by December 31 of the calendar year immediately preceding the plan year. Deferral commitments can be stated as a percentage or a flat dollar amount as allowed by the plan administrator. A participant s participation agreement will remain in effect only for the immediately succeeding plan year. Distributions are made in accordance with the

requirements of Code Section 409A.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

**17. Share-based compensation plans**

At December 31, 2011, the Company had three stock option and award plans and one stock purchase plan which are described below.

*2004 Long Term Incentive Plan*

The 2004 Long Term Incentive Plan (the 2004 LTIP Plan ) is a long term incentive plan that was originally adopted in April 2004. The 2004 LTIP Plan was approved by shareholders on June 29, 2004 and 2.0 million shares were reserved for issuance under this plan (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. On June 20, 2007, the Company s shareholders approved amendments and a restatement of the 2004 LTIP Plan, providing for the following major changes: an increase in the number of shares available for grant from 2.0 million shares to 2.8 million shares, a specific allowance for grants of restricted stock awards, and a provision for fixed awards to non-employee directors on the date of their first election to the Board and on each subsequent re-election. On June 19, 2008, the Company s shareholders approved further amendments to the 2004 LTIP Plan to increase the number of shares available for grant from 2.8 million shares to 3.1 million shares, to increase the annual grant to non-employee directors from 3,000 shares to 5,000 shares, and to limit in the future the number of shares that may be awarded under the plan as full value awards to 100,000 shares. At December 31, 2011, there were 2,371,147 options outstanding under the 2004 LTIP Plan, of which 1,891,828 were exercisable; in addition, there were 69,000 shares of restricted stock outstanding, none of which were vested.

*Staff Share Option Plan*

The Staff Stock Option Plan (the Staff Plan ) is a fixed stock option plan which was adopted in April 1992. Under the Staff 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 Plan expire ten years after the date of grant. There are no options left to be granted under the Staff Plan. At December 31, 2011, there were 58,125 options outstanding and exercisable under the Staff Plan.

*Performance Accelerated Stock Option Inducement Grants*

On December 30, 2003, the Company granted inducement stock option awards to two key executives of Breg, in conjunction with the acquisition of Breg. The exercise price was fixed at $38.00 per share on November 20, 2003, when the Company announced it had entered into an agreement to acquire Breg. The inducement grants included both service-based and performance-based vesting provisions. The inducement grants became 100% vested on the fourth anniversary of the grant date but are subject to certain exercisability limitations. Following vesting on December 30, 2007, the original inducement grants limited the executives ability to exercise specific numbers of options during the years 2008 through 2012. Prior to the options fully vesting and as an inducement for the executives to extend the term of their employment agreements for one year, in November 2007 the Company entered into amended award agreements with the two executives. The amended agreements did not change the vesting date of the options, but provided that the options granted thereunder will only be exercisable during the fixed period beginning January 1, 2009 and ending on December 31, 2010**.** In December 2008, in order to meet certain requirements of Code Section 409A and the Treasury Regulations

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

promulgated thereunder, and fulfill the Company s desire to extend each of the executives terms of employment with the Company, the Company and the executives entered into second amended and restated award agreements. The second amended agreements provided for the election by the executives of respective periods during which they can exercise options. Bradley Mason elected to exercise 50,000 options in each of the following periods: April 1, 2010 through December 31, 2010, January 1, 2011 through December 31, 2011 and January 1, 2012 through December 31, 2012. William Hopson elected to exercise his 50,000 options in the period between January 1, 2011 and December 31, 2011. Subject to certain termination of employment provisions and notwithstanding any other provisions of the second amended agreements, any portion of the options that are not exercised during their respective exercise periods will not be exercisable thereafter and will lapse and be cancelled. At December 31, 2011, there were 130,000 options outstanding and exercisable under the inducement grants.

*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). On June 20, 2008, the Company s shareholders approved an amendment and restatement of the plan, providing for the following major change: (i) to allow officers and directors of Orthofix Inc. to participate in the plan on the same basis as our other employees, (ii) to provide that the Company will assume and adopt the plan, as amended, in lieu of Orthofix Inc. acting as sponsor of the plan, (iii) to allow non-employee directors of the Company to participate in the plan, (iv) to increase by 500,000 shares the maximum number of shares available for issuance under the plan, and (v) to provide that the determination of the value of common stock under the plan will be determined either on the first or last day of the plan year, whichever date renders the lower value. These changes were generally effective for the plan year starting January 1, 2009. In June 2009, the Company s shareholders approved a further amendment to the Stock Purchase Plan to increase the number of shares available for grant from 950,000 shares to 1,400,000 shares. In May 2010, the Company s shareholders approved an additional increase of 450,000 shares available for grant for a total of 1,850,000 shares.

