ORTHOFIX INTERNATIONAL N V
Form 10-K
March 16, 2007

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

**FORM 10-K**

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File Number: 0-19961

**ORTHOFIX INTERNATIONAL N.V.**
(Exact name of registrant as specified in its charter)

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

599-9-4658525
(Registrant's telephone number, including area code)

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

None

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes £ No 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large Accelerated filer £ Accelerated filer T Non-accelerated filer £

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, 2006, as reported by the Nasdaq National Market, was approximately $611.2 million. Shares of common stock held by executive officers and directors and persons who own 5% or more of the outstanding common stock have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not a determination for any other purpose.

As of March 13 , 2007, 16,472,443 shares of common stock were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain sections of the registrant's Proxy Statement to be filed with the Commission in connection with the 2007 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 IA 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 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 and the other risks described under Item 1A – "Business – 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.*

### OVERVIEW

We are a diversified orthopedic products 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 equipment used principally by musculoskeletal medical specialists for orthopedic applications. Our main products are invasive and minimally invasive spinal implant products and related biologics; non-invasive 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.

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, 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 Securities and Exchange Commission. 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 EDGAR database (http://www.sec.gov).

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**Important Events**

On December 11, 2006, we announced that Chief Executive Officer Alan W. Milinazzo had been appointed to the Company's Board of Directors, to fill the vacancy on the Board of Directors left by the retirement of Mr. Robert Gaines-Cooper, one of Orthofix's founders and the Chairman of the Board from 1989 to 2004. Mr. Milinazzo does not currently serve on any committees of the Board of Directors. Mr. Gaines-Cooper, retired as director of Orthofix International N.V. on December 5, 2006.

On September 22, 2006, we completed the acquisition of privately held Blackstone Medical, Inc. ("Blackstone"), a company specializing in the design, development and marketing of spinal implant and related biologics products. The purchase price for the acquisition was $333.0 million, subject to certain closing adjustments, plus transaction costs totaling approximately $9.2 million as of December 31, 2006. Financing costs were approximately $6.0 million. The acquisition and related costs were financed with $330.0 million of senior secured bank debt and cash on hand. The Company's results, for the year ended December 31, 2006, include the results of Blackstone from the date of acquisition along with the impact of purchase accounting and interest expense associated with the acquisition.

On February 16, 2006, we announced that Alan W. Milinazzo, 47, the Company's then Chief Operating Officer, had been promoted to Group President and Chief Executive Officer effective April 1, 2006. Mr. Milinazzo succeeded Charles W. Federico, who remains a Director of Orthofix. Mr. Milinazzo joined the Company on September 6, 2005, in a newly established position of Chief Operating Officer, from Medtronic Inc. where he was Vice President of Medtronic's Vascular business, as well as Vice President and General Manager of Medtronic's Coronary and Peripheral business.

On September 30, 2005, we announced that we had reached an agreement to settle the patent litigation between our subsidiary Novamedix Distribution, Ltd. and Kinetic Concepts, Inc. ("KCI") related to our A-V Impulse System®. Under the terms of the settlement, KCI agreed to pay Novamedix $75 million, and we received a limited assignment of certain KCI foot pump patent rights. KCI retains rights in the patents and will maintain its Plexi Pulse foot pump product line going forward. The settlement resolves and settles all claims between the parties. In the first quarter of 2006, we distributed approximately $22.9 million of the settlement proceeds to certain parties including former owners of Novamedix, pursuant to contracts requiring those disbursements.

**Business Strategy**

Our business strategy is to offer innovative, cost-effective orthopedic products to the Spine, Orthopedic, Sports Medicine and Vascular market sectors that reduce both patient suffering and healthcare costs. We intend to continue to expand applications for our products by utilizing synergies among our core technologies. We intend to expand our product offerings through business or product acquisition and assignment or licensing agreements, as well as through our own product development efforts. We will leverage our sales and distribution network by selling our products in all markets in which we can generate adequate financial returns. We intend to continue to enhance physician relationships through extensive education efforts as well as strengthen contracting and reimbursement relationships through our dedicated sales and administrative staff.

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**Business Segments and Market Sectors**

Our business is divided into four reportable segments: Orthofix Domestic ("Domestic"), Blackstone, Breg, and Orthofix International ("International"). Domestic consists of operations of our subsidiary Orthofix Inc. that 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. We have designated Blackstone, our newly acquired subsidiary, as a business segment. Blackstone specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone uses distributor sales representatives to sell Spine products domestically and internationally. 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.

**Business Segment (a):**

| | Year ended December 31, (In US$ thousands) | | | | | |
|---|---|---|---|---|---|---|
| | 2006 | | 2005 | | 2004 | |
| | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Domestic | $ 152,560 | 42% | $ 135,084 | 43% | $ 118,074 | 41% |
| Blackstone | 28,134 | 8% | - | - | - | - |
| Breg | 76,219 | 21% | 72,022 | 23% | 68,294 | 24% |
| International | 108,446 | 29% | 106,198 | 34% | 100,270 | 35% |
| Total | $ 365,359 | 100% | $ 313,304 | 100% | $ 286,638 | 100% |

(a) Prior to 2006 our operations in Mexico and Brazil were included within the Orthofix Domestic segment. Conversely, in 2006 such operations are included within Orthofix International. The prior year presentation has been restated to conform with the current presentation.

Additional financial information regarding our business segments can be found in Part II, Item 8, "Financial Statements and Supplementary Data", as well as in Item 7, "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 net sales of our Company more clearly than our business segments.

Our market sectors, which were reformatted in 2006 to more clearly associate our products with markets, are Spine, Orthopedics, Sports Medicine, Vascular, and Other.

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**Market Sector:**

| | Year ended December 31, (In US$ thousands) | | | | | |
|---|---|---|---|---|---|---|
| | 2006 | | 2005 | | 2004 | |
| | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Spine | $ 145,113 | 40% | $ 101,622 | 33% | $ 81,373 | 28% |
| Orthopedics | 95,799 | 26% | 92,097 | 29% | 90,112 | 31% |
| Sports Medicine | 79,053 | 22% | 72,970 | 23% | 68,488 | 24% |
| Vascular | 21,168 | 6% | 23,887 | 8% | 25,226 | 9% |
| Other | 24,226 | 6% | 22,728 | 7% | 21,439 | 8% |
| Total | $ 365,359 | 100% | $ 313,304 | 100% | $ 286,638 | 100% |

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

**Products**

Our revenues are generally derived from the sales of products in four market sectors, Spine (40%), Orthopedics (26%), Sports Medicine (22%) and Vascular (6%), which together accounted for (94%) of our total net sales in 2006. Sales of Other products, including airway management products for use during anesthesia, woman’s care and other products, accounted for (6%) of our total net sales in 2006.

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

| **Product** | **Primary Application** |
|---|---|
| ***Spine Products*** | |
| Spinal-Stim® | PEMF non-invasive lumbar spine bone growth stimulator |
| Cervical-Stim® | PEMF non-invasive cervical spine bone growth stimulator |
| 3 Degree/Reliant | Plating systems implanted during anterior cervical spine fusion procedures |
| Hallmark | A cervical plating system implanted during anterior cervical spine fusion procedures |
| ICON 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 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 VBR System | A modular device implanted during the replacement of degenerated or deformed spinal vertebrae to provide additional anterior support |
| Construx Mini VBR System | Smaller, unibody versions of the Construx VBR System, implanted during the replacement of degenerated or deformed spinal vertebrae |
| Unity Lumbosacral Fixation System | A plating system implanted during anterior lumbar spine fusion procedures |
| Ngage Surgical Mesh | A modular metallic interbody implant placed between two vertebrae to restore disc space and increase stability that has been lost due to degeneration or deformity |
| Newbridge Laminoplasty Fixation System | A device implanted during a posterior surgical procedure to expand the cervical vertebrae and relieve pressure on the spinal canal |
| Trinity Bone Matrix | An adult stem-cell based bone growth matrix used during surgery to enhance the success of a spinal fusion procedure |
| Alloquent Allografts | Interbody devices made of cortical bone that is used 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, XCaliber™, Contour VPS, VeroNail and Centronail |
| Physio-Stim® | PEMF long bone non-invasive bone growth stimulator |
| PC.C.P® | Percutaneous compression plating system for hip fractures |
| eight-Plate Guided Growth System® | Treatment to treat the bowed legs or knock knees of children |
| Cemex | Bone cement |
| ISKD® | Internal limb-lengthening device |
| OSCAR | Ultrasonic bone cement removal |
| ***Sports Medicine*** | |
| Breg Bracing | Bracing products which provide support and protection of limbs and extremities during healing and rehabilitation |
| Polar Care® | Cold therapy products to reduce swelling, pain and accelerate the rehabilitation process |
| Pain Care® | Pain therapy products that provide continuous post-surgical infusion of local anesthetic into surgical site |
| ***Vascular*** | |
| A-V Impulse System | 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 |

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

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

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***Spine***

Spine product sales represented 40% of our total net sales in 2006.

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 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.

Orthofix's 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.

The wide array of spine implants offered by Blackstone are used during surgical procedures intended to treat a variety of spine conditions. Most of these surgeries are fusion procedures in the cervical and lumbar spine that utilize Blackstone's metal plates, rods and screws, their interbody devices or vertebral body replacements, and their biologic bone growth product.

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 vertebrae encompass the thoracic and lumbar, or thoracolumbar , sections of the spine. The thoracic area helps protect the internal organs in the body's abdomen by attaching to the rib cage, and is the least mobile segment of the spine. The lumbar area carries the greatest portion of the body's weight, allowing some rotation and handling the majority of the bending. The vast majority of medical procedures involving the spine are performed in the cervical and lumbar segments.

Spinal bending and rotation are accomplished through the vertebral discs located between each vertebrae. 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 ultimately require medical intervention in order to relive 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 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 posterially, 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 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 biologic material designed to accelerate the formation of new bone around the graft which ultimately results in the desired fusion.

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Orthofix's wholly-owned subsidiary, Blackstone, provides a wide array of implants designed for use primarily in cervical 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 biologic bone grafting product, called Trinity™ Matrix.

The majority of implants offered by Blackstone are made of titanium metal. This includes the 3 Degree, Reliant and Hallmark cervical plates. Additionally, the Spinal Fixation System (SFS) and the Ascent POCT System are sets of rods, crossbars and screws which are implanted during posterior fusion procedures. The more recently introduced ICON Modular Spinal Fixation System is designed to be used in minimally-invasive posterior lumbar fusion procedures. The Company also offers specialty plates that are used in less common procedures, and as such are not manufactured by many device makers. This would include the Newbridge Laminoplasty Fixation System used to expand the cervical vertebrae and relieve pressure on the spinal canal, as well as the Unity plate which is used in anterior lumbar fusion procedures.

Blackstone also offers a variety of devices made of PEEK, which is a thermoplastic material with mechanical properties that make it ideal for use in certain medical devices. The products Blackstone offers that are made of this material include vertebral body replacements and interbody devices. As the name would suggest, vertebral body replacements are used to replace a patient's degenerated or deformed vertebrae. On the other hand, interbody devices replace a damaged disc, restoring the space that had been lost between two vertebrae. Blackstone also offers interbody devices, or cages, made of titanium metal.

Blackstone is also a distributor of biologic products, including interbody devices made of human cadaveric bone that has been harvested from donors and carved by a machine into a desired shape, and a unique adult stem cell-based product used 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 donors. It 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, Orthofix offers two spinal bone growth stimulation devices. Our stimulation products use a pulsing electromagnetic field ("PEMF") technology 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. Orthofix has sponsored independent research at the Cleveland Clinic, where scientists conducted animal and cellular studies to identify the influence of Orthofix's PEMF signals on bone cells. Four of the six studies have been published; one in each of the years 2003, 2004, 2005, and 2006. One of the two remaining studies has been accepted for publication in a peer-reviewed journal; the publication date is to be determined and the final manuscript is currently under journal review. Among other insights, the studies illustrate the positive effects of PEMF on bone loss, callus formation, and collagen. Furthermore, characterization and visualization of the Orthofix PEMF waveform is paving the way for signal optimization for a variety of applications and indications.

Spinal-Stim was the first non-invasive spinal fusion stimulator system commercially available in the United States. Spinal-Stim is designed for the treatment of the lower thoracic and lumbar regions of the spine. Some spine fusion patients are at greater risk than most patients 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

vertebra in one procedure. For these patients, post-surgical bone growth stimulation using Spinal-Stim has been shown to increase the probability of fusion, without the need for additional surgery. According to internal sales data, more than 190,000 patients have been treated using Spinal-Stim since the product was introduced in 1990. The device uses proprietary technology and a wavelength to generate a pulsed electromagnetic field (PEMF) signal. Our FDA approval to market Spinal-Stim commercially is for both failed fusions and healing enhancement as an adjunct to initial spinal fusion surgery.

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On December 28, 2004, we received approval from the U.S. Food and Drug Administration (FDA) to market our Cervical-Stim® bone growth stimulator. Cervical-Stim® is the first and only FDA-approved bone growth stimulator for use as an adjunct to cervical (upper) spine fusion in certain high-risk patients.

The FDA approval of Cervical-Stim® is based upon a pre-market approval ("PMA") application that included the results of a prospective, randomized, multi-center clinical investigation of Cervical-Stim. The clinical trial randomized a total of 323 "high-risk" patients who had undergone cervical fusion surgery for degenerative conditions. The trial defined "high risk" as patients who had at least two risk factors. Results showed that 84% of patients who wore the device healed and 69% of patients who did not wear the device healed. These results are clinically significant.

***Orthopedics***

Orthopedics products represented 26% of our total net sales in 2006.

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

*Fixation*

For a fracture to heal properly, without misalignment or rotation, the bone must be set and fixed in the correct position. The bone must be kept stable, but not absolutely rigid, in order to alleviate pain, maintain the correct alignment and initiate new bone formation for proper healing. Fractures initially should not bear any weight but, at the appropriate time in the healing cycle, benefit from gradually increasing micromovement, weight-bearing and function, which further stimulate the new bone formation. In most fracture cases, physicians use casting, the simplest available non-surgical procedure. We believe, however, that approximately 15-20% of all fractures require surgical intervention.

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. Unlike other treatments for fractures, 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.

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 as plates that are attached with the use of screws. A nail is inserted into the hollow core of a fractured long bone, such as the humerus, tibia and fibula, found in human arms and legs. 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 set of rods, rings and screws attached at the fracture site from outside the arm or leg, and is held in place by the screws that extend from the device through the patient's skin into the fractured bone. The choice of whether to use an internal or external fixation device is driven in large part by physician preference. Many patients, however, favor internal fixation devices for aesthetic reasons.

