ORTHOFIX INTERNATIONAL N V
Form 10-K
March 12, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

TANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008
or
£TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

Netherlands Antilles (State or other jurisdiction of incorporation or organization)	N/A (I.R.S. Employer Identification No.)
7 Abraham de Veerstraat Curaçao Netherlands Antilles (Address of principal executive offices)	N/A (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 (Title of Class)	Nasdaq Global Select Market (Name of Exchange on Which Registered)

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes £ No T

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

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 at least the past 90 days.
Yes T No £

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):
Large Accelerated filer £ Accelerated filer T Non-accelerated filer £ (Do not check if a smaller reporting company)
Smaller reporting company £

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

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, 2008, as reported by the Nasdaq Global Select Market, was approximately $485 million.

As of March 11, 2009, 17,103,142 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 2009 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," "anticipates," "believes," "estimates," "projects," "predicts," "potential" or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any such statement, or the risk factors described in Item 1A under the heading "Risk Factors," to reflect new information, the occurrence of future events or circumstances or otherwise.

Factors that could cause actual results to differ materially from those indicated by the forward-looking statements or that could contribute to such differences include, but are not limited to, unanticipated expenditures, changing relationships with customers, suppliers and strategic partners, unfavorable results in litigation or escrow claim matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations, difficulties integrating newly acquired businesses or products, difficulties completing strategic acquisitions or dispositions and the 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 global diversified medical device company offering a broad line of surgical and non-surgical products principally in the Spine, Orthopedics, Sports Medicine and Vascular market sectors. 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 products 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” known informally in the industry as “biologics”); non-invasive bone growth stimulation products designed to enhance the success rate of spinal fusions and to treat non-union fractures; external and internal fixation devices used in fracture treatment, 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 designed to enhance venous circulation, cold therapy, bone cement and devices for removal of bone cement used to fix artificial implants and airway management products used in anesthesia applications.

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, Mexico, Brazil and Puerto Rico. In several other markets we distribute our products through independent distributors.

Orthofix International N.V. is a limited liability company, organized under the laws of the Netherlands Antilles on October 19, 1987. Our principal executive offices are located at 7 Abraham de Veerstraat, Curaçao, Netherlands Antilles, telephone number: 599-9-465-8525. 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 as part of the IDEA database (http://www.sec.gov).

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2008 and 2009 Business Highlights

Product Portfolio Highlights

We continued to expand our products with several new product developments and acquisitions. We also continued to expand our global distribution of our broad product portfolios.

- We received pre-market notification approval, which is commonly referred to as 510(k) approval from the Food and Drug Administration ("FDA") for our new PILLAR(TM) SA spine interbody device and initiated limited market release.
- We received 510(k) approval from the FDA for our Firebird(TM) Spinal Fixation System and initiated limited market release.
- We acquired intellectual property and related technology for a spinal fixation system from Intelligent Implant Systems, LLC.
- We entered into a collaborative agreement with Musculoskeletal Transplant Foundation ("MTF") to develop and commercialize a new stem cell-based allograft.

Global Distribution Highlights

- We also received notification of approval to begin selling our CentroNail family of nailing systems in Japan.
- We received a 10-year exclusive license with Texas Scottish Rite Hospital for Children to extend our collaboration which supplies the TRUE/LOK(TM) External Fixation System to the global orthopedic market.

Business Highlights

Key Management Changes – We made several key management changes recently. In 2008, we appointed Bradley R. Mason (formerly the President of our subsidiary, Breg) to the newly created position of Group President, North America and he also holds the position of President of Orthofix Spine. In June 2008, we appointed Denise Pedulla to the newly created position of Senior Vice President and Chief Compliance Officer. In September 2008, we appointed Robert S. Vaters as our Executive Vice President and Chief Financial Officer.

Amended Credit Facility – In September 2008, we entered into the first amendment to our existing credit agreement dated September 22, 2006. The amendment, which we requested, includes revisions that relax the leverage ratio requirements and clarify certain defined terms in the agreement, among other changes. We believe the changes in the amendment allow us greater flexibility to execute on our global strategies. At December 31, 2008, the term loan is a $150.0 million LIBOR loan, with a 3.0% LIBOR floor, plus a margin of 4.5% and a $130.7 million prime rate loan plus a margin of 3.5%.

Consolidation and Reorganization of Businesses – We have announced several initiatives to consolidate and reorganize our current businesses during the year. Currently, we are consolidating and reorganizing our spine business which will combine the current operations of our Blackstone business in New Jersey and Massachusetts into our Texas facility which currently houses our spine stimulation and U.S. orthopedics operations. In 2008, we closed facilities in Germany and United Kingdom and we will also be closing our facility in Huntersville, NC. These initiatives are part of our effort to increase our operating efficiency and reduce expenses.

Sale of Operations – We completed the sale of intellectual property, business assets and distribution rights related to the Pain Care(R) line of ambulatory infusion pumps previously designed, manufactured and distributed by our Sports Medicine business unit. The sale of these assets is consistent with our strategic goal of focusing on our core sports medicine business including bracing and cold therapy markets. The proceeds from the sale were used to pay down

borrowing on our credit facility in advance of the scheduled maturity date.

Deleveraging the Balance Sheet – We continue to focus on reducing our balance on our credit facility. In 2008, we made principal payments of approximately $17.0 million on our credit facility, of which, $13.7 million was made in advance of the scheduled maturity date. The outstanding credit facility balance was $280.7 million and $297.7 million at December 31, 2008 and 2007, respectively. Our leverage ratio, as defined in the credit facility was 3.42 at December 31, 2008.

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Implementation of Enhanced Corporate Compliance and Ethics Program – We implemented our enhanced corporate compliance and ethics program, Integrity Advantage(TM), during 2008. The program is designed to promote legal compliance and ethical business practices throughout our domestic and international businesses.

Business Strategy

Our business strategy is to offer innovative, orthopedic products to the Spine, Orthopedic, Sports Medicine, and Vascular market sectors that reduce both patient suffering and healthcare costs. Our strategy for growth and profitability includes the following initiatives by market sector:

Spine: Provide a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of spinal conditions. Our main tactics and objectives are;

- Increase revenues with market penetration of spine stimulation;
- Continue new product introductions of spine implants and biologics;
- Improve gross margins on spine implants and biologic products with the introduction of Trinity(R) Evolution(TM); and
- Decrease sales and marketing and general and administrative expenses with the previously mentioned consolidation and reorganization plan.

Orthopedic: Provide a portfolio of non-invasive and implantable products that allow physicians to successfully treat a variety of Orthopedic conditions ranging from trauma to deformity correction. Our main tactics and objectives are;

- Continue new product introductions;
- Maintaining focus on sales of internal fixation, external fixation along with deformity correction devices by expanding sales into the U.S., Latin America, Europe, and Asia;
- Optimize product offerings within each of our geographic markets;
- Focus on sales of long-bone stimulation and biologics in U.S.; and
- Decrease sales and marketing and general and administrative expenses with the previously mentioned consolidation and reorganization plan.

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

- Leverage strong distribution channels with well-established distributor partners;
- Leverage strong market share in high growth areas such as Osteoarthritis knee bracing and Cold Therapy; and
- Launch innovative products into new and existing market segments.

Other Financial and Business Initiatives:

- Reduce operating losses and negative cash flow at Blackstone;
- Continue deleveraging the balance sheet;
- Continue to expand our product 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 and reimbursement relationships.

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Business Segments and Market Sectors

Our business is divided into four reportable segments: Domestic, Blackstone, Breg, and International. Domestic consists of operations of our subsidiary Orthofix Inc., which uses both direct and distributor sales representatives to sell Spine and Orthopedic products to hospitals, doctors, and other healthcare providers in the U.S. market. Blackstone ("Blackstone") consists of Blackstone Medical, Inc., based in Wayne, New Jersey and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Blackstone specializes in the design, development and marketing of spinal implant and related HCT/P products. Blackstone distributes its products through a network of domestic and international distributors, sales representatives and affiliates. Breg designs, manufactures, and distributes orthopedic products for post-operative reconstruction and rehabilitative patient use and sells those Sports Medicine products through a network of domestic and international distributors, sales representatives, and affiliates. International consists of locations in Europe, Mexico, Brazil, and Puerto Rico, as well as independent distributors outside the United States. International uses both direct and distributor sales representatives to sell Spine, Orthopedic, Sports Medicine, Vascular, and Other products to hospitals, doctors and other healthcare providers.

Business Segment:

	Year ended December 31, (In US$ thousands)					
	2008		2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	$ 188,807	36%	$ 166,727	34%	$ 152,560	42%
Blackstone	108,966	21%	115,914	24%	28,134	8%
Breg	89,478	17%	83,397	17%	76,219	21%
International	132,424	26%	124,285	25%	108,446	29%
Total	$ 519,675	100%	$ 490,323	100%	$ 365,359	100%

Additional financial information regarding our business segments can be found in Part II, Item 8 under the heading "Financial Statements and Supplementary Data", as well as in Part II, Item 7 under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations".

We maintain our books and records by business segment; however, we use market sectors to describe our business. The Company's segment information is prepared on the same basis that the Company's management reviews the financial information for operational decision making purposes. Market sectors, which categorize our revenues by types of products, describe the nature of our business more clearly than our business segments.

Our market sectors are Spine, Orthopedics, Sports Medicine, Vascular, and Other.

Market Sector:

	Year ended December 31, (In US$ thousands)					
	2008		2007		2006	
	Net Sales	Percent of Total Net	Net Sales	Percent of Total Net	Net Sales	Percent of Total Net

		Sales		Sales		Sales
Spine	$ 252,239	49%	$ 243,165	49%	$ 145,113	40%
Orthopedics	129,106	25%	111,932	23%	95,799	26%
Sports Medicine	94,528	18%	87,540	18%	79,053	22%
Vascular	17,890	3%	19,866	4%	21,168	6%
Other	25,912	5%	27,820	6%	24,226	6%
Total	$ 519,675	100%	$ 490,323	100%	$ 365,359	100%

Additional financial information regarding our market sectors can be found in Part II, Item 8 under the heading “Financial Statements and Supplementary Data”, as well as in Part II, Item 7 under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

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Products

Our revenues are generally derived from the sales of products in four market sectors, Spine (49%), Orthopedics (25%), Sports Medicine (18%) and Vascular (3%), which together accounted for 95% of our total net sales in 2008. Sales of Other products, including airway management products for use during anesthesia, woman's care and other products, accounted for 5% of our total net sales in 2008.

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

Product	Primary Application
Spine Products	
Spinal-Stim(R)	Pulsed electromagnetic field ("PEMF") non-invasive lumbar spine bone growth stimulator
Cervical-Stim(R)	PEMF non-invasive cervical spine bone growth stimulator
Origin(TM) DBM with Bioactive Glass	A bone void filler
3 Degree/Reliant	Plating systems implanted during anterior cervical spine fusion procedures
Hallmark(R)	A cervical plating system implanted during anterior cervical spine fusion procedures
ICON(TM) Modular Spinal Fixation System	A system of rods, crossbars and modular pedicle screws designed to be implanted during a minimally invasive posterior lumbar spine fusion procedure
Ascent(R) 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
Construx(R) VBR System	A modular device implanted during the replacement of degenerated or deformed spinal vertebrae to provide additional anterior support
Construx(R) Mini VBR System	Smaller, unibody versions of the Construx VBR System, implanted during the replacement of degenerated or deformed spinal vertebrae
Unity(R) Lumbosacral Fixation System	A plating system implanted during anterior lumbar spine fusion procedures
Ngage(R) Surgical Mesh	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

Newbridge(R) Laminoplasty Fixation System	A device implanted during a posterior surgical procedure designed to expand the cervical vertebrae and relieve pressure on the spinal canal
Trinity(R) Bone Matrix	An adult stem cell based bone growth matrix used during surgery that is designed to enhance the success of a spinal fusion procedure
Alloquent(R) 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

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Product	Primary Application
Orthopedic Products	
Fixation	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus(R), XCaliber(TM), Contours VPS(R), VeroNail(R), Centronail(R), and TRUE/LOK(TM)
Physio-Stim(R)	PEMF long bone non-invasive bone growth stimulator
Gotfried PC.C.P(R)	Percutaneous compression plating system for hip fractures
eight-Plate Guided Growth System(R)	Treatment for the bowed legs or knock knees of children
Cemex(R)	Bone cement
ISKD(R)	Internal limb-lengthening device
OSCAR	Ultrasonic bone cement removal
Sports Medicine Products	
Breg(R) Bracing	Bracing products which are designed to provide support and protection of limbs, extremities and back during healing and rehabilitation
Polar Care(R)	Cold therapy products that are designed to reduce swelling, pain and accelerate the rehabilitation process
Vascular Products	
A-V Impulse System(R)	Enhancement of venous circulation, used principally after orthopedic procedures to prevent deep vein thrombosis
Non-Orthopedic Products	
Laryngeal Mask	Maintenance of airway during anesthesia
Other	Several non-orthopedic products for which various Orthofix subsidiaries hold distribution rights

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In 2008, the Company announced the following significant product developments:

- 510(k) approval from the FDA for the new PILLAR SA spine interbody device. The new spinal device is designed to be used in most cases as a stand-alone implant between the spinal vertebrae or as a partial vertebral body replacement, without the need for supplemental internal fixation, during lumbar spinal fusion procedures. Potential benefits of eliminating the need for supplemental fixation include less trauma for the patient, and cost savings for hospital resulting from reduced surgery times. The Company expects PILLAR SA to be available in the U.S. in 2009.

- 510(k) approval from the FDA for the Company's Firebird(TM) Spinal Fixation System. Firebird is a comprehensive system with a modular screw designed to provide surgeons with intra-operative flexibility during various thoracolumbar spine procedures, including the treatment of degenerative disc disease and deformity corrections. The system is also designed to be used in minimally invasive surgical procedures utilizing a percutaneous screw delivery system and the ProView(TM) Minimal Access Portal (MAP) System. The Company expects to make the Firebird system widely available in the U.S. beginning during the first quarter of 2009.

- Trinity(R) Evolution(TM), the adult stem cell-based allograft developed in collaboration with the Musculoskeletal Transplant Foundation (MTF) is expected to be released in the second quarter of 2009. Trinity(R) Evolution(TM) is an adult stem cell-based bone growth matrix designed to advance the surgical use of allografts by providing characteristics similar to an autograft used in spinal and orthopedic surgeries.

We have proprietary rights in all of the above products with the exception of the Laryngeal Mask, Cemex(R), ISKD(R), eight-Plate Guided Growth System(R), Contours VPS(R) and Trinity(R) Bone Matrix. We have the exclusive distribution rights for the Laryngeal Mask and Cemex(R) in Italy, for the Laryngeal Mask in the United Kingdom and Ireland and for the ISKD(R), eight-Plate Guided Growth System(R) and Contours VPS(R) worldwide. We have U.S. distribution rights for Trinity(R) Bone Matrix for use in spinal and orthopedic applications.

We have numerous trademarked products and services including but not limited to the following: Orthofix(R), ProCallus(R), XCaliber(TM), Gotfried PC.C.P(R), Spinal-Stim(R), Cervical-Stim(R), Physio-Stim(R), Origin(TM) DBM, Blackstone(R), Alloquent(R), Ascent(R), Construx(R), Hallmark(R), ICON(TM), Newbridge(R), Ngage(R), Trinity(R) Matrix, Unity(R), Breg(R), Polar Care(R), and Fusion(R).

Spine

Spine product sales represented 49% of our total net sales in 2008.

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 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 at many points along the continuum of care, offering non-operative, pre-operative, operative and post-operative products. 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.

Blackstone offers a wide array of spinal implants 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 Blackstone's metal plates, rods and screws, interbody spacers, or vertebral body replacement devices, and human cellular and tissue based products (HCT/P) as well as interbody spacers or to promote bone growth.

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Additionally, bone growth stimulators used in spinal applications are designed to enhance 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 Implants

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 posteriorly, or from the 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 HCT/P material designed to accelerate the formation of new bone around the graft which ultimately results in the desired fusion.

Blackstone provides 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, Blackstone's product portfolio includes a unique adult stem cell-based HCT/P bone grafting product called Trinity(R) Matrix.

The majority of implants offered by Blackstone are made of titanium metal. This includes the 3 Degree, Reliant and Hallmark(R) cervical plates. Additionally, the Spinal Fixation System ("SFS"), the ICON(TM) Modular Spinal Fixation System, the Firebird(TM) Spinal Fixation Systems, the Ascent(R) and Ascent(R) LE POCT Systems are sets of rods, crossbars and screws which are implanted during posterior fusion procedures. The ICON(TM) Modular Spinal Fixation System and the more recently introduced Firebird(TM) Spinal Fixation System are both designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with Blackstone's ProView(TM) Minimal Access Portal (MAP) System. The Company also offers 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(R) Laminoplasty Fixation System that is designed to expand the cervical vertebrae and relieve pressure on the spinal canal, as well as the Unity(R) plate which is used in anterior lumbar fusion procedures.

Blackstone also offers 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. Blackstone also offers the Ngage(TM) Surgical Mesh System made of titanium metal.

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Blackstone is also a distributor of HCT/P products including interbody devices made of human cadaveric bone that have been harvested from donors and carved by a machine into a desired shape, and a unique adult stem cell-based product 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.

Spinal Bone Growth Stimulators

Separate from Blackstone, we offer two spinal bone growth stimulation devices, Spinal-Stim(R) and Cervical-Stim(R), 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. Clinical data shows our PEMF signal enhances the body's enzyme activities, induces mineralization, encourages new vascular penetration and results in a process that generates new bone growth at the spinal fusion site. We have sponsored independent research at the Cleveland Clinic, where scientists conducted animal and cellular studies to identify the influence of our PEMF signals on bone cells. From this effort, a total of six studies have been published in peer-reviewed journals. Among other insights, the studies illustrate the positive effects of PEMF on bone loss, callus formation, and collagen. Furthermore, we believe that characterization and visualization of the Orthofix PEMF waveform is paving the way for signal optimization for a variety of applications and indications.

Spinal-Stim(R) is a non-invasive spinal fusion stimulator system commercially available in the U.S. Spinal-Stim(R) is designed for the treatment of the lower thoracic and lumbar regions of the spine. Some spine fusion patients are at greater risk of not generating new bone around the damaged vertebrae after the operation. These patients typically have one or more risk factors such as smoking, obesity or diabetes, or their surgery involves the revision of a previously attempted fusion procedure that failed, or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical bone growth stimulation using Spinal-Stim(R) has been shown to increase the probability of fusion, without the need for additional surgery. According to internal sales data, more than 259,000 patients have been treated using Spinal-Stim(R) since the product was introduced in 1990. The device uses proprietary technology and a wavelength to generate a PEMF signal. Our approval from the U.S. Food and Drug Administration ("FDA") to market Spinal-Stim(R) commercially is for both failed fusions and healing enhancement as an adjunct to initial spinal fusion surgery.

On December 28, 2004, we received approval from the FDA to market our Cervical-Stim(R) bone growth stimulator. Cervical-Stim(R) is an FDA-approved bone growth stimulator for use as an adjunct to cervical (upper) spine fusion in certain high-risk patients.

Orthopedics

Orthopedics products represented 25% of our total net sales in 2008.

The medical devices offered in Orthofix's Orthopedic market sector are used for two primary purposes: bone fracture management and bone deformity correction.

Bone Fracture Management

Fixation

Our fracture management products consist of fixation devices designed to stabilize a broken bone until it can heal, as well as non-invasive post-surgical bone growth stimulation devices designed to accelerate the body's formation of new bone. Our fixation products come in two main types: external devices and internal devices. We initially focused on the production of external fixation devices for management of fractures that require surgery. External fixation devices are used to stabilize fractures from outside the skin with minimal invasion into the body. Our 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. We believe that it is among the most minimally invasive and least complex surgical options for fracture management.

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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. 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. Some patients, however, favor internal fixation devices for aesthetic reasons.

An example of one of our external fixation devices is the XCaliber(TM) 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(TM) fixators allows X-rays to pass through the device and provides the surgeon with improved X-ray visualization of the fracture and alignment. In addition, these three configurations cover a broad range of fractures with very little inventory. The XCaliber(TM) fixators are provided pre-assembled in sterile kits to decrease time in the operating room.

Our proprietary XCaliber(TM) 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 an external fixation device designed for the treatment of fractures is our Sheffield(TM) fixator. The Sheffield fixator is radiolucent and uses fewer components than other products used for limb reconstruction. In addition, we believe that the Sheffield fixator is more stable and stronger than most competing products – two critical concerns for a long-term limb reconstruction treatment. We believe other advantages of the Sheffield fixator over competing products include the rapid assembly, ease of use and the numerous possibilities for customization for each individual patient.

Examples of our internal fixation devices include:

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

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

    - The Gotfried Percutaneous Compression Plating or Gotfried PC.C.P(R) System is a method of stabilization and fixation for hip-fracture surgery developed by Y. Gotfried, M.D. that we believe is minimally invasive. Traditional hip-fracture surgery can require a 5-inch-long incision down the thigh, but the Gotfried PC.C.P(R) System involves two smaller incisions, each less than one inch long. The Gotfried PC.C.P(R) System then allows a surgeon to work around most muscles and tendons rather than cutting through them. We believe that major benefits of this new approach to hip-fracture surgery include (1) a significant reduction of complications due to a less traumatic

operative procedure; (2) reduced blood loss and less pain (important benefits for the typically fragile and usually elderly patient population, who often have other medical problems); (3) faster recovery, with patients often being able to bear weight a few days after the operation; and (4) improved post-operative results.

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Bone Growth Stimulation

Our Physio-Stim(R) bone growth 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(R) 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 bone growth stimulators are designed to use a low level of PEMF signals to activate the body's natural healing process. The stimulation products that we currently market are external and apply bone growth stimulation without implantation or other surgical procedures.

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 144,000 patients have been treated using Physio-Stim(R) for long bone non-unions since the product was introduced.

Bone Deformity Correction

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

Sports Medicine

Sports Medicine product sales represented 18% of our total net sales in 2008.

We believe 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(R) Bracing and Polar Care(R). Approximately 61% of Breg's net revenues were attributable to the sale of bracing products in 2008, 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 33% of Breg's 2008 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 4% of Breg's 2008 net revenues came from the sale of other rehabilitative products. Breg sells its products through a network of domestic and international independent distributors, 15 employee sales representatives and related international subsidiaries.

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Breg(R) 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(R) and X2K(R) 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 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 accomodate later stages of rehabilitation. The Breg T-Scope(R) 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.

Osteoarthritic braces are used to treat patients suffering from osteoarthritis of the knee. Osteoarthritis ("OA") is a form of damage to, or degeneration of, the articular surface of a joint. This line of custom and off-the-shelf braces is designed to shift the load going through the knee, provide additional stability and reduce pain. In some cases, this type of brace may serve as a cost-efficient alternative to total knee replacement. Breg's single upright Solus(R) which is based on Fusion(R) technology, is our newest bracing design delivering optimal comfort and pain relief for patients suffering from OA.