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, 2011, 1,224,756 shares had been issued under the Stock Purchase Plan.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

*Share-Based Compensation:*

As of December 31, 2011, the unamortized compensation expense relating to options granted and expected to be recognized was $3.4 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, 2011, 2010 and 2009 and the assumptions for each of these years in which grants were awarded:

| (US$ in thousands, except assumptions) | Year Ended December 31, 2011 | Year Ended December 31, 2010 (1) | Year Ended December 31, 2009 |
|---|---|---|---|
| Cost of sales | $ 153 | $ 210 | $ 677 |
| Sales and marketing | 2,031 | 3,505 | 3,045 |
| General and administrative | 4,322 | 4,105 | 6,467 |
| Research and development | 142 | 318 | 563 |
| | | | |
| Total | $ 6,648 | $ 8,138 | $ 10,752 |
| | | | |
| **Assumptions:** | | | |
| Expected term | 4.58 years | | 4.00 years |
| Expected volatility | 49.6% 49.9% | | 45.0% 48.7% |
| Risk free interest rate | 0.90% 2.26% | | 1.60% 2.57% |
| Dividend rate | | | |
| Weighted average fair value of options granted during the year | $ 14.21 | $ | $ 9.29 |

(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, 2011 and 2010 and changes during the year ended December 31, 2011 are presented below:

| | 2011 | |
|---|---|---|
| | Options | Weighted Average |

| | | | Exercise Price |
|---|---|---|---|
| Outstanding at December 31, 2010 | 2,989,469 | $ | 33.20 |
| Granted | 386,000 | $ | 33.08 |
| Exercised | (587,407) | $ | 29.99 |
| Forfeited | (228,790) | $ | 38.88 |
| | | | |
| Outstanding at December 31, 2011 | 2,559,272 | $ | 33.41 |
| | | | |
| Options exercisable at December 31, 2011 | 2,079,953 | | |

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

**Outstanding and exercisable by price range as of December 31, 2011**

| Range of Exercise Prices | | Options Outstanding Number Outstanding | Options Outstanding Weighted Average Remaining Contractual Life | Options Outstanding Weighted Average Exercise Price | Options Exercisable Number Exercisable | Options Exercisable Weighted Average Exercise Price |
|---|---|---|---|---|---|---|
| $10.42 | $25.01 | 452,162 | 5.80 | $ 22.73 | 343,009 | $ 22.57 |
| $25.05 | $28.50 | 189,500 | 6.63 | $ 25.45 | 168,500 | $ 25.31 |
| $28.95 | $28.95 | 267,447 | 5.57 | $ 28.95 | 267,447 | $ 28.95 |
| $29.17 | $32.77 | 265,709 | 5.86 | $ 30.59 | 171,543 | $ 31.32 |
| $33.00 | $37.36 | 274,750 | 8.32 | $ 34.36 | 44,750 | $ 34.63 |
| $37.76 | $38.00 | 275,499 | 1.94 | $ 37.83 | 275,499 | $ 37.87 |
| $38.11 | $39.24 | 279,224 | 3.94 | $ 38.23 | 279,224 | $ 38.23 |
| $39.94 | $43.04 | 325,698 | 3.96 | $ 41.40 | 300,698 | $ 41.50 |
| $44.87 | $50.50 | 221,783 | 4.24 | $ 45.64 | 221,783 | $ 45.64 |
| $50.99 | $50.99 | 7,500 | 5.04 | $ 50.99 | 7,500 | $ 50.99 |
| | | | | | | |
| $10.42 | $50.99 | 2,559,272 | 5.12 | $ 33.41 | 2,079,953 | $ 34.02 |

The weighted average remaining contractual life of exercisable options was 4.28 years at December 31, 2011. The total intrinsic value of options exercised was $4.2 million, $3.0 million and $0.1 million for the years ended December 31, 2011, 2010 and 2009, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2011 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 $35.23 closing price of the Company s stock on December 31, 2011. The aggregate intrinsic value of options outstanding was $10.8 million, $4.8 million and $10.9 million for the years ended December 31, 2011, 2010 and 2009, respectively. The aggregate intrinsic value of options exercisable was $8.4 million, $2.1 million and $1.9 million for the years ended December 31, 2011, 2010 and 2009, respectively.