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

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Our proprietary XCaliber™ bone screws are designed to be compatible with our external fixators and reduce inventory for our customers. Some of these screws are covered with hydroxyapatite, a mineral component of bone that reduces superficial inflammation of soft tissue. 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 soft 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 fixator. The Sheffield fixator is radiolucent and uses fewer components than other products used for limb reconstruction. In addition, 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 is a new state of the art nailing system for stabilizing fractures in the femur, tibia and humerus. 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 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 as soon as possible after the operation. It uses a dual screw configuration that provides more stability than previous single screw designs; and

- The Gotfried Percutaneous Compression Plating or PC.C.P® System is another minimally invasive method of stabilization and fixation for hip-fracture surgery developed by Y. Gotfried, M.D. Traditional hip-fracture surgery can require a 5-inch-long incision down the thigh, but the PC.C.P® System involves two smaller incisions, each less than one inch long. The PC.C.P® System then allows a surgeon to work around most muscles and tendons rather than cutting through them. 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); and (3) faster recovery, with patients often being able to bear weight a few days after the operation, and improved post-operative results.

*Bone Growth Stimulation*

Our Physio-Stim® bone growth stimulator products use a pulsed electromagnetic field (PEMF) technology similar to that described previously in the discussion of our spine stimulators. The primary difference is that the Physio-Stim® physical configuration is designed for use on bones found in areas other than the spine.

A bone's regenerative power results in most fractures healing naturally within a few months. In certain situations, however, fractures do not heal or heal slowly, resulting in "non-unions." Traditionally, orthopedists have treated such fracture conditions surgically, often by means of a bone graft with fracture fixation devices, such as bone plates, screws or intramedullary rods. These are examples of "invasive" treatments. Our patented bone growth stimulators use a low level of PEMF signals to activate the body's natural healing process and have proven successful in treating fracture non-unions. The stimulation products that we currently market are external and apply bone growth stimulation without implantation or other surgical procedures.

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Our patient data shows that eight out of ten patients with fracture non-unions that use Physio-Stim® are healed by our product without additional invasive surgical treatment. The 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 123,000 patients have been treated using Physio-Stim® for long bone non-unions since the product was introduced.

*Deformity Corrections*

In addition to the treatment of bone fractures, we also design, manufacture and distribute devices that are used to treat congenital bone conditions, such as limb length discrepancies, angular deformities (e.g., bowed legs in children), or degenerative diseases, as well as conditions resulting from a previous trauma. Examples of products offered in these areas include the eight-Plate Guided Growth System® and the Intramedullary Skeletal Kinetic Distractor, or ISKD®. The ISKD® system is a patented, internal limb-lengthening device that uses a magnetic sensor to monitor limb-lengthening progress on a daily basis. ISKD® is an expandable tubular device that is completely implanted inside the bone to be lengthened. Only the patient and surgeon need know the bone is being lengthened. Once implanted, ISKD® lengthens the patient's bone gradually, and, after lengthening is completed, the system stabilizes the lengthened bone. ISKD® is the only 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 22% of our total net sales in 2006.

We believe Breg 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 three product categories: Breg Bracing, Polar Care and Pain Care. Approximately 58% of Breg's net revenues were attributable to the sale of bracing products in 2006, including: (1) functional braces for 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 29% of Breg's 2006 net revenues came from the sale of cold therapy products used to minimize the pain and swelling following knee, shoulder, elbow and back injuries or surgery. Approximately 7% of Breg's 2006 net revenues came from the sale of pain therapy products used for patient control over post-operative pain management after common Sports Medicine procedures such as arthroscopy of the knee and shoulder. Approximately 6% of Breg's 2006 net revenues came from the sale of other rehabilitative products. Breg sells its products through a network of domestic and international independent distributors and related international subsidiaries.

*Breg Bracing*

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

Ligament braces 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. All ligament braces are also available with a patellofemoral option to address tracking and subsequent pain of the patellofemeral joint. We market the ligament product line under the Fusion™ and X2K™ brand names.

Post-operative braces limit a patient's range of motion after knee surgery and protect the repaired ligaments and/or joints from stress and strain. These braces 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-op 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" for use during later stages of rehabilitation. The Breg T-Scope® is a premium brace in the post-operative bracing market and has every feature available offered in our post-operative knee braces, including telescoping bars, easy application, full range of motion and a drop lock feature.

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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, providing additional stability and reducing pain. In some cases, this type of brace may serve as a cost-efficient alternative to total knee replacement. Breg's CounterForce Plus, our newest bracing technology for patients suffering from OA, is based on a functional knee brace design that controls both anterior/posterior and varus/valgus instabilities.

*Cold Therapy*

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

The Polar Care® product uses a circulation system 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® 500, Polar Care® 500 LITE, Polar Care® 300, Polar Cub and cold gel packs.

*Infusion Pumps*

We manufacture, market and sell a line of pain therapy products called Pain Care®. This product line includes the Pain Care® 3200 and 4200 lines of disposable, pain management infusion pumps. These pain management systems provide a continuous infusion of local anesthetic dispensed directly into the surgical site following a surgical procedure. The Pain Care® family provides infusions, controlled by the patient, of a local anesthetic to alleviate and moderate severe pain experienced following surgery. We also sell the ePain Care, an electronic, reusable infusion pump, which delivers a bolus of local anesthetic in a programmable treatment protocol.

*Other*

Additionally, Breg offers a line of continuous passive motion (CPM) and home therapy products to accommodate post-surgical ambulation and recovery from shoulder, knee and ankle injuries.

***Vascular***

Vascular product sales respresented 6% of our total net sales in 2006. Our non-invasive post-surgical vascular therapy product, called the A-V Impulse System, 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, 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.

The A-V Impulse System 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 or hand, as would occur naturally during normal walking or hand clenching. Conventionally, in order to reduce the incidence of deep vein thrombosis, heparin or related pharmacological products have been administered during and after operations. The

A-V Impulse System has been demonstrated to give prophylactic benefits that are comparable to the forms of pharmacological treatment but without their adverse side effects, the most serious of which typically is bleeding. The A-V Impulse System is distributed in the United States by Kendall Healthcare ("Kendall"), a division of Tyco Healthcare Group LP. Outside the United States, the A-V Impulse System is sold directly by our distribution subsidiaries in the United Kingdom, Italy and Germany and through selected distributors in the rest of the world.

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***Other Products***

Other product sales represented 6% of our total net sales in 2006.

*Laryngeal Mask*

The Laryngeal Mask, a product of Venner Capital S.A. (formally known as LMA International S.A.), is an anesthesia medical device used for establishing and maintaining the patient's airway during an operation. We have exclusive distribution rights for the Laryngeal Mask in the United Kingdom, Ireland and Italy.

*Other*

We hold distribution rights for several other non-orthopedic products including Mentor breast implants in Brazil and women's care 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; Springfield, Massachusetts; Verona, Italy; McKinney, Texas; Vista, California; and Andover, United Kingdom.

We maintain interactive relationships with prestigious spine and orthopedic centers in the United States, Europe, Japan and South and Central America, including research and development centers such as 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.

To support its new product development efforts, Blackstone identifies noted spine surgeons each year to participate in its Executive Medical Advisory Board ("eMAB"). These physicians, who typically have at least 10 years of experience in spine surgery, assist Blackstone in setting the overall direction of its research and development efforts based on emerging trends and technologies in the field. The eMAB also assists with the identification and allocation of resources necessary to carry out specific research and development initiatives. The eMAB meets formally once a year and also provides additional ongoing support to management through discussions throughout the year. In addition to the eMAB , Blackstone maintains a Medical Advisory Board of approximately 50 surgeons from across the country who are involved in various aspects of product development including early product evaluation and the development of product operating guides.

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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 transition. In 2005 and 2004, we spent $11.8 million and $11.5 million, respectively, on research and development.

**Patents, Trade Secrets, Assignments and Licenses**

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

**Government Regulation**

Sales of medical devices, including our products, are subject to regulatory requirements in the U.S. and abroad which regulate the development, approval, testing, manufacture, labeling, marketing and sale of medical products and which 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.

Our products are subject to the regulatory powers of the U.S. Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments Act of 1976 to the Federal Food, Drug, and Cosmetics Act, as amended, and regulations issued or proposed hereunder. With certain exceptions, our products fall into FDA classifications that require a less rigorous standard of review by the FDA pursuant to Section 510(k) of the 1976 Amendments than devices that require pre-market approval applications. However, our bone growth stimulation products are classified as Class III by the FDA, and have been approved for commercial distribution in the United States following our submission of the required pre-market approval applications. We also have under development, an artificial cervical disc product which is currently classified as FDA Class III. As such, this product is required to complete a rigorous pre-market approval process including a human clinical trial. 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 pre-market approval process including a human clinical trial. In addition, our subsidiary, Blackstone Medical, is a distributor of a product for bone repair and reconstruction under the brand name Trinity™ Matrix which is an allogeneic bone matrix containing viable adult mesenchymal stem cells. We believe that Trinity™ Matrix is properly classified by the FDA under its 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. Rather, 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™ 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 and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining FDA 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 for the manufacture and sale of our products and that they are generally in compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance. If the FDA came to believe that we were not in compliance with applicable law or regulations, it could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or our employees and could recommend criminal prosecution to the Department of Justice. In addition, the regulatory process may delay the marketing of new products for lengthy periods and impose substantial additional costs if the FDA lengthens review times for new devices. The FDA also has the ability to reclassify medical devices from one category of regulatory classification to another and there can be no assurance that one or more of our products will not be reclassified. Reclassification can, among other things, adversely affect the level of reimbursement that can be obtained for that product.

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.

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 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 patient for, or the purchase, order, or recommendation of, any item or service reimbursed by a healthcare program, (including Medicare and Medicaid), (2) require that claims for payment submitted to the government healthcare programs be truthful, (3) prohibit the transmission of protected healthcare information to persons not authorized to receive that information, (4) require the provision of certain information to the government, and (5) 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 U.S. Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or 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 submit electronic claims. Consequently, health information that we access, collect, analyze, and otherwise use and/or disclose may include protected health information that is subject to HIPAA. As noted above, many state laws also pertain to the confidentiality of health

information. Such laws are not necessarily preempted by HIPAA, in particular those state laws that afford greater privacy protection to the individual than HIPAA. These state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

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**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 United States, 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.

*Primary Markets*

In 2006, Domestic accounted for 42% of total net sales; Blackstone accounted for 8% of total net sales; Breg accounted for 21% of total net sales; and International accounted for 29% 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 table of revenue by payor type.)

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*Sales, Marketing and Distributor Network*

We have established a broad distribution network comprised of direct sales representatives and distributors. This established distribution network provides us with a strong platform to introduce new products and expand sales of existing products. We distribute our products through a sales and marketing force of approximately 508 direct sales and marketing representatives. Our products are also sold through distributors. Worldwide we have approximately 280 independent distributors who represent our products in approximately 65 countries. The table below highlights the makeup of our sales, marketing and distribution network at December 31, 2006.

| | Direct Sales & Marketing Headcount | | | Distributors | | |
|---|---|---|---|---|---|---|
| | United States | International | Total | United States | International | Total |
| Domestic | 280 | - | 280 | 32 | - | 32 |
| Blackstone | 40 | 4 | 44 | 38 | 25 | 63 |
| Breg | 26 | 3 | 29 | 48 | 61 | 109 |
| International | 6 | 149 | 155 | - | 76 | 76 |
| Total | 352 | 156 | 508 | 118 | 162 | 280 |

In our largest market, the United States, our sales, marketing and distributor 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 biologics products and a distributor 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 primarily a distributor network for Breg products.

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

*Marketing and Product Education*

We seek to market our products principally to medical professionals and group purchasing organizations (“GPO”) or hospital organizations who buy on a large scale. The focus on marketing to physicians is designed to complement our product development and marketing strategy, which seeks to encourage and maintain product development relationships with the leading orthopedic, trauma and other surgeons. These relationships facilitate the introduction of design improvements and create innovative products that meet the needs of surgeons and patients, thereby expanding the market for our products. The focus on selling to GPO’s and large national accounts reflects a recent 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 2006 were attended by over 850 surgeons and over 450 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.

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Blackstone maintains a Los Angeles Spine Center to educate spine surgeons on its products. Blackstone currently holds training sessions at the center every other month with groups of 9 to 10 physicians who come from around the world to view surgery, work on cadavers and participate in a spinal conference. Spine surgeons have also come to the center on an individual basis to see various new products used in surgery. They have also brought X-rays to review difficult cases and discuss various trends in the marketplace. Blackstone also has relationships with a number of hospitals and noted spine surgeons around the country that periodically participate in physician training events, and it has plans to expand the Los Angeles Spine Center in 2007. Additional planned future programs include a surgical fellows internship and additional one day seminars.

**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 biologic 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. OSCAR competes principally with products produced by Biomet, Inc. and Norian Corporation. The principal non-pharmacological products competing with our A-V Impulse System are manufactured by Huntleigh Technology PLC and Kinetic Concepts Inc.

The principal competitors for the Breg bracing and cold therapy products include DJO Inccorporated, Biomet, Ossur Lf. and various smaller private companies. For pain therapy products, the principal competitors are I-Flow Corporation, Stryker Corp. and DJO Incorporated.

We believe that our competitive position is strong with respect to 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 Allograft biologic 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. We generally source for distribution other biologics products including Trinity™ Matrix, our adult stem-cell based bone growth matrix product. 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. Adequate raw material inventory supply is maintained to avoid product flow interruptions. We have not experienced difficulty in obtaining the materials necessary to meet our production schedule. Trinity™ Matrix Multipotential Cellular Bone Matrix is a single source product obtained under an exclusive distribution agreement through December 2008. Under this agreement, as long as we purchase 80% of the product manufactured by the supplier, we maintain our position as the only spine manufacturer with exclusive distribution rights to the product. The supply of Trinity™ Matrix as well as the Alloquent implants are made from human tissue where availability is subject to supply of human donors.

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Our products are currently manufactured and assembled in the United States, 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 – Government Regulation." We actively monitor each of our subcontractors in order to maintain manufacturing and quality standards and product specification conformity.

Our business is generally not seasonal in nature. However, sales associated with products for elective procedures appear to be influenced by the somewhat lower level of such procedures performed in the late summer. Certain of the Breg bracing products experience greater demand in the fall and winter corresponding with high school and college football schedules and winter sports. In addition, we do not consider the backlog of firm orders to be material.