Polar Care(R)

We manufacture, market and sell a cold therapy product line, Polar Care(R). Breg entered the market for cold therapy products in 1991 when it introduced the Polar Care(R) 500, a cold therapy device used to reduce swelling, minimize the need for post-operative pain medications and generally accelerate the rehabilitation process. Today, we believe that cold therapy is a standard of care with physicians despite limited historical reimbursement by insurance companies over the years. We believe that based on the increasing acceptance of cold therapy, reimbursement by insurance companies is improving.

The Polar Care(R) product uses a circulation system designed to provide constant fluid flow rates to ensure safe 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 provides continuous cold therapy for the relief of pain. Breg's cold therapy line consists of the Polar Care(R) 500, Kodiak(R), Polar Care(R) 300, Polar Cub and cold gel packs.

Vascular

Vascular product sales represented 3% of our total net sales in 2008.

Our non-invasive post-surgical vascular therapy product, called the A-V Impulse System(R), is primarily used on patients following orthopedic joint replacement procedures. It is 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. For patients who cannot walk or are immobilized, we believe that this product simulates the effect that would occur naturally during normal walking or hand flexion with a mechanical method and without the side effects and complications of medication.

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The A-V Impulse System(R) consists of an electronic controller attached to a special inflatable slipper or glove, or to an inflatable bladder within a cast, which promotes the return of blood to the veins and the inflow of blood to arteries in the patient's arms and legs. The device operates by intermittently impulsing veins in the foot, calf or hand, as would occur naturally during normal walking or hand clenching. The A-V Impulse System(R) is distributed in the U.S. by Covidien Ltd. Outside the U.S., the A-V Impulse System(R) is sold directly by our distribution subsidiaries in the United Kingdom, Italy and Germany and through selected distributors in the rest of the world.

Other Products

Other product sales represented 5% of our total net sales in 2008.

Laryngeal Mask

The Laryngeal Mask, a product of The Laryngeal Mask Company Limited, is an anesthesia medical device designed to establish and maintain the patient's airway during an operation. We have exclusive distribution rights for the Laryngeal Mask in Italy through June 2009, and the United Kingdom and Ireland through June 2010.

Other

We hold distribution rights for several other non-orthopedic products including Mentor breast implants in Brazil and Womancare products in the United Kingdom.

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. Our primary research and development facilities are located in Wayne, New Jersey; Verona, Italy; McKinney, Texas; Vista, California; and Andover, United Kingdom.

We maintain interactive relationships with spine and orthopedic centers in the U.S., Europe, Japan and South and Central America, including research and development centers such as the Musculoskeletal Transplant Foundation ("MTF"), the Cleveland Clinic Foundation, Rutgers University, and the University of Verona in Italy. 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 2008 and 2007, we spent $30.8 million and $24.2 million, respectively, on research and development. In 2006 we spent $15.0 million on research and development and recorded a $40.0 million charge for In Process Research and Development as part of the purchase accounting for the Blackstone acquisition.

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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

The Company began implementation of its enhanced compliance program, which it branded the Integrity Advantage(TM) Program, in February 2008 at Blackstone. In June 2008, the Company hired a Chief Compliance Officer to oversee implementation of the Integrity Advantage(TM) Program throughout the Company. It is a fundamental policy of the 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 the Company’s domestic and international businesses.

The Company's Integrity Advantage(TM) 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(TM) Program include:

- Organizational oversight by senior-level personnel responsible for the compliance function within the 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.

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Government Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act, or the FDCA, as implemented and enforced by the U.S. Food and Drug Administration, or 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 require either premarket notification ("510(k)") clearance or approval of a premarket approval application ("PMA") from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring approval of a PMA.

Manufacturers of most class II medical devices are required to obtain 510(k) clearance prior to marketing their devices. To obtain 510(k) clearance, a company must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" in intended use and in technological and performance characteristics to another legally marketed 510(k)-cleared "predicate device." By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. With certain exceptions, most of our products are subject to the 510(k) clearance process.

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 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. We also have under development, an artificial cervical disc product which is currently classified as FDA Class III and will require a human clinical trial and PMA approval. We also have under development other products designed to treat degenerative spinal disc disease but which allow greater post-surgical mobility than standard surgical approaches involving spinal fusion techniques. Certain of these products may be classified as FDA Class III products and may require PMA approval process including a human clinical trial.

In addition, Blackstone is a distributor of a product for bone repair and reconstruction under the brand name Trinity(R) Matrix which is an allogeneic bone matrix containing viable adult mesenchymal stem cells. We believe

that Trinity(R) Matrix 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. Blackstone 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(R) Matrix 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."

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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, or 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. 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, or 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.

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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 prices charged for medical products and services. The Medicare program is expected to continue to implement a new payment mechanism for certain items of durable medical equipment, or DME, via the implementation of its competitive bidding program. The initial implementation was terminated shortly after it began in 2008 and CMS is required to start the rebid process in 2009. Payment rates for DME will be determined based on bid prices rather than the current Medicare DME fee schedule.

Orthofix Inc. a subsidiary of Orthofix NV received accreditation status by the Accreditation Commission for Health Care, Inc., (ACHC) for the services of Durable Medical, Prosthetics, Orthotics and Supplies (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. Accreditation is a voluntary activity where healthcare organizations submit to peer review their internal policies, processes and patient care delivery against national standards. 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 United States Department of Health and Human Services, the United States Department of Justice, and other federal, state and local agencies. Among other things, these laws and others generally: (1) prohibit the provision of any thing 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 the 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.

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.

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Primary Markets

In 2008, Domestic accounted for 36% of total net sales; Blackstone accounted for 21% of total net sales; Breg accounted for 17% of total net sales; and International accounted for 26% of total net sales. No single non-governmental customer accounted for greater than 5% of total net sales. Sales to customers were broadly distributed.

Our products sold in the United States are either prescribed by medical professionals for the care of their patients or selected by physicians, sold to hospitals, clinics, surgery centers, independent distributors or other healthcare providers, all of whom may be primarily reimbursed for the healthcare products provided to patients by third-party payors, such as government programs, including Medicare and Medicaid, private insurance plans and managed care programs. Our products are also sold in many other countries, such as the United Kingdom, France and Italy, which have publicly funded healthcare systems as well as private insurance plans. See Item 1A “Risk Factors”, page 24 for a table of estimated revenue by payor type. For additional information about geographic areas, see Item 8 “Financial Statements and Supplementary Data.”

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 564 direct sales and marketing representatives. Worldwide we also have approximately 290 independent distributors for our products in approximately 65 countries. The table below highlights the makeup of our sales, marketing and distribution network at December 31, 2008.

	Direct Sales & Marketing Headcount			Distributors		
	United States	International	Total	United States	International	Total
Domestic	290	-	290	32	1	33
Blackstone	52	5	57	42	23	65
Breg	75	1	76	33	75	108
International	7	134	141	1	83	84
Total	424	140	564	108	182	290

In our largest 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 bone growth stimulation products and Blackstone HCT/P products and a distribution network for Blackstone spinal implant products. The Orthopedic market sector is addressed by a hybrid distribution network of predominately direct sales supplemented by distributors. The Sports Medicine market sector is addressed primarily by a distribution network for Breg products.

Outside the U.S., we employ both direct sales representatives and distributors within our international sales subsidiaries. We also utilize independent distributors in Europe, the Far East, the Middle East and Central and South America in countries where we do not have subsidiaries. In order to provide support to our independent distribution

network, we have a group of sales and marketing specialists who regularly visit independent distributors to provide training and product support.

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Marketing and Product Education

We seek to market our products principally to medical professionals and group purchasing organizations ("GPOs") which are hospital organizations which buy on a large scale. We believe there is a developing focus on selling to GPOs and large national accounts which 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 in printed, video and multimedia formats. To provide additional advanced training for surgeons, we organize monthly multilingual teaching seminars at our facility in Verona, Italy. The Verona product education seminars, which in 2008 were attended by over 590 surgeons and over 125 distributor representatives and sales specialists from around the world, include 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 locally for surgeons in the application of certain of our products. We also provide sales training at our training centers in McKinney, Texas and at our Breg training center in Vista, California. Additionally, we have implemented a web-based sales training program, which provides continued training to our sales representatives.

Competition

Our bone growth stimulation products compete principally with similar products marketed by Biomet Spine a business unit of Biomet, Inc, DJO Incorporated, and Exogen, Inc., a subsidiary of Smith & Nephew plc. Our Blackstone spinal implant and HCT/P products compete with products marketed by Medtronic, Inc., De Puy, a division of Johnson and Johnson, Synthes AG, Stryker Corp., Zimmer, Inc., 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 non-pharmacological products competing with our A-V Impulse System(R) are manufactured by Huntleigh Technology PLC and Kinetic Concepts, Inc.

The principal competitors for the Breg bracing and cold therapy products include DJO Incorporated, Biomet, Inc., Ossur Lf. 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 Blackstone spinal implant and Alloquent(R) 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 manufactures 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 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.

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 United States. 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.

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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(R) 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 $20.2 million, $27.2 million and $12.6 million in 2008, 2007 and 2006, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. In 2008, we invested $20.2 million in capital expenditures of which $10.4 million were related to Blackstone and included the acquisition of intellectual property and related technology for a spinal fixation system from Intelligent Implant Systems, LLC (“IIS”). We currently plan to invest approximately $24 million in capital expenditures during 2009 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, 2008, we had 1,418 employees worldwide. Of these, 500 were employed at Domestic, 156 were employed at Blackstone, 477 were employed at Breg and 285 were employed at International. Our relations with our Italian employees, who numbered 108 at December 31, 2008, 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 1,418 employees, 564 were employed in sales and marketing functions, 275 in general and administrative, 428 in production and 151 in research and development.

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Item 1A. Risk Factors

In addition to the other information contained in the 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.

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 recently been increasingly poor and uncertain due to a sharp turndown in the economy and difficulties in the credit markets. If economic growth in the United States and other countries continues to slow, 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. In addition, weakening consumer financial strength and demand could cause a substantial reduction in the sale of our products.

Our acquisition of Blackstone could continue to present challenges for us.

On September 22, 2006, we completed the acquisition of Blackstone. The acquisition has presented several initial challenges to our business. In 2008, we recorded several expenses from the impairment of goodwill and intangible assets related to the Blackstone business, including a $57.0 million impairment loss related to the Blackstone trademark, a $126.9 million goodwill impairment loss, and a $105.7 million impairment charge related to the distribution network and technologies at Blackstone. We have also received several subpoenas, including from the U.S. Department of Health and Human Services, Office of the Inspector General, related to the Blackstone business. These subpoenas and related government investigations have required the use of significant management time and resources.

We are in the process of continuing to integrate the operations of Blackstone into our business. We may not be able to successfully integrate Blackstone's operations into our business and achieve the benefits that we originally anticipated at the time of the acquisition. The continued integration of Blackstone's operations into our business involves numerous risks, including:

- difficulties in incorporating Blackstone's product lines, sales personnel and marketing operations into our business;
- the diversion of our resources and our management's attention from other business concerns;
- the loss of any key distributors;
- the loss of any key employees; and
- the assumption of unknown liabilities, such as the costs and expenses related to the current inquiries by the Department of Health and Human Service Office of Inspector General, as described in Item 3, Legal Proceedings.

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In addition, Blackstone's business is subject to many of the same risks and uncertainties that apply to our other business operations, such as risks relating to the protection of Blackstone's intellectual property and proprietary rights, including patents that it owns or licenses. If Blackstone's intellectual property and proprietary rights are challenged, or if third parties claim that Blackstone infringes on their proprietary rights, our business could be adversely affected.

Failure to overcome these risks or any other problems encountered in connection with the acquisition of Blackstone could adversely affect our business, prospects and financial condition. In addition, if Blackstone's operations and financial results continue not to meet our expectations, we may not realize synergies, operating efficiencies, market position, or revenue growth we originally anticipated from the acquisition.

Expensive litigation and government investigations, and difficulties recouping disputed amounts currently being held in escrow in connection with the Blackstone acquisition, may reduce our earnings.

As described under Item 3, "Legal Proceedings", we are named as a defendant in a number of lawsuits and have received subpoenas requesting information from governmental authorities, including the U.S. Department of Health and Human Services, Office of Inspector General, and two separate federal grand jury subpoenas. We are complying with the subpoenas and intend to cooperate with any related government investigation. The outcome of these and any other lawsuits brought against us, and these and other investigations of us, are inherently uncertain, and adverse developments or outcomes could result in significant monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows.

As also described under Item 3, "Legal Proceedings", we may have rights to indemnification under the merger agreement for the Blackstone acquisition for losses incurred in connection with some of these matters, and we have submitted claims for indemnification from the escrow fund established in connection with the merger agreement for certain of these matters. However, the representative of the former shareholders of Blackstone has objected to many of these indemnification claims and expressed an intent to contest them in accordance with the terms of the merger agreement. There can be no assurance that we will ultimately be successful in seeking indemnification in connection with any of these matters.

In the event certain of these matters result in significant settlement costs or judgments against us and we are not able to successfully recoup such amounts from the escrow fund, these matters could have a significant negative effect on our operations and financial performance.

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

We intend to introduce several new products to the market in 2009, including the Firebird (TM) pedicle screw system, the Pillar SA interbody device and the Trinity (R) Evolution(TM) adult stem cell-based allograft, among others. 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(R) Evolution(TM) 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(R) Evolution(TM) is classified as an HCT/P product, it could from time to time be subject to recall for safety or administrative reasons.

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We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality, or assure the protection, of these assets.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that compete directly with, ours. Numerous patents covering our technologies have been issued to us, and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the United States. Some patent applications in the United States are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by several months, we may not be the first to invent, or file patent applications on any of our discoveries. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to, or licensed by us and may not provide adequate protection or competitive advantages for our products. Patents that are issued may be challenged, invalidated or circumvented by our competitors. Furthermore, our patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary expertise and continuing technological innovation that we protect, in part, by entering into confidentiality agreements with assignors, licensees, suppliers, employees and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. If patents are not issued with respect to our products arising from research, we may not be able to maintain the confidentiality of information relating to these products. In addition, if a patent relating to any of our products lapses or is invalidated, we may experience greater competition arising from new market entrants.

Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.

There has been substantial litigation in the medical device industry with respect to the manufacture, use and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to defend against allegations relating to the infringement of patent or proprietary rights of third parties. Any such litigation could, among other things:

- require us to incur substantial expense, even if we are successful in the litigation;
- require us to divert significant time and effort of our technical and management personnel;
- result in the loss of our rights to develop or make certain products; and
- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation.

Although patent and intellectual property disputes within the orthopedic medical devices industry have often been settled through assignments, licensing or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. Furthermore, the required assignments or licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a judicial or administrative proceeding or a failure to obtain necessary assignments or licenses could prevent us from manufacturing and selling some products or increase our costs to market these products.

For example, our subsidiary, Blackstone, maintains a license agreement with Cross Medical, Inc./Biomet Spine (“Cross/Biomet”) covering certain pedicle screw products currently sold by Blackstone. Prior to the completion of its

acquisition by us, Blackstone requested that Cross/Biomet consent to the assignment of the license agreement to the extent Blackstone's acquisition by the Company constituted an assignment thereunder. The Company believes that no consent is necessary for Blackstone to maintain its rights under the license agreement and that to the extent such consent is necessary, Cross/Biomet is required to provide it under the terms of the agreement. The Company also believes that it has properly interpreted the scope of the license. However, there can be no assurance that Cross/Biomet will not challenge Blackstone's rights under the license agreement if current negotiations are not successful.

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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 consequent material adverse effect on our sales and profitability.

Third-party payors, whether private or governmental entities, also 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 the Company's products is currently unknown, but we cannot provide assurances that the resulting actions would not restrict Medicare coverage for our products. It is also possible that the government's focus on coverage of off-label uses of the FDA-approved devices 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. Our products are sold in many countries, such as the United Kingdom, France, and Italy, with 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 is expected to continue to implement a competitive bidding program for durable medical equipment paid for by the Medicare program. CMS conducted an initial implementation of the competitive bidding program in 2008 which was terminated in that same year. CMS is required to start the rebid of the initial implementation in 2009. The Company's 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. The competitive bidding process is projected to be expanded further in 2011, yet final decisions concerning which products and areas will be affected have not been announced. While some of our products are designated by the Food and Drug Administration 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.

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We estimate that our revenue by payor type is:

- Independent Distributors 23%
- Third Party Insurance 20%
- International Public Healthcare Systems 12%
- Direct (hospital) 36%
- U.S. Government – Medicare, Medicaid, TriCare 8%
- Self pay 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 Food and Drug Administration, or 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 – Government Regulation."

The approval or clearance by governmental authorities, including the FDA in the United States, is generally required before any medical devices may be marketed in the United States 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 Quality System Regulation (QSR) and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of those actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition and results of operations.

We may be subject to federal and state health care fraud and abuse laws, and could face substantial penalties if we are unable to fully comply with such laws.

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

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the Federal Health Care Programs Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing and discounting policies, and relationships with health care 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 health care 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 payers 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 payers, including commercial insurers.

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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 of 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. Moreover, 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.

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

Our Blackstone subsidiary distributes a product under the brand name Trinity(R) Matrix which is an allogeneic bone matrix containing viable cadaveric adult mesenchymal stem cells. Our right to distribute this product will terminate on June 30, 2009. We believe that Trinity(R) Matrix is properly classified under the 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 drug. There can be no assurance that the FDA would agree that this category of regulatory classification applies to Trinity(R) Matrix 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 postmarket regulatory requirements. The success of our Trinity(R) Matrix 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. The supply of Trinity(R) Matrix is derived from human cadaveric donors. The supply of such donors is inherently unpredictable and can fluctuate over time. Because Trinity(R) is classified as an HCT/P product, it can from time to time be subject to recall for safety or administrative reasons.

Blackstone also distributes allograft products which are also 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/Ps 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 postmarket 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.

In May 2009, the Company expects to begin distributing Trinity(R) Evolution(TM), a next generation adult stem cell-based allograft developed in collaboration with the Musculoskeletal Transplant Foundation (MTF). Trinity(R) Evolution(TM) is an allogeneic bone matrix containing viable adult mesenchymal stem cells. We believe that Trinity(R) Evolution(TM) is properly classified under the 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 drug. There can be no assurance that the FDA would agree that this category of regulatory classification applies to Trinity(R) Evolution(TM) 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 postmarket regulatory requirements. Our ability to continue to sell the Trinity(R) Evolution(TM) product also 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. Moreover, the success of our Trinity(R) Evolution(TM) 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. The supply of Trinity(R) Evolution(TM) is derived from human cadaveric donors. The supply of such donors is inherently unpredictable and can fluctuate over time. Because Trinity(R) Evolution(TM) is classified as an HCT/P product, it can from time to time be subject to recall for safety or administrative reasons.

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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.

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 orthopedic products successfully depends, in part, on the acceptance of the products by independent third parties (including hospitals, doctors, other healthcare providers and third-party payors) as well as patients. Unanticipated side effects or unfavorable publicity concerning any of our products could have an adverse effect on our ability to maintain hospital approvals or achieve acceptance by prescribing physicians, managed care providers and other retailers, customers and patients.

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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 – Competition."

We depend on our senior management team.

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

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

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

Termination of our existing relationships with our independent sales representatives or distributors could have an adverse effect on our business.

We sell our products in many countries through independent distributors. Generally, our independent sales representatives and our distributors have the exclusive right to sell our products in their respective territories and are generally prohibited from selling any products that compete with ours. The terms of these agreements vary in length 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.

We are party to numerous contractual relationships.

We are party to numerous contracts in the normal course of our business. We have contractual relationships with suppliers, distributors and agents, as well as service providers. In the aggregate, these contractual relationships are necessary for us to operate our business. From time to time, we amend, terminate or negotiate our contracts. We are also periodically subject to, or make claims of breach of contract, or threaten legal action relating to our contracts. These actions may result in litigation. At any one time, we have a number of negotiations under way for new or amended commercial agreements. We devote substantial time, effort and expense to the administration and

negotiation of contracts involved in our business. However, these contracts may not continue in effect past their current term or we may not be able to negotiate satisfactory contracts in the future with current or new business partners.

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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 United States that are subject to the impact of foreign exchange rates. The fluctuations of foreign exchange rates during 2008 have had a positive impact of $4.2 million on net sales outside of the United States. 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, 2008, we had outstanding a currency swap to hedge a 43.0 million Euro 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. Further, in 2006 we restructured and consolidated our International operations in part through a series of intercompany transactions. Tax authorities in these jurisdictions may challenge our treatment of such intercompany transactions. If we are unsuccessful in defending our treatment of intercompany transactions, we may be subject to additional tax liability or penalty, which could adversely affect our profitability.

We are subject to differing customs and import/export rules in several jurisdictions in which we operate.

We import and export our products to and from a number of different countries around the world. These product movements involve subsidiaries and third-parties operating in jurisdictions with different customs and import/export rules and regulations. Customs authorities in such jurisdictions may challenge our treatment of customs and import/export rules relating to product shipments under aspects of their respective customs laws and treaties. If we are unsuccessful in defending our treatment of customs and import/export classifications, we may be subject to additional customs duties, fines or penalties that could adversely affect our profitability.

Provisions of Netherlands Antilles law may have adverse consequences to our shareholders.

Our corporate affairs are governed by our Articles of Association and the corporate law of the Netherlands Antilles as laid down in Book 2 of the Civil Code (CCNA). Although some of the provisions of the CCNA resemble some of the provisions of the corporation laws of a number of states in the United States, 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 United States. For example, there is no statutory right of appraisal under Netherlands Antilles corporate law nor is there a right for shareholders of a Netherlands Antilles corporation to sue a corporation derivatively. In addition, we have been advised by Netherlands Antilles counsel that it is unlikely that (1) the courts of the Netherlands Antilles 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 the Netherlands Antilles in relation to liabilities predicated upon the U.S. federal securities laws.

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 United States represented 26% of our total net sales in 2008. 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 United States. Accordingly, our future results could be harmed by a variety of factors, including:

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- 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 U.S. Foreign Corrupt Practices Act ("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 incurrence of 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.

When we acquired Blackstone on September 22, 2006, one of our wholly-owned subsidiaries, Orthofix Holdings, Inc. (Orthofix Holdings), entered into a senior secured bank credit facility with a syndicate of financial institutions to finance the transaction. Orthofix 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 seven-year amortizing term loan facility of $330.0 million of which $280.7 million and $297.7 million was outstanding at December 31, 2008 and 2007, respectively, and (2) a six-year revolving credit facility of $45.0 million upon which we had not drawn as of December 31, 2008. On September 29, 2008, we entered into an amendment to the credit agreement.