*Restricted Stock:*

During the year ended December 31, 2008, the Company granted to employees 83,434 shares of restricted stock, which vest at various dates through December 2011. 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 $1.8 million at December 31, 2011.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

A summary of the status of our restricted stock as of December 31, 2011 and 2010 and changes during the year ended December 31, 2011 are presented below:

| | Shares | | Weighted Average Grant Date Fair Value |
|---|---|---|---|
| Non-vested as of December 31, 2010 | 16,647 | $ | 32.38 |
| Granted | 94,000 | $ | 29.23 |
| Vested | (36,647) | $ | 30.66 |
| Cancelled | (5,000) | $ | 29.23 |
| | | | |
| Non-vested as of December 31, 2011 | 69,000 | $ | 29.23 |

**18. 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, | | |
|---|---|---|---|
| | 2011 | 2010 | 2009 |
| Weighted average common shares-basic | 18,219,343 | 17,601,956 | 17,119,474 |
| Effect of diluted securities: | | | |
| Unexercised stock options net of treasury share repurchase | | 311,589 | 83,469 |
| | | | |
| Weighted average common share-diluted | 18,219,343 | 17,913,545 | 17,202,943 |

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 1,487,809 and 1,750,213 outstanding options not included in the diluted earnings per share computation for the fiscal years ended December 31, 2011 and 2010, respectively, because the inclusion of these options was anti-dilutive.

**19. 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.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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 | $ | |

**20. 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. Due to the continuing contractual involvement of these agreements, the transaction did not meet the criteria for presentation as discontinued operations.

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**ORTHOFIX INTERNATIONAL N.V.**

**Notes to the consolidated financial statements (cont.)**

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, 2011.

| **(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.

**21. Quarterly financial data (unaudited)**

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

| | **1 st Quarter** | **2 nd Quarter** | **3 rd Quarter** | **4 th Quarter** | **Year** |
|---|---|---|---|---|---|
| **2011** | | | | | |
| Net sales | $ 139,165 | $ 143,551 | $ 144,747 | $ 151,525 | $ 578,988 |
| Gross profit | $ 105,804 | $ 108,858 | $ 108,718 | $ 116,422 | $ 439,802 |
| Net income (loss) | $ (35,801)(2) | $ 9,958 | $ 12,378 | $ 12,392 | $ (1,073) |
| | | | | | |
| Net income (loss) per common share: | | | | | |
| Basic | $ (2.00) | $ 0.55 | $ 0.67 | $ 0.67 | $ (0.06) |
| Diluted | $ (2.00) | $ 0.54 | $ 0.66 | $ 0.65 | $ (0.06) |
| | | | | | |
| **2010** | | | | | |
| Net sales | $ 138,823 | $ 142,845 | $ 138,906 | $ 143,796 | $ 564,370 |
| Gross profit | $ 106,129 | $ 108,758 | $ 106,640 | $ 111,127 | $ 432,654 |

| | | | | | |
|---|---|---|---|---|---|
| Net income | $ 17,492(1) | $ 10,232 | $ 8,520 | $ 7,964 | $ 44,208 |
| | | | | | |
| Net income per common share: | | | | | |
| Basic | $ 1.00(3) | $ 0.58 | $ 0.48 | $ 0.45 | $ 2.51 |
| Diluted | $ 0.99(3) | $ 0.57 | $ 0.48 | $ 0.44 | $ 2.47 |

(1) Includes the $12.0 million gain on sale of the divested vascular business (see Note 20).

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

(3) The sum of per share earnings by quarter may not equal earnings per share for the year due to the change in average share calculations. This is in accordance with prescribed reporting requirements.

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**Orthofix International N.V.**

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

**Condensed Balance Sheets (unaudited)**

| (US$ in thousands) | December 31, 2011 | December 31, 2010 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 19,433 | $ 2,882 |
| Prepaid expenses and other current assets | 487 | 489 |
| Total current assets | 19,920 | 3,371 |
| Other long term assets | 61 | 113 |
| Investments in and amounts due from subsidiaries and affiliates | 307,202 | 307,397 |
| Total assets | $ 327,183 | $ 310,881 |
| **Liabilities and shareholder s equity** | | |
| Current liabilities | $ 3,900 | $ 1,879 |
| Long-term liabilities | 8,112 | 8,111 |
| Shareholder s equity: | | |
| Common stock | 1,846 | 1,772 |
| Additional paid in capital | 214,310 | 195,402 |
| Accumulated earnings | 97,254 | 98,327 |
| Accumulated other comprehensive income | 1,761 | 5,390 |
| | 315,171 | 300,891 |
| Total liabilities and shareholder s equity | $ 327,183 | $ 310,881 |