**Capital Expenditures**

We had tangible and intangible capital expenditures in the amount of $12.6 million, $12.2 million and $12.2 million in 2006, 2005 and 2004, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. We currently plan to invest approximately $17 million in capital expenditures during 2007 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, 2006, we had 1,324 employees worldwide. 428 were employed at Domestic, 150 were employed at Blackstone, 422 were employed at Breg and 324 were employed at International. Our relations with our Italian employees, who numbered 98 at December 31, 2006, 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 1,324 employees, 508 were employed in sales and marketing functions, 263 in general and administrative, 457 in production and 96 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.*

**Our acquisition of Blackstone Medical could present challenges for us.**

On September 22, 2006, we completed the acquisition of Blackstone Medical. We are in the process of integrating the operations of Blackstone Medical into our business. We may not be able to successfully integrate Blackstone Medical's operations into our business and achieve the anticipated benefits of the acquisition. The integration of Blackstone Medical's operations into our business involves numerous risks, including:

- difficulties in incorporating Blackstone Medical'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.

In addition, Blackstone Medical'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 Medical's intellectual property and proprietary rights, including patents that it owns or licenses. If Blackstone Medical's intellectual property and proprietary rights are challenged, or if third parties claim that Blackstone Medical 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 Medical could adversely affect our business, prospects and financial condition. In addition, if Blackstone Medical's operations and financial results do not meet our expectations, we may not realize synergies, operating efficiencies, market position, or revenue growth we anticipate from the acquisition.

**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.

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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 devices 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. At this time, Cross/Biomet and the Company are in discussions about the terms of such consent and the scope of products marketed by Blackstone that fall within the ambit of the license. 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.

**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 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 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 polices that address whether a particular product, treatment modality, device or therapy will be subject to reimbursement and, if so, at what level of payment.

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The Centers for Medicare and Medicaid Services ("CMS"), in its ongoing implementation of the Medicare program recently obtained information from an advisory panel known as the Medicare Evidence Development and Coverage Advisory Committee ("MedCAC") that could affect our business. Specifically, in one meeting, MedCAC addressed the use of bone growth stimulators such as those manufactured by the Company and certain biological products (known generally as "orthobiologics") for the repair of non-union bone fractures, while in another meeting it addressed evidence relating to indications for spinal fusion, clinical outcomes relating to different spinal fusion procedures and the generalizability of this information to the Medicare population. In addition, CMS 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. As required by law, the Centers for Medicare and Medicaid Services ("CMS") is expected to implement a competitive bidding program for durable medical equipment paid for by the Medicare program. The competitive bidding program is likely to begin with a limited set of products in limited areas in 2007, be expanded to more areas and more products in 2009, and implemented in full some time thereafter. 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.

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. CMS, in its ongoing implementation of the Medicare program recently obtained information from an advisory panel known as the Medicare Evidence Development and Coverage Advisory Committee ("MedCAC") that could affect our business. Specifically, in one meeting, MedCAC addressed the use of bone growth stimulators such as those manufactured by the Company and certain biological products (known generally as "orthobiologics") for the repair of non-union bone fractures, while in another meeting it addressed evidence relating to indications for spinal fusion, clinical outcomes relating to different spinal fusion procedures and the generalizability of this information to the Medicare population. In addition, CMS 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 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.

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We estimate that revenue by payor type is:

- Independent Distributors 27%
- Third Party Insurance 22%
- International Public Healthcare Systems 16%
- Direct (hospital) 23%
- U.S. Government – Medicare, Medicaid, TriCare 10%
- Self pay 2%

**We 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, manufacture, 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 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 and other regulatory 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. Our subsidiary, Orthofix Inc., is currently involved in a proceeding before the FDA addressing whether the FDA classification of Physio-Stim and Spinal-Stim bone growth stimulation products should be reclassified from FDA Class III to FDA Class II. We are actively participating in this proceeding, and maintain that the current FDA Class III classification is correct. A meeting was held on June 2, 2006 before the FDA's Orthopedic and Rehabilitation Devices Panel (the "Panel") for the purpose of gathering information to allow the Panel to make a recommendation to the FDA regarding reclassification. At that meeting, the Panel determined that the present FDA Class III classification for the products at issue is proper. On January 17, 2007, the FDA issued a federal register notice announcing that it was prepared to adopt the position of the Panel that the bone growth stimulator products at issue should remain in FDA Class III and opened the record for public comment. We do not know when the FDA will reach a determination on this classification issue or whether any such determination would adversely impact our ability to market or sell these products.

Our profitability depends, in part, upon the ability of the Company, our sales representatives, and our distributors to obtain and maintain all necessary certificates, permits, approvals and clearances from U.S. and foreign regulatory

authorities and to operate in compliance with applicable regulations. If the FDA or other U.S. or foreign regulatory authority determines that we were not in compliance with applicable law or regulations, it could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or our employees and could recommend criminal prosecution to the Department of Justice. Any such consequences could have a material adverse effect on our business, financial condition or results of operations.

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**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:

- 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.

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 and the curtailment or restructuring of our operations. 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.

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

Our Blackstone Medical subsidiary distributes a product under the brand name Trinity™ Matrix which is an allogeneic bone matrix containing viable adult mesenchymal stem cells. We believe that Trinity™ 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™ Matrix and the reclassification of this product 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 and compliance with additional postmarket regulatory requirements. Our ability to continue to sell the Trinity™ Matrix product also depends on our supplier continuing to have access to donated human tissue for their supply of mesenchymal stem cells, as well as, the maintenance of high standards by the supplier in its stem cell collection methodology. Moreover, the success of our Trinity™ 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.

Blackstone Medical 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.

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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 us.

**Fluctuations in insurance expense could adversely affect our profitability.**

We hold a number of insurance policies, including product liability insurance, director's 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, 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 expected to continue to undergo, 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.

The approval and introduction of Bone Morphogenic Proteins (BMPs) by Medtronic Sofamor Danek Group have shown market acceptance as a substitute for autograft bone in spinal fusion surgeries. Our Spinal-Stim product is FDA approved for both failed fusions and healing enhancement as an adjunct to spinal fusion surgery, most typically for multilevel or high-risk patients. While BMPs are considered or classified as a bone growth material, they have yet to be clinically proven to be effective or approved for use in the high-risk patients such as those who use our Spinal-Stim and our new Cervical-Stim products. Off-label use or the FDA approval of BMPs for risk indications could have an adverse effect on sales of our bone-growth stimulation products in high-risk patients. Additionally, in 2004, Artificial Spinal Discs were introduced into the market as an alternative to spinal fusions. The use of artificial discs on certain patients could have an adverse effect on sales of our products in such patients. In addition, the increased usage of internal fixation plates and nails could have an adverse effect on sales of our external fixation products for the repair of certain fractures.

**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 fragmented and 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.

**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.

**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 2006 have had a positive impact of $0.6 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, 2006, we had outstanding a currency swap to hedge a 42.6 million Euro foreign currency exposure.

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**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 29% of our total net sales in 2006. 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:

- 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;

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- 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.

**Our subsidiary Orthofix Holdings, Inc.'s senior secured bank credit facility contains significant financial and operating restrictions and requires mandatory prepayments that may have an adverse effect on our operations and limit our ability to grow our business.**

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 for which $315.2 million was outstanding at December 31, 2006, and (2) a six-year revolving credit facility of $45.0 million upon which we had not drawn as of December 31, 2006.

Further, in addition to scheduled debt payments, the credit agreement 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 credit agreement 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. See Part II, Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" - "Liquidity and Capital Resources" of this Form 10-K.

**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.

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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 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. In particular, beginning in the first quarter of 2006, the calculation of share-based compensation expense under SFAS No. 123(R) required us to use valuation methodologies (which were not developed for use in valuing employee stock options) and a number of assumptions, estimates and conclusions regarding matters such as expected forfeitures, expected volatility of our share price, the expected dividend rate with respect to our common stock and the exercise behavior of our employees. Furthermore, there are no means, under applicable accounting principles, to compare and adjust our expense if and when we learn of additional information that may affect the estimates that we previously made, with the exception of changes in expected forfeitures of share-based awards. Factors may arise over time that leads us to change our estimates and assumptions with respect to future share-based compensation arrangements, resulting in variability in our share-based compensation expense over time. Changes in forecasted share-based compensation expense could impact our gross margin percentage; research and development expenses; sales and marketing expenses; general and administrative expenses; and our tax rate.

## Item 1B. Unresolved Staff Comments

None.

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**Item 2. Properties**

Our principal facilities are:

| Facility | Location | 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 |
| Sales management and distribution for Blackstone. | Laichingen, Germany | 2,422 | 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. and Orthofix Inc. | Huntersville, NC | 10,084 | Leased |
| Sales management, distribution and administrative offices | South Devon, England | 2,500 | Leased |
| Sales management, distribution and administrative offices for A-V Impulse 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 |
| Sales management, distribution and administrative facility for Brazil | São Paulo, Brazil | 4,415 | Leased |

| | | | |
|---|---|---|---|
| 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 | Mexicali, Mexico | 63,000 | Leased |
| Sales management, distribution and administrative facility for Puerto Rico | Guaynabo, Puerto Rico | 4,400 | Leased |

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**Item 3. Legal Proceedings**

The Company's subsidiary, Blackstone Medical, is a defendant in 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. The plaintiffs allege that (i) they are 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 Medical's making, selling, offering for sale, and using within the United States its Blackstone Anterior Cervical Plate, 3º Anterior Cervical Plate Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products is infringing and has infringed the Patents, and that such infringement has been willful. The Complaint does not specifically state an amount of damages. Blackstone Medical has denied infringement and asserts that the Patents are invalid.

We are from time to time involved in legal proceedings in the normal course of business which may include, but are not limited to, product liability actions.

Although we cannot predict the outcome of any proceedings or claims made against us, management does not currently expect that the ultimate outcome of any such proceedings or claims will have a material adverse effect on our financial position, results of operations or cash flows. However, there can be no assurance that the ultimate resolution of any claim will not have a material adverse impact on our financial position, results of operations, or cash flows.

**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 2006.

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## PART II

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

**Market for Our Common Stock**

Our common stock is traded on the Nasdaq Global Select Market under the symbol "OFIX." The following table shows the quarterly range of high and low sales prices for our common stock as reported by Nasdaq for each of the two most recent fiscal years ended December 31, 2006. As of March 13, 2007 we had approximately 254 holders of record of our common stock. The closing price of our common stock on March 13, 2007 was $49.48.

| | High | Low |
|---|---|---|
| 2005 | | |
| First Quarter | $ 42.44 | $ 36.24 |
| Second Quarter | 48.61 | 37.57 |
| Third Quarter | 46.98 | 40.59 |
| Fourth Quarter | 45.09 | 35.30 |
| | | |
| 2006 | | |
| First Quarter | $ 48.48 | $ 38.76 |
| Second Quarter | 42.00 | 35.00 |
| Third Quarter | 46.40 | 38.01 |
| Fourth Quarter | 50.48 | 42.08 |

**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 2006 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 Central 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 do 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, 2001. 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, 2006, 2005, 2004, 2003 and 2002 have been derived from our audited consolidated financial statements. The financial data as of December 31, 2006 and 2005 and for the years ended December 31, 2006, 2005, and 2004 should be read in conjunction with, and are qualified in their entirety by, reference to, Item 7 – "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, | | | | |
|---|---|---|---|---|---|
| | **2006** | **2005** | **2004** | **2003** | **2002** |
| | (In US$ thousands, except margin and per share data) | | | | |
| **Consolidated operating results** | | | | | |
| Net sales | $ 365,359 | $ 313,304 | $ 286,638 | $ 203,707 | $ 177,595 |
| Gross profit | 271,734 | 229,516 | 207,461 | 152,617 | 132,776 |
| Gross profit margin | 74% | 73% | 72% | 75% | 75% |
| Total operating income | 8,853 | 59,706 | 56,568 | 44,568 | 42,939 |
| Net income (loss) (1) (2) (3) | (7,042) | 73,402 | 34,149 | 24,730 | 25,913 |
| Net income (loss) per share of common stock (basic) | (0.44) | 4.61 | 2.22 | 1.76 | 1.96 |
| Net income (loss) per share of common stock (diluted) | (0.44) | 4.51 | 2.14 | 1.68 | 1.76 |

(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) Net income for 2005 includes $37.4 million of income after tax related to the KCI settlement.

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

| **Consolidated financial position** | As of December 31, | | | | |
|---|---|---|---|---|---|
| (at year-end) | **2006** | **2005** | **2004** | **2003** | **2002** |
| | (In US$ thousands, except share data) | | | | |
| Total assets | $ 862,285 | $ 473,861 | $ 440,969 | $ 413,179 | $ 220,774 |
| Total debt | 315,467 | 15,287 | 77,382 | 110,207 | 7,420 |
| Shareholders' equity | 392,635 | 368,885 | 297,172 | 240,776 | 168,084 |
| Weighted average number of shares of common stock outstanding (basic) | 16,165,540 | 15,913,475 | 15,396,540 | 14,061,447 | 13,196,524 |
| | | | | | |
| Weighted average number of shares of common stock outstanding (diluted) | 16,165,540 | 16,288,975 | 15,974,945 | 14,681,883 | 14,685,236 |

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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 biologics; 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 (loss) component of shareholders' equity.

Our financial condition, results of operations and cash flows are not significantly impacted by seasonality trends. 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 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 biologics products. The purchase price for the acquisition was $333.0 million, subject to certain closing adjustments, plus transaction costs totaling approximately $9.2 million as of December 31, 2006. The acquisition and related costs were financed with $330.0 million of senior secured bank debt and cash on hand. Financing costs were approximately $6.0 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's domestic and international operations. 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) as well as independent export distribution operations. Group Activities are comprised of the operating expenses and identifiable assets of Orthofix International N.V. and its US 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, investments, intangible assets and goodwill, income taxes, litigation and contingencies. We base our estimates on historical experience and various other assumptions and believe our estimates for the carrying values of assets and liabilities are reasonable. 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 biologic 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 SFAS No. 142, "Goodwill and Other Intangible Assets," require that goodwill and indefinite lived intangible assets be tested at least annually for impairment. As a result, we evaluate the recoverability and measure the potential impairment of our goodwill under SFAS 142. The annual impairment test requires an estimation of the fair value of the reporting unit, which involves judgment. We performed the impairment test of goodwill as required by SFAS No. 142 and noted no impairment related to the carrying value of goodwill or indefinite lived intangible assets as of December 31, 2006.

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

***Tax Matters***

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

***Share-based compensation***

Prior to the adoption of SFAS No. 123(R) on January 1, 2006, we accounted for our employee stock option plans and employee stock purchase plan using the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees and its related interpretations, and had adopted the disclosure only provisions of SFAS No. 123, Accounting for Stock-Based Compensation and its related interpretation.