The credit agreement, as amended, contains negative covenants applicable to Orthofix and its subsidiaries, including restrictions on indebtedness, liens, dividends and mergers and sales of assets. The credit agreement also contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to Orthofix and its subsidiaries on a consolidated basis. A breach of any 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. Management believes the Company was in compliance with these financial covenants as measured at December 31, 2008. The Company further believes that it should be able to meet these financial covenants in future fiscal quarters, however, there can be

no assurance that it 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 senior secured bank credit facility requires mandatory prepayments that may have an adverse effect on our operations and limit our ability to grow our business

Further, in addition to scheduled debt payments, the credit agreement, as amended, requires us to make mandatory prepayments with (a) the excess cash flow (as defined in the credit agreement) of Orthofix and its subsidiaries, in an amount equal to 50% of the excess annual cash flow beginning with the year ending December 31, 2007, provided, however, if the leverage ratio (as defined in the credit agreement) is less than or equal to 1.75 to 1.00, as of the end of any fiscal year, there will be no mandatory excess cash flow prepayments, with respect to such fiscal year (b) 100% of the net cash proceeds of any debt issuances by Orthofix or any of its subsidiaries or 50% of the net cash proceeds of equity issuances by any such party, excluding the exercise of stock options, provided, however, if the leverage ratio is less than or equal to 1.75 to 1.00 at the end of the preceding fiscal year, Orthofix Holdings shall not be required to prepay the loans with the proceeds of any such debt or equity issuance, (c) the net cash proceeds of asset dispositions over a minimum threshold, or (d) unless reinvested, insurance proceeds or condemnation awards. These mandatory prepayments could limit our ability to reinvest in our business.

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, and in recent months the volatility has reached unprecedented levels. 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 continue to maintain a six-year revolving credit facility of $45.0 million upon which we have not drawn as of December 31, 2008. 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 seven-year amortizing term loan facility of $330.0 million for which $280.7 was outstanding as of December 31, 2008. Obligations under the senior secured credit facility have a floating interest rate of the London Inter-Bank Offered Rate (“LIBOR”) plus a margin or prime rate plus a margin. Currently, the term loan is a $150.0 million LIBOR loan, with a 3.0% LIBOR floor, plus a margin of 4.5% and a $130.7 million prime rate loan plus a margin of 3.5%. 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. The amount outstanding under the Swap as of December 31, 2008 was $150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of December 31, 2008 the interest rate on the debt related to the Swap was 9.8%. Our overall effective interest rate, including the impact of the Swap, as of December 31, 2008 on our senior secured debt was 8.4%.

In recent months, LIBOR rates have experienced unprecedented short-term volatility due to disruptions occurring in global financial and credit markets. During this period, LIBOR rates have experienced substantial short-term increases. As described above, although the Swap reduces the impact of these increases on us, increases in LIBOR rates increase the interest expense that we incur under our term loan. (See Item 7A, Quantitative and Qualitative Disclosures about Market Risk in this Form 10-K.) Further, in the event that our counterparties under the Swap were to cease to be able to satisfy their obligations under the Swap for any reason, our interest expense could be further increased.

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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 Part II, 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

The accounting treatment of goodwill and other identified intangibles could result in future asset impairments, which would be recorded as operating losses.

Financial Accounting Standards Board ("FASB") SFAS No. 142, "Goodwill and Other Intangible Assets," 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. SFAS No. 142 requires that goodwill and intangible assets with indefinite lives be tested at least annually for impairment. If Orthofix finds that the carrying value of goodwill or a certain intangible asset exceeds its fair value, it will reduce the carrying value of the goodwill or intangible asset to the fair value, and Orthofix will recognize an impairment loss. Any such impairment losses are required to be recorded as non-cash operating losses.

During the third quarter, due to the recent trend of decreasing revenues at Blackstone, among other matters, we evaluated the fair value of our indefinite-lived trademarks and goodwill at Blackstone. As a result, we recorded an impairment charge of $57.0 million relating to these trademarks. The fair value of goodwill was estimated using the expected present value of future cash flows. We determined that the carrying amount of goodwill related to Blackstone exceeded its implied fair value, and recognized a goodwill impairment loss of $126.9 million.

In addition, SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" requires that intangible assets with definite lives, such as Orthofix's developed technologies and distribution network assets, be tested for impairment if indicators of impairment, as defined in the standard exist. During the third quarter of 2008, we determined that an indicator of impairment existed with respect to the definite-lived intangible assets at Blackstone. We compared the expected cash flows to be generated by the definite lived intangible assets on an undiscounted basis to the carrying value of the intangible asset. We determined the carrying value exceeded the undiscounted cash flow and impaired the distribution network and developed technologies at Blackstone to the fair value which resulted in an impairment charge of $105.7 million.

Certain of the impairment tests require Orthofix 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, Orthofix is unable to predict whether impairments of goodwill or other indefinite lived intangibles will occur in the future.

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 Stimulation and Orthopedic Products and administrative facility for Orthofix Inc.	McKinney, TX	70,000	Leased
Sales management, distribution, research and development and administrative offices for Blackstone.	Springfield, MA	19,000	Leased
Sales management, research and development and administrative offices for Blackstone.	Wayne, NJ	16,548	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
Administrative offices for Orthofix International N.V. (rent of $27 per square foot, furnished)	Boston, MA	7,250	Leased
Administrative offices for Orthofix International N.V.	Huntersville, NC	7,225	Leased
Sales management, distribution and administrative offices	South Devon, England	2,500	Leased
Sales management, distribution and administrative offices for A-V Impulse(R) System and 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 Mexico	Mexico City, Mexico	3,444	Leased
	Alphaville, Brazil	4,690	Leased

Sales management, distribution and administrative facility for Brazil			
Sales management, distribution and administrative facility for Brazil	São Paulo, Brazil	1,184	Leased

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Sales management, distribution and administrative facility for France	Gentilly, France	3,854	Leased
Sales management, distribution and administrative facility for Germany	Valley, Germany	3,000	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	Vista, California	104,832	Leased
Manufacturing facility for Breg products, including the A-V Impulse System(R) Impads	Mexicali, Mexico	63,000	Leased
Sales management, distribution and administrative facility for Puerto Rico	Guaynabo, Puerto Rico	4,400	Leased

Item 3. Legal Proceedings

Effective October 29, 2007, our subsidiary, Blackstone, entered into a settlement agreement with respect to a patent infringement lawsuit captioned Medtronic Sofamor Danek USA Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH v. Blackstone Medical, Inc., Civil Action No. 06-30165-MAP, filed on September 22, 2006 in the United States District Court for the District of Massachusetts. In that lawsuit, the plaintiffs had alleged that (i) they were the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, 6,936,051 B2, 6,398,783 B1 and 7,066,961 B2 (the “Patents”), and (ii) Blackstone's making, selling, offering for sale, and using within the United States of its Blackstone Anterior Cervical Plate, 3º Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products infringed the Patents, and that such infringement was willful. The Complaint requested both damages and an injunction against further alleged infringement of the Patents. Blackstone denied infringement and asserted that the Patents were invalid. On July 20, 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 us 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 has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement. The settlement agreement is not expected to have a material impact on the Company’s consolidated financial position, results of operations or cash flows.

On or about July 23, 2007, 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 seeks 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 concerns 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 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 has 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 United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is 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.

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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 November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. To our knowledge, the plaintiffs have not served either Blackstone or the Company with a copy of the complaint. The complaint alleges a cause of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants, as well as a cause of action for retaliation and wrongful discharge. The Company believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the United States Attorney's Office for the District of Massachusetts. The Company intends to defend vigorously against this lawsuit. On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the United States Attorney's Office for the District of Nevada ("USAO-Nevada subpoena"). The subpoena seeks documents for the period from January 1999 to the date of issuance of the subpoena. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On February 29, 2008, Blackstone received a Civil Investigative Demand ("CID") from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The Company believes that the CID seeks documents concerning Blackstone's financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from this matter.

The Ohio Attorney General's Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix, Inc (the "Ohio AG Subpoena"). The Ohio AG Subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. The Company believes that the Ohio AG Subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG Subpoena.

Blackstone has cooperated with the government's request in each of the subpoenas set forth above. The Company is unable to predict what actions, if any, might be taken by the governmental authorities that have issued these subpoenas or what impact, if any, the outcome of these matters might have on the Company's consolidated financial position, results of operations or cash flows.

By order entered on January 4, 2007, the United States District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The complaint alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan. On December 29, 2006, the U.S. Department of Justice filed a notice of non-intervention in the case. Plaintiff subsequently amended the complaint to add the Company as a defendant. On January 3, 2008, Dr. Chan pled guilty to one count of knowingly soliciting and receiving kickbacks from a medical device distributor in a criminal matter in which neither the Company nor any of its business units or employees were defendants. In January 2008, Dr. Chan entered into a settlement agreement with the plaintiff and certain governmental entities in the civil qui tam action, and on February 21, 2008, a joint stipulation of dismissal of claims against Dr. Chan in the action was filed with the court, which removed him as a defendant in the action. On July 11, 2008, the court granted a motion to dismiss the Company as a defendant in the action. Blackstone remains a defendant. The Company believes that Blackstone has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us 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 has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement.

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Between January 2007 and May 2007, Blackstone and Orthofix Inc. were named defendants, along with other medical device manufacturers, in three civil lawsuits alleging that Dr. Chan had performed unnecessary surgeries in three different instances. In January 2008, the Company learned that Orthofix Inc. was named a defendant, along with other medical device manufacturers, in a fourth civil lawsuit alleging that Dr. Chan had performed unnecessary surgeries. All four civil lawsuits were filed in the Circuit Court of White County, Arkansas. The Company has reached a settlement in all four civil lawsuits, and the court has entered an order of dismissal in two of the four cases. The settlement agreements are not expected to have a material impact on our consolidated financial position, results of operations or cash flows. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from one of these four civil lawsuits. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement.

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow account. As of December 31, 2008 and 2007, included in Other Current Assets is approximately $8.3 million and $2.1 million of escrow receivable balances related to the Blackstone matters described above, respectively.

In addition to the foregoing claims, the Company has submitted claims for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for losses that have or may result from certain claims against Blackstone alleging that plaintiffs and/or claimants were entitled to payments for Blackstone stock options not reflected in Blackstone's corporate ledger at the time of Blackstone's acquisition by the Company, or that their shares or stock options were improperly diluted by Blackstone. To date, the representative of the former shareholders of Blackstone has not objected to approximately $1.5 million in such claims from the escrow fund, with certain claims remaining pending.

The Company cannot predict the outcome of any proceedings or claims made against the Company or its subsidiaries described in the preceding paragraphs and there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

In addition to the foregoing, 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.

Item 4. Submission of Matters to a Vote of Security Holders

There were no matters submitted to a vote of security holders during the fourth quarter of 2008.

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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(R) 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(R) for each of the two most recent fiscal years ended December 31, 2008. As of March 11, 2009 we had approximately 556 holders of record of our common stock. The closing price of our common stock on March 11, 2009 was $13.45.

	High	Low
2007		
First Quarter	$ 51.77	$ 47.11
Second Quarter	53.43	43.26
Third Quarter	50.00	42.01
Fourth Quarter	61.66	47.91
2008		
First Quarter	$ 59.96	$ 35.50
Second Quarter	40.29	28.46
Third Quarter	29.83	17.07
Fourth Quarter	20.03	8.65

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 resulting from the recently completed Blackstone acquisition 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 2008 that were not registered under the Securities Act.

Exchange Controls

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

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Taxation

Under the laws of the Netherlands Antilles 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, the Netherlands Antilles will not be subject to Netherlands Antilles 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; the Netherlands Antilles does not impose a withholding tax on dividends paid by us. There are no gift or inheritance taxes levied by the Netherlands Antilles when, at the time of such gift or at the time of death, the relevant holder of common shares was not domiciled in the Netherlands Antilles. No reciprocal tax treaty presently exists between the Netherlands Antilles and the United States.

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, 2003. 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, 2008, 2007, 2006, 2005 and 2004 have been derived from our audited consolidated financial statements. The financial data as of December 31, 2008 and 2007 and for the years ended December 31, 2008, 2007 and 2006 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 United States (US GAAP).

	Year ended December 31,				
	2008	2007	2006	2005	2004
	(In US$ thousands, except margin and per share data)				
Consolidated operating results					
Net sales	$ 519,675	$ 490,323	$ 365,359	$ 313,304	$ 286,638
Gross profit(5)	367,661	361,291	271,734	229,516	207,461
Gross profit margin(5)	71%	74%	74%	73%	72%
Total operating income (loss)	(256,949)	38,057	9,946	99,795	56,568
Net income (loss) (1) (2) (3) (4)	(228,554)	10,968	(7,042)	73,402	34,149
Net income (loss) per share of common stock (basic)	(13.37)	0.66	(0.44)	4.61	2.22
Net income (loss) per share of common stock (diluted)	(13.37)	0.64	(0.44)	4.51	2.14

(1) Net loss for 2006 includes $40.0 million after tax earnings charge related to In-Process Research and Development costs related to the Blackstone acquisition.

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

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

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

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

	As of December 31,				
Consolidated financial position (at year-end)	2008	2007	2006	2005	2004
	(In US$ thousands, except share data)				
Total assets	$ 561,215	$ 885,664	$ 862,285	$ 473,861	$ 440,969
Total debt	282,769	306,635	315,467	15,287	77,382
Shareholders' equity	202,061	433,940	392,635	368,885	297,172
Weighted average number of shares of common stock outstanding (basic)	17,095,416	16,638,873	16,165,540	15,913,475	15,396,540

Weighted average number of shares of common stock outstanding (diluted)	17,095,416	17,047,587	16,165,540	16,288,975	15,974,945

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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 accounting principles generally accepted in the United States. 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 orthopedic products company offering a broad line of surgical and non-surgical products for the Spine, Orthopedics, Sports Medicine and Vascular market sectors. 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 bone growth stimulation products used to enhance the success rate of spinal fusions and to treat non-union fractures; external and internal fixation devices used in fracture treatment, 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 enhancing venous circulation, cold therapy, other pain management products, bone cement and devices for removal of bone cement used to fix artificial implants and airway management products used in anesthesia applications.

We have administrative and training facilities in the United States and Italy and manufacturing facilities in the United States, the United Kingdom, Italy and Mexico. We directly distribute our products in the United States, the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Mexico, 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 the Company and its 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 United States 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 (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(R) 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."

On September 22, 2006, we completed the acquisition of Blackstone Medical, Inc. (“Blackstone”), a privately held company specializing in the design, development and marketing of spinal implant and related HCT/P products. The purchase price for the acquisition was $333.0 million, subject to certain closing adjustments, plus transaction costs totaling approximately $12.6 million. The acquisition and related costs were financed with $330.0 million of senior secured bank debt and cash on hand. Financing costs were approximately $6.4 million.

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Effective with the acquisition of Blackstone, we manage our operations as four business segments: Domestic, Blackstone, Breg, and International. Domestic consists of operations of our subsidiary Orthofix, Inc. Blackstone consists of Blackstone Medical, Inc., based in Springfield, Massachusetts and its two subsidiaries, Blackstone GmbH and Goldstone GmbH along with international distributors. Breg consists of Breg's domestic operations and international distributors. International consists of operations which are located in the rest of the world, excluding Blackstone's international operations, and distributors along with Breg's international distributors. Group Activities are comprised of the operating expenses and identifiable assets of Orthofix International N.V. and its U.S. holding company, Orthofix Holdings, Inc.

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 accounting principles generally accepted in the United States. 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 allowance for doubtful accounts, sales allowances and adjustments, inventories, intangible assets and goodwill, income taxes, derivatives and litigation and contingencies. 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

For bone growth stimulation and certain bracing products that are prescribed by a physician, we recognize revenue when the product is placed on and accepted by the patient. For domestic spinal implant and HCT/P products, we recognize revenue when the product has been utilized and we have received a confirming purchase order 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 only on delivery. We derive a significant amount of our revenues in the United States 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. Some billings are subject to review by such 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 in 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 write-down in the future may be necessary.

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Goodwill and Other Intangible Assets

The provisions of Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets ("SFAS No. 142"), require 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. SFAS No. 142 requires that we test goodwill and intangible assets with indefinite lives 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 will be recorded as non-cash operating losses.

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," intangible assets with definite lives should be tested for impairment if a Triggering Event, as defined in the standard, occurs. Upon a Triggering Event, we are to compare the cash flows to be generated by the intangible asset on an undiscounted basis to the carrying value of the intangible asset and record an impairment charge based on the fair value of the intangible if the carrying value exceeds the undiscounted cash flow.

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 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, 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. For instruments designated as a fair value hedge, we ensure an exposed position is being hedged and the changes in fair value of such instruments are recognized in earnings.

We follow SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended and interpreted, which requires that all derivatives be recorded 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 affects net earnings.

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 SFAS No. 133.

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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.

As part of the total Blackstone purchase price, approximately $50.0 million was placed into an escrow account, against which we can make claims for reimbursement for certain defined items relating to the acquisition for which we are indemnified. As described in Note 17 to the consolidated financial statements, the Company has certain contingencies arising from the acquisition that we expect will be reimbursable from the escrow account should we have to make a payment to a third party, including legal fees incurred related to the matter. We believe that the amount that we will be required to pay relating to the contingencies will not exceed the amount of the escrow account; however, there can be no assurance that the contingencies will not exceed the amount of the escrow account.

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 FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109” (“FIN 48”), 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, 2008, we have $0.7 million of unrecognized tax benefits compared with $1.7 million of unrecognized tax benefits at December 31, 2007 and accrued interest and penalties of $0.4 million and $0.5 million at December 31, 2008 and 2007, respectively.

Share-based Compensation

As of January 1, 2006, we began recording compensation expense associated with stock options and other share-based compensation in accordance with SFAS No. 123(R), using the modified prospective transition method and therefore we have not restated results for prior periods. Under the modified prospective transition method, share-based compensation expense for 2008, 2007 and 2006 includes: (a) compensation cost for all share-based awards granted on or after January 1, 2006 as determined based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R) and (b) share-based compensation awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123. We

recognize these compensation costs ratably over the vesting period, which is generally three years. As a result of the adoption of SFAS No. 123(R), our pre-tax income for the years ended December 31, 2008 2007 and 2006 has been reduced by share-based compensation expense of approximately $10.6 million, $11.9 million and $7.9 million, respectively.

The fair value of each share-based award is estimated on the date of grant using the Black-Scholes valuation model for option pricing. The model relies upon management assumptions for expected volatility rates based on the historical volatility (using daily pricing) of our common stock and the expected term of options granted, which is estimated based on a number of factors including the vesting term 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 used in the model is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award. In accordance with SFAS No. 123(R), we reduce the calculated Black-Scholes value by applying a forfeiture rate, based upon historical pre-vesting option cancellations.

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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,		
	2008 (%)	2007 (%)	2006 (%)
Net sales	100	100	100
Cost of sales	29	26	26
Gross profit (1)	71	74	74
Operating expenses			
Sales and marketing	40	38	40
General and administrative	16	15	15
Research and development (2)	6	5	15
Amortization of intangible assets	3	4	2
Impairment of certain intangible assets	56	4	-
Total operating income (loss)	(49)	8	2
Net income (loss) (1) (2)	(44)	2	(2)

(1) Includes effect of obsolescence provision representing 2% points in the year ended December 31, 2008.

(2) Research and development and net loss for 2006 includes $40.0 million of In-Process Research and Development costs related to the Blackstone acquisition.

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 Segment:

	Year ended December 31, (In US$ thousands)					
	2008		2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	$ 188,807	36%	$ 166,727	34%	$ 152,560	42%
Blackstone	108,966	21%	115,914	24%	28,134	8%
Breg	89,478	17%	83,397	17%	76,219	21%
International	132,424	26%	124,285	25%	108,446	29%
Total	$ 519,675	100%	$ 490,323	100%	$ 365,359	100%

Our revenues are derived from sales of products into the market sectors of Spine, Orthopedics, Sports Medicine, Vascular and Other.

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Market Sector:

	Year ended December 31, (In US$ thousands)					
	2008		2007		2006	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	$ 252,239	49%	$ 243,165	49%	$ 145,113	40%
Orthopedics	129,106	25%	111,932	23%	95,799	26%
Sports Medicine	94,528	18%	87,540	18%	79,053	22%
Vascular	17,890	3%	19,866	4%	21,168	6%
Other	25,912	5%	27,820	6%	24,226	6%
Total	$ 519,675	100%	$ 490,323	100%	$ 365,359	100%

2008 Compared to 2007

Net sales increased 6% to $519.7 million in 2008 compared to $490.3 million in 2007. The impact of foreign currency increased sales by $4.2 million in 2008 when compared to 2007.

Sales by Business Segment:

Net sales in Domestic increased 13% to $188.8 million in 2008 compared to $166.7 million in 2007. Domestic represented 36% and 34% of our total net sales in 2008 and 2007, respectively. The increase in sales was primarily the result of a 12% increase in sales in the Spine market sector which was attributable to increased demand for both our Spinal-Stim(R) and Cervical-Stim(R) products. The increase in Domestic's net sales was also attributable to an increase in our Orthopedic market sector which included a 15% increase in sales of Physio-Stim(R) products as compared to the prior year period and an increase in sales of human cellular and tissue based products ("HCT/P products", often referred to as biologic products) used in orthopedic applications for which there were no comparable sales in the prior year.

Domestic Sales by Market Sector:

(In US$ thousands)			
	2008	2007	Growth
Spine	$ 141,753	$ 126,626	12%
Orthopedics	47,054	40,101	17%
Domestic	$ 188,807	$ 166,727	13%

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Net sales in Blackstone were $109.0 million in 2008 compared to $115.9 million in 2007. Blackstone's net sales represented 21% and 24% of our total net sales in 2008 and 2007, respectively. During the integration of Blackstone into our business we have experienced distributor terminations, government investigations and the replacement of one of our products with a successor product, all of which negatively impacted our sales during the year ended December 31, 2008. These decreases in sales have been partially offset by the increase in sales of our HCT/P products. All of Blackstone's sales are recorded in our Spine market sector.

Net sales in Breg increased 7% to $89.5 million in 2008 compared to $83.4 million in 2007. Breg's net sales represented 17% of our total net sales during both years ended December 31, 2008 and 2007. The increase in Breg's net sales was primarily attributable to sales of Breg Bracing(R) products, which increased 12% in 2008, primarily as a result of increased sales of our Fusion XT(TM) and other new products. Further, sales of our cold therapy products increased 16% when compared to the prior year due to the recent launch of our new Kodiak(R) cold therapy products. These increases were partially offset by a decrease in sales of our pain therapy products as a result of the sale of operations related to our Pain Care(R) line of ambulatory infusion pumps during March 2008. All of Breg's sales are recorded in our Sports Medicine market sector.

Net sales in International increased 7% to $132.4 million in 2008 compared to $124.3 million in 2007. International net sales represented 26% and 25% of our total net sales in 2008 and 2007, respectively. The impact of foreign currency increased International sales by 3% or $4.0 million when compared to 2007. The increase in International sales was attributable to the Orthopedic market sector which increased 14% primarily as a result of increased sales of our internal fixation products including the eight-Plate Guided Growth System(R), which increased 68% as well as an 8% increase in sales of our external fixation products. The Sports Medicine market sector increased 22% compared to 2007 due to increased distribution of Breg products. The Vascular market sector decreased 10% compared to the prior year. Sales of distributed products, which include the Laryngeal Mask, decreased approximately 7%.

International Sales by Market Sector:

(In US$ thousands)	2008	2007	Growth
Spine	$ 1,520	$ 625	143%
Orthopedics	82,052	71,831	14%
Sports Medicine	5,050	4,143	22%
Vascular	17,890	19,866	(10)%
Other	25,912	27,820	(7)%
International	$ 132,424	$ 124,285	7%

Sales by Market Sector:

Sales of our Spine products grew 4% to $252.2 million in 2008 from $243.2 million in 2007. The increase of $9.1 million is primarily due to a 12% increase in sales of spinal stimulation products in the United States. This increase was partially offset by a decrease in sales of Blackstone products as a result of distributor terminations, government investigations and the replacement of one of our products with a successor product, all of which negatively impacted our sales during the year ended December 31, 2008. Spine product sales were 49% of our total net sales in both years ended December 31, 2008 and 2007, respectively.