*See accompanying notes to condensed financial statements.*

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**Orthofix International N.V.**

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

**Condensed Statements of Operations (unaudited)**

| (US$ in thousands) | Year Ended December 31, 2011 | Year Ended December 31, 2010 | Year Ended December 31, 2009 |
|---|---|---|---|
| (Expenses) income: | | | |
| General and administrative | $ (11,503) | $ (13,146) | $ (10,444) |
| Equity in earnings of investments in subsidiaries and affiliates | 11,111 | 59,620 | 36,592 |
| Other, net | 7 | (390) | 301 |
| | | | |
| Income (loss) before income taxes | (385) | 46,084 | 26,449 |
| Income tax expense | (688) | (1,876) | (1,977) |
| | | | |
| Net income (loss) | $ (1,073) | $ 44,208 | $ 24,472 |

*See accompanying notes to condensed financial statements.*

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**Orthofix International N.V.**

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

**Condensed Statement of Cash Flows**

| (US$ in thousands) | Year Ended December 31, 2011 | Year Ended December 31, 2010 | Year Ended December 31, 2009 |
|---|---|---|---|
| Net income (loss) | $ (1,073) | $ 44,208 | $ 24,472 |
| Equity in earnings of investments in subsidiaries and affiliates | (11,111) | (59,620) | (36,592) |
| Cash used in other operating activities | (1,779) | 7,497 | 3,574 |
| Net cash used in operating activities | (13,963) | (7,915) | (8,546) |
| Cash flows from investing activities: | | | |
| Distributions and amounts received from subsidiaries | 5,875 | 21,597 | 13,237 |
| Capital expenditures | | (5) | (114) |
| Net cash provided by investing activities | 5,875 | 21,592 | 13,123 |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of common stock | 20,113 | 7,854 | 70 |
| Contributions to subsidiaries and affiliates | 2,789 | (21,274) | (4,672) |
| Repurchase of equity | | | (220) |
| Tax benefit on exercise of stock options | 1,737 | 2,222 | 25 |
| Net cash provided by financing activities | 24,639 | (11,198) | (4,797) |
| Net increase (decrease) in cash and cash equivalents | 16,551 | 2,479 | (220) |
| Cash and cash equivalents at the beginning of the year | 2,882 | 403 | 623 |
| Cash and cash equivalents at the end of the year | $ 19,433 | $ 2,882 | $ 403 |

*See accompanying notes to condensed financial statements.*

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**Orthofix International N.V.**

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

**Notes to Condensed Financial Statements (unaudited)**

**1. Background and basis of presentation**

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

**2. Restricted net assets of subsidiaries**

Certain of the Company s subsidiaries have restrictions, with an effective date of August 30, 2010, 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, 2011 and 2010 was approximately $186.0 million and $178.5 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 15 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, $21.6 million and $13.2 million for the years ended December 31, 2011, 2010 and 2009, respectively.

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**Orthofix International N.V.**

**Schedule 2 Valuation and Qualifying Accounts**

For the years ended December 31, 2011, 2010 and 2009:

| (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 |
|---|---|---|---|---|---|
| **2011** | | | | | |
| Allowance for doubtful accounts receivable | $ 7,250 | $ 11,532 | $ (485) | $ (8,252) | $ 10,045 |
| Inventory allowance | 29,425 | 5,463 | | (5,448) | 29,440 |
| Deferred tax valuation allowance | 21,023 | (1,907) | | | 19,116 |
| | | | | | |
| **2010** | | | | | |
| Allowance for doubtful accounts receivable | $ 7,205 | $ 8,746 | $ (60) | $ (8,641) | $ 7,250 |
| Inventory allowance | 23,881 | 7,376 | | (1,832) | 29,425 |
| Deferred tax valuation allowance | 17,239 | 3,784 | | | 21,023 |
| | | | | | |
| **2009** | | | | | |
| Allowance for doubtful accounts receivable | $ 6,473 | $ 7,335 | $ (70) | $ (6,533) | $ 7,205 |
| Inventory allowance | 21,168 | 8,760 | | (6,047) | 23,881 |
| Deferred tax valuation allowance | 14,370 | 2,869 | | | 17,239 |