As of January 1, 2006, we began recording compensation expense associated with stock options and other equity-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, stock-based compensation expense for 2006 includes: (a) compensation cost for all stock-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) stock-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(R). 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 net income for the year ended December 31, 2006 has been reduced by stock-based compensation expense, net of taxes, of approximately $5.2 million.

The fair value of each equity 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. 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. 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 our common stock and an employee's average length of service. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award.

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**Selected Financial Data**

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

| | Year ended December 31, | | |
|---|---|---|---|
| | **2006** | **2005** | **2004** |
| | (%) | (%) | (%) |
| Net sales | 100 | 100 | 100 |
| Cost of sales | 26 | 27 | 28 |
| Gross profit | 74 | 73 | 72 |
| Operating expenses | | | |
| Sales and marketing | 40 | 37 | 36 |
| General and administrative | 15 | 11 | 11 |
| Research and development [1] | 15 | 4 | 4 |
| Amortization of intangible assets | 2 | 2 | 2 |
| Total operating income | 2 | 19 | 19 |
| Net income (loss) [1] [2] | (2) | 23 | 12 |

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[1] Research and development and net loss for 2006 includes $40.0 million of In Process Research and Development costs related to the Blackstone acquisition.

[2] Net income for 2005 includes $37.4 million of net income after tax related to the KCI settlement.

**Segment and Market Sector Revenue**

The following tables display net sales by business segment and net sales by market sector. We provide net sales by market sector for information purposes only. We keep our books and records and account for net sales, costs of sales and expenses by business segment. In 2006, concurrent with the acquisition of Blackstone, we have redefined our business segments and market sectors. All prior period information has been restated to conform to the new segments and market sectors.

**Business Segment:**

| | Year ended December 31, (In US$ thousands) | | | | | |
|---|---|---|---|---|---|---|
| | **2006** | | **2005** | | **2004** | |
| | **Net Sales** | **Percent of Total Net Sales** | **Net Sales** | **Percent of Total Net Sales** | **Net Sales** | **Percent of Total Net Sales** |
| Domestic | $ 152,560 | 42% | $ 135,084 | 43% | $ 118,074 | 41% |
| Blackstone | 28,134 | 8% | - | - | - | - |
| Breg | 76,219 | 21% | 72,022 | 23% | 68,294 | 24% |
| International | 108,446 | 29% | 106,198 | 34% | 100,270 | 35% |
| Total | $ 365,359 | 100% | $ 313,304 | 100% | $ 286,638 | 100% |

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

**Market Sector:**

| | Year ended December 31, (In US$ thousands) | | | | | |
|---|---|---|---|---|---|---|
| | 2006 | | 2005 | | 2004 | |
| | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales | Net Sales | Percent of Total Net Sales |
| Spine | $ 145,113 | 40% | $ 101,622 | 33% | $ 81,373 | 28% |
| Orthopedics | 95,799 | 26% | 92,097 | 29% | 90,112 | 31% |
| Sports Medicine | 79,053 | 22% | 72,970 | 23% | 68,488 | 24% |
| Vascular | 21,168 | 6% | 23,887 | 8% | 25,226 | 9% |
| Other | 24,226 | 6% | 22,728 | 7% | 21,439 | 8% |
| Total | $ 365,359 | 100% | $ 313,304 | 100% | $ 286,638 | 100% |

**2006 Compared to 2005**

Net sales increased 17% to $365.4 million in 2006, which included $28.1 million of net sales attributable to Blackstone, compared to $313.3 million in 2005. The impact of foreign currency increased sales by $0.6 million in 2006 when compared to 2005.

*Sales by Business Segment:*

Net sales in Domestic increased 13% to $152.6 million in 2006 compared to $135.1 million in 2005. Domestic represented 42% and 43% of our total net sales in 2006 and 2005, respectively. The increase in sales was primarily the result of a 15% increase in sales in the Spine market sector which was attributable to increased demand for both our Cervical-Stim® and Spinal-Stim® products. The Orthopedics market sector also experienced a 7% increase in 2006 compared to 2005. This increase is primarily due to growth in sales of newer internal fixation products such as the eight-plate and ISKD®. External fixation devices are sharing the market for treatment of difficult fractures with internal fixation alternatives such as plating and nailing. Recognizing this trend, we are continuing to expand our offering of internal fixation products, such as the Contours VPS® for distal radius fractures, the PC.C.P® for hip fractures, and the recently introduced Veronail also for hip fractures and on limited release the CentroNail.

**Orthofix Domestic Sales by Market Sector:**

| (In US$ thousands) | 2006 | 2005 | Growth |
|---|---|---|---|
| Spine | $ 116,701 | $ 101,470 | 15% |
| Orthopedics | 35,813 | 33,569 | 7% |
| Other | 46 | 45 | 22% |
| Total | $ 152,560 | $ 135,084 | 13% |

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Net sales in Blackstone were $28.1 million in 2006, which represents 8% of total sales in 2006. Blackstone was acquired on September 22, 2006 and therefore only sales after that date are included on our sales. There are no sales for Blackstone for the comparable period of the prior year. All of Blackstone's sales are recorded in our Spine market sector. On a pro forma basis Blackstone sales increased 51% when compared to 2005 and would have represented 21% of pro forma total net sales in 2006.

Net sales in Breg increased 6% to $76.2 million in 2006 compared to $72.0 million in 2005. This increase in sales was primarily attributable to the sale of Breg bracing products, which increased 11% in 2006 and to Breg Polar Care® products, which increased 5% in 2006. Our new Fusion XT™ knee brace was the primary contributor to the increase. This increase was partially offset by a 12% decrease in sales for pain therapy products resulting from delayed introduction of new pain therapy products. All of Breg's sales are recorded in our Sports Medicine market sector. Breg net sales represented 21% and 23% of our total net sales in 2006 and 2005, respectively.

Net sales in International increased 2% to $108.4 million in 2006 from $106.2 million in 2005. International net sales represented 29% and 34% of our total net sales in 2006 and 2005, respectively. The International Sports Medicine market sector increased $1.9 million compared to 2005 due to increased distribution of Breg products and the acquisition during the year of our German distributor for Breg products. The Orthpedics market sector increased 2% due to increased sales of internal fixation devices, including the ISKD® and increased sales of the Physio-Stim®. These increases were partially offset by decreases in sales of external fixation devices and OSCAR. The Vascular market sector decreased compared to the prior year due to pricing and competitive pressures while sales of other product sales increased compared to the prior year. The impact of foreign currency increased International sales by 1.0% or $0.6 million when compared to 2005.

**Orthofix International Sales by Market Sector:**

| **(In US$ thousands)** | **2006** | **2005** | **Growth** |
|---|---|---|---|
| Spine | $ 278 | $ 152 | 83% |
| Orthopedics | 59,986 | 58,528 | 2% |
| Sports Medicine | 2,834 | 948 | 199% |
| Vascular | 21,168 | 23,887 | (11)% |
| Other | 24,180 | 22,683 | 7% |
| International | $ 108,446 | $ 106,198 | 2% |

*Sales by Market Sector:*

Sales of our Spine products grew 43% to $145.1 million in 2006 from $101.6 million in 2005. As discussed above, the increase is primarily due to increased sales of Spinal-Stim® and Cervical-Stim® products attributable to increased demand in the United States together with the addition of Blackstone Spine sales from September 22, 2006.

Sales of our Orthopedics products increased 4% to $95.8 million in 2006 compared to $92.1 million in 2005. The increase in this market sector is primarily attributable to increased sales of internal fixation devices which have been added to our product offering and increased sales of Physio-Stim®. This market sector was negatively impacted by sales of external fixation devices, which decreased 1% compared to the prior year.

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Sales of our Sports Medicine products increased 8% or $6.1 million from $73.0 million to $79.1 million. As discussed above, the increase in sales is primarily due to sales of our Breg Bracing Products, particularly the Fusion XT™ knee brace as well as by increased sales of Breg products in the International Market.

Sales of our Vascular products decreased 11% to $21.2 million in 2006, compared to $23.9 million in 2005 due to increased world-wide competition.

Sales of Other products grew 7% to $24.2 million in 2006 compared to $22.7 million in 2005 due to increased sales of women's care and other distributed products in the UK and Brazil with essentially flat sales of airway management products.

*Gross Profit* — Gross profit increased 18.4% to $271.7 million in 2006 from $229.5 million in 2005, primarily due to the increase of 16.6% in net sales including the addition of Blackstone sales. Gross profit as a percentage of net sales in 2006 was 74.4% compared to 73.3% in 2005 reflecting in part the impact of the inclusion of Blackstone with higher gross margins. The improvement in gross margin was also attributable to a favorable product mix, resulting from the sales of higher margin stimulation products as well as ongoing operational improvement initiatives. Gross margins were impacted negatively by the inclusion of a charge to cost of sales of approximately $1.0 million from September 22, 2006 for the amortization of the step-up in value of acquired Blackstone inventory. Additional step-up amortization totaling approximately $2.7 million will be incurred over the first three quarters of 2007.

*Sales and Marketing Expenses* — Sales and marketing expenses, which include commissions, royalties and bad debt provision, generally increase and decrease in relation to sales. Sales and marketing expenses increased $30.3 million to $145.7 million in 2006 from $115.4 million in 2005, an increase of 26.3% on a sales increase of 16.6%. The higher sales and marketing expense relates to the inclusion of Blackstone sales and marketing expense for which there is no 2005 comparable cost (approximately $13.0 million), higher commissions and other variable costs including bad debt provisions and sales tax (approximately $7.0 million), distribution termination costs following the Blackstone acquisition (approximately $4.5 million), stock compensation costs related to the adoption of SFAS 123(R) (approximately $1.4 million) and other costs intended to build our distribution capabilities. Sales and marketing expenses as a percentage of net sales increased to 39.9% in 2006 from 36.8% in 2005.

*General and Administrative Expenses* — General and administrative expenses increased $17.3 million to $53.3 million in 2006 from $36.1 million in 2005. The increase is primarily attributable to the inclusion of Blackstone general and administrative expense of $2.1 million for which there is no 2005 comparable cost , share-based compensation of $4.6 million related to the adoption of SFAS 123(R) for which there is no comparable cost in 2005, management transition and divisional restructuring costs (approximately $2.6 million) and additional corporate development, legal and professional costs ($2.6 million). General and administrative expense as a percent of net sales was 14.6% in 2006 and 11.5% in 2005.

*Research and Development Expenses* — Research and development expenses increased $43.2 million to $55.0 million in 2006 from $11.8 million in 2005. The increase in research and development expense includes a charge of $40.0 million related to the write-off of in–process research and development resulting from the Blackstone acquisition. Of the remaining increase, approximately $2.8 million is related to Blackstone, for which there was no comparable cost in 2005. Share-based compensation costs related to the adoption of SFAS 123(R) were $0.4 million, for which there was also no comparable cost in the prior year. Research and Development expense as a percent of sales was 15.1% in 2006 and 3.8% in 2005.

*Amortization of Intangible Assets* — Amortization of intangible assets was $8.9 million in 2006 compared to $6.6 million in 2005. The increase in amortization expense was due to the amortization associated with definite-lived intangible assets acquired in the Blackstone acquisition. The acquisition of Blackstone will increase amortization of

intangibles by approximately $11.1 million in 2007.

*Interest Income* — Interest income earned on cash balances held during the period was $2.2 million in 2006 compared to $0.9 million in 2005.

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*Interest Expense* — Interest expense was $8.4 million in 2006 compared to $6.4 million in 2005. We incurred interest expense on borrowings under our senior secured term loan which financed the Blackstone acquisition of $6.9 million. 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.

*Other Income (Expense), Net* — Other income (expense), net was income of $2.5 million in 2006 compared to income of $1.2 million in 2005. Other income in 2006 was primarily attributable to a $2.1 million foreign currency gain related to an uncovered intercompany loan of 42.6 million Euro created as part of a European restructuring. In December we arranged a currency swap to hedge the intercompany exposure and minimize future foreign currency exchange risk related to the intercompany position.

*KCI Settlement, Net of Related Costs* — In the first quarter of 2006, we entered into final agreements with certain former owners of Novamedix, which established the portion of the proceeds we were required to disburse in connection with the KCI settlement. Accordingly, we recorded a gain of $1.1 million, which was the difference between what we had reserved to disburse at December 31, 2005 and the amount of the final settlement obligations.

*Income Tax Expense* — In 2006 and 2005, the effective tax rate was 210.5% and 23.2%, respectively. 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 provision in Italy. Without these discrete items, our worldwide effective tax rate was 35% in 2006. The effective tax rate in 2005 was affected by the gain recorded from the KCI settlement which was recorded at Novamedix Distribution Limited, a wholly-owned Cypriot subsidiary, which is in a favorable tax jurisdiction. Without this discrete item, our worldwide effective tax rate was 35% in 2005.

*Net Income (Loss)* — Net loss for 2006 was $7.0 million compared to net income of $73.4 million in 2005 and reflects the items noted above. Net loss was $0.44 per basic share and $0.44 per diluted share in 2006, compared to net income of $4.61 per basic share and $4.51 per diluted share in 2005. The weighted average number of basic common shares outstanding was 16,165,540 and 15,913,475 during 2006 and 2005, respectively. The weighted average number of diluted common shares outstanding was 16,165,540 and 16,288,975 during 2006 and 2005, respectively.

**2005 Compared to 2004**

Net sales increased 9% to $313.3 million in 2005 compared to $286.6 million in 2004. The impact of foreign currency increased sales by $1.2 million in 2005 when compared to 2004.

*Sales by Business Segment:*

Net sales in Domestic increased 14% to $135.1 million in 2005 compared to $118.1 million in 2004. The Domestic net sales represented 43% and 41% of our total net sales in 2005 and 2004, respectively. The increase in sales was primarily the result of a 25% increase in sales in the Spine market sector attributable to sales of Cervical-Stim, which was approved by the FDA in December 2004, and growth in the sales of Spinal-Stim, used for lumbar applications. The Domestic Orthopedics market sector decreased 9% in 2005 compared to 2004. This decrease is attributable to a decline in external fixation sales as well as decline in Physio-Stim long bone stimulation sales resulting from increased competition and the cannibalization of some stimulation sales, previously recorded in the Orthopedic market sector, by the recent introduction of the Cervical-Stim. The decrease in external fixation was partially offset by sales of recently introduced internal fixation products like the eight-plate and ISKD limb lengthening system. In the Domestic Orthopedic market sector, external fixation devices are sharing the market for treatment of difficult fractures with alternatives such as plating, nailing and biologics. Recognizing this trend, we

have introduced the VPS Contour plate for distal radius fractures, the Osteomax bone void filler product line, and anticipate the introduction of other internal fixation and biologic products to our Domestic Orthopedic product line. The following table illustrates sales by market sector in Domestic:

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| (In thousands) | 2005 | 2004 | Growth |
|---|---|---|---|
| Spine | $ 101,470 | $ 81,182 | 25% |
| Orthopedics | 33,569 | 36,874 | (9)% |
| Other | 45 | 18 | 150% |
| Domestic | $ 135,084 | $ 118,074 | 14% |

Net sales in Breg increased 5% to $72.0 million in 2005 compared to $68.3 million in 2004. This increase in sales was primarily attributable to the sale of Breg bracing products, which increased 10% in 2005. Our new Fusion XT™ knee brace, which experienced positive market response upon its limited introduction, contributed to this increase. This increase was partially offset by an 8% decrease in sales for pain therapy products resulting in part from delays in the introduction of new pain therapy products. All of Breg's sales are recorded in our Sports Medicine market sector. Breg net sales represented 23% and 24% of our total net sales in 2005 and 2004, respectively.