Sales of our Orthopedics products increased 15% to $129.1 million in 2008 compared to $111.9 million in 2007. The increase of $17.2 million can be mainly attributed to a 45% increase in sales of our internal fixation devices including the eight-Plate Guided Growth System(R) as well as a 6% increase in sales of our external fixation devices. Also attributing to the increase in sales was a 14% increase in sales of our Physio-Stim(R) products as compared to the prior year period and an increase in sales of HCT/P products used in orthopedic applications for which there were no comparable sales in the prior year. Orthopedic product sales were 25% and 23% of our total net sales for the years ended December 31, 2008 and 2007, respectively.

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Sales of our Sports Medicine products increased 8% from $87.5 million in 2007 to $94.5 million in 2008. As discussed above, the increase of $7.0 million is primarily due to sales of our Breg(R) bracing products as well as our cold therapy products, offset by a decrease in our pain therapy products, which can be mainly attributed to the sale of operations relating to our Pain Care(R) line in March 2008. Sports Medicine product sales were 18% of our total net sales for both years ended December 31, 2008 and 2007.

Sales of our Vascular products, which consist of our A-V Impulse System(R), decreased 10% to $17.9 million in 2008, compared to $19.9 million in 2007. Vascular product sales were 3% and 4% of our total net sales for the years ended December 31, 2008 and 2007, respectively.

Sales of our Other products, which include the sales of our Laryngeal Mask as well as our woman's care line, decreased 7% to $25.9 million. Other product sales were 5% and 6% of our total net sales for the years ended December 31, 2008 and 2007, respectively.

Gross Profit — Gross profit increased 2% to $367.7 million in 2008 compared to $361.3 million in 2007, primarily due to the 6% increase in net sales from the prior year. In the year ended December 31, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one of our products with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. The change in estimate resulted in an increase in the reserve for inventory obsolescence of approximately $10.9 million. During the year ended December 31, 2007, we recorded a charge of $2.7 million for amortization of the step-up in inventory associated with the Blackstone acquisition. Since the step-up in the Blackstone inventory from purchase accounting was fully amortized during 2007, no such amortization was recorded during the year ended December 31, 2008. Gross profit as a percent of sales in 2008 was 70.7% compared to 73.7% in 2007. Gross profit, excluding the additional reserve recorded at Blackstone was 73.0% in the year ended December 31, 2008. The lower margin is principally the result of changes in product and geographic mix.

Sales and Marketing Expenses — Sales and marketing expenses, which include commissions, royalties and bad debt provisions generally increase and decrease in relation to sales. Sales and marketing expense increased $19.9 million to $206.9 million in 2008 from $187.0 million in 2007. The increase is attributed to increased expense in order to support increased sales activity, including higher commissions on higher sales. In addition sales and marketing expense included approximately $2.0 million of costs incurred related to the completed exploration of the potential divestiture of our orthopedic fixation business. Sales and marketing as a percent of net sales for 2008 and 2007 were 39.8% and 38.1%, respectively.

General and Administrative Expenses — General and administrative expenses increased 12%, or $8.9 million, to $81.8 million in 2008 from $72.9 million in 2007. The increase is due primarily to approximately $4.4 million of costs incurred in connection with the Company's potential divestiture of certain orthopedic fixation assets and other strategic transaction during the first and second quarters of 2008. The Company also incurred approximately $3.8 million of corporate reorganization expenses in the third and fourth quarters of 2008. General and administrative expenses as a percent of net sales were 15.7% and 14.9% in 2008 and 2007, respectively.

Research and Development Expenses - Research and development expenses increased $6.6 million to $30.8 million in 2008 compared to $24.2 million in 2007. In 2008, we incurred $6.1 million in expenses related to the Company's collaboration with MTF on the development and commercialization of Trinity(R) Evolution(TM). Research and development expenses as a percent of net sales were 5.9% in 2008 and 4.9% in 2007.

Amortization of Intangible Assets — Amortization of intangible assets was $17.1 million in 2008 compared to $18.2 million in 2007. This decrease can be primarily attributed to the impairment of certain intangible assets at Blackstone

in the third quarter of 2008.

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Impairment of Goodwill and Certain Intangible Assets – In 2008, we incurred $289.5 million of expense related to the impairment of goodwill and certain intangible assets. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," we performed an impairment analysis of indefinite-lived intangibles. We determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by $57.0 million. Due to the recent trend of decreasing revenues at Blackstone, we evaluated the fair value of goodwill at Blackstone. The fair value of Blackstone was estimated using the expected present value of future cash flows. We determined that the carrying amount of goodwill related to Blackstone exceeded its implied fair value, and recognized a goodwill impairment loss of $126.9 million. In addition, in accordance with SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" we determined that a Triggering Event had occurred with respect to the definite-lived intangible assets at Blackstone. We compared the expected cash flows to be generated by the Blackstone reporting unit, which represented the lowest level at which separate cash flows are identifiable, on an undiscounted basis to the carrying value of the reporting unit. We determined the carrying value exceeded the undiscounted cash flow and ,as a result, impaired the distribution network and technologies at Blackstone to their fair values which resulted in an impairment charge of $105.7 million. In 2007, as part of our annual impairment test under SFAS No. 142, we determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by $20.0 million because the book value exceeded the fair value.

Gain on Sale of Pain Care(R) Operations –Gain on sale of Pain Care(R) operations was $1.6 million and represented the gain on the sale of operations related to our Pain Care(R) line of ambulatory infusion pumps during March 2008. No such gain was recorded in the same period of 2007.

Interest Expense – Interest expense was $20.2 million in 2008 compared to $24.7 million in 2007. Interest expense in 2008 and 2007 included interest expense of $18.2 million and $22.4 million, respectively, related to the senior secured term loan used to finance the Blackstone acquisition. This decrease can be mainly attributed to less outstanding principal from the comparable period in the prior year.

Unrealized non-cash loss on interest rate swap – In the fourth quarter of 2008, the Company incurred an unrealized non-cash loss of approximately $8.0 million which resulted from changes in the fair value of the Company's interest rate swap. Due to declining interest rates and a LIBOR floor in our amended credit facility, the effectiveness of the swap was no longer deemed highly effective; therefore changes in the fair value of the swap agreement are required to be reported in earnings through the expiration of the swap in June 2011.

Loss on Refinancing of Senior Secured Term Loan – In the third quarter of 2008, we incurred $5.7 million of expense related to the refinancing of the senior secured term loan used to finance the Blackstone acquisition. This included a $3.7 million non-cash write-off of previously capitalized debt placement costs and $2.0 million of fees associated with the amendment. We anticipated that we would not remain in compliance with certain financial covenants included in the senior secured credit facility and, consequently, negotiated an amendment of our financial covenants, among other things, with our lenders effective September 29, 2008. There was no comparable charge in 2007.

Other, net – Other, net was expense of $4.7 million in 2008 compared to income of $0.4 million in 2007. The decrease can be mainly attributed to the effect of foreign exchange. During 2008, we recorded foreign exchange losses of $3.0 million principally as a result of a rapid strengthening of the US Dollar against various foreign currencies including the Euro, Pound, Peso and Brazilian Real. Several of our foreign subsidiaries hold trade or intercompany payables or receivables in currencies (most notably the US Dollar) denominated in 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 estimated worldwide effective tax rates were 22.5% and 25.5% during 2008 and 2007, respectively. The effective tax rate for 2008 reflected discrete items resulting from the impairment of goodwill for which we receive no tax benefit, the sale of operations related to our Pain Care(R) operations and the lapse of a

FIN 48 reserve item. Excluding these discrete items, our effective tax rate would have been 36.5%. The effective tax rate for 2007 included a tax credit for research and development expense related to 2003 thru 2006. Without the benefit for the research and development tax credits our estimated worldwide effective tax rate for 2007 would have been 31.6%. The increase in the effective tax rate, excluding discrete items, primarily relates to the suspension of the Company's intercompany deferred consideration agreement in the first quarter of 2008.

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Net Income (Loss) – Net loss for 2008 was $228.6 million, or ($13.37) per basic and diluted share, compared to net income of $11.0 million, or $0.66 per basic share and $0.64 per diluted share in 2007. The weighted average number of basic common shares outstanding was 17,095,416 and 16,638,873 during 2008 and 2007, respectively. The weighted average number of diluted common shares outstanding was 17,095,416 and 17,047,587 during 2008 and 2007, respectively.

2007 Compared to 2006

Net sales increased 34% to $490.3 million in 2007, which included $115.9 million of net sales attributable to Blackstone, compared to $28.1 million in 2006. The impact of foreign currency increased sales by $8.3 million in 2007 when compared to 2006.

Sales by Business Segment:

Net sales in Domestic increased 9% to $166.7 million in 2007 compared to $152.6 million in 2006. Domestic represented 34% and 42% of our total net sales in 2007 and 2006, respectively. The increase in sales was primarily the result of a 9% increase in sales in the Spine market sector which was attributable to increased demand for both our Spinal-Stim(R) and Cervical-Stim(R) products. The Orthopedics market sector also experienced a 12% increase in 2007 compared to 2006. This increase is primarily due to a 15% increase in sales of Physio-Stim(R) due to an increase in demand and a 48% increase in sales of internal fixation due to growth in sales of newer fixation products including the Veronail(R), Contours VPS(R) and the eight-Plate Guided Growth System(R). This increase was partially offset by an 11% decrease in external fixation devices because external fixation devices are sharing the market for treatment of difficult fractures with internal fixation alternatives such as plating and nailing.

Domestic Sales by Market Sector:

(In US$ thousands)	2007	2006	Growth
Spine	$ 126,626	$ 116,701	9%
Orthopedics	40,101	35,859	12%
Domestic	$ 166,727	$ 152,560	9%

Net sales in Blackstone were $115.9 million in 2007 compared to $28.1 million in 2006. Blackstone represented 24% and 8% of our total net sales in 2007 and 2006, respectively. Blackstone was acquired on September 22, 2006 and therefore only sales after that date are included in our sales for 2006. All of Blackstone's sales are recorded in our Spine market sector. On a pro forma basis Blackstone sales increased 30% when compared to 2006 primarily due to an increase in sales of HCT/P products and would have represented 21% of pro forma total net sales in 2006. During the integration of Blackstone into our business, we have experienced substantial turnover of sales management and distributors. We have replaced approximately 80% of the sales management personnel and a number of distributors. Our sales prospectively will be negatively impacted until these distributors are established in selling Blackstone products.

Net sales in Breg increased 9% to $83.4 million in 2007 compared to $76.2 million in 2006. This increase in sales was primarily attributable to sales of Breg Bracing(R) products, which increased 11% in 2007 due to increased demand for our Fusion(R) knee brace and to Breg cold therapy products, which increased 13% in 2007 due to increased demand for our newly introduced Kodiak product line. These increases were partially offset by a 12%

decrease in sales for pain therapy products due to reduced utilization by providers. All of Breg's sales are recorded in our Sports Medicine market sector.

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Net sales in International increased 15% to $124.3 million in 2007 compared to $108.4 million in 2006. International net sales represented 25% and 29% of our total net sales in 2007 and 2006, respectively. The increase in International sales was attributable to the Orthopedics market sector which increased 20% due to increased sales of internal fixation devices, including the ISKD(R) and eight-plate Guided Growth System(R) and increased sales of other orthopedic products. These increases were slightly offset by decreases in sales of external fixation devices which are due to internal fixation alternative devices sharing the market as discussed above. The Sports Medicine market sector increased $1.3 million compared to 2006 due to increased distribution of Breg products. The Vascular market sector decreased 6% compared to the prior year due mainly to pricing and competitive pressures. The impact of foreign currency increased International sales by 6% or $7.9 million when compared to 2006.

International Sales by Market Sector:

(In US$ thousands)	2007	2006	Growth
Spine	$ 625	$ 278	125%
Orthopedics	71,831	59,986	20%
Sports Medicine	4,143	2,834	46%
Vascular	19,866	21,168	(6)%
Other	27,820	24,180	15%
International	$ 124,285	$ 108,446	15%

Sales by Market Sector:

Sales of our Spine products grew 68% to $243.2 million in 2007 from $145.1 million in 2006. The increase is primarily due to the acquisition of Blackstone which was completed at the end of the third quarter 2006 and due to increased sales of Spinal-Stim(R) and Cervical-Stim(R) which increased 5% and 12%, respectively, due to increased demand in the United States as mentioned above.

Sales of our Orthopedics products increased 17% to $111.9 million in 2007 compared to $95.8 million in 2006. The increase in this market sector is primarily attributable to increased sales of internal fixation devices of 51%, increased sales of Physio-Stim(R) of 19% and other orthopedic products when compared to the prior year. These increases were slightly offset by sales of external fixation devices, which decreased 5% compared to the prior year due to internal fixation alternative devices sharing the market as discussed above.

Sales of our Sports Medicine products increased 11% from $79.1 million in 2006 to $87.5 million in 2007. As discussed above, the increase in sales is primarily due to increased demand of our Breg Bracing(R) products, including our Fusion(R) knee brace and cold therapy products including the recently introduced Kodiak product line.

Sales of our Vascular products decreased 6% to $19.9 million in 2007, compared to $21.2 million in 2006 due to increased world-wide competition.

Sales of Other products grew 15% to $27.8 million in 2007 compared to $24.2 million in 2006 due to increased sales of airway management products, women’s care and other distributed products.

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Gross Profit — Gross profit increased 33% to $361.3 million in 2007 compared to $271.7 million in 2006, primarily due to the 34% increase in net sales from the prior year. Gross profit as a percent of net sales in 2007 was 73.7% compared to 74.4% in 2006. During 2007, we experienced negative impacts from the amortization of the step-up in inventory of $2.7 million associated with the Blackstone acquisition. Operational pressures on Blackstone gross profit margins resulting from the impacts of product and channel mix changes were offset by higher sales of higher margin stimulation products.

Sales and Marketing Expenses — Sales and marketing expenses, which include commissions, royalties and bad debt provisions, increased $41.3 million to $187.0 million in 2007 from $145.7 million in 2006. The increase is mainly due the inclusion of Blackstone for the full year 2007 (approximately $38.5 million) as well as higher commissions, royalties and other variable costs associated with higher sales, an increase in SFAS No. 123(R) expense of $1.3 million, and other costs intended to build our distribution capabilities. Additionally, 2006 sales and marketing expense included $4.5 million in distributor termination costs related to the Blackstone acquisition . These increases were partially offset by decreased sales tax expense of $3.5 million in 2007 principally due to favorable rulings and classifications relating to the taxability of certain of our stimulation devices. Although generally we see an increase or decrease in sales and marketing expenses in relation to sales, in 2007 we experienced an increase of 28% on a sales increase of 34% due to the reasons above. Further, sales and marketing as a percent of sales for 2007 and 2006 were 38.1% and 39.9%, respectively.

General and Administrative Expenses — General and administrative expenses increased 37%, or $19.6 million, to $72.9 million in 2007 from $53.3 million in 2006. The increase is primarily attributable to an increase in general and administrative expenses at Blackstone from the prior year of $12.4 million as Blackstone was not acquired until September 22, 2006. Also included in the increase in general and administrative expenses was management transition costs of $1.6 million, which included $0.7 million of non-cash share-based compensation and a further increase of SFAS No. 123(R) expense of $2.6 million, and costs related to strategic initiatives of $1.3 million. General and administrative expenses as a percent of net sales were 14.9% and 14.6% in 2007 and 2006, respectively.

Research and Development Expenses — Research and development expenses decreased 56%, or $30.8 million, to $24.2 million in 2007 from $55.0 million in 2006. The decrease is related to a charge of $40.0 million in 2006 for the write-off of in–process research and development resulting from the Blackstone acquisition, which was partially offset by an increase in research and development expenses at Blackstone of $9.8 million and an increase in SFAS No. 123(R) expense of $0.4 million from 2006. Research and development expenses as a percent of net sales were 4.9% in 2007 and 15.1% in 2006.

Amortization of Intangible Assets — Amortization of intangible assets was $18.2 million in 2007 compared to $8.9 million in 2006. The increase in amortization expense was primarily due to the amortization associated with definite-lived intangible assets acquired in the Blackstone acquisition in September 2007.

Impairment of Certain Intangible Assets – In 2007, we incurred $21.0 million of expense related to the impairment of certain intangible assets. As part of our annual impairment test under SFAS No. 142, we determined that the Blackstone trademark, an indefinite-lived intangible asset, was impaired by $20.0 million because the book value exceeded the fair value. We also impaired intangibles related to our Orthotrac product by $1.0 million. There is no comparable cost in 2006.

KCI Settlement, Net of Litigation Costs — The gain, net of litigation costs, on the settlement of the KCI litigation in 2006 was $1.1 million for which there was no comparable gain in 2007.

Interest Income — Interest income earned on cash balances held during the period was $1.0 million in 2007 compared to $2.2 million in 2006.

Interest Expense — Interest expense was $24.7 million in 2007 compared to $8.4 million in 2006. We incurred $22.4 and $6.9 million of interest expense on borrowings under our senior secured term loan which financed the Blackstone acquisition in 2007 and 2006, respectively. Also, during 2007, additional interest expense of $1.2 million was incurred under a line of credit in Italy and we amortized $1.1 million of debt costs. During 2006, additional interest expense of $1.5 million was incurred on the senior secured term loan associated with the Breg acquisition which was repaid in the first quarter of 2006 and under a line of credit in Italy.

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Other Income (Expense), Net — Other income (expense), net was income of $0.4 million in 2007 compared to income of $2.5 million in 2006. The other income in 2007 was due to foreign currency gains resulting from the weakening of the United States dollar. Other income in 2006 was primarily attributable to a $2.1 million foreign currency gain related to an unhedged intercompany loan of 42.6 million Euro created as part of a European restructuring. In December 2006, we arranged a currency swap to hedge the substantial majority of intercompany exposure and minimize future foreign currency exchange risk related to the intercompany position.

Income Tax Expense — In 2007 and 2006, the effective tax rate was 25.5% and 210.5%, respectively. The effective tax rate for 2007 reflects a $0.9 million tax benefit resulting from research and development tax credit claims relating to years 2003 thru 2006. Excluding the tax benefit for research and development tax credits, our effective tax rate would have been 31.6%. The effective tax rate for 2007 also includes $1.3 million of tax expense as the result of tax rate changes in various tax jurisdictions, with the majority of the amount related to rate changes in Italy. The effective tax rate for 2006 reflects the non-deductibility, for tax purposes, of the $40.0 million purchased in-process research and development charge associated with the Blackstone acquisition. Excluding the charge for in-process research and development, our effective tax rate would have been 28.8%. Our 2006 tax rate also benefited from a one-time tax benefit of $2.8 million resulting from our election to adopt a new tax position in Italy. Without these discrete items, our worldwide effective tax rate was 35% in 2006.

Net Income (Loss) — Net income for 2007 was $11.0 million compared to net loss of $7.0 million in 2006 and reflects the items noted above. Net income was $0.66 per basic share and $0.64 per diluted share in 2007, compared to net loss of $0.44 per basic and diluted share in 2006. The weighted average number of basic common shares outstanding was 16,638,873 and 16,165,540 during 2007 and 2006, respectively. The weighted average number of diluted common shares outstanding was 17,047,587 and 16,165,540 during 2007 and 2006, respectively.

Liquidity and Capital Resources

Cash and cash equivalents at December 31, 2008 were $25.6 million, of which $11.0 million is subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $41.5 million at December 31, 2007, of which $16.5 million was subject to certain restrictions under the senior secured credit agreement described below.

Net cash provided by operating activities was $26.8 million in 2008 compared to $21.5 million in 2007, an increase of $5.3 million. Net cash provided by operating activities is comprised of net income (loss), non-cash items (including impairment charges, share-based compensation, inventory provisions and non-cash purchase accounting items from the Blackstone and Breg acquisitions) and changes in working capital, including changes in restricted cash. Net income decreased $239.5 million to a net loss of $228.6 million in 2008 compared to net income of $11.0 million in 2007. Non-cash items for 2008 increased to $282.6 million compared to $54.6 in 2007 as a result of the impairment of goodwill and intangible assets of $289.5 million, the change in estimate for inventory provisions of $10.9 million, the $8.0 million unrealized non-cash loss on our interest rate swap and the loss on refinancing of our senior secured term loan of $3.7 million. These increases were partially offset by the change in deferred taxes of $79.2 million, primarily attributable to the intangibles impairment, and the $1.6 million gain on the sale of the operations related to the Breg Pain Care(R) line. Working capital accounts consumed $27.3 million of cash in 2008 compared to $44.0 million in 2007. The principal uses of cash for working capital can be mainly attributable to increases in accounts receivable and inventory to support additional sales and certain operational initiatives. Specifically, increases in inventory at Blackstone were approximately $18.3 million which included significant purchases of Trinity(R) bone growth matrix due, in part, to the pending expiration of a related supply agreement. Overall performance indicators for our two primary working capital accounts, accounts receivable and inventory, reflect days sales in receivables of 77 days at December 31, 2008 compared to 78 days at December 31, 2007 and inventory turns of 1.5 times at December 31, 2008 and December 31, 2007. Also included in the uses of working capital were $8.5 million in payments related to

strategic initiatives with MTF, $4.7 million in payments related to the potential divestiture which is no longer being pursued of certain orthopedic fixation assets and $7.8 million in costs related to matters occurring at Blackstone prior to the acquisition and for which we are seeking reimbursement from the applicable escrow fund.

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Net cash used in investing activities was $13.9 million in 2008, compared to $30.4 million during 2007. During 2008, we sold the operations of our Pain Care(R) line of ambulatory infusion pumps for net proceeds of $6.0 million. During 2008, we also sold a portion of our ownership in OPED AG, a German based bracing company, for net proceeds of $0.8 million. Also, in 2008, we invested $20.2 million in capital expenditures, of which $10.4 million were related to Blackstone and included the acquisition of intellectual property and related technology for a spinal fixation system from IIS. During 2007, we invested $27.2 million in capital expenditures of which $7.9 million was related to the acquisition of inSWing(TM) interspinous process spacers at Blackstone. In 2007, we also invested $3.1 million in subsidiaries and affiliates which was a result of adjustments in purchase accounting related to Blackstone and a purchase of a minority interest in our subsidiaries in Mexico and Brazil.

Net cash used in financing activities was $22.3 million in 2008 compared to $7.7 million provided by financing activities in 2007. In 2008, we repaid approximately $17.1 million against the principal on our senior secured term loan, of which $10.0 million was paid on a discretionary basis, and repaid $6.7 million related to borrowings by our Italian subsidiary. In addition, we received proceeds of $1.7 million from the issuance of 51,052 shares of our common stock upon the exercise of stock options and shares issued pursuant to the stock purchase plan. In 2007, we repaid $17.5 million against the principal on our senior secured term loan and borrowed $8.1 million to support working capital in our Italian subsidiary. In addition, we received proceeds of $15.1 million from the issuance of 592,445 shares of our common stock upon the exercise of stock options.

On September 22, 2006 our wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. (“Orthofix Holdings”), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. Certain terms of the senior secured credit facility were amended September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of $330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of $45.0 million. As of December 31, 2008 we had no amounts outstanding under the revolving credit facility and $280.7 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of the London Inter-Bank Offered Rate (“LIBOR”) plus a margin or prime rate plus a margin. Currently, the term loan is a $150.0 million LIBOR loan, with a 3.0% LIBOR floor, plus a margin of 4.5% and a $130.7 million prime rate loan plus a margin of 3.5%, which are adjusted based upon the credit rating of the Company and its subsidiaries. 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. The amount outstanding under the Swap as of December 31, 2008 was $150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of December 31, 2008 the interest rate on the debt related to the Swap was 9.8%. Our overall effective interest rate, including the impact of the Swap, as of December 31, 2008 on our senior secured debt was 8.4%.

The credit agreement contains certain financial covenants, including a fixed charge coverage ratio and a leverage ratio applicable to Orthofix and its subsidiaries on a consolidated basis. A breach of any 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. Management believes the Company was in compliance with these financial covenants as measured at December 31, 2008 and 2007. The Company further believes that it should be able to meet these financial covenants in future fiscal quarters, however, there can be no assurance that it 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.

At December 31, 2008, we had outstanding borrowings of $1.9 million and unused available lines of credit of approximately 5.2 million Euro ($7.3 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.

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On July 24, 2008, we entered into an agreement with Musculoskeletal Transplant Foundation ("MTF") to collaborate on the development and commercialization of a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, we will invest up to $10.0 million in the development of the new stem cell-based bone growth biologic matrix that will be designed to provide the beneficial properties of an autograft in spinal and orthopedic surgeries. After the completion of the development process, the Company and MTF will operate under the terms of a separate commercialization agreement. Under the terms of this 10-year agreement, MTF will source the tissue, process it to create the bone growth matrix, and package and deliver it in accordance with orders received directly from customers and from the Company. The Company will have exclusive global marketing rights for the new allograft and will receive a marketing fee from MTF based on total sales. We account for this collaborative arrangement considering guidance included in Emerging Issues Task Force Issue No. 07-1 "Accounting for Collaborative Arrangements." We currently plan for the new allograft to be launched in the U.S. in May 2009. Approximately $6.1 million of expenses incurred under the terms of the agreement are included in research and development expense in 2008. We have also entered into an agreement with IIS, as mentioned above, where we have purchased $2.5 million of intellectual property and related technology. IIS will continue to perform research and development functions related to the technology and under the agreement, we will pay IIS an additional amount, up to $4.5 million for research and development performance milestones.

We believe that current cash balances together with projected cash flows from operating activities, the unused availability of the $45.0 million revolving credit facility, the available Italian line of credit, and our debt capacity are sufficient to cover anticipated working capital and capital expenditure needs including research and development costs and research and development projects formerly mentioned, over the near term.

Contractual Obligations

The following chart sets forth our contractual obligations as of December 31, 2008:

Contractual Obligations	Payments Due By Period				
(In US$ thousands)	Total	2009	2010-2012	2013-2014	2015 and thereafter
Senior secured term loan	$ 280,700	$ 3,300	$ 86,625	$ 190,775	$ -
Estimated interest on senior secured term loan(1)	84,911	19,989	58,630	6,292	
Other borrowings	162	29	133	-	-
Uncertain tax positions	707	-	707	-	-
Operating leases	11,261	4,655	6,386	220	-
Total	$ 377,741	$ 27,973	$ 152,481	$ 197,287	$ -

(1) Estimated interest on senior secured term loan excludes any potential effects of the interest rate swap agreement and 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, 2008.

The aggregate maturities of long-term debt after December 31, 2008 are as follows: 2009 - $3.3 million, 2010 - $3.4 million, 2011 - $3.4 million, 2012 - $80.0 million, 2013 - $190.8 million.

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In addition to scheduled contractual payment obligations on the debt as set forth above, our credit agreement requires us to make mandatory prepayments with (a) the excess cash flow (as defined in the credit agreement) of Orthofix International N.V. and its subsidiaries, in an amount equal to 50% of the excess annual cash flow beginning with the year ending December 31, 2007, provided, however, if the leverage ratio (as defined in the credit agreement) is less than or equal to 1.75 to 1.00, as of the end of any fiscal year, there will be no mandatory excess cash flow prepayment, with respect to such fiscal year, (b) 100% of the net cash proceeds of any debt issuances by Orthofix International N.V. or any of its subsidiaries or 50% of the net cash proceeds of equity issuances by any such party, excluding the exercise of stock options, provided, however, if the leverage ratio is less than or equal to 1.75 to 1.00 at the end of the preceding fiscal year, Orthofix Holdings shall not be required to prepay the loans with the proceeds of any such debt or equity issuance in the immediately succeeding fiscal year, (c) the net cash proceeds of asset dispositions over a minimum threshold, or (d) unless reinvested, insurance proceeds or condemnation awards.

Off-balance Sheet Arrangements

As of December 31, 2008 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, liquidity, capital expenditures or capital resources that are material to investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can vary sales, cost of sales, and costs of operations, 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 and we do not enter into derivative or other financial investments for trading or speculative purposes. As of December 31, 2008, we had a currency swap transaction in place to minimize future foreign currency exchange risk related to a 43.0 million Euro intercompany note foreign currency exposure. See Item 7 under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – 2007 Compared to 2006 – Other Income (Expense), Net”.

We are exposed to interest rate risk in connection with our senior secured term loan and borrowings under our revolving credit facility, which bear interest at floating rates based on LIBOR or the prime rate 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. We had an interest rate swap in place as of December 31, 2008 to minimize interest rate risk related to our LIBOR-based borrowings.

As of December 31, 2008, we had $280.7 million of variable rate term debt represented by borrowings under our senior secured term loan at a floating interest rate of LIBOR, with a LIBOR floor of 3.0% plus a margin or the prime rate plus a margin. Currently, the term loan is a $150.0 million LIBOR loan plus a margin of 4.50% and a $130.7 million prime rate loan plus a margin of 3.5%, which are adjusted based upon the credit rating of the Company and its subsidiaries. In June 2008, we entered into a Swap with a notional amount of $150.0 million and an expiration date of June 30, 2011. The amount outstanding under the Swap as of December 31, 2008 was $150.0 million. Under the Swap we will pay a fixed rate of 3.73% and receive interest at floating rates based on the three month LIBOR rate at each quarterly re-pricing date until the expiration of the Swap. As of December 31, 2008 the interest rate on the debt related to the Swap was 9.8%. Our overall effective interest rate, including the impact of the Swap, as of December 31, 2008 on our senior secured debt was 8.4%. Based on the balance outstanding under the senior secured term loan combined with the Swap as of December 31, 2008, an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause an increase in interest expense of approximately $2.8 million on an annual basis.

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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, 2008, we had an unhedged intercompany receivable denominated in Euro for approximately $17.2 million. We recorded a foreign currency loss in 2008 of $1.1 million which resulted from the weakening of the Euro against the U.S. dollar during the period.

We also are subject to currency exposure from translating the results of our global operations into the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The U.S. dollar equivalent of international sales denominated in foreign currencies was favorably impacted in 2008 and 2007 by foreign currency exchange rate fluctuations with the weakening of the U.S dollar against the local foreign currency during these periods. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, 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 report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, 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, 2008 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

Certain information required by Item 10 of Form 10-K and information required by Items 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

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

Name	Age	Position
James F. Gero	64	Chairman of the Board of Directors
Alan W. Milinazzo	49	Chief Executive Officer, President and Director
Robert S. Vaters	48	Executive Vice President and Chief Financial Officer
Bradley R. Mason	55	Group President, North America
Michael Simpson	47	President, Orthofix Inc.
Raymond C. Kolls	46	Senior Vice President, General Counsel and Corporate Secretary
Michael M. Finegan	45	Vice President, Business Development and President of Biologics
Denise E. Pedulla	49	Senior Vice President, Chief Compliance Officer-Global Compliance and Government Affairs
Brad Lee	43	President, Breg, Inc.
Luigi Ferrari	41	President, Orthofix International Orthopedic Fixation
Peter J. Hewett	73	Deputy Chairman of the Board of Directors
Charles W. Federico	61	Director
Jerry C. Benjamin (2) (3)	68	Director
Walter von Wartburg (1)	69	Director
Thomas J. Kester (1) (2)	62	Director
Kenneth R. Weisshaar (2) (3)	58	Director
Guy Jordan (1) (3)	60	Director
Maria Sainz	42	Director

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(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of Nominating and Governance Committee

All directors hold office until the next annual general or special meeting of our shareholders and until their successors have been elected and qualified. 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 director and executive officer.

James F. Gero. Mr. Gero became Chairman of Orthofix International N.V. on December 2, 2004 and has been a Director of Orthofix International N.V. since 1998. Mr. Gero became a Director of AME Inc. in 1990. He is a Director of Intrusion, Inc., and Drew Industries, Inc. and is a private investor.

Alan W. Milinazzo. Mr. Milinazzo joined Orthofix International N.V. in 2005 as Chief Operating Officer and succeeded to the position of Chief Executive Officer effective as of April 1, 2006. From 2002 to 2005, Mr. Milinazzo was Vice President of Medtronic, Inc.'s Vascular business as well as Vice President and General Manager of Medtronic's Coronary and Peripheral businesses. Prior to his time with Medtronic, Mr. Milinazzo spent 12 years as an executive with Boston Scientific Corporation in numerous roles, including Vice President of Marketing for SCIMED

Europe. Mr. Milinazzo brings more than two and a half decades of experience in the management and marketing of medical device businesses, including positions with Aspect Medical Systems and American Hospital Supply. He earned a bachelor's degree, cum laude, at Boston College in 1981.

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Robert S. Vaters. Mr. Vaters became Executive Vice President and Chief Financial Officer of Orthofix N.V. on September 7, 2008. 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. Inamed Corporation, a global medical device company was acquired by Allergan Inc. in March of 2006. Since 2006, Mr. Vaters has been General Partner of a health care private equity firm, which he co-founded, and serves on the Board of Reliable Biopharmaceutical Corporation, a private health care company.

Michael Simpson. Mr. Simpson became President of Orthofix Inc. in 2007. From 2002 to 2006, Mr. Simpson was Vice President of Operations for Orthofix Inc. In 2006, Mr. Simpson was promoted to Senior Vice President of Global Operations and General Manager, Orthofix Inc. responsible for world wide manufacturing and distribution. With more than 20 years of experience in a broad spectrum of industries he has held the following positions: Chief Operating Officer, Business Unit Vice President, Vice President of Operations, Vice President of Sales, Plant Manager, Director of Finance and Director of Operations. His employment history includes the following companies: Texas Instruments, Boeing, McGaw/IVAX, Mark IV Industries, Intermec and Unilever

Bradley R. Mason. Mr. Mason became Group President, North America in June 2008 after serving as Vice President of Orthofix International N.V. since December 2003 upon the acquisition of Breg, Inc. Mr. Mason founded Breg in 1989 with five other principal shareholders. Mr. Mason has over 25 years of experience in the medical device industry, some of which were spent with dj Orthopedics (formally DonJoy) where he was a founder and held the position of Executive Vice President. Mr. Mason is the named inventor on 35 issued patents in the orthopedic product arena with several other patents pending.

Raymond C. Kolls, J.D. Mr. Kolls became Vice President, General Counsel and Corporate Secretary of Orthofix International N.V. on July 1, 2004. Mr. Kolls was named Senior Vice President, General Counsel and Corporate Secretary effective October 1, 2006. From 2001 to 2004, Mr. Kolls was Associate General Counsel for CSX Corporation. Mr. Kolls began his legal career as an attorney in private practice with the law firm of Morgan, Lewis & Bockius.

Michael M. Finegan. Mr. Finegan joined Orthofix International N.V. in June 2006 as Vice President of Business Development. Mr. Finegan was named President of Biologics in March 2009. 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.

Denise E. Pedulla, J.D., M.P.H. Ms. Pedulla joined Orthofix in June 2008 as Senior Vice President and Chief Compliance Officer. Prior to joining Orthofix, Ms. Pedulla spent eight years as an attorney in private practice. Ms. Pedulla was formerly Vice President, Compliance, Regulatory and Government Affairs and Associate General Counsel for Fresenius Medical Care North America.

Brad Lee. Mr. Lee became President of BREG in July 2008. 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 of International Orthopedic Fixation in April 2008. Since February 2006, 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.

Peter J. Hewett. Mr. Hewett was appointed Deputy Chairman of the Board of Directors in 2005 and has been a non-executive Director of Orthofix International N.V. since March 1992. He was the Deputy Group Chairman of Orthofix International N.V. between March 1998 and December 2000. Previously, Mr. Hewett served as the Managing Director of Caradon Plc, Chairman of the Engineering Division, Chairman and President of Caradon Inc., Caradon Plc's U.S. subsidiary and a member of the Board of Directors of Caradon Plc of England. In addition, he was responsible for Caradon Plc's worldwide human resources function, and the development of its acquisition opportunities.

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Charles W. Federico. Mr. Federico has been a Director of Orthofix International N.V. from October 1996, President and Chief Executive Officer of Orthofix International N.V. from January 1, 2001 until April 1, 2006 and President of Orthofix, Inc. from October 1996 to January 1, 2001. From 1985 to 1996 Mr. Federico was the President of Smith & Nephew Endoscopy (formerly Dyonics, Inc.). From 1981 to 1985, Mr. Federico served as Vice President of Dyonics, initially as Director of Marketing and subsequently as General Manager. Previously, he held management and marketing positions with General Foods Corporation, Puritan Bennett Corporation and LSE Corporation. Mr. Federico is a director of SRI/Surgical Express, Inc., BioMimetic Therapeutics, Inc., Power Medical Innovations, Inc. and MAKO Surgical Corp.

Jerry C. Benjamin. Mr. Benjamin became a non-executive Director of Orthofix International N.V. in March 1992. He has been a General Partner of Advent Venture Partners, a venture capital management firm in London, since 1985. Mr. Benjamin is a director of Micromet, Inc., Ivax Diagnostics, Inc. and a number of private health care companies.

Walter von Wartburg, Ph.D. Dr. von Wartburg became a non-executive Director of Orthofix International N.V. in June 2004. He is an attorney and has practiced privately in his own law firm in Basel, Switzerland since 1999, specializing in life sciences law. He has also been a Professor of administrative law and public health policy at the Saint Gall Graduate School of Economics in Switzerland for 25 years. Previously, he held top management positions with Ciba Pharmaceuticals and Novartis at their headquarters in Basel, Switzerland.

Thomas J. Kester, CPA. Mr. Kester became a non-executive Director of Orthofix International N.V. in August 2004. Mr. Kester retired after 28 years, 18 as an audit partner, from KPMG LLP in 2002. While at KPMG, he served as the lead audit engagement partner for both public and private companies and also served four years on KPMG's National Continuous Improvement Committee. Mr. Kester earned a Bachelor of Science degree in mechanical engineering from Cornell University and an MBA degree from Harvard University.

Kenneth R. Weisshaar. Mr. Weisshaar became a non-executive Director of Orthofix International N.V. in December 2004. From 2000 to 2002, Mr. Weisshaar served as Chief Operating Officer and strategy advisor for Sensatex, Inc. Prior to that, Mr. Weisshaar spent 12 years as a corporate officer at Becton Dickson, a medical device company, where at different times he was responsible for global businesses in medical devices and diagnostic products and served as Chief Financial Officer and Vice President, Strategic Planning. Mr. Weisshaar earned a Bachelor of Science degree from Massachusetts Institute of Technology and an MBA from Harvard University. Mr. Weisshaar is a director of Precision Therapeutics, Inc.

Guy J. Jordan, Ph.D. Dr. Jordan became a non-executive Director of Orthofix International N.V. in December 2004. Most recently, from 1996 to 2002, Dr. Jordan served as a Group President at CR Bard, Inc., a medical device company, where he had strategic and operating responsibilities for Bard's global oncology business and functional responsibility for all of Bard's research and development. Dr. Jordan earned a Ph.D. in organic chemistry from Georgetown University as well as an MBA from Fairleigh Dickinson University. He also currently serves on the boards of VasoNova, Inc. and EndoGastric Solutions, Inc.

Maria Sainz. Ms. Sainz became a non-executive Director of Orthofix International N.V. in June 2008. She currently serves as the President and CEO of Concentric Medical. Prior to joining Concentric Medical she was President of Guidant Corporation's Cardiac Surgery Division and a member of Guidant's Management Committee prior to their acquisition by Boston Scientific. She gained significant experience in the medical device market with Lilly MDD, Guidant and Boston Scientific. Ms. Sainz holds a Bachelors and Masters Degree of Arts from the Universidad Complutense de Madrid, and a Masters Degree in International Management from AGSIM in Arizona.

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Audit Committee

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended. Messrs. Benjamin, Kester and Weisshaar currently serve as members of the Audit Committee. All of the members of our Audit Committee are "independent" as defined by the current SEC and NASDAQ(R) rules. Our Board of Directors has determined that Messrs. Benjamin, Kester and Weisshaar are "audit committee financial experts" in accordance with current SEC rules.

Code of Ethics

We have adopted a code of ethics applicable to our directors, officers and employees worldwide, including our Chief Executive Officer and Chief Financial Officer. A copy of our code of ethics is available on our website at www.orthofix.com.

Section 16(a) Beneficial Ownership Reporting Compliance

We will provide the information regarding Section 16(a) beneficial ownership reporting compliance 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 "Section 16(a) Beneficial Ownership Reporting Compliance," and 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
3.1	Certificate of Incorporation of the Company (filed as an exhibit to the Company’s annual report on Form 20-F dated June 29, 2001 and incorporated herein by reference).
3.2	Articles of Association of the Company as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.1	Orthofix International N.V. Amended and Restated Stock Purchase Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).
10.2	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).
10.3	Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company’s current report on Form 8-K filed June 26, 2007 and incorporated herein by reference).
10.4	Amendment No. 1 to the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed June 20, 2008 and incorporated herein by reference).
10.5	Form of Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (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).
10.6	Form of Nonqualified Stock Option 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).

10.7 Form of Restricted Stock Grant Agreement under the Orthofix International N.V. Amended and Restated 2004 Long Term Incentive Plan (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).

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10.8 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).

10.9 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 Acquisition Agreement dated as of November 20, 2003, among Orthofix International N.V., Trevor Acquisition, Inc., Breg, Inc. and Bradley R. Mason, as shareholders' representative (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).

10.11 Amended and Restated Voting and Subscription Agreement dated as of December 22, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed on January 8, 2004 and incorporated herein by reference).

10.12 Amendment to Employment Agreement dated December 29, 2005 between Orthofix Inc. and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed December 30, 2005 and incorporated herein by reference).

10.13* Form of Indemnity Agreement.

10.14 Settlement Agreement dated February 23, 2006, between Intavent Orthofix Limited, a wholly-owed subsidiary of Orthofix International N.V. and Galvin Mould (filed as an exhibit to the Company's annual report on Form 8-K filed on April 17, 2006 and incorporated herein by reference).

10.15 Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.16 Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.17 Amended and Restated Employment Agreement, dated December 6, 2007, between Orthofix Inc. and Michael M. Finegan. (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.18 Credit Agreement, dated as of September 22, 2006, among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, the several banks and other financial institutions as may from time to time become parties thereunder, and Wachovia Bank, National Association (filed as an exhibit to the Company's current report on Form 8-K filed September 27, 2006 and incorporated herein by reference).

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10.19 First Amendment to Credit Agreement, dated September 29, 2008, by and among Orthofix Holdings, Inc., Orthofix International N.V., certain domestic subsidiaries of Orthofix International N.V., Colgate Medical Limited, Victory Medical Limited, Swiftsure Medical Limited, Orthofix UK Ltd, and Wachovia Bank, National Association, as administrative agent on behalf of the Lenders under the Credit Agreement (filed as an exhibit to the Company's current report on Form 8-K filed September 29, 2008 and incorporated herein by reference).

10.20 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).

10.21 Employment Agreement, dated as of September 22, 2006, between Blackstone Medical, Inc. and Matthew V. Lyons (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2006, as amended, and incorporated herein by reference).

10.22 Amended and Restated Employment Agreement dated December 6, 2007 between Orthofix Inc. and Timothy M. Adams (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.23 Nonqualified Stock Option Agreement between Timothy M. Adams and Orthofix International N.V. dated November 19, 2007 (filed as an exhibit to the Company's current report on Form 8-K filed November 21, 2007 and incorporated herein by reference).

10.24 Employment Agreement between Orthofix Inc. and Scott Dodson, dated as of December 10, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.25 Employment Agreement between Orthofix Inc. and Michael Simpson, dated as of December 6, 2007 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.26 Description of Director Fee Policy (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2007, as amended, and incorporated herein by reference).

10.27 Summary of Orthofix International N.V. Annual Incentive Program (filed as an exhibit to the Company's current report on Form 8-K filed April 11, 2008, and incorporated herein by reference).

10.28 Employment Agreement between Orthofix Inc. and Thomas Hein dated as of April 11, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).

10.29 Nonqualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan, dated April 11, 2008, between Orthofix International N.V. and Thomas Hein (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).

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10.30 Summary of Consulting Arrangement between Orthofix International N.V. and Peter Hewett (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2008 and incorporated herein by reference).

10.31 Employment Agreement between Orthofix Inc. and Denise E. Pedulla dated as of June 9, 2008 (filed as an exhibit to the company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference).

10.32 Form of 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).

10.33 Employment Agreement between Orthofix Inc. and Robert S. Vaters effective September 7, 2008 (filed as an exhibit to the company's current report on Form 8-K filed September 10, 2008 and incorporated herein by reference).

10.34 Offer Letter from Orthofix International N.V. to Robert S. Vaters dated September 5, 2008 (filed as an exhibit to the Company's current report on Form 8-K filed September 10, 2008 and incorporated herein by reference).

10.35+ Letter Agreement between Orthofix Inc. and Oliver Burckhardt dated August 28, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).

10.36 Notice of Termination from Orthofix Inc. to Oliver Burckhardt dated August 27, 2008 (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference).

10.37 Employment Agreement between Orthofix Inc. 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).

10.38 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).

10.39 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).

21.1*	List of Subsidiaries.
23.1*	Consent of Ernst & Young LLP.
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.

* 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.

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SIGNATURES

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

ORTHOFIX INTERNATIONAL N.V.

Dated: March 12, 2009

By: /s/ Alan W. Milinazzo
Name: Alan W. Milinazzo
Title: Chief Executive Officer and President

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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/ Alan w. Milinazzo Alan W. Milinazzo	Chief Executive Officer, President and Director	March 12, 2009
/s/ Robert S. vaters Robert S. Vaters	Executive Vice President and Chief Financial Officer	March 12, 2009
/s/ james f. gero James F. Gero	Chairman of the Board of Directors	March 12, 2009
/s/ peter j. hewett Peter J. Hewett	Deputy Chairman of the Board of Directors	March 12, 2009
/s/ Charles w. federico Charles W. Federico	Director	March 12, 2009
/s/ jerry c. benjamin Jerry C. Benjamin	Director	March 12, 2009
/s/ walter von wartburg Walter von Wartburg	Director	March 12, 2009
/s/ thomas j. kester Thomas J. Kester	Director	March 12, 2009
/s/ kenneth r. weisshaar Kenneth R. Weisshaar	Director	March 12, 2009
/s/ guy jordan Guy Jordan	Director	March 12, 2009
/s/ Maria Sainz Maria Sainz	Director	March 12, 2009

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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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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 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 have full and free access to the Audit Committee.