Net sales in International increased 6% to $106.2 million in 2005 from $100.3 million in 2004. International net sales represented 34% and 35% of our total net sales in 2005 and 2004, respectively. Our Orthopedic market sector continues to contribute to the growth in International, led primarily by the sales of external fixation products, the Physio-Stim® and the PC.C.P® hip fracture system. The Vascular market sector continues to be impacted by a decrease in sales of the A-V Impulse product when compared to the same period of the prior year. This decrease is primarily attributable to the competitive landscape for this product and decreased prices to our principal U.S. distributor. The impact of foreign currency increased International sales by $0.6 million for 2005 when compared to 2004. The following table illustrates sales by market sector in International:

| (In thousands) | 2005 | 2004 | Growth |
|---|---|---|---|
| Spine | $ 152 | $ 191 | (20)% |
| Orthopedics | 58,528 | 53,238 | 10% |
| Sports Medicine | 948 | 194 | 389% |
| Vascular | 23,887 | 25,226 | (5)% |
| Other | 22,683 | 21,421 | 6% |
| International | $ 106,198 | $ 100,270 | 6% |

*Sales by Market Sector:*

Net sales of our Spine products grew 25% to $101.6 million in 2005 from $81.4 million in 2004. This increase is primarily due to sales of Cervical-Stim®, which was approved by the FDA in December 2004 and began selling in January 2005, and growth of our Spinal-Stim®, used for lumbar applications.

Sales of our Orthopedic products increased 2% to $92.1 million in 2005 compared to $90.1 million in 2004. The increase is attributable to sales of fixation products which overall increased 6%. Growth in this market sector was negatively impacted by a decrease of 10% in sales of stimulation products used for long bone applications. The growth in this product has been impacted by increased competition and the effect of cannibalization of some stimulation sales previously recorded in this market sector by Cervical-Stim®.

Sales of our Vascular A-V Impulse product decreased 5% to $23.9 million in 2005 compared to $25.2 million in 2004 for the reasons discussed above.

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Sales of our Other products grew 6% to $22.7 million in 2005 compared to $21.4 million in 2004. The increase was primarily due to an increase in sales of women's care and other products. This increase was slightly offset by a decrease in sales of airway management products due to increased competition as a result of this product coming off patent.

*Gross Profit* — Gross profit increased 11% to $229.5 million in 2005 from $207.5 million in 2004, primarily due to the increase of 9% in net sales. Gross profit as a percentage of net sales in 2005 was 73.3% compared to 72.4% in 2004. The improvement in gross profit margin in 2005 as compared to 2004 is due to operational process improvements which increased margins on our stimulation products, and a more favorable product mix resulting from higher sales of higher margin stimulation products.

*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 expenses increased $12.9 million to $115.4 million in 2005 from $102.5 million in 2004, an increase of 13% on a sales increase of 9%. Sales and marketing expenses as a percentage of net sales increased to 36.8% in 2005 from 35.7% in 2004. The higher sales and marketing expense relates to higher commissions and other variable costs on higher sales, additional personnel, principally in Domestic, and higher related benefits costs, all of which were deemed to be more operational in nature. In addition, we discretionarily spent approximately $3.1 million for market development efforts in our Latin Americas subsidiaries and marketing programs.

*General and Administrative Expenses* — General and administrative expenses increased $5.4 million to $36.1 million in 2005 from $30.6 million in 2004. This increase is a result of corporate development, higher costs associated with Section 404 of the Sarbanes-Oxley Act of 2002, legal activity, employee benefit costs in the United States, consulting and training costs associated with implementing an Oracle system at Breg, and sponsorships at Breg. We also had an increase in the area of business development, when compared to the same period of the prior year. We added a new Chief Operating Officer during the current year to lead these activities and have incurred costs of outside consultants to help us define market potential and target and assess new opportunities. General and administrative expense as a percent of net sales was 12% in 2005 and 11% in 2004.

*Research and Development Expenses* — Research and development expenses increased $0.3 million to $11.8 million in 2005 from $11.5 million in 2004, an increase of 3%, and remained constant as a percentage of net sales at 4%.

*Amortization of Intangible Assets* — Amortization of intangible assets was $6.6 million in 2005 compared to $6.3 million in 2004.

*Interest Income* — Interest income earned on cash balances held during the period was $0.9 million in 2005 compared to $0.3 million in 2004.

*Interest Expense* — Interest expense was $6.4 million in 2005 compared to $6.3 million in 2004 primarily due to an increase of approximately $2.0 million in the amortization of debt placement costs resulting from the prepayment of debt on the senior secured term loan and an increase in interest rates in 2005. These additional costs were offset by lower interest expense incurred on lower outstanding debt balances following debt prepayments as well as the termination of an interest rate swap agreement that reduced interest expense by $0.4 million.

*Loss in Joint Venture, Net* — In 2005, we did not record a loss in joint venture and in 2004 we recorded a net loss of $0.3 million. During 2004, we sold part of our ownership in the OrthoRx joint venture. This sale resulted in a gain of approximately $0.8 million. The gain was offset by our portion of the joint venture's operating losses in 2004 of approximately $1.1 million. As of December 31, 2005 our ownership percentage in the joint venture was 6.4% and our investment in the joint venture had been reduced to zero through the equity method of accounting.

*Other Income (Expense), Net* — Other income (expense), net was income of $1.2 million in 2005 compared to income of $1.3 million in 2004. Other income in 2005 was attributable to $2.4 million of deferred royalty income resulting from the conclusion of the BoneSource agreement with Stryker which was partially offset by $0.9 million of foreign currency losses. In 2004, other income was generated from the sale of our interest in a U.K. facility that resulted in a gain of approximately $0.6 million and foreign exchange gains of $0.9 million, primarily as a result of uncovered trade receivables denominated in Euros in subsidiaries whose functional currency is the U.S. Dollar. These gains were slightly offset with a loss in joint venture of $0.3 million.

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*KCI Settlement, Net of Related Costs* — In September 2005, we reached an agreement to settle our case against Kinetics Concepts Inc. ("KCI"). The gain, net of related costs, for 2005 was $40.1 million, compared to costs of $1.6 million in 2004. The net gain recorded in 2005 was subject to adjustment based on potential differences between the amount accrued and final contractual obligations.

*Income Tax Expense* — In 2005 and 2004, the effective tax rate was 23.2% and 32.2%, respectively. The effective tax rate in 2005 was primarily affected by the KCI settlement gain recorded at Novamedix Distribution Limited, a wholly-owned Cypriot subsidiary, which is in a favorable tax jurisdiction. Excluding the nonrecurring KCI settlement, our effective tax rate was approximately 35% for 2005. The increase in our effective tax rate excluding the KCI litigation settlement is primarily attributable to a change in tax law in the United Kingdom and earning more taxable income in higher tax jurisdictions such as the United States.

*Net Income* — Net income for 2005 was $73.4 million compared to $34.1 million in 2004, an increase of 115%. Net income was $4.61 per basic share and $4.51 per diluted share in 2005, compared to $2.22 per basic share and $2.14 per diluted share in 2004, an increase in diluted earnings per share of 111%. Net income for 2005 included a gain of $37.4 million or $2.35 per basic share and $2.30 per diluted share from the settlement of the KCI litigation. The weighted average number of basic common shares outstanding was 15,913,475 and 15,396,540 during 2005 and 2004, respectively. The weighted average number of diluted common shares outstanding was 16,288,975 and 15,974,945 during 2005 and 2004, respectively.

**Liquidity and Capital Resources**

Cash and cash equivalents at December 31, 2006 were $33.2 million, of which $7.2 million is subject to certain restrictions under the senior secured credit agreement described below. This compares to cash and cash equivalents of $77.5 million at December 31, 2005, of which $13.8 million was subject to certain restrictions under a previous senior secured credit agreement, which was fully repaid and cancelled as of March 31, 2006.

Net cash provided by operating activities was $8.2 million in 2006 compared to $106.7 million, including $67.5 million from the KCI settlement, in 2005, a decrease of $101.6 million. Net cash provided by operating activities is comprised of net income (loss), non-cash items (including share based compensation and non-cash purchase accounting items from the Blackstone acquisition, notably in-process research and development) and changes in working capital including changes in restricted cash. Net income (loss) decreased approximately $80.4 million, to a net loss of $7.0 million in 2006 from net income of $73.4 million in 2005. The reduction of net income includes $40.0 million of in-process research and development from the Blackstone transaction and the non-recurrence of $37.4 million in after tax income from the KCI settlement in 2005. Non-cash items of $56.7 million in 2006 increased $36.1 million compared to 2005 principally due to in-process research and development costs of $40.0 million and $7.9 million in share based compensation costs offset by non-cash usage from deferred taxes related to the Blackstone transaction of $12.3 million. Working capital accounts consumed $41.5 million of cash in 2006, including a reduction of other current liabilities related principally to previously accrued contractual payments made in 2006 to former Novamedix shareholders following the KCI settlement. Excluding the effect of KCI settlement payments, working capital consumed $15.3 million of cash in 2006 compared to $12.7 million in 2005. The principal uses of working capital were for increases in accounts receivable and inventory to support sales growth and certain operational initiatives. Inventory growth and resultant lower inventory turns reflect inventory investment to open an international distribution center, the purchase of safety stock of A-V Impulse Impads to support the transfer of production from the UK to Mexico and inventories associated with new internal fixation products.

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Net cash used in investing activities was $354.9 million in 2006, compared to $12.2 million during 2005. On September 22, 2006 we purchased Blackstone for $333.0 million plus various transaction costs. In the first quarter of 2006 we also paid $1.1 million to purchase 52% of our Breg distributor in Germany. Further, we invested $12.6 million in capital expenditures in 2006 compared to $12.2 million in 2005. In 2007 we anticipate the use of cash for capital expenditures will be approximately $17.0 million.

Net cash used in financing activities was $307.8 million in 2006 compared to $55.6 million in 2005. In 2006 we received proceeds of $11.5 million from the issuance of 436,610 shares of our common stock upon the exercise of stock options and shares purchased pursuant to our employee stock purchase plan. In March 2006, we repaid the remaining $14.8 million of outstanding principal from a $110 million senior term loan used to finance the Breg acquisition in December 2003. On September 22, 2006, we entered into a new $330 million senior secured term loan, which along with cash balances were used to finance the acquisition of Blackstone and pay debt issuance costs of $6.0 million and other costs associated with the transaction. In December 2006, we repaid approximately $14.8 million against the principal on this senior secured term loan. During the year we also received a tax benefit of $2.2 million on the exercise of non-qualified stock options.

On September 22, 2006, our wholly-owned US 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. The senior secured credit facility provides for (1) a seven-year amortizing term loan 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, 2006 and as of March 14, 2007, we had no amounts outstanding under the revolving credit facility and $315.2 million outstanding under the term loan facility. Obligations under the senior secured term loan have a floating interest rate of LIBOR plus a margin or prime plus a margin. Based on LIBOR plus a margin of 1.75%. The interest rate as of December 31, 2006 on our senior secured term loan is 7.12%. The Company, certain foreign subsidiaries of the Company, including Colgate Medical Ltd. (Orthofix Holding’s immediate parent) and certain of Orthofix Holding’s direct and indirect subsidiaries, including Orthofix Inc., Breg and Blackstone, have guaranteed the obligations of Orthofix Holdings under the senior secured credit facility. The obligations of Orthofix Holdings under the senior secured bank facility and the guarantors under their guarantees are secured by the pledge of their respective assets located in the United States.

At December 31, 2006, we had outstanding borrowings of $0.1 million and unused available lines of credit of approximately $6.2 million Euros ($8.1 million) under a line of credit established in Italy to finance the working capital of our Italian operations. The terms of the line of credit give us the option to borrow amounts in Italy at rates determined at the time of borrowing.

We continue to search for viable acquisition candidates that would expand our global presence as well as additional products appropriate for current distribution channels. An acquisition of another company or product line by us could result in our incurrence of additional debt and contingent liabilities.

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

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*Contractual Obligations*

The following chart sets forth our contractual obligations as of December 31, 2006:

| **Contractual Obligations** | **Payments Due By Period** | | | | |
|---|---|---|---|---|---|
| **(In thousands)** | **Total** | **Less Than 1 Year** | **1 to 3 Years** | **4 to 5 Years** | **Over 5 Years** |
| Senior secured term loan | $ 315,175 | $ 3,300 | $ 6,600 | $ 6,600 | $ 298,675 |
| Other borrowings | 200 | 39 | 92 | 69 | - |
| Operating Leases | 15,204 | 4,388 | 6,248 | 4,070 | 498 |
| Total | $ 330,579 | $ 7,727 | $ 12,940 | $ 10,739 | $ 299,173 |

On September 22, 2006, a new credit agreement was entered into by Orthofix Holdings, Inc., Orthofix International N.V. and certain of their domestic and foreign direct and indirect subsidiaries concurrent with the closing of the Blackstone acquisition. This credit agreement includes a seven year, $330.0 million term loan on which $315.2 million was outstanding at December 31, 2006.

In addition to scheduled contractual obligations of 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 prepayments, 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, (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, 2006 we did not have any material 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.

## 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 goods, 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 nor do we enter into derivative or other financial investments for trading or speculative purposes. As of December 31, 2006, we had a currency swap transaction in place to minimize future foreign currency exchange risk related to a 42.6 million Euro intercompany note foreign currency exposure. See Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – 2006 Compared to 2005 – “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 London Inter-Bank Offered Rate (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.

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As of December 31, 2006, we had $315.2 million of variable rate term debt represented by borrowings under our senior secured term loan at a floating interest rate of LIBOR or prime rate plus a margin, currently LIBOR plus 1.75%. The effective interest rate as of December 31, 2006 on the senior secured term loan is 7.12%. Based on the balance outstanding under the credit facility as of December 31, 2006 an immediate change of one percentage point in the applicable interest rate on the variable rate debt would cause an increase or decrease in interest expense of approximately $3.2 million on an annual basis.