James F. Gero
Chairman of the Board of Directors

Alan W. Milinazzo
President, Chief Executive Officer and Director

Robert S. Vaters
Executive Vice President and Chief Financial Officer

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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, 2008 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, 2008, 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

Alan W. Milinazzo
President, Chief Executive Officer and Director

Robert S. Vaters
Executive Vice President and Chief Financial Officer

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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 the accompanying consolidated balance sheets of Orthofix International N.V. as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

As discussed in Note 15 to the consolidated financial statements, the Company adopted Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109, effective January 1, 2007.

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, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 11, 2009

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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, 2008 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, 2008, 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, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2008 of Orthofix International N.V. and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 11, 2009

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Consolidated Balance Sheets as of December 31, 2008 and 2007

(U.S. Dollars, in thousands except share and per share data)	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 14,594	$ 25,064
Restricted cash	10,998	16,453
Trade accounts receivable, less allowance for doubtful accounts of $6,473 and $6,441 at December 31, 2008 and 2007, respectively	110,720	108,900
Inventories, net	91,185	93,952
Deferred income taxes	17,543	11,373
Prepaid expenses	6,923	8,055
Other current assets	22,687	16,980
Total current assets	274,650	280,777
Investments, at cost	2,095	4,427
Property, plant and equipment, net	32,660	33,444
Patents and other intangible assets, net	53,546	230,305
Goodwill	182,581	319,938
Deferred taxes and other long-term assets	15,683	16,773
Total assets	$ 561,215	$ 885,664
Liabilities and shareholders' equity		
Current liabilities:		
Bank borrowings	$ 1,907	$ 8,704
Current portion of long-term debt	3,329	3,343
Trade accounts payable	22,179	22,526
Accounts payable to related parties	1,686	2,189
Other current liabilities	45,894	36,544
Total current liabilities	74,995	73,306
Long-term debt	277,533	294,588
Deferred income taxes	4,509	75,908
Other long-term liabilities	2,117	7,922
Total liabilities	359,154	451,724
Contingencies (Note 17)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 17,103,142 and 17,038,304 issued and outstanding as of December 31, 2008 and 2007, respectively	1,710	1,704
Additional paid-in capital	167,818	157,349
Retained earnings	29,647	258,201
Accumulated other comprehensive income	2,886	16,686
Total shareholders' equity	202,061	433,940
Total liabilities and shareholders' equity	$ 561,215	$ 885,664

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

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Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006

(U.S. Dollars, in thousands, except share and per share data)	2008	2007	2006
Net sales	$ 519,675	$ 490,323	$ 365,359
Cost of sales	152,014	129,032	93,625
Gross profit	367,661	361,291	271,734
Operating expenses (income)			
Sales and marketing	206,913	186,984	145,707
General and administrative	81,806	72,902	53,309
Research and development, including $40,000 of purchased in-process research and development in 2006	30,844	24,220	54,992
Amortization of intangible assets	17,094	18,156	8,873
Impairment of goodwill and certain intangible assets	289,523	20,972	-
Gain on sale of Pain Care(R) operations	(1,570)	-	-
KCI settlement, net of litigation costs	-	-	(1,093)
	624,610	323,234	261,788
Operating income (loss)	(256,949)	38,057	9,946
Other income (expense)			
Interest income	542	1,043	2,236
Interest expense	(20,216)	(24,720)	(8,361)
Unrealized non-cash loss on interest rate swap	(7,975)	-	-
Loss on refinancing of senior secured term loan	(5,735)	-	-
Other, net	(4,702)	355	2,498
Other income (expense), net	(38,086)	(23,322)	(3,627)
Income (loss) before income taxes	(295,035)	14,735	6,319
Income tax benefit (expense)	66,481	(3,767)	(13,361)
Net (loss) income	$ (228,554)	$ 10,968	$ (7,042)
Net income (loss) per common share - basic	$ (13.37)	$ 0.66	$ (0.44)
Net income (loss) per common share - diluted	$ (13.37)	$ 0.64	$ (0.44)
Weighted average number of common shares - basic	17,095,416	16,638,873	16,165,540
Weighted average number of common shares - diluted	17,095,416	17,047,587	16,165,540

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

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Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2008, 2007 and 2006

(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, 2005	16,009,249	$ 1,602	$ 106,746	$ 255,475	$ 5,062	$ 368,885
Net loss	–	–	–	(7,042)	–	(7,042)
Other comprehensive income:						
Unrealized loss on derivative instrument (net of taxes of $30)	–	–	–	–	(55)	(55)
Translation adjustment	–	–	–	–	9,253	9,253
Total comprehensive income						2,156
Tax benefit on exercise of stock options	–	–	2,175	–	–	2,175
Share-based compensation expense	–	–	7,912	–	–	7,912
Common shares issued	436,610	43	11,464	–	–	11,507
At December 31, 2006	16,445,859	1,645	128,297	248,433	14,260	392,635
Cumulative effect adjustment for the adoption of FIN 48	–	–	–	(1,200)	–	(1,200)
Net income	–	–	–	10,968	–	10,968
Other comprehensive income:						
Unrealized gain on derivative instrument (net of taxes of $586)	–	–	–	–	1,585	1,585
Translation adjustment	–	–	–	–	841	841
Total comprehensive income						12,194
Tax benefit on exercise of stock options	–	–	2,145	–	–	2,145
Share-based compensation expense	–	–	11,913	–	–	11,913
Common shares issued	592,445	59	14,994	–	–	15,053
At December 31, 2007	17,038,304	1,704	157,349	258,201	16,686	433,940
Net loss	–	–	–	(228,554)	–	(228,554)
Other comprehensive income:						
Unrealized gain on derivative instrument (net of taxes of $609)	–	–	–	–	1,567	1,567

Translation adjustment	–	–	–	–	(15,367)	(15,367)
Total comprehensive loss						(242,354)
Tax benefit on exercise of stock options	–	–	22	–	–	22
Reclassification adjustment for tax benefit on exercise of stock options	–	–	(1,870)			(1,870)
Share-based compensation expense	–	–	10,589	–	–	10,589
Common shares issued	64,838	6	1,728			1,734
At December 31, 2008	17,103,142	$ 1,710	$ 167,818	$ 29,647	$ 2,886	$ 202,061

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

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Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006

(U.S. Dollars, in thousands)	2008	2007	2006
Cash flows from operating activities:			
Net income (loss)	$ (228,554)	$ 10,968	$ (7,042)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	31,279	28,531	16,457
Amortization of debt costs	911	1,085	501
Provision for doubtful accounts	7,261	7,326	5,475
Deferred taxes	(79,158)	(12,168)	(12,363)
Share-based compensation	10,589	11,913	7,912
Change in Blackstone inventory obsolescence estimate	10,913	-	-
Loss on refinancing of senior secured term loan	3,660	-	-
In-process research and development	-	-	40,000
Impairment of goodwill and certain intangible assets	289,523	20,972	-
Change in fair value of interest rate swap	7,975	-	-
Impairment of investments held at cost	1,500	-	-
Amortization of step up of fair value in inventory	493	2,718	1,001
Gain on sale of Pain Care(R) operations	(1,570)	-	-
Other	(743)	(5,816)	(1,314)
Changes in operating assets and liabilities, net of effect of acquisitions:			
Restricted cash	5,444	(9,153)	6,582
Accounts receivable	(13,182)	(8,685)	(10,308)
Inventories	(13,731)	(22,745)	(13,868)
Prepaid expenses and other current assets	(5,046)	(5,855)	(4,521)
Accounts payable	675	303	6,448
Other current liabilities	(1,469)	2,102	(26,789)
Net cash provided by operating activities	26,770	21,496	8,171
Cash flows from investing activities:			
Payments made in connection with acquisitions and investments, net of cash acquired	(500)	(3,142)	(342,290)
Capital expenditures for property, plant and equipment	(15,600)	(18,537)	(11,225)
Capital expenditures for intangible assets	(4,592)	(8,692)	(1,388)
Proceeds from sale of assets	769	-	-
Proceeds from sale of Pain Care(R) operations	5,980	-	-
Net cash used in investing activities	(13,943)	(30,371)	(354,903)
Cash flows from financing activities:			
Net proceeds from issue of common shares	1,734	15,053	11,507
Payment of refinancing fees and debt issuance costs	(283)	(184)	(5,884)
Repayment of long-term debt	(17,069)	(17,483)	(15,139)
Tax benefit on non-qualified stock options	22	2,145	2,175
Proceeds from long-term debt	-	25	315,175
Proceeds from (repayment of) bank borrowings	(6,721)	8,131	(10)
Net cash provided by (used in) financing activities	(22,317)	7,687	307,824
Effect of exchange rates changes on cash	(980)	371	1,003
Net decrease in cash and cash equivalents	(10,470)	(817)	(37,905)
Cash and cash equivalents at the beginning of the year	25,064	25,881	63,786
Cash and cash equivalents at the end of the year	$ 14,594	$ 25,064	$ 25,881

Supplemental disclosure of cash flow information			
Cash paid during the year for:			
Interest	$ 19,311	$ 27,477	$ 7,386
Income taxes	$ 12,602	$ 15,908	$ 31,773

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

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Notes to the consolidated financial statements

Description of business

Orthofix International N.V. (the "Company") is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment, principally for the Orthopedic products market.

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.

The results of acquired businesses are included in the consolidated statements of operations from the date of their acquisition. All intercompany accounts, transactions and profits are eliminated in the consolidated financial statements. The Company's investments in which it does not have significant influence or control are accounted for under the cost method of accounting.

(b) Foreign currency translation

Foreign currency translation is performed in accordance with Statement of Financial Accounting Standards ("SFAS") No. 52, "Foreign Currency Translation." 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 the translation of foreign currency are recorded in the accumulated other comprehensive income component of shareholders' equity. Transactional foreign currency gains and losses, including intercompany transactions that are not long-term investing in nature, are included in other income (expense), net and were $(2.7) million, $0.8 million and $2.8 million for the years ended December 31, 2008, 2007 and 2006, respectively.

(c) 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 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.

(d) Reporting currency

The reporting currency is the United States Dollar.

(e) 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 exposure to interest rate fluctuations. During 2008, 2007 and 2006, the Company made use of a foreign currency swap agreement entered into in December 2006 to manage exposure to foreign currency fluctuations. See Note 11 for additional information.

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Notes to the consolidated financial statements (cont.)

(f) Long-lived assets

Property, plant and equipment is stated at cost less accumulated depreciation. Plant and equipment also includes instrumentation and other working assets. 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, equipment	2 to 10
Instrumentation	3 to 4
Furniture and fixtures	4 to 8

Expenditures for maintenance and repairs and minor renewals and improvements, which do not extend the lives of the respective assets, are expensed. 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”), certain trademarks, licenses, customer relationships and distribution networks. Identifiable intangible assets which are considered definite lived are generally amortized over their useful lives using a method of amortization that reflects the pattern in which the economic benefit of the intangible assets are consumed. The Company’s weighted average amortization period for developed technologies and distribution networks is 11 and 9 years, respectively.

SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” requires that intangible assets with definite lives, such as Orthofix’s developed technologies and distribution network assets, be 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, 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 the Company expects to generate from the asset using a risk-adjusted discount rate. 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 trademarks at least annually. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. In performing the test, the Company utilizes the two-step approach prescribed under SFAS No. 142, “Goodwill and Other Intangible Assets”. The

first step requires a comparison of the carrying value of the reporting units, as defined in the standard, to the fair value of these units. For purposes of performing the annual goodwill impairment test, assets and liabilities, including corporate assets, which relate to a reporting unit's operations, and would be considered in determining fair value, are allocated to the individual reporting units. The Company allocates assets and liabilities not directly related to a specific reporting unit, but from which the reporting unit benefits, based primarily on the respective contribution of each reporting unit. If the carrying value of a reporting unit exceeds its fair value, the Company will perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any.

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Notes to the consolidated financial statements (cont.)

The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill to its carrying value. If the Company was unable to complete the second step of the test prior to the issuance of the Company's financial statements and an impairment loss was probable and could be reasonably estimated, the Company would recognize the Company's best estimate of the loss in the current period financial statements and disclose that the amount is an estimate. The Company would then recognize any adjustment to that estimate in subsequent reporting periods, once the Company has finalized the second step of the impairment test.

Certain of the impairment tests require Orthofix to make an estimate of the fair value of goodwill and other intangible assets, which is 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, Orthofix is unable to predict whether impairments of goodwill or other indefinite lived intangibles will occur in the future.

(g) Revenue recognition and accounts receivable

Revenue is generally recognized as income in the period in which title passes and the products are delivered. For bone growth stimulation and certain bracing products 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. The Company derives a significant amount of revenues in the United States 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 such third-party payors and may be subject to adjustment. For royalties, revenues are recognized when the royalty is earned. Revenues for inventory delivered on consignment are recognized as the product is used by the consignee. Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs are included in cost of sales.

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collection and payor reimbursement experience is an integral part of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. 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.

(h) Research and development costs

Expenditures for research and development are expensed as incurred. In accordance with SFAS No. 141 "Business Combinations" and Emerging Issues Task Force ("EITF") Consensus No. 96-7 "Accounting for Deferred Taxes on In-Process Research and Development Activities Acquired in a Purchase Business Combination," the Company

recognizes acquired in-process research and development to research and development expense on the day of acquisition, with no corresponding tax benefit.

On July 24, 2008, the Company entered into an agreement with Musculoskeletal Transplant Foundation ("MTF") to collaborate on the development and commercialization of a new stem cell-based bone growth biologic matrix. Under the terms of the agreement, the Company will invest up to $10.0 million in the development of the new stem cell-based bone growth biologic matrix that will be designed to provide the beneficial properties of an autograft in spinal and orthopedic surgeries. After the completion of the development process, the Company and MTF will operate under the terms of a separate commercialization agreement. Under the terms of this 10-year agreement, MTF will source the tissue, process it to create the bone growth matrix, and package and deliver it in accordance with orders received directly from customers and from the Company. The Company will have exclusive global marketing rights for the new allograft and will receive a marketing fee from MTF based on total sales. The Company accounts for collaborative arrangements considering guidance included in Emerging Issues Task Force Issue No. 07-1 "Accounting for Collaborative Arrangements," as there was no other prevailing guidance. Approximately $6.1 million of expenses incurred under the terms of the agreement are included in research and development expense in the year ended December 31, 2008.

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Notes to the consolidated financial statements (cont.)

(i) Income taxes

Income taxes have been provided using the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes." Deferred income taxes arise because of differences in the treatment of income and expense items for financial reporting and income tax purposes. Deferred tax assets and liabilities resulting from such differences are recorded based on the enacted tax rates that will be in effect when the differences are expected to reverse. The Company has operations in various tax jurisdictions.

On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" ("FIN 48"), which clarifies the accounting for uncertainty in income taxes. As a result of the implementation of FIN 48, the Company recognized $1.2 million in additional liability for unrecognized tax benefits (including interest and penalties), which was accounted for as a reduction to the January 1, 2007 balance of retained earnings. As of December 31, 2008, the Company had $0.7 million of unrecognized tax benefits.

(j) Net income per common share

Net income per common share is computed in accordance with SFAS No. 128, "Earnings per Share." Net income per common share – basic is computed using the weighted average number of common shares outstanding during each of the respective years. Net income 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. Common equivalent shares represent the dilutive effect of the assumed exercise of outstanding share options (see Note 20) and the only differences between basic and diluted shares result solely from the assumed exercise of certain outstanding share options and warrants. In 2006 and 2008, the effect of options was not included in the calculation because the inclusion would have been anti-dilutive.

(k) 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.

(l) 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 10 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 Colgate Medical Limited and its subsidiaries. All credit party subsidiaries have access to this cash for operational and debt repayment purposes.

(m) Sale of accounts receivable

The Company follows the provisions of SFAS No. 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishment of Liabilities". Trade accounts receivables sold without recourse are removed from the balance sheet at the time of sale. The Company generally does not require collateral on trade receivables.

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Notes to the consolidated financial statements (cont.)

(n) Use of estimates in preparation of financial statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 contractual allowances, doubtful accounts, inventories, taxes and potential goodwill and intangible asset impairment. Actual results could differ from these estimates.

(o) Reclassifications

Certain prior year amounts have been reclassified to conform to the 2008 presentation. The reclassifications have no effect on previously reported net earnings or shareholders' equity.

(p) Share-based compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123(R) (revised 2004), "Share-Based Payment," using the modified prospective transition method. Under this transition method, share-based compensation expense recognized in 2008, 2007 and 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). 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 term 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. For the year ended December 31, 2008, options were valued at an expected term of 3.92 years, expected volatility of 28.4%, risk-free interest rates between 1.52% and 3.49%, and a dividend rate of zero. The Company has chosen to use the "short-cut method" to determine the pool of windfall tax benefits as of the adoption of SFAS No. 123(R).

As of December 31, 2008, the unamortized compensation expense relating to options granted and expected to be recognized is $8.5 million. This expense is expected to be recognized over a weighted average period of 1.34 years.

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Notes to the consolidated financial statements (cont.)

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, 2008, 2007 and 2006:

(In US$ thousands)	Year Ended December 31, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006
Cost of sales	$ 175	$ 403	$ 238
Sales and marketing (1)	1,890	2,749	1,411
General and administrative	7,731	7,884	5,537
Research and development	793	877	726
Total	$ 10,589	$ 11,913	$ 7,912

(1) There are no performance requirements and there was no consideration received for share-based compensation awarded to sales and marketing employees.

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. 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 $3.5 million at December 31, 2008.

(q) Recently Issued Accounting Standards

In May 2008, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 162, “The Hierarchy of Generally Accepted Accounting Principles.” The Statement identified the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. The Statement is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.” We do not anticipate the adoption of SFAS No. 162 to have a material impact on the Company’s results of operations or financial position.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133.” SFAS No. 161 requires entities to provide greater transparency through additional disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 “Accounting for Derivative Instruments and Hedging Activities” and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity’s financial position, results of operations, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company is currently evaluating the

potential impact of adopting SFAS No. 161 on the Company's disclosures of its derivative instruments and hedging activities.

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Notes to the consolidated financial statements (cont.)

In December 2007, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-1, "Accounting for Collaborative Arrangements" (EITF 07-1). EITF 07-1 provides guidance related to the classification of the payments between participants, the appropriate income statement presentation, as well as disclosures related to certain collaborative arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and will be adopted by the Company in the first quarter of 2009. The Company applied the guidance included in EITF 07-1 to collaborative arrangements entered into in 2008 for such contracts in which there was no prevailing guidance.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations (revised 2007)." SFAS No. 141(R) amends SFAS No. 141, "Business Combinations," and provides revised guidance for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree. It also provides disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008 and is to be applied prospectively. The Company is currently evaluating the potential impact of adopting SFAS No. 141(R) on its consolidated financial position and results of operations.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB 51," which establishes accounting and reporting standards pertaining to ownership interest in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of any retained noncontrolling equity investment when a subsidiary is deconsolidated. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We do not anticipate the adoption of SFAS No. 160 to have a material impact on the Company's results of operations or financial position.

(r) Fair value of financial instruments

The carrying amounts reflected in the Consolidated Balance Sheets for cash and cash equivalents, 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 long-term secured debt carries a floating rate of interest and therefore, the carrying value is considered to approximate fair value.

(s) Advertising costs

The Company expenses all advertising costs as incurred. Advertising expense for the years ended December 31, 2008, 2007 and 2006 was $1.1 million, $1.8 million and $1.0 million, respectively.

(t) Derivative instruments

The Company manages its exposure to fluctuations 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. For instruments designated as a fair value hedge, the Company ensures an exposed position is being hedged and the changes in fair value of such instruments are recognized in earnings.

The Company follows SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities,” as amended and interpreted, which requires that all derivatives be recorded 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 affects net earnings.

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Notes to the consolidated financial statements (cont.)

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 SFAS No. 133.

See Note 11 for a description of the types of derivative instruments the Company utilizes.

(u) Accumulated other comprehensive income (loss)

Accumulated other comprehensive income (loss) is comprised of foreign currency translation adjustments, and the effective portion of the gain (loss) for derivatives designated and accounted for as a cash flow hedge. The components of other comprehensive income (loss) are as follows:

(In US$ thousands)	Foreign Currency Translation Adjustments	Fair Value of Derivatives	Accumulated Other Comprehensive Income
Balance at December 31, 2007	$ 15,156	$ 1,530	$ 16,686
Balance at December 31, 2008	(211)	3,097	2,886

2. Acquisitions

Blackstone Acquisition

On September 22, 2006, the Company purchased 100% of the stock of Blackstone Medical, Inc. ("Blackstone") for a purchase price of $333.0 million plus acquisition costs. The acquisition and related costs were financed with approximately $330.0 million of senior secured bank debt, as described in Note 10, and cash on hand. Blackstone, a company based in Springfield, Massachusetts, which was privately held when acquired by the Company, specializes in the design, development and marketing of spinal implant and related HCT/P products. Blackstone's product lines include spinal fixating devices including hooks, rods, screws, plates, various spacers and cages and related HCT/P products. The Company considered this acquisition as a way to fortify and further advance its business strategy to expand its spinal sector. The acquisition broadened the Company's product lines, reduced reliance on the success of any single product and enlarged channel opportunities for products from Blackstone's and the Company's existing operations.

The acquisition has been accounted for using the purchase method in accordance with SFAS No. 141, "Business Combinations". The purchase price has been allocated to the assets acquired and liabilities assumed based on their estimated fair market value at the date of acquisition. The purchase price allocation resulted in goodwill of $136.2 million and $202.0 million of intangible assets. In 2007 and 2008, the Company recorded impairment charges related to certain assets recorded at Blackstone, see Note 6, "Patents and Other Intangible Assets" and Note 7, "Goodwill" for further detail.

The purchase price was allocated to assets acquired, purchased in-process research and development and liabilities assumed based on their estimated fair market value at the acquisition date. The amount of the purchase price allocated to purchased in-process research and development was recognized at the date of acquisition and resulted in a charge of

$40.0 million. This charge was included in the research and development expense line item on the Consolidated Statements of Operations for the year ended December 31, 2006 and was not deductible for income tax purposes in the United States.

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Notes to the consolidated financial statements (cont.)

Of the total Blackstone purchase price, $50.0 million was placed into an escrow account. As described in the Agreement and Plan of Merger, the Company can make claims for reimbursement from the escrow account for certain defined items relating to the acquisition for which the Company is indemnified. See Note 17, “Contingencies” for further information.

The summary unaudited pro forma condensed results of operations and earnings per share, for the year ended December 31, 2006, assuming consummation of the Blackstone acquisition as of January 1, 2006, is as follows:

(In US$ thousands)	Year Ended December 31, 2006	
	As Reported	Pro Forma*
Net sales	$ 365,359	$ 427,489
Net income (loss)	(7,042)	16,494
Per share data:		
Basic	$ (0.44)	$ 1.02
Diluted	$ (0.44)	$ 1.01

* In-process research and development charge of $40.0 million recorded during the year ended December 31, 2006 has been excluded from the pro forma financial information.

International Medical Supplies Distribution GmbH Acquisition

In February 2006, the Company purchased 52% of International Medical Supplies Distribution GmbH (“IMES”), a German distributor of Breg products, for $1.5 million plus closing adjustments and acquisition costs. The operations of the acquired distributor are included in the Company's Statements of Operations from the date of acquisition. The results of operations would not be materially different if the acquisition had been consolidated as of January 1, 2006. The final purchase price included approximately $0.1 million of working capital and $1.0 million of goodwill.

3. Inventories

(In US$ thousands)	December 31, 2008	2007
Raw materials	$ 9,314	$ 10,804
Work-in-process	8,829	6,100
Finished products	57,151	42,384
Field inventory	13,633	13,997
Consignment inventory	23,426	30,560
	112,353	103,845
Less reserve for obsolescence	(21,168)	(9,893)
	$ 91,185	$ 93,952

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Notes to the consolidated financial statements (cont.)

See Note 1 “Summary of significant accounting policies” part (c) “Inventories” for a description of field inventory.

In the year ended December 31, 2008, due to reduced projections in revenue, distributor terminations, new products, and the replacement of one product with a successor product, the Company changed its estimates regarding the inventory allowance at Blackstone, primarily based on estimated net realizable value using assumptions about future demand and market conditions. The change in estimate resulted in an increase in the reserve for obsolescence of approximately $10.9 million.

4. Investments

The Company had total investments held at cost of $2.1 million and $4.4 million as of December 31, 2008 and 2007, respectively. Investments at December 31, 2008 are comprised of an investment of $1.8 million in OPED AG, a German-based bracing company, and $0.3 million in Biowave Corporation, a pain therapy company. During the third quarter of 2008, the Company sold a portion of its ownership in OPED AG, for net proceeds of $0.8 million. The Company has assessed these cost investments as of December 31, 2008 and 2007, noting no impairment in carrying value.

The Company also has an investment in OrthoRx. The investment was reduced to zero in 2004. For the year ended December 31, 2008, the Company’s investment in Innovative Spinal Technologies (IST), which was recorded at $1.5 million as of December 31, 2007, was reduced to zero.

5. Property, plant and equipment

(In US$ thousands)	December 31, 2008	2007
Cost		
Buildings	$ 3,340	$ 3,445
Plant, equipment and instrumentation	76,827	75,900
Furniture and fixtures	10,638	10,266
	90,805	89,611
Accumulated depreciation	(58,145)	(56,167)
	$ 32,660	$ 33,444

Depreciation expense for the years ended December 31, 2008, 2007 and 2006 was $14.2 million, $10.4 million and $7.6 million, respectively.

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Notes to the consolidated financial statements (cont.)

6. Patents and other intangible assets

(In US$ thousands)	December 31, 2008	2007
Cost		
Patents and developed technologies	$ 25,602	$ 107,235
Trademarks – definite lived (subject to amortization)	105	714
Trademarks – indefinite lived (not subject to amortization)	23,382	80,844
Distribution networks	44,586	98,586
	93,675	287,379
Accumulated amortization		
Patents and developed technologies	(13,194)	(28,254)
Trademarks – definite lived (subject to amortization)	(105)	(559)
Distribution networks	(26,830)	(28,261)
Patents and other intangible assets, net	$ 53,546	$ 230,305

Amortization expense for intangible assets is estimated to be approximately $6.3 million, $6.2 million, $6.1 million, $4.9 million and $6.7 million for the periods ending December 31, 2009, 2010, 2011, 2012 and 2013 and thereafter, respectively.

During the third quarter of 2008, the Company determined that a test for impairment of indefinite lived assets at Blackstone in accordance with SFAS No. 142 “Goodwill and Other Intangible Assets,” was necessary due to decreasing revenues at Blackstone, among other matters. The Company evaluated the indefinite-lived intangible assets which included the Blackstone Trademark acquired during the acquisition of Blackstone. The impairment analysis resulted in the carrying value, as adjusted for an impairment charge recognized in the fourth quarter of 2007, of the Trademark exceeding the fair value for which the Company recognized a $57.0 million impairment charge included in Impairment of Goodwill and Certain Intangible Assets in the year ended December 31, 2008.

Also, during the third quarter of 2008, the Company determined that an impairment indicator as described in SFAS No. 144 “Accounting for the Impairment or Disposal of Long-Lived Assets” occurred with respect to the definite-lived intangibles at Blackstone. Due to the impairment indicator, the Company compared the expected cash flows to be generated by the Blackstone reporting unit, which represented the lowest level at which cash flows are specifically identifiable, on an undiscounted basis to the carrying value of the reporting unit’s assets, including goodwill. The Company determined the carrying value of the Blackstone reporting unit exceeded the related undiscounted cash flows, this determination resulted in the impairment of the distribution network and technologies at Blackstone based on their fair values. The resulting impairment charge of $105.7 million is included in Impairment of Goodwill and Certain Intangible Assets.

7. Goodwill

Under SFAS No. 142, “Goodwill and Other Intangible Assets,” goodwill is subject to annual or more frequent impairment testing if indicators of impairment exist, using the guidance and criteria described in the standard. This testing requires the comparison of carrying values to fair values of reporting units, as defined in the standard, and when appropriate, the carrying value of impaired assets is reduced to fair value. During the third quarter of 2008, due to the matters described in Note 6 above, the Company also performed an impairment analysis of the goodwill at

Blackstone. The impairment analysis resulted in a goodwill impairment charge of $126.9 million because the carrying value exceeded the implied fair value of goodwill. For a discussion of acquisitions and the associated goodwill, see Note 2.

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Notes to the consolidated financial statements (cont.)

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

(In US$ thousands)	Domestic	Blackstone	Breg	International	Total
At December 31, 2006	$ 31,793	$ 132,784	$ 101,322	$ 47,171	$ 313,070
Acquisitions (1)	-	-	-	1,558	1,558
Purchase price adjustment (2)	-	3,456	-	-	3,456
Foreign currency	-	-	-	1,854	1,854
At December 31, 2007	31,793	136,240	101,322	50,583	319,938
Disposals (3)	-	-	(2,027)	-	(2,027)
Purchase price adjustment (1)	-	-	-	(365)	(365)
Impairment (4)	-	(126,873)	-	-	(126,873)
Foreign currency	-	-	-	(8,092)	(8,092)
At December 31, 2008	$ 31,793	$ 9,367	$ 99,295	$ 42,126	$ 182,581

(1) Purchase of the remaining 38.74% of the minority interest in Mexican subsidiary and 4.00% of the minority interest in Brazilian subsidiary.

(2) Principally relates to legal fees incurred in connection with the acquisition of Blackstone and related contingencies.

(3) Sale of operations relating to the Pain Care(R) business at Breg during the first quarter of 2008.

(4) The impairment analysis resulted in a goodwill impairment charge of $126.9 million because the carrying value exceeded the implied fair value of goodwill. The fair value of the Blackstone reporting unit was estimated using a combination of the income approach, which estimates the fair value of the reporting units based on the expected present value of future cash flows and, to a lesser extent, the market approach, which estimates the fair value of the reporting units based on comparable market indicators such as multiples of earnings measures.

The income approach, which was more heavily weighted in the Company's development of fair value, calculates fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting these after-tax cash flows to a present value using a risk-adjusted discount rate. This methodology is consistent with how the Company estimates the fair value of reporting units during its annual goodwill impairment tests. In applying the income approach to calculate the fair value of the Blackstone reporting unit, the Company used reasonable estimates and assumptions about future revenue contributions and cost structures. In addition, the application of the income approach requires judgment in determining a risk-adjusted discount rate at the reporting unit level. The Company based this determination on estimates of weighted-average costs of capital of a market participant. The Company performed a peer company analysis and considered the industry weighted-average return on debt and equity from a market participant perspective.

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Notes to the consolidated financial statements (cont.)

To calculate the amount of the goodwill impairment charge, the Company allocated the fair value of the Blackstone reporting unit to all of its assets and liabilities, in-process research and development and certain unrecognized intangible assets, in order to determine the implied fair value of goodwill at September 30, 2008. This allocation process required judgment and the use of additional valuation assumptions in deriving the individual fair values of the Blackstone reporting unit's assets and liabilities as if the Blackstone reporting unit had been acquired in a business combination. The Company believes its determined fair values and the resulting goodwill impairment charge are based on reasonable assumptions and represent the best estimate of these amounts at September 30, 2008.

As of December 31, 2008, the Company performed its annual impairment review of its other reporting units and updated its Blackstone impairment review and determined there was no additional impairment of goodwill.

8. Bank borrowings

	December 31,	
(In US$ thousands)	2008	2007
Borrowings under line of credit	$ 1,907	$ 8,704

The weighted average interest rate on borrowings under lines of credit as of December 31, 2008 and 2007 was 5.86% and 4.79%, respectively.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 5.2 million Euros ($7.3 million) and 1.3 million Euros ($2.0 million) at December 31, 2008 and 2007, respectively, in its Italian line of credit. These lines of credit provide 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.

9. Other current liabilities

	December 31,	
(In US$ thousands)	2008	2007
Accrued expenses	$ 12,247	$ 9,278
Salaries and related taxes payable	15,738	18,413
Interest rate swap	7,975	-
Income taxes payable	2,833	1,964
Other payables	7,101	6,889
	$ 45,894	$ 36,544

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Notes to the consolidated financial statements (cont.)

10. Long-term debt

(In US$ thousands)	December 31, 2008	2007
Long-term obligations	$ 280,700	$ 297,700
Other loans	162	231
	280,862	297,931
Less current portion	(3,329)	(3,343)
	$ 277,533	$ 294,588

On September 22, 2006, the Company's wholly-owned U.S. holding company subsidiary, Orthofix Holdings, Inc. ("Orthofix Holdings"), entered into a senior secured credit facility with a syndicate of financial institutions to finance the acquisition of Blackstone. Certain terms of the senior secured credit facility were amended September 29, 2008. The senior secured credit facility provides for (1) a seven-year amortizing term loan facility of $330.0 million, the proceeds of which, together with cash balances were used for payment of the purchase price of Blackstone; and (2) a six-year revolving credit facility of $45.0 million. As of December 31, 2008, the Company had no amounts outstanding under the revolving credit facility and $280.7 million outstanding under the term loan facility. As of December 31, 2007, the Company had no amounts outstanding under the revolving credit facility and $297.7 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of LIBOR, with a LIBOR floor of 3.0% plus a margin or prime rate plus a margin. Currently, the term loan is a $150.0 million LIBOR loan plus a margin of 4.50% and a $130.7 million prime rate loan plus a margin of 3.5%. The effective interest rate as of December 31, 2008 and 2007 on the senior secured credit facility was 8.4% and 6.58%, respectively.

Each of the domestic subsidiaries of the Company (which includes Orthofix Inc., Breg Inc., and Blackstone), Colgate Medical Limited and Victory Medical have guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of the subsidiaries under their guarantees are secured by the pledges of their respective assets.

In conjunction with obtaining the senior secured credit facility, the Company incurred debt issuance costs of $6.4 million which it has been amortizing over the life of the facility. A portion of the capitalized debt issuance costs included in other long-term assets related to the senior secured credit facility were expensed as a result of the amendment on September 29, 2008, and are included in the loss on refinancing of senior secured term loan. In connection with the amendment to the credit facility, the Company paid additional fees of $2.4 million in the year ended December 31, 2008, of which $2.1 million are included in the loss on refinancing of senior secured term loan. As of December 31, 2008, $0.8 million of debt issuance costs which relate to the Company's revolving credit facility are included in other long-term assets. As of December 31, 2007, debt issuance costs related to the senior secured term loan and the revolving credit facility were $5.2 million.

Certain subsidiaries of the Company have restrictions on their ability to pay dividends or make intercompany loan advances pursuant to the Company's senior secured credit facility. The net assets of Orthofix Holdings and its subsidiaries are restricted for distributions to the parent company and its foreign subsidiaries. Domestic subsidiaries of the Company which are parties to the credit facility 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, 2008 is $111.3 million compared to $300.7 million at December 31, 2007.

Weighted average interest rates on current maturities of long-term obligations as of December 31, 2008 and 2007 were 8.4% and 6.58%, respectively.

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Notes to the consolidated financial statements (cont.)

The aggregate maturities of long-term debt after December 31, 2008 are as follows: 2009 - $3.3 million, 2010 - $3.4 million, 2011 - $3.4 million, 2012 - $80.0 million, 2013 - $190.8 million.

11. Derivative instruments

In 2006, the Company entered into a cross-currency swap agreement 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 derivative instrument, a ten-year fully amortizable agreement with a notional amount of $63.0 million, is scheduled to expire on December 30, 2016. The instrument is designated as a cash flow hedge. The amount outstanding under the agreement as of December 31, 2008 is $56.7 million. Under the agreement, the Company pays Euro and receives U.S. dollars based on scheduled cash flows in the agreement. During each year ended December 31, 2008 and 2007, the Company recorded the unrealized gain on the change in fair value of this swap arrangement of $1.6 million, within other comprehensive income/(loss).

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 the Company incurred an unrealized, non-cash loss of approximately $8.0 million which resulted from changes in the fair value of the Company's interest rate swap. During the second and third quarters of 2008, the interest rate swap was accounted for as a cash flow hedge, and changes in its value were recorded as part of accumulated other comprehensive income on the balance sheet. Due to declining interest rates and a LIBOR floor in the Company's amended credit facility, the effectiveness of the swap was no longer deemed highly effective; therefore cash flow accounting is no longer applied and mark-to-market adjustments are required to be reported in current earnings through the expiration of the swap in June 2011. The swap continues to provide an economic hedge against fluctuating interest rate exposure on the $150.0 million portion of outstanding debt it covers, should the LIBOR interest rate rise above 3.73%.

12. Fair value measurements

As described in Note 1, the Company adopted SFAS No. 157 effective January 1, 2008. SFAS No. 157 defines fair value 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. SFAS No. 157 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

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

(In US$ thousands)	Balance at December 31, 2008	Level 1	Level 2	Level 3

Derivative financial instruments(1)		
Cash flow hedges:		
Interest rate hedge	$ (7,975)	$ (7,975)
Cross currency hedge	$ 681	$ 681

(1) See Note 11, “Derivative instruments”.

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Notes to the consolidated financial statements (cont.)

13. Commitments

Leases

The Company has entered into operating leases for facilities and equipment. Rent expense under the Company's operating leases for the years ended December 31, 2008, 2007 and 2006 was approximately $5.6 million, $5.2 million and $4.2 million, respectively. Future minimum lease payments under operating leases as of December 31, 2008 are as follows:

(In US$ thousands)

2009	$	4,655
2010		3,822
2011		1,932
2012		632
2013		218
Thereafter		2
Total	$	11,261

In February 2009, as part of the consolidation and reorganization of the Company's spine business from New Jersey and Massachusetts into the Texas facility, the Company entered into a ten year operating lease in Lewisville, Texas which includes future minimum lease payments of $1.2 million per year for the first five years and $1.3 million per year for the following five years. This lease will commence upon the earlier of occupancy or completion of improvements, but no earlier than January 31, 2010.

14. Business segment information

The Company's segment information is prepared on the same basis that the Company's management reviews the financial information for operational decision making purposes. The Company is comprised of the following segments:

Domestic
Domestic consists of operations in the United States of Orthofix, Inc. which designs, manufactures and distributes stimulation and orthopedic products. Domestic uses both direct and distributor sales representatives to sell Spine and Orthopedic products to hospitals, doctors and other healthcare providers in the United States market.

Blackstone
Blackstone ("Blackstone") consists of Blackstone Medical, Inc., based in Springfield, Massachusetts, and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Blackstone specializes in the design, development and marketing of spinal implant and related HCT/P products.

Breg
Breg ("Breg") consists of Breg, Inc. Breg, based in Vista, California, designs, manufactures, and distributes Orthopedic products for post-operative reconstruction and rehabilitative patient use and sells its products through a network of

domestic and international distributors, sales representatives and affiliates.

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Notes to the consolidated financial statements (cont.)

International

International consists of international operations located in Europe, Mexico, Brazil and Puerto Rico, as well as independent distributors located outside the United States. International uses both direct and distributor sales representatives to sell Spine, Orthopedics, Sports Medicine, Vascular and Other products to hospitals, doctors, and other healthcare providers.

Group Activities

Group Activities are comprised of the Parent's and Orthofix Holdings' operating expenses and identifiable assets.

The tables below present information by reportable segment:

	External Sales			Intersegment Sales		
(In US$ thousands)	2008	2007	2006	2008	2007	2006
Domestic	$ 188,807	$ 166,727	$ 152,560	$ 5,871	$ 4,090	$ 3,511
Blackstone	108,966	115,914	28,134	3,999	5,925	699
Breg	89,478	83,397	76,219	5,583	3,780	1,651
International	132,424	124,285	108,446	24,914	27,893	50,521
Total	$ 519,675	$ 490,323	$ 365,359	$ 40,367	$ 41,688	$ 56,382

Operating Income (Expense)			
(In US$ thousands)	2008	2007	2006
Domestic	$ 64,301	$ 55,297	$ 36,560
Blackstone(1) (2)	(330,755)	(26,110)	(39,268)
Breg	12,393	9,717	6,218
International	18,664	19,973	18,674
Group Activities	(20,812)	(19,003)	(11,262)
Eliminations	(740)	(1,817)	(976)
Total	$ (256,949)	$ 38,057	$ 9,946

(1) Includes $40.0 million of In-Process Research and Development related to the acquisition of Blackstone in 2006

(2) Includes $289.5 and $20.0 million charge for impairment of certain Blackstone assets in 2008 and 2007, respectively.

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Notes to the consolidated financial statements (cont.)

The following table presents identifiable assets by segment, excluding intercompany balances and investments in consolidated subsidiaries.

Identifiable Assets (In US$ thousands)	2008	2007
Domestic	$ 110,981	$ 118,178
Blackstone	121,508	404,788
Breg	172,398	180,157
International	146,444	177,586
Group activities	10,624	20,063
Eliminations	(740)	(15,108)
Total	$ 561,215	$ 885,664

The following table presents depreciation and amortization, income tax expense (benefit) and other income (expense) by segment:

	Depreciation and amortization			Income tax expense (benefit)			Other income (expense)		
(In US$ thousands)	2008	2007	2006	2008	2007	2006	2008	2007	2006
Domestic	$ 2,674	$ 2,831	$ 2,934	$ 25,457	$ 21,803	$ 14,444	$ (1,414)	$ 69	$ 300
Blackstone	15,837	13,975	2,011	(86,857)	(16,186)	(1,710)	73	475	199
Breg	7,750	8,048	8,154	2,676	1,799	125	(119)	(89)	(24)
International	4,794	3,497	3,347	(222)	(520)	(1,042)	(7,460)	6,178	97
Group activities	224	180	11	(7,535)	(3,129)	1,544	(29,166)	(29,955)	(4,199)
Total	$ 31,279	$ 28,531	$ 16,457	$ (66,481)	$ 3,767	$ 13,361	$ (38,086)	$ (23,322)	$ (3,627)

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Notes to the consolidated financial statements (cont.)

Capital expenditures of tangible and intangible assets for each segment are as follows:

(In US$ thousands)	2008	2007	2006
Domestic	$ 1,813	$ 2,936	$ 2,240
Blackstone	10,355	15,278	1,473
Breg	3,071	2,706	3,496
International	4,757	6,309	5,360
Group activities	196	-	44
Total	$ 20,192	$ 27,229	$ 12,613

Geographical information

Analysis of net sales by geographic destination:

(In US$ thousands)	2008	2007	2006
U.S.	$ 381,016	$ 359,007	$ 263,442
U.K.	27,465	33,109	26,708
Italy	26,075	25,175	23,436
Other	85,119	73,032	51,773
International	138,659	131,316	101,917
Total	$ 519,675	$ 490,323	$ 365,359

There are no sales in the Netherlands Antilles.

Analysis of property, plant and equipment and other assets by geographic area:

(In US$ thousands)	2008	2007
U.S.	$ 21,409	$ 22,455
Italy	6,540	7,063
U.K.	2,044	2,955
Others	4,762	5,398
Total	$ 34,755	$ 37,871

There are no long-lived assets in the Netherlands Antilles.

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Notes to the consolidated financial statements (cont.)

	Sales by Market Sector for the year ended December 31, 2008				
(In US$ thousands)	Domestic	Blackstone	Breg	International	Total
Spine	$ 141,753	$ 108,966	$ -	$ 1,520	$ 252,239
Orthopedics	47,054	-	-	82,052	129,106
Sports Medicine	-	-	89,478	5,050	94,528
Vascular	-	-	-	17,890	17,890
Other	-	-	-	25,912	25,912
Total	$ 188,807	$ 108,966	$ 89,478	$ 132,424	$ 519,675

	Sales by Market Sector for the year ended December 31, 2007				
(In US$ thousands)	Domestic	Blackstone	Breg	International	Total
Spine	$ 126,626	$ 115,914	$ -	$ 625	$ 243,165
Orthopedics	40,101	-	-	71,831	111,932
Sports Medicine	-	-	83,397	4,143	87,540
Vascular	-	-	-	19,866	19,866
Other	-	-	-	27,820	27,820
Total	$ 166,727	$ 115,914	$ 83,397	$ 124,285	$ 490,323

	Sales by Market Sector for the year ended December 31, 2006				
(In US$ thousands)	Domestic	Blackstone	Breg	International	Total
Spine	$ 116,701	$ 28,134	$ -	$ 278	$ 145,113
Orthopedics	35,813	-	-	59,986	95,799
Sports Medicine	-	-	76,219	2,834	79,053
Vascular	-	-	-	21,168	21,168
Other	46	-	-	24,180	24,226
Total	$ 152,560	$ 28,134	$ 76,219	$ 108,446	$ 365,359

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Notes to the consolidated financial statements (cont.)

15. Income taxes

Income (loss) before provision (benefit) for income taxes consisted of:

	Year ended December 31,		
(In US$ thousands)	2008	2007	2006
U.S.	$ (304,542)	$ 551	$ (11,264)
Non-U.S.	9,507	14,184	17,583
	$ (295,035)	$ 14,735	$ 6,319

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

	Year ended December 31,		
(In US$ thousands)	2008	2007	2006
U.S.			
-Current	$ 12,697	$ 10,501	$ 12,231
-Deferred	(81,661)	(10,817)	(1,601)
Non-U.S.			
-Current	(53)	2,134	13,745
-Deferred	2,536	1,949	(11,014)
Total tax expense	$ (66,481)	$ 3,767	$ 13,361

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

(In US$ thousands)	2008	2007
Goodwill	$ (901)	$ 184
Patents, trademarks and other intangible assets	(12,760)	(82,841)
Property, plant and equipment	(2,172)	(1,133)
Other current	(4,509)	7,882
Inventories and related reserves	9,108	4,453
Accrued compensation	10,669	3,549
Allowance for doubtful accounts	4,254	3,370
Interest	9,284	3,781
Net operating loss carryforwards	15,320	12,768
Other long-term	7,383	1,560
Valuation allowance	(14,370)	(11,377)
Net deferred tax asset (liability)	$ 21,306	$ (57,804)

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Notes to the consolidated financial statements (cont.)