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 face 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 face transactional currency exposures when foreign subsidiaries (or the Company itself) enter into transactions, denominated in currencies other than their functional currency. For the period from August 1, 2006 to December 15, 2006, we had an uncovered intercompany receivable denominated in Euro of approximately 46.2 million due to a European restructuring. On December 15, 2006 we entered into a currency swap transaction with a bank to offset this exposure. During the period from August 1, 2006 to December 15, 2006 we recorded a foreign currency gain of $2.1 million which resulted from the strengthening of the Euro against the U.S. Dollar during that period.

We also face 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 2006 and 2005 by foreign currency exchange rate fluctuations with the weakening of the U.S. dollar against the local foreign currency in 2006 and 2005. The U.S. dollar equivalent of the related costs denominated in these foreign currencies was unfavorably impacted in 2006 and 2005. 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

As of December 31, 2006, we performed an evaluation under the supervision and with the participation of our Company’s management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our Company’s disclosure controls and procedures. Based on the evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that our Company’s disclosure controls and procedures were effective as of the end of the period covered by this report.

On September 22, 2006 the Company acquired Blackstone Medical, Inc. and, as a result, is integrating the processes, systems and controls relating to the acquired subsidiary into the Company’s existing system of internal control over financial reporting. Except for the processes, systems, and controls relating to the integration of Blackstone Medical, Inc. there have not been any changes in the Company’s internal control over financial reporting during the year ended December 31, 2006 that have materially affected or are reasonably likely to materially affect, its 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 annual report on 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 | 62 | Chairman of the Board of Directors |
| Alan W. Milinazzo | 47 | Chief Executive Officer, President and Director |
| Thomas Hein | 59 | ChieChief Financial Officer |
| Matthew Lyons | 43 | PresPresident, Blackstone Medical, Inc. |
| Bradley R. Mason | 53 | VicePresident and President, Breg, Inc. |
| Raymond C. Kolls | 44 | Senior Vice President, General Counsel and Corporate Secretary |
| Michael M. Finegan | 43 | Vice President Business Development |
| Oliver Burckhardt | 34 | President, Orthofix International |
| Peter J. Hewett | 71 | Deputy Chairman of the Board of Directors |
| Charles W. Federico | 59 | Director |
| Jerry C. Benjamin (2) (3) | 66 | Director |
| Walter von Wartburg (1) | 67 | Director |
| Thomas J. Kester (1) (2) | 60 | Director |
| Kenneth R. Weisshaar (2) (3) | 56 | Director |
| Guy Jordan (1) (3) | 58 | Director |
| Stefan Widensohler (1) (3) | 47 | Director |

(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 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 January 1, 2005 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 in 2005 as Chief Operating Officer and succeeded to the position of CEO 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 SCEMED 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 1980.

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**Thomas Hein, CPA.** Mr. Hein became the Chief Financial Officer of Orthofix International N.V. on July 1, 2002. For the prior three years, Mr. Hein had been the Chief Financial Officer of Orthofix Inc., our wholly- owned U.S. subsidiary. From 1996 to 1999, Mr. Hein was the Chief Financial Officer for Prime Vision Health Inc., a diversified healthcare services company. From 1988 to 1996, Mr. Hein was Vice President of Finance and Chief Financial Officer of MDT Corporation, a sterilization and hospital capital equipment company. Previously, he held financial management positions with Metheus Corporation, Memorex Corporation and Kaiser Aetna.

**Matthew Lyons.** Mr. Lyons became President, Blackstone Medical, Inc. in October 2006 upon the acquisition of Blackstone Medical, Inc. He is also President and Chief Executive Officer of Blackstone which he co-founded in 1996. Mr. Lyons has over twenty years of experience in the medical device industry starting in product development in 1986 for Osteonics Corp, Division of Stryker, and product Development Manager for Exactech Inc., and Vice President of Brimfield Precision, Inc. as a co-owner. Mr. Lyons is named on numerous Patents in orthopedics and is a graduate of Syracuse University where he earned his Bachelor of Science degree in Mechanical Engineering.

**Bradley R. Mason.** Mr. Mason became a Vice President of Orthofix International N.V. in December 2003 upon the acquisition of Breg, Inc. He is also the President of Breg, Inc., which he founded 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 in June 2006 as Vice President of Business Development. 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.

**Oliver Burckhardt.** Mr. Burckhardt joined Orthofix in 2006 as President, Orthofix International. From 1998 to 2006, Mr. Burckhardt was with Aesculap where he was Vice President of Marketing and Sales for the Spine Division in the U.S. Additionally, he has served in a senior global marketing position with Aesculap and assumed several different sales positions with Johnson & Johnson's Ethicon and Mitek Divisions in Europe.

**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

**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. Phoqus, Ltd. and a number of private health care companies.

**Dr. Walter von Wartburg.** 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 MIT and an MBA from Harvard University. He currently also serves on the board of Digene Corporation.

**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 Specialized Health Products International, Inc., Xillix Technologies Corporation and EndoGastric Solutions, Inc.

**Stefan Widensohler.** Mr. Widensohler became a non-executive Director of Orthofix International N.V. in February 2005. Mr. Widensohler has been the President and Chief Executive Officer of KRAUTH medical group, a European medical supply distributor based in Germany, since 1992. Previously, he was General Manager of MEDICALIS, now a GE Company. Mr. Widensohler holds a degree in economics from the Private Academy of Bad Harzburg, Germany. He is Deputy Chairman of the Board of BV-Med, the German Health Industry Manufacturer's Association and is an Active Member of the German Economic Council. He currently also serves on the board of St. Jude Medical, Inc.

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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 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.

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**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. |
| 10.1 | Orthofix Inc. Employee Stock Purchase Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). |
| 10.2 | Orthofix International N.V. Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). |
| 10.3 | Form of Performance Accelerated Stock Option under the Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). |
| 10.4 | Form of Performance Accelerated Stock Option Inducement Agreement (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated here in by reference). |
| 10.5 | Orthofix International N.V. 2004 Long Term Incentive Plan, as amended (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2004 and |

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| | incorporated herein by reference). |
| 10.6 | Form of Nonqualified Stock Option Agreement Under the Orthofix International N.V. 2004 Long Term Incentive Plan (filed as an exhibit to the Company's current report on Form 8-K filed April 17, 2006 and incorporated herein by reference). |
| 10.7 | Form of Nonqualified Stock Option Agreement for Non-Employee Directors under the Orthofix International N.V. 2004 Long Term Incentive Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2004 and incorporated herein by reference). |

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| 10.8* | Orthofix Deferred Compensation Plan. |
| 10.9 | Employment Agreement, dated as of April 15, 2005, between the Company and Charles W. Federico (filed as an exhibit to the Company's current report on Form 8-K filed April 18, 2005 and incorporated herein by reference). |
| 10.10 | Employment Agreement, dated as of July 13, 2006, between the Company and Thomas Hein (filed as an exhibit to the Company's annual report on Form 8-K filed July 18, 2006 and incorporated herein by reference). |
| 10.11 | Employment Agreement, dated as of November 20, 2003, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2003and incorporated herein by reference). |
| 10.12 | Full Recourse Promissory Note between Orthofix International N.V. and Charles W. Federico dated January 10, 2002 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). |
| 10.13 | Full Recourse Promissory Note between Orthofix International N.V. and Gary D. Henley dated January 10, 2002 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). |
| 10.14 | 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). |
| 10.15 | Voting and Subscription Agreement dated as of November 20, 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 January 8, 2004 and incorporated herein by reference). |
| 10.16 | Employee Agreement, as amended, dated December 29, 2005 between Orthofix International N.V. 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). |
| 10.17 | |

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|---|---|
| | Form of Indemnity Agreement (filed as an exhibit to the Company's annual report on Form 10-K filed December 31, 2005 and incorporated herein by reference). |
| 10.18 | Settlement Agreement dated February 23, 2006, between Intavent Orthofix Limited, a wholly-owned 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). |
| 10.19 | Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Alan W. Milinazzo (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference). |
| 10.20 | Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Raymond C. Kolls (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference). |
| 10.21 | Employment Agreement, dated July 13, 2006, between Orthofix Inc. and Michael M. Finegan (filed as an exhibit to the Company's current report on Form 8-K filed July 18, 2006 and incorporated herein by reference). |
| 10.22 | 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 current report on Form 8-K filed September 27, 2006 and incorporated herein by reference). |
| 10.23 | 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 Equityholder's Representative (filed as an exhibit to the Company's current report on Form 8-K filed August 7, 2006 and incorporated herein by reference). |

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| 10.24* | Employment Agreement, dated as of September 22, 2006, between Blackstone Medical, Inc. and Matthew V. Lyons. |
| 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.

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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 16, 2007

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<br>**Alan W. Milinazzo** | Chief Executive Officer,<br>President and Director | March 16, 2007 |
| /s/ THOMAS HEIN<br>**Thomas Hein** | Chief Financial Officer<br>(Principal Accounting Officer) | March 16, 2007 |
| /s/ JAMES F. GERO<br>**James F. Gero** | Chairman of the Board of Directors | March 16, 2007 |
| /s/ PETER J. HEWETT<br>**Peter J. Hewett** | Deputy Chairman of the Board of Directors | March 16, 2007 |
| /s/ CHARLES W. FEDERICO<br>**Charles w. Federico** | Director | March 16, 2007 |
| /s/ JERRY C. BENJAMIN<br>**Jerry C. Benjamin** | Director | March 16, 2007 |
| /s/ WALTER VON WARTBURG<br>**Walter von Wartburg** | Director | March 16, 2007 |
| /s/ THOMAS J. KESTER<br>**Thomas J. Kester** | Director | March 16, 2007 |
| /s/ KENNETH R. WEISSHAAR<br>**Kenneth R. Weisshaar** | Director | March 16, 2007 |
| /s/ GUY JORDAN<br>**Guy Jordan** | Director | March 16, 2007 |
| /s/ STEFAN WIDENSOHLER<br>**Stefan Widensohler** | Director | March 16, 2007 |

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Index to Consolidated Financial Statements



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

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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

**Thomas Hein**
Chief Financial Officer

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**Management's Report on Internal Control over Financial Reporting**

Our management is also responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

Our management, including our principal executive officer and principal financial officer, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006. In conducting its assessment, our management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework. We completed the acquisition of Blackstone Medical, Inc. ("Blackstone") on September 22, 2006 as more fully described in Note 2 to the consolidated financial statements. As part of our ongoing integration activities, we are in the process of incorporating the operations of Blackstone into our controls and procedures and we expect to complete the process by no later than September 22, 2007. Management has excluded from its evaluation of effectiveness of its internal control over financial reporting, as of December 31, 2006, certain elements of the internal control over financial reporting of Blackstone. We plan to include these businesses into our assessment of the effectiveness of our internal controls within one year of the acquisition.

Based on this assessment, our management concluded that the Company's internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2006. Reasonable assurance includes the understanding that there is a remote likelihood that material misstatements will not be prevented or detected on a timely basis.

Our independent registered public accounting firm has issued an attestation report on management's assessment of our internal control over financial reporting, which appears on the following page of this Annual Report on Form 10-K.

**James F. Gero**
Chairman of the Board of Directors

**Alan W. Milinazzo**
President, Chief Executive Officer and Director

**Thomas Hein**
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, 2006 and 2005, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. 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 the 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 financial position of Orthofix International N.V. at December 31, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 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, presents fairly in all material respects the information set forth therein.

As discussed in Note 1, the Company adopted Financial Accounting Standards Board Statement No. 123(R), Share-Based Payments, as of January 1, 2006 using the modified prospective application method.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Orthofix International N.V.'s internal control over financial reporting as of December 31, 2006, 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 14, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Charlotte, North Carolina
March 14, 2007

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**Report of Independent Registered Public Accounting Firm on Management's Assessment and the Effectiveness of Internal Control Over Financial Reporting**

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Orthofix International N.V. maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Blackstone Medical, Inc., which is included in the 2006 consolidated financial statements of Orthofix International N.V. and constituted 46% of total assets as of December 31, 2006 and 8% of revenues for the year then ended. Our audit of internal control over financial reporting of Orthofix International N.V. also did not include an evaluation of the internal control over financial reporting of Blackstone Medical, Inc.

In our opinion, management's assessment that Orthofix International N.V. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Orthofix International N.V. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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 as of December 31, 2006 and 2005, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 of Orthofix International N.V. and our report dated March 14, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Charlotte, North Carolina
March 14, 2007

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**Consolidated Balance Sheets as of December 31, 2006 and 2005**

| (U.S. Dollars, in thousands except share and per share data) | | | 2006 | 2005 |
|---|---|---|---|---|
| **Assets** | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | | | $ 25,881 | $ 63,786 |
| Restricted cash | | | 7,300 | 13,762 |
| Trade accounts receivable, less allowance for doubtful accounts of $6,265and $4,155 at December 31, 2006 and 2005, respectively | | | 104,662 | 80,745 |
| Inventories | | | 70,395 | 32,853 |
| Deferred income | | | 6,971 | 4,511 |
| Prepaid expenses | | | 5,641 | 4,165 |
| Other current assets | | | 13,118 | 7,453 |
| Total current assets | | | 233,968 | 207,275 |
| Securities and other investments | | | 4,082 | 4,082 |
| Property, plant and equipment, net | | | 25,311 | 18,987 |
| Patents and other intangible assets, net | | | 261,159 | 65,585 |
| Goodwill, net | | | 313,070 | 174,738 |
| Other long-term assets | | | 24,695 | 3,194 |
| Total assets | | | $ 862,285 | $ 473,861 |
| **Liabilities and shareholders' equity** | | | | |
| Current liabilities: | | | | |
| Bank borrowings | | | $ 78 | $ 79 |
| Current portion of long-term debt | | | 3,334 | 15,187 |
| Trade accounts payable | | | 23,577 | 9,891 |
| Accounts payable to related parties | | | 2,474 | 1,711 |
| Other current liabilities | | | 31,577 | 51,208 |
| Total current liabilities | | | 61,040 | 78,076 |
| Long-term debt | | | 312,055 | 21 |
| Deferred income taxes | | | 95,019 | 25,652 |
| Other long-term liabilities | | | 1,536 | 1,227 |
| Total liabilities | | | 469,650 | 104,976 |
| | | | | |
| Commitments and contingencies (Notes 12 and 16) | | | | |
| Shareholders' equity | | | | |
| Common shares $0.10 par value | | | | |
| Authorized: | 50,000,000 | (2005:50,000,000) | | |
| Issued: | 16,445,859 | (2005:16,009,249) | 1,645 | 1,602 |
| Outstanding: | 16,445,859 | (2005:16,009,249) | | |
| Additional paid-in capital | | | 128,297 | 106,746 |
| | | | 129,942 | 108,348 |
| Retained earnings | | | 248,433 | 255,475 |
| Accumulated other comprehensive income | | | 14,260 | 5,062 |
| Total shareholders' equity | | | 392,635 | 368,885 |
| | | | | |
| Total liabilities and shareholders' equity | | | $ 862,285 | $ 473,861 |