The valuation allowance as of December 31, 2008 and 2007 was $14.4 million and $11.4 million, respectively. The net increase in the valuation allowance of $3.0 million during the year relates to current period foreign losses not benefitted. The valuation allowance is attributable to net operating loss carryforwards 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, 2008.

As part of the acquisition of Blackstone, the Company acquired a federal net operating loss carryforward of $31.1 million which was subject to annual section 382 limitations. During 2006, the Company utilized $7.4 million of these federal net operating loss carryforwards, and the remaining operating losses were utilized during 2007. The Company also has tax net operating loss carryforwards in other taxing jurisdictions of approximately $55.1 million with the majority of the losses related to the Company's Netherlands operations expiring in various amounts in tax years beginning in 2009. The Company has provided a valuation allowance against these net operating loss carryforwards since it does not believe that this deferred tax asset can be realized prior to expiration.

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.

(In US$ thousands, except percentages)	2008		2007		2006	
	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ (103,263)	35%	$ 5,179	35%	$ 2,221	35%
State taxes, net	(4,798)	1.6%	317	2.1%	1,394	22.0%
Foreign rate differential	(1,422)	0.5%	(2,504)	(17.0)%	(4,589)	(72.3)%
Valuation allowance – foreign losses	3,031	(1.0)%	2,665	18.0%	2,875	45.3%
Italy step-up amortization	(2,527)	0.9%	(2,115)	(14.3)%	(2,778)	(43.8)%
Blackstone purchased research and development	(165)	0.1%	(1,320)	(8.9)%	14,000	220.6%
Domestic manufacturing deduction	(741)	0.3%	(453)	(3.1)%	-	
Reserves, net	(1,093)	0.4%	372	(2.5)%	-	
Goodwill impairment	44,406	(15.2)%	-	0.0%	-	
Permanent items	900	(0.3)%	451	3.0%	-	
Tax rate changes	(2,320)	0.8%	1,266	8.6%	-	

Other items, net	1,511	(0.6)%	(91)	(0.4)%	238	3.7%
Income tax expense/effective rate	(66,481)	22.5%	$ 3,767	25.5%	$ 13,361	210.5%

The Company’s gross unrecognized tax benefit was $0.7 million and $1.7 million for the years ended December 31, 2008 and December 31, 2007 respectively.

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Notes to the consolidated financial statements (cont.)

A reconciliation of the gross unrecognized tax benefits for the years ended December 31, 2008 and December 31, 2007 follows:

	2008	2007
Balance as of January 1,	$ 1,707	$ 1,346
Additions for current year tax positions	-	175
Additions for prior year tax positions	-	186
Reductions related to expirations of statute of limitations	(1,000)	-
Balance as of December 31,	$ 707	$ 1,707

The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within its global operations in income tax expense. During 2008, the Company recognized approximately $45 thousand in interest and penalties. The Company had approximately $0.4 million and $0.5 million accrued for the payment of interest and penalties as of December 31, 2008 and December 31, 2007 respectively.

The entire $0.7 million of unrecognized tax benefits would affect the Company's effective tax rate if recognized. As of December 31, 2008, the Company does not expect the amount of unrecognized tax benefits to change significantly over the next twelve months.

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, 2004. The statute of limitations for the various state tax filings is closed in most instances for the years prior to December 31, 2005. There are certain state tax statutes open for years from 1997 forward due to current examinations. The statute of limitations with respect the major foreign tax filing jurisdictions is closed for years prior to December 31, 2004.

The Company has not recorded additional income taxes applicable to undistributed earnings of foreign subsidiaries (residing outside the Netherlands Antilles) that are considered to be indefinitely reinvested and the taxes attributable to such amounts not deemed to be indefinitely reinvested are not material. In the event that undistributed earnings which have been deemed to be indefinitely reinvested no longer meet the criteria to remain as such, these undistributed earnings will also be considered when calculating any potential future tax liabilities relating to undistributed foreign earnings. Total undistributed earnings, which amounted to approximately $219.4 million, $186.0 million and $191.1 million at December 31, 2008, 2007 and 2006, respectively, may become taxable upon their remittance as dividends or upon the sale or liquidation of these foreign subsidiaries. It is not practicable to determine the amounts of net additional income tax that may be payable if such earnings were repatriated.

16. Related parties

The following related party balances and transactions as of and for the three years ended December 31, 2008, between the Company and other companies in which directors and/or executive officers have an interest are reflected in the consolidated financial statements. The Company buys components related to the A-V Impulse(R) System and buys the Laryngeal Mask from companies in which a former board member has a beneficial minority interest. The Company sells bracing products to OrthoRx.

	Year ended December 31,		
(In US$ thousands)	2008	2007	2006

Sales	$ 2,278	$ 1,474	$ 1,741
Purchases	$ 12,681	$ 13,119	$ 16,733
Accounts payable	$ 1,686	$ 2,189	$ 2,474
Accounts receivable	$ 460	$ 5	$ 86
Due from officers (included in other long-term assets)	$ -	$ -	$ 208

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Notes to the consolidated financial statements (cont.)

17. Contingencies

Litigation

Effective October 29, 2007, our subsidiary, Blackstone, entered into a settlement agreement with respect to a patent infringement lawsuit captioned Medtronic Sofamor Danek USA Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH v. Blackstone Medical, Inc., Civil Action No. 06-30165-MAP, filed on September 22, 2006 in the United States District Court for the District of Massachusetts. In that lawsuit, the plaintiffs had alleged that (i) they were the exclusive licensees of United States Patent Nos. 6,926,718 B1, 6,936,050 B2, 6,936,051 B2, 6,398,783 B1 and 7,066,961 B2 (the "Patents"), and (ii) Blackstone's making, selling, offering for sale, and using within the United States of its Blackstone Anterior Cervical Plate, 3º Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products infringed the Patents, and that such infringement was willful. The Complaint requested both damages and an injunction against further alleged infringement of the Patents. Blackstone denied infringement and asserted that the Patents were invalid. On July 20, 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 us 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 has objected to the indemnification claim and intends to contest it in accordance with the terms of the Blackstone Merger Agreement. The settlement agreement is not expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

On or about July 23, 2007, 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 seeks 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 concerns 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 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 has 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 United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents from the Company for the period January 1, 2000 through July 15, 2007. The Company believes that the subpoena concerns the compensation of physician consultants and related matters, and further believe that it is 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 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 November 21, 2008, the U.S. Department of Justice filed a notice of non-intervention in the case. To our knowledge, the plaintiffs have not served either Blackstone or the Company with a copy of the complaint. The complaint alleges a

cause of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on physician consultants, as well as a cause of action for retaliation and wrongful discharge. The Company believes that this lawsuit is related to the matters described above involving the Department of Health and Human Services, Office of the Inspector General, and the United States Attorney's Office for the District of Massachusetts. The Company intends to defend vigorously against this lawsuit. On or about September 27, 2007, Blackstone received a federal grand jury subpoena issued by the United States Attorney's Office for the District of Nevada ("USAO-Nevada subpoena"). The subpoena seeks documents for the period from January 1999 to the date of issuance of the subpoena. The Company believes that the subpoena concerns payments or gifts made by Blackstone to certain physicians. On February 29, 2008, Blackstone received a Civil Investigative Demand ("CID") from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. The Company believes that the CID seeks documents concerning Blackstone's financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from this matter.

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Notes to the consolidated financial statements (cont.)

The Ohio Attorney General's Office, Health Care Fraud Section has issued a criminal subpoena, dated August 8, 2008, to Orthofix, Inc (the "Ohio AG Subpoena"). The Ohio AG Subpoena seeks documents for the period from January 1, 2000 through the date of issuance of the subpoena. The Company believes that the Ohio AG Subpoena arises from a government investigation that concerns the compensation of physician consultants and related matters. On September 18, 2008, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from the USAO-Nevada subpoena, the Massachusetts CID and the Ohio AG Subpoena.

Blackstone has cooperated with the government's request in each of the subpoenas set forth above. The Company is unable to predict what actions, if any, might be taken by the governmental authorities that have issued these subpoenas or what impact, if any, the outcome of these matters might have on the Company's consolidated financial position, results of operations or cash flows.

By order entered on January 4, 2007, the United States District Court for the Eastern District of Arkansas unsealed a qui tam complaint captioned Thomas v. Chan, et al., 4:06-cv-00465-JLH, filed against Dr. Patrick Chan, Blackstone and other defendants including another device manufacturer. The complaint alleges causes of action under the False Claims Act for alleged inappropriate payments and other items of value conferred on Dr. Chan. On December 29, 2006, the U.S. Department of Justice filed a notice of non-intervention in the case. Plaintiff subsequently amended the complaint to add the Company as a defendant. On January 3, 2008, Dr. Chan pled guilty to one count of knowingly soliciting and receiving kickbacks from a medical device distributor in a criminal matter in which neither the Company nor any of its business units or employees were defendants. In January 2008, Dr. Chan entered into a settlement agreement with the plaintiff and certain governmental entities in the civil qui tam action, and on February 21, 2008, a joint stipulation of dismissal of claims against Dr. Chan in the action was filed with the court, which removed him as a defendant in the action. On July 11, 2008, the court granted a motion to dismiss the Company as a defendant in the action. Blackstone remains a defendant. The Company believes that Blackstone has meritorious defenses to the claims alleged and the Company intends to defend vigorously against this lawsuit. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us 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 has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement.

Between January 2007 and May 2007, Blackstone and Orthofix Inc. were named defendants, along with other medical device manufacturers, in three civil lawsuits alleging that Dr. Chan had performed unnecessary surgeries in three different instances. In January 2008, the Company learned that Orthofix Inc. was named a defendant, along with other medical device manufacturers, in a fourth civil lawsuit alleging that Dr. Chan had performed unnecessary surgeries. All four civil lawsuits were filed in the Circuit Court of White County, Arkansas. The Company has reached a settlement in all four civil lawsuits, and the court has entered an order of dismissal in two of the four cases. The settlement agreements are not expected to have a material impact on our consolidated financial position, results of operations or cash flows. On September 17, 2007, the Company submitted a claim for indemnification from the escrow fund established in connection with the Merger Agreement for any losses to us resulting from one of these four civil lawsuits. The Company was subsequently notified by legal counsel for the former shareholders that the representative of the former shareholders of Blackstone has objected to the indemnification claim and intends to contest it in accordance with the terms of the Merger Agreement.

The Company is unable to predict the outcome of each of the escrow claims described above in the preceding paragraphs or to estimate the amount, if any, that may ultimately be returned to the Company from the escrow fund

and there can be no assurance that losses to us from these matters will not exceed the amount of the escrow account. As of December 31, 2008 and 2007, included in Other Current Assets is approximately $8.3 million and $2.1 million of escrow receivable balances related to the Blackstone matters described above, respectively.

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Notes to the consolidated financial statements (cont.)

In addition to the foregoing claims, the Company has submitted claims for indemnification from the escrow fund established in connection with the Blackstone Merger Agreement for losses that have or may result from certain claims against Blackstone alleging that plaintiffs and/or claimants were entitled to payments for Blackstone stock options not reflected in Blackstone's corporate ledger at the time of Blackstone's acquisition by the Company, or that their shares or stock options were improperly diluted by Blackstone. To date, the representative of the former shareholders of Blackstone has not objected to approximately $1.5 million in such claims from the escrow fund, with certain claims remaining pending.

The Company cannot predict the outcome of any proceedings or claims made against the Company or its subsidiaries described in the preceding paragraphs and there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on our consolidated financial position, results of operations, or cash flows.

In addition to the foregoing, 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.

United Kingdom Payroll Taxes

In 2007, Intavent Orthofix Limited, the Company’s UK distribution subsidiary, received an inquiry from H.M. Revenue and Customs (HMRC) relating to the tax treatment of gains made by UK employees on the exercise of stock options. The Company is in the process of formulating a response to HMRC. Based on preliminary calculations, a provision of $0.5 million has been provided, of which the Company has paid $0.2 million. The Company cannot predict the ultimate outcome of its discussions with HMRC.

Concentrations of credit risk

Financial instruments which potentially subject the Company to concentrations of credit risk are primarily cash investments and accounts receivable. Cash investments are primarily in money market funds deposited with major financial center banks. Concentrations of credit risk with respect to accounts receivable are limited due to the large number of entities comprising the Company’s customer base. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. Certain of these customers rely on third party healthcare payers, such as private insurance companies and governments, to make payments to the Company on their behalf. Accounts receivable in countries where the government funds medical spending are primarily located in North Africa, Middle East, South America, Asia and Europe. The Company has considered special situations when establishing allowances for potentially uncollectible accounts receivable in such countries as India, Egypt and Turkey. The Company also records reserves for bad debts for all other customers based on a variety of factors, including the length of time the receivables are past due, the financial condition of the customer, macroeconomic conditions and historical experiences. The Company maintains reserves for potential credit losses and such losses have been within management’s expectations.

The Company sells via a direct sales force and distributors. There were no customers that accounted for 5% or more of net sales in 2008, 2007 or 2006.

18. Pensions and deferred compensation

Orthofix Inc. sponsors a defined contribution plan (the "Orthofix Inc. 401(k) Plan") covering substantially all full time 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 compensation deferred. During the years ended December 31, 2008, 2007 and 2006, expenses incurred relating to 401(k) Plans, including matching contributions, were approximately $1.8 million, $1.5 million and $1.1 million, respectively.

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Notes to the consolidated financial statements (cont.)

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 2008, 2007 and 2006 were approximately $1.0 million, $1.0 million and $0.5 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 2008, 2007 and 2006 was approximately $0.5 million, $0.4 million and $0.4 million, respectively. Deferred compensation payments of $0.5 million, $0.3 million and $0.3 million were made in 2008, 2007 and 2006, respectively. The balance as of December 31, 2008 and 2007 of $1.7 million 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 Orthofix, 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 Orthofix 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 Orthofix 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.

19. Share-based compensation plans

At December 31, 2008, 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 four 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 10 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, 2008, there were 2,666,395 options outstanding under the 2004 LTIP Plan, of which 1,181,744 were exercisable; in addition, there were 118,993 shares of restricted stock outstanding, none of which were vested.

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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, 2008, there were 133,625 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 – 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, 2009. In December 2008, in order to meet certain requirements of Code Section 409A and the Treasury Regulations 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 has 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 has 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, 2008, there were 200,000 options outstanding and exercisable under the inducement grants.

Inducement Stock Option Agreement

In the year ended December 31, 2008, stock options were granted pursuant to a standalone inducement stock option agreement, on terms substantially the same as grants made under the Company's Amended and Restated 2004 Long Term Incentive Plan. The grant of 150,000 stock options vests in one-third increments annually.

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Notes to the consolidated financial statements (cont.)

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.

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 1st to December 31st, or, if lower, on the last day of the plan year. The aggregate number of shares reserved for issuance under the Employee Stock Purchase Plan is 950,000 shares. As of December 31, 2008, 429,688 shares had been issued under the Stock Purchase Plan.

Summaries of the status of the Company's stock option plans as of December 31, 2008 and 2007 and changes during the years ended on those dates are presented below:

	2008		2007	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	2,444,235	$ 42.39	2,264,361	$ 35.67
Granted	1,263,200	$ 27.64	817,601	$ 49.33
Exercised	(4,917)	$ 29.73	(517,869)	$ 24.33
Forfeited*	(552,498)	$ 49.21	(119,858)	$ 40.58
Outstanding at end of year	3,150,020	$ 35.30	2,444,235	$ 42.39
Options exercisable at end of year	1,515,370		979,365	
Weighted average fair value of options granted during the year		$ 7.51		$ 15.21

No options were granted during 2008 or 2007 at less than market value.

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Notes to the consolidated financial statements (cont.)

Outstanding and exercisable by price range as of December 31, 2008

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$10.42 - $25.05	360,250	9.12	$ 19.06	29,250	$ 21.45
$28.50 - $28.50	18,750	3.53	$ 28.50	18,750	$ 28.50
$28.95 - $28.95	622,300	9.50	$ 28.95	28,000	$ 28.95
$29.17 - $37.76	535,022	6.92	$ 34.61	359,222	$ 35.59
$38.00 - $38.00	200,000	5.00	$ 38.00	200,000	$ 38.00
$38.11 - $38.11	368,931	7.40	$ 38.11	254,198	$ 38.11
$38.40 - $42.97	375,000	7.53	$ 40.95	207,670	$ 41.00
$42.99 - $44.87	208,599	6.34	$ 43.08	202,766	$ 43.06
$44.97 - $44.97	317,000	8.41	$ 44.97	121,344	$ 44.97
$45.35 - $57.72	144,168	7.19	$ 48.50	94,170	$ 47.55
	3,150,020	7.79	$ 35.30	1,515,370	$ 39.08

The weighted average remaining contractual life of exercisable options was 6.44 years at December 31, 2008. The total intrinsic value of options exercised was $88,000, $14.6 million and $1.9 million for the years ended December 31, 2008, 2007 and 2006, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2008 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 $15.33 closing price of the Company's stock on December 31, 2008. The aggregate intrinsic value of options outstanding was $0.5 million, $38.1 million and $26.5 million for the years ended December 31, 2008, 2007 and 2006, respectively. The aggregate intrinsic value of options exercisable was $10,000, $19.4 million and $11.9 million for the years ended December 31, 2008, 2007 and 2006, respectively.

A summary of the status of our restricted stock as of December 31, 2008 and changes during the year is presented below:

	Shares	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2007	65,787	$ 47.41
Granted	83,434	$ 32.19
Vested	(19,416)	$ 46.52
Cancelled	(10,812)	$ 40.73
Non-vested as of December 31, 2008	118,993	$ 37.49

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Notes to the consolidated financial statements (cont.)

20. Earnings per share

For each of the three years in the period ended December 31, 2008, there were no adjustments to net income (loss) for purposes of calculating basic and diluted net income (loss) per common share. 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,		
	2008	2007	2006
Weighted average common shares-basic	17,095,416	16,638,873	16,165,540
Effect of diluted securities:			
Unexercised stock options net of treasury share repurchase	-	408,714	-
Weighted average common share-diluted	17,095,416	17,047,587	16,165,540

For the years ended December 31, 2008 and 2006, the effects of all potentially dilutive options were excluded from the computation of diluted earnings per share because the Company had a net loss and, therefore, the effect would have been anti-dilutive. 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 309,651 outstanding options not included in the diluted earnings per share computation for the fiscal year ended December 31, 2007, because the options' exercise prices were greater than the average market price of the common shares.

21. Quarterly financial data (unaudited)

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

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
2008					
Net sales	$ 128,032	$ 130,039	$ 129,301	$ 132,303	$ 519,675
Gross profit	93,794	94,991	81,303	97,573	367,661
Net income (loss)	3,606	5,808	(237,251)	(717)	(228,554)
Net income (loss) per common share:					
Basic	0.21	0.34	(13.87)	(0.04)	(13.37)
Diluted	0.21	0.34	(13.87)	(0.04)	(13.37)
2007					
Net sales	$ 117,032	$ 123,336	$ 121,120	$ 128,835	$ 490,323
Gross profit	86,236	90,328	90,378	94,350	361,291
Net income (loss)	6,267	7,189	8,028	(10,515)	10,968
Net income (loss) per common share:					
Basic	0.38	0.43	0.48	(0.62)	0.66
Diluted	0.37	0.43	0.48	(0.62)	0.64

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

(U.S. Dollars, in thousands)	December 31, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 623	$ 10,048
Prepaid expenses and other current assets	484	239
Total current assets	1,107	10,287
Other long term assets	274	252
Investments in and amounts due from subsidiaries and affiliates	207,125	427,804
Total assets	$ 208,506	$ 438,343
Liabilities and shareholder's equity		
Current liabilities	$ 1,669	$ 1,191
Long-term liabilities	4,776	3,212
Shareholder's equity		
Common stock	1,710	1,704
Additional paid in capital	167,818	157,349
Accumulated earnings	29,647	258,201
Accumulated other comprehensive income	2,886	16,686
	202,061	433,940
Total liabilities and shareholder's equity	$ 208,506	$ 438,343

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

(U.S. Dollars, in thousands)	December 31, 2008	December 31, 2007	December 31, 2006
(Expenses) Income			
General and administrative	$ (11,945)	$ (10,172)	$ (8,774)
Equity in earnings of investments in subsidiaries and affiliates	(215,310)	22,334	692
Other, net	481	653	2,800
Income (loss) before income taxes	(226,774)	12,815	(5,282)
Income tax expense	(1,780)	(1,847)	(1,760)
Net income (loss)	$ (228,554)	$ 10,968	$ (7,042)

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

(U.S. Dollars, in thousands)	December 31, 2008	December 31, 2007	December 31, 2006
Net income (loss)	$ (228,554)	$ 10,968	$ (7,042)
Equity in earnings of investments in subsidiaries and affiliates	215,310	(22,334)	(692)
Cash used in other operating activities	2,350	(772)	(1,066)
Net cash used in operating activities	(10,894)	(12,138)	(8,800)
Cash flows from investing activities:			
Distributions and amounts received from subsidiaries	11,074	21,991	24,468
Capital Expenditures	(196)	-	-
Net cash provided by investing activities	10,878	21,991	24,468
Cash flows from financing activities:			
Net proceeds from issuance of common stock	1,734	17,198	11,507
Dividends to subsidiaries and affiliates	(11,165)	(27,748)	(24,845)
Tax benefit on exercise of stock options	22	-	2,175
Net cash used in financing activities	(9,409)	(10,550)	(11,163)
Net (decrease) increase in cash and cash equivalents	(9,425)	(697)	4,505
Cash and cash equivalents at the beginning of the year	10,048	10,745	6,240
Cash and cash equivalents at the end of the year	$ 623	$ 10,048	$ 10,745

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

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 September 22, 2006, 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, 2008 and 2007 was approximately $111.3 million and $300.7 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 10, Note 13 and Note 17 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 $11.1 million, $22.0 million and $24.5 million for the years ended December 31, 2008, 2007 and 2006, respectively.

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Schedule 2 — Valuations and Qualifying Amounts

For the years ended December 31, 2008, 2007 and 2006:

(US Dollars, in thousands)		Additions				
Provisions from assets to which they apply:	Balance at beginning of year	Charged to cost and expenses	Charged to other accounts	Deductions/ Other	Blackstone Acquisition	Balance at end of year
2008						
Allowance for doubtful accounts receivable	$ 6,441	$ 7,261	$ (133)	$ (7,096)	$ -	$ 6,473
Inventory provisions	9,893	14,858	(22)	(3,561)	-	21,168
Deferred tax valuation allowance	11,377	2,993	-	-	-	14,370
2007						
Allowance for doubtful accounts receivable	6,265	7,431	44	(7,299)	-	6,441
Inventory provisions	7,213	3,472	52	(844)	-	9,893
Deferred tax valuation allowance	9,428	2,665	(716)	-	-	11,377
2006						
Allowance for doubtful accounts receivable	4,155	5,475	41	(3,634)	228	6,265
Inventory provisions	3,334	3,042	242	(1,310)	1,905	7,213
Deferred tax valuation allowance	6,324	3,024	80	-	-	9,428