*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, 2006, 2005 and 2004**

| (U.S. Dollars, in thousands, except share and per share data) | 2006 | 2005 | 2004 |
|---|---|---|---|
| Net sales | $ 365,359 | $ 313,304 | $ 286,638 |
| Cost of sales | 93,625 | 83,788 | 79,177 |
| Gross profit | 271,734 | 229,516 | 207,461 |
| Operating expenses | | | |
| Sales and marketing | 145,707 | 115,422 | 102,453 |
| General and administrative | 53,309 | 36,050 | 30,621 |
| Research and development, including $40 million of purchased in-process research and development | 54,992 | 11,766 | 11,471 |
| Amortization of intangible assets | 8,873 | 6,572 | 6,348 |
| | 262,881 | 169,810 | 150,893 |
| Total operating income | 8,853 | 59,706 | 56,568 |
| Other income (expense) | | | |
| Interest income | 2,236 | 905 | 341 |
| Interest expense | (8,361) | (6,373) | (6,307) |
| Other, net | 2,524 | 1,188 | 1,325 |
| KCI settlement, net of litigation costs | 1,093 | 40,089 | (1,568) |
| Other income (expense), net | (2,508) | 35,809 | (6,209) |
| Income before minority interests and income taxes | 6,345 | 95,515 | 50,359 |
| Minority interests | (26) | - | - |
| Income before income taxes | 6,319 | 95,515 | 50,359 |
| Income tax expense | (13,361) | (22,113) | (16,210) |
| Net income (loss) | $ (7,042) | $ 73,402 | $ 34,149 |
| Net income (loss) per common share - basic | $ (0.44) | $ 4.61 | $ 2.22 |
| Net income (loss) per common share - diluted | $ (0.44) | $ 4.51 | $ 2.14 |
| Weighted average number of common shares - basic | 16,165,540 | 15,913,475 | 15,396,540 |
| Weighted average number of common shares - diluted | 16,165,540 | 16,288,975 | 15,974,945 |

*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, 2006, 2005 and 2004**

| (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, 2003 | 14,980,010 | $ 1,498 | $ 81,960 | $ 147,924 | $ 9,394 | $ 240,776 |
| Net income | – | – | – | 34,149 | – | 34,149 |
| Other comprehensive income: | | | | | | |
| Unrealized gain on derivative instrument (net of taxes of $40) | – | – | – | – | 92 | 92 |
| Translation adjustment | – | – | – | – | 5,653 | 5,653 |
| Total comprehensive income | | | | | | 39,894 |
| Tax benefit on exercise of stock options | – | – | 3,667 | – | – | 3,667 |
| Common shares issued | 731,933 | 74 | 12,761 | – | – | 12,835 |
| At December 31, 2004 | 15,711,943 | 1,572 | 98,388 | 182,073 | 15,139 | 297,172 |
| Net income | – | – | – | 73,402 | – | 73,402 |
| Other comprehensive income: | | | | | | |
| Reclassification adjustment for gain on termination of derivative instrument (net of taxes of $40) | – | – | – | – | (92) | (92) |
| Translation adjustment | – | – | – | – | (9,985) | (9,985) |
| Total comprehensive income | | | | | | 63,325 |
| Tax benefit on exercise of stock options | – | – | 1,329 | – | – | 1,329 |
| Common shares issued | 297,306 | 30 | 7,029 | – | – | 7,059 |
| 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 |

*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, 2006, 2005 and 2004**

| (U.S. Dollars, in thousands) | 2006 | 2005 | 2004 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income (loss) | $ (7,042) | $ 73,402 | $ 34,149 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Depreciation and amortization | 16,457 | 14,867 | 14,396 |
| Amortization of debt costs | 501 | 2,666 | 684 |
| Minority interests | 26 | - | - |
| Deferred royalty income | - | (2,443) | - |
| Provision for doubtful accounts | 5,475 | 4,753 | 4,266 |
| Share based compensation | 7,912 | - | - |
| Loss (Gain) on sale or disposal of fixed assets | 518 | 896 | (692) |
| Deferred taxes | (12,363) | (1,533) | (3,874) |
| In process research & development | 40,000 | - | - |
| Tax benefit on non-qualified stock options | - | 1,329 | 3,667 |
| Other | (1,858) | (7) | (107) |
| Changes in operating assets and liabilities: | | | |
| Restricted cash | 6,582 | 540 | (14,302) |
| Accounts receivable | (10,308) | (13,293) | (6,658) |
| Inventories | (12,867) | (1,498) | (882) |
| Other current assets | (4,521) | (2,119) | 1,427 |
| Trade accounts payable | 6,448 | 2,834 | (2,931) |
| Other current liabilities | (26,789) | 26,279 | (1,658) |
| Net cash provided by operating activities | 8,171 | 106,673 | 27,485 |
| Cash flows from investing activities: | | | |
| Payments made in connection with acquisitions and investments, net of cash acquired | (342,290) | - | (2,556) |
| Capital expenditures for tangible and intangible assets | (12,613) | (12,248) | (12,243) |
| Proceeds from sale of assets and marketable securities | - | - | 1,635 |
| Proceeds from sale of joint venture | - | - | 1,300 |
| Proceeds from settlement of distributor agreement | - | - | 440 |
| Net cash used in investing activities | (354,903) | (12,248) | (11,424) |
| Cash flows from financing activities: | | | |
| Net proceeds from issue of common shares | 11,507 | 6,471 | 12,247 |
| Payment of debt issuance costs | (5,884) | - | (821) |
| Tax benefit on non-qualified stock options | 2,175 | - | - |
| Proceeds from loans and borrowings | 330,000 | 193 | - |
| Repayment of loans and borrowings | (29,974) | (62,278) | (33,534) |
| Net cash provided (used in) by financing activities | 307,824 | (55,614) | (22,108) |
| Effect of exchange rates changes on cash | 1,003 | (969) | 635 |
| Net increase (decrease) in cash and cash equivalents | (37,905) | 37,842 | (5,412) |
| Cash and cash equivalents at the beginning of the year | 63,786 | 25,944 | 31,356 |
| Cash and cash equivalents at the end of the year | $ 25,881 | $ 63,786 | $ 25,944 |
| **Supplemental disclosure of cash flow information** | | | |
| Cash paid during the year for: | | | |
| Interest | $ 7,386 | $ 3,753 | $ 5,237 |
| Income taxes | $ 31,773 | $ 26,290 | $ 12,854 |

*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 consolidation. The equity method of accounting is used when the Company has significant influence over operating decisions but cannot exercise control. Under the equity method, original investments are recorded at cost and adjusted by the Company's share of undistributed earnings or losses of these companies. 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 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) and were $2.8 million, ($1.0) million and $0.9 million for the years December 31, 2006, 2005 and 2004, 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 goods, field inventory and consignment inventory includes the cost of materials, labor and production. Field inventory represents immediately saleable finished goods 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 income and

expenditures. During 2006, the Company made use of an interest rate swap agreement and foreign currency forward contracts to manage these exposures of fluctuations in interest rates. 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 and any impairment charges as computed in accordance with the Company's policy. Depreciation is computed on a straight-line basis over the useful lives of the assets, except for land, which is not depreciated. Depreciation of leasehold improvements is computed over the shorter of the lease term or the useful life of the asset. The useful lives are as follows:

| | Years |
|---|---|
| Buildings | 25 to 33 |
| Plant and equipment | 2 to 10 |
| Furniture and fixtures | 4 to 8 |

Expenditures for maintenance and repairs and minor renewals and improvements, which do not extend the life of the respective asset, 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, trademarks, licenses, customer relationships and distribution networks and they are generally amortized using the straight-line method over estimated useful lives of 5 to 25 years for all acquisitions completed prior to June 30, 2001. For acquisitions completed subsequent to June 30, 2001, identifiable intangible assets 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. Intangible assets deemed to have indefinite lives and goodwill are not subject to amortization in accordance with Statement of Financial Accounting Standards (SFAS) No. 142.

The Company reviews long-lived and indefinite lived intangible assets at least annually or when events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. For long-lived amortizable intangible assets, the Company recognizes an impairment loss when the sum of undiscounted expected future cash flows over the assets remaining estimated useful lives are less than the carrying value of such assets. For long-lived intangible assets not subject to amortization, the Company recognizes an impairment loss when the sum of discounted expect future cash flows are less than the carrying value of such assets. The measurement for such impairment loss is then based on the fair value of the related asset or group of assets.

**(g) Revenue recognition**

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 and accepted by the patient. For domestic spinal implant and biologic 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. Some 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.

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

**(h) Research and development costs**

Expenditures for research and development are expensed as incurred. In accordance with EITF 96-7 "Accounting for Deferred Taxes on In-Process Research and Development Activities Acquired in a Purchase Business Combination", the Company writes off acquired in-process research and development to research and development expense on the day of acquisition.

**(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.

**(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. Common equivalent shares represent the diluted effect of the assumed exercise of outstanding share options (see Note 19 to the Consolidated Financial Statements) and the only differences between basic and diluted shares result solely from the assumed exercise of certain outstanding share options and warrants.

**(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") is restricted. The senior secured bank facility, described further in Note 10, restricts only the Parent's access to the cash held by Colgate Medical Limited and its subsidiaries. All other subsidiaries of the Orthofix Group have access to this cash for operational 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.

**(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 intangibles impairment. Actual results could differ from these estimates.

**(o) Reclassifications**

Certain prior year amounts have been reclassified to conform to the 2006 presentation. The reclassifications have no effect on previously reported net income or shareholders' equity.

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

**(p) Stock based compensation**

Prior to January 1, 2006, the Company accounted for stock based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations, as permitted by SFAS No. 123, Accounting for Stock-Based Compensation. Stock-based employee compensation expense was recognized relating to options granted at exercise prices lower than the fair market value of the underlying stock on the date of the grant.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123(R), Share-Based Payment, using the modified prospective transition method. Under this transition method, compensation cost recognized in 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, which is consistent with our valuation techniques previously utilized for options in footnote disclosures required under SFAS No. 123. Such value is recognized as expense over the service period net of estimated forfeitures. Results for prior periods have not been restated. 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 our common stock and an employee’s average length of service. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award. For the year ended December 31, 2006, options were valued at risk-free interest rates between 4.35% and 5.07%, expected volatility of 33.4%, expected term of 4.3 years 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 a result of adopting SFAS No. 123(R) on January 1, 2006 the Company's income before income taxes and net income for the year ended December 31, 2006, are $7.3 million and $5.2 million lower, respectively, than if it had continued to account for share-based compensation under APB 25. Basic and diluted earnings per share for the year ended December 31, 2006 would have been $0.32 and $0.32 higher, respectively, if the Company had not adopted SFAS No. 123(R). As of December 31, 2006, the compensation expense relating to options already granted and expected to be recognized is $14.2 million. This expense is expected to be recognized over a weighted average period of 1.47 years.

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

The following table shows the detail of stock-based compensation by line item in the Consolidated Statements of Operations for the year ended, December 31, 2006 (in thousands):

| **(In thousands)** | **Year Ended December 31, 2006** |
|---|---|
| Cost of sales | $ 238 |
| Sales and marketing (2) | 1,411 |
| General and administrative | 5,243 (1) |
| Research and development | 432 |
| Total | $ 7,324 |

(1) Amount includes $656 of stock-based compensation from the accelerated vesting of options associated with the transition of senior management in the first quarter of 2006.
(2) There are no performance requirements and there was no consideration received for stock-based compensation awarded to sales and marketing employees.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Statement of Cash Flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits resulting from the tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. The $2.2 million excess tax benefit classified as a financing cash inflow, for the year ended December 31, 2006, would have been classified as an operating cash inflow had the Company not adopted SFAS No. 123(R).

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

The following table illustrates the effect on net income and earnings per share if the fair value based method had been applied to all stock-based awards granted for all periods presented.

| | Year ended December 31, | | |
|---|---|---|---|
| **(In thousands except per share data)** | **2006** | **2005** | **2004** |
| Net income | | | |
| As reported | $ (7,042) | $ 73,402 | $ 34,149 |
| Add: Stock-based employee compensation expense included in reported net income, net related tax effects | 5,191 | 347 | 346 |
| Less: Total stock-based employee compensation expense determined under fair value method for all awards, net of tax | (5,191) | (3,348) | (1,944) |
| Pro forma | $ (7,042) | $ 70,401 | $ 32,551 |
| Net income per common share – basic | | | |
| As reported | $ (0.44) | $ 4.61 | $ 2.22 |
| Pro forma | $ (0.44) | $ 4.42 | $ 2.11 |
| Net income per common share – diluted | | | |
| As reported | $ (0.44) | $ 4.51 | $ 2.14 |
| Pro forma | $ (0.44) | $ 4.32 | $ 2.04 |

**(q) Recently issued Accounting Standards**

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. This Statement defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosure related to the use of fair value measures in financial statements. The Statement is to be effective for the Company's financial statements issued in 2008; however, earlier application is encouraged. The Company is currently evaluating the timing of adoption and the impact that adoption might have on its financial position or results of operations.

In July 2006, the FASB issued 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 tax positions. This Interpretation requires that the Company recognize in the consolidated financial statements the impact of a tax position that is more likely than not to be sustained upon examination based on the technical merits of the position. The provisions of FIN 48 will be effective as of the beginning of the Company's 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on the consolidated financial statements.

In June 2006, the FASB ratified Emerging Issues Task Force ("EITF") Issue No. 06-3, How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation). This standard allows companies to present in their statements of operations any taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer, such as sales, use, value-added, and some excise taxes, on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company is currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

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

In February 2006, the FASB issued SFAS No. 155, Accounting for Certain Hybrid Instruments, which is an amendment to SFAS No. 133 and SFAS No. 140. SFAS No. 155 allows financial instruments which have embedded derivatives to be accounted for as a whole (eliminating the need to bifurcate the derivative from its host) if the holder elects to account for the instrument as a whole instrument on a fair value basis. This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The Company does not believe the adoption of this statement will have a material impact on the financial statements.

**(r) Fair value of financial instruments**

The carrying amounts reflected in the consolidated balance sheet for cash and cash equivalents, restricted cash, accounts receivable, short-term bank debt 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 approximates fair value.

**(s) Advertising costs**

The Company expenses all advertising costs as incurred. Advertising expense for the years ended December 31, 2006, 2005 and 2004 was $1.0 million, $0.5 million and $0.5 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 Statement of Financial Accounting Standards ("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.

The Company's foreign currency hedges are forward contracts used to manage its foreign currency exposure related to a portion of the Company's accounts receivable that are denominated in Euros. These forward contracts have been

accounted for as a fair value hedge in accordance with SFAS No. 133. In addition, 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.

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

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

**(u) Other comprehensive income**

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 and changes in other comprehensive income (loss) are as follows:

| (In thousands) | Foreign Currency Translation Adjustments | Fair Value of Derivatives | Accumulated Other Comprehensive Income/(Loss) |
|---|---|---|---|
| Balance at December 31, 2003 | $ 9,394 | $ - | $ 9,394 |
| Unrealized gain on derivative instrument, net of tax of $40 | - | 92 | 92 |
| Foreign currency translation adjustment | 5,653 | - | 5,653 |
| Balance at December 31, 2004 | 15,047 | 92 | 15,139 |
| Reclassification adjustment for gain on derivative instrument, net of tax of $40 | - | (92) | (92) |
| Foreign currency translation adjustment | (9,985) | - | (9,985) |
| Balance at December 31, 2005 | 5,062 | - | 5,062 |
| Unrealized gain (loss) on derivative instrument, net of tax of $30 | - | (55) | (55) |
| Foreign currency translation adjustment | 9,253 | - | 9,253 |
| Balance at December 31, 2006 | $ 14,315 | $ (55) | $ 14,260 |

**2 Acquisitions**

The following acquisitions were recorded using the purchase method of accounting:

*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 and is subject to certain closing adjustments. 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 privately held company based in Springfield, Massachusetts, specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone's product lines include spinal fixating devices including hooks, rods, screws, plates, various spacers and cages and related biologics 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 Orthofix’s existing operations.

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

Factors that contributed to the valuation of Blackstone included the recognition that Blackstone had established itself as what the Company believes to be one of the largest private spine companies with a broad portfolio of spinal product offerings. Further, Blackstone has a strong brand name and product identity in the spinal industry. Blackstone has a history of sales and earnings growth that compares favorably to the fast growing spinal market that its product lines serve. Orthofix valued Blackstone after reviewing a range of valuation methodologies provided by its financial advisors for the transaction, including comparable publicly-traded companies, comparable precedent transactions, discounted cash flow analysis and comparison to Orthofix's trading multiples.

The acquisition has been accounted for using the purchase method in accordance with SFAS No. 141, Business Combinations. The purchase price has been preliminarily allocated to the assets acquired and liabilities assumed based on their estimated fair market value at the date of acquisition.

A preliminary allocation of the purchase price reflects the following:

| | |
|---|---|
| Current assets, other than cash | $ 40,101 |
| Fixed assets acquired | 2,872 |
| Intangible assets not subject to amortization – registered trademarks | 77,000 |
| Intangible assets subject to amortization (12-16 year weighted average useful life): | |
| Distribution Networks (12 – 16 year weighted average useful life) | 55,000 |
| Patents (13 year weighted average useful life) | 70,000 |
| | $ 244,973 |
| Goodwill (indefinite lived intangible asset) | 132,784 |
| In-process research and development | 40,000 |
| Deferred tax asset | 14,985 |
| Total assets acquired | $ 432,742 |
| | |
| Current liabilities | $ (13,037) |
| Deferred tax liability | (78,442) |
| Total liabilities assumed | (91,479) |
| Net assets acquired | $ 341,263 |

The results of Blackstone’s operations have been included in the Company’s consolidated results of operations from the date of acquisition.

The preliminary purchase price has been allocated to assets acquired, purchased in-process research and development, and liabilities assumed based on their estimated fair value at the acquisition date. The amount of the purchase price allocated to purchased in-process research and development was written off at the date of acquisition and resulted in a charge of $40.0 million. This charge is included in the research and development expense line item on the Consolidated Statements of Operations and was principally comprised of the value of the Dynamic Stabilization and Cervical Disk which together accounted for 93% of the fair value. The fair value of the in-process research and development was estimated using the discounted earnings method. The amount written off as purchased in-process research and development is not deductible for income tax purposes in the United States. In addition, other items that may affect the final purchase price allocation include finalization of acquisition costs, revisions to tangible and

intangible assets based on final assessments and other information that provides a better estimate of the fair value of the assets acquired and the liabilities assumed.

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

There are no residual values for any of the intangible assets subject to amortization acquired during the Blackstone acquisition. Definite lived intangible assets acquired in the Blackstone acquisition consist of:

| (In thousands) | Fair value at Acquisition | Remaining Useful Life |
|---|---|---|
| Distribution network | $ 55,000 | 12 to 16 Years |
| Patents | 70,000 | 13 Years |
| Total definite lived intangible assets | $ 125,000 | |

The Company has determined that trademarks acquired during the Blackstone acquisition, valued at $77.0 million, are indefinite lived intangible assets. The Company considered the criteria prescribed by paragraphs 11 (a), (c), (e) and (f) of SFAS 142 in determining that registered trademarks acquired during the Blackstone acquisition have an indefinite life. The Company is not aware of any legal, regulatory, or contractual provisions that limit the useful lives of these registered trademarks. The Company does not believe the effects of obsolescence, demand, competition, or other economic factors will cause the useful lives of these registered trademarks to be limited. The Company concluded that no legal, regulatory, contractual, competitive, economic, or other factors limit the useful life of the registered trademarks to the Company, and therefore the useful lives of the registered trademarks are considered to be indefinite.

The summary unaudited pro forma condensed results of operations and earnings per share, for the years ended, December 31, 2006 and 2005, assuming consummation of the Blackstone acquisition as of January 1, 2005, are as follows:

| (In thousands) | Year Ended December 31, 2006 | | Year Ended December 31, 2005 | |
|---|---|---|---|---|
| | As Reported | Pro Forma* | As Reported | Pro Forma* |
| Net sales | $ 365,359 | $ 427,489 | $ 313,304 | $ 373,005 |
| Net income (loss) | (7,042) | 16,494 | 73,402 | 52,255 |
| Per share data: | | | | |
| Basic | $ (0.44) | $ 1.02 | $ 4.61 | $ 3.28 |
| Diluted | $ (0.44) | $ 1.02 | $ 4.51 | $ 3.21 |

* 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*

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

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 statement 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.

*Puerto Rico Distributor Acquisition*

In the first quarter 2004, the Company purchased a distributor in Puerto Rico for $1.4 million, which consisted of $1.1 million in cash and $0.3 million of assumed liabilities. The final purchase price included approximately $0.9 million of working capital and $0.5 million of goodwill. The operations of the acquired distributor are included in the accompanying consolidated statement of operations from the date of acquisition.

**3 Inventories**

| (In thousands) | December 31, 2006 | 2005 |
|---|---|---|
| Raw materials | $ 8,384 | $ 7,242 |
| Work-in-process | 6,665 | 3,344 |
| Finished goods | 34,901 | 11,538 |
| Field inventory | 7,485 | 7,404 |
| Consignment inventory | 20,173 | 6,659 |
| | 77,608 | 36,187 |
| Less reserve for obsolescence | (7,213) | (3,334) |
| | $ 70,395 | $ 32,853 |

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

**4 Securities and other investments**

The Company had total investments held at cost of $4.1 million as of December 31, 2006 and 2005 comprised of an investment of $1.5 million in Innovative Spinal Technologies (IST), a start-up company focused on commercializing spinal products, and $2.6 million in OPED AG, a German-based bracing company. The Company's ownership percentage in IST is 2.87%. The Company has assessed these cost investments noting no impairment in carrying value. The Company also has an investment in OrthoRx. The investment was reduced to zero in 2004. As of December 31, 2006, the Company's ownership percentage in OrthoRx has been reduced to 5.5%.

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

**5 Property, plant and equipment**

| (In thousands) | December 31, 2006 | 2005 |
|---|---|---|
| **Cost** | | |
| Buildings | $ 2,852 | $ 2,131 |
| Plant and equipment | 59,316 | 47,498 |
| Furniture and fixtures | 8,791 | 6,896 |
| | 70,959 | 56,525 |
| Accumulated depreciation | (45,648) | (37,538) |
| | $ 25,311 | $ 18,987 |

Depreciation expense for the years ended December 31, 2006, 2005 and 2004 was $7.6 million, $8.3 million and $7.8 million, respectively.

**6 Patents and other intangible assets**

| (In thousands) | December 31, 2006 | 2005 |
|---|---|---|
| **Cost** | | |
| Patents and other | $ 99,731 | $ 26,501 |
| Trademarks – definite lived (subject to amortization) | 860 | 836 |
| Trademarks – indefinite lived (not subject to amortization) | 100,900 | 23,900 |
| Distribution networks | 98,586 | 42,343 |
| | 300,077 | 93,580 |
| **Accumulated amortization** | | |
| Patents and other | (20,727) | (17,172) |
| Trademarks – definite lived (subject to amortization) | (460) | (387) |
| Distribution networks | (17,731) | (10,436) |
| | $ 261,159 | $ 65,585 |

Amortization expense for intangible assets is estimated to be approximately $19.1 million, $20.7 million, $19.9 million, $19.6 million and $17.9 million for the periods ending December 31, 2007, 2008, 2009, 2010 and 2011, respectively.

The Company has performed the impairment test of indefinite-lived assets in accordance with FAS 142 and has determined that no impairment exists.

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

**7 Goodwill**

Under SFAS No. 142, intangible goodwill is subject to annual impairment testing using the guidance and criteria described in the standard. This testing requires the comparison of carrying values to fair values, and when appropriate, the carrying value of impaired assets is reduced to fair value. The Company has performed the impairment test of goodwill and has determined that no impairment exists. For a discussion of acquisitions since January 1, 2004 and the associated goodwill, see Note 2 to the Consolidated Financial Statements.

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

| (In thousands) | Domestic | Blackstone | Breg | International | Total |
|---|---|---|---|---|---|
| At December 31, 2004 | $ 31,793 | $ - | $ 101,322 | $ 45,774 | $ 178,889 |
| Foreign Currency | - | - | - | (4,151) | (4,151) |
| At December 31, 2005 | 31,793 | - | 101,322 | 41,623 | 174,738 |
| Acquisitions | - | 132,784 | - | 1,086 | 133,870, |
| Foreign Currency | - | - | - | 4,462 | 4,462 |
| At December 31, 2006 | $ 31,793 | $ 132,784 | $ 101,322 | $ 47,171 | $ 313,070 |

**8 Bank borrowings**

| (In thousands) | December 31, 2006 | 2005 |
|---|---|---|
| Borrowings under line of credit | $ 78 | $ 79 |

The weighted average interest rate on borrowings under lines of credit as of December 31, 2006 and 2005 was 3.00% for both years.

Borrowings under lines of credit consist of borrowings in Euros. The Company had unused available lines of credit of 6.2 million Euros ($8.1 million) and 6.8 million Euros ($8.0 million) at December 31, 2006 and 2005, respectively, in its Italian line of credit, which gives 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.

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

9 **Other current liabilities**

| (In thousands) | December 31, 2006 | 2005 |
|---|---|---|
| Accrued expenses | $ 4,289 | $ 7,206 |
| Salaries and related taxes payable | 15,201 | 11,032 |
| Income taxes payable | 3,988 | 2,044 |
| Other payables | 8,099 | 4,724 |
| KCI settlement proceeds due to third parties | - | 26,202 |
| | $ 31,577 | $ 51,208 |

**10 Long-term debt**

| (In thousands) | December 31, 2006 | 2005 |
|---|---|---|
| Long-term obligations | $ 315,175 | $ 14,750 |
| Other loans | 214 | 458 |
| | 315,389 | 15,208 |
| Less current portion | (3,334) | (15,187) |
| | $ 312,055 | $ 21 |

On September 22, 2006 our wholly-owned US 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. 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, 2006 we had no amounts outstanding under the revolving credit facility and $315.2 million outstanding under the term loan facility. Obligations under the senior secured credit facility have a floating interest rate of LIBOR plus a margin or prime rate plus a margin. Currently, the term loan is a LIBOR loan, and the margin is 1.75%, which margin is adjusted quarterly based upon the leverage ratio of the Company and its subsidiaries. The effective interest rate as of December 31, 2006 on the senior secured debt is 7.12%.

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

In conjunction with obtaining the senior secured bank facility and the amendment thereto, the Company incurred debt issuance costs of $6.0 million. As of December 31, 2006, $5.8 million of capitalized debt costs is included in other long-term assets.

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

Certain subsidiaries of the Company have effective 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 Inc. and its subsidiaries are restricted for distributions to the parent company. All other subsidiaries of the Orthofix Group have access to these net assets for operational purposes. The amount of restricted net assets of Orthofix Holdings Inc. and its subsidiaries as of December 31, 2006 is $247.2 million.

Weighted average interest rates on current maturities of long-term obligations as of December 31, 2006 and 2005 were 7.12% and 6.12%, respectively.

The aggregate maturities of long-term debt after December 31, 2006 are as follows: 2007 - $3.3 million, 2008 - $3.3 million, 2009 - $3.4 million, 2010 - $3.4, 2011 - $3.3 million, thereafter - $298.7 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, 2006 is $63.0 million. Under the agreement, the Company pays Euro and receives U.S. dollars based on scheduled cash flows in the agreement. During 2006, the Company recognized the unrealized loss on the change in fair value of this swap arrangement of $0.1 million within other comprehensive income.

In 2005 and 2006 the Company utilized foreign currency forward contracts to manage its foreign currency exposure related to a portion of the Company's accounts receivable that are denominated in Euros. The strategy of the foreign currency contracts is to neutralize the foreign currency impact on earnings when converting 5.0 million Euros of accounts receivable into U.S. dollars. The conversion of the underlying exposure and the forward contracts offset and had no net impact on earnings in 2006. The Company paid cash of $0.6 million to settle forward contracts for the year and received cash of $0.3 million from the settlement of the foreign currency exposures in 2005. All foreign currency forward contracts entered into in the year ended December 31, 2006 , have been accounted for as fair value hedges in accordance with SFAS No. 133 and the related gains (losses) were recorded in other income and the related tax amounts in taxation.

In 2004, the Company utilized an interest rate swap to manage its interest rate exposure related to a portion of the Company senior secured term loan. The derivative instrument, a three-year fully amortizable agreement with a notional amount of $50.0 million, was scheduled to expire on June 27, 2007. The instrument was designated as a cash flow hedge. The Company terminated the agreement on December 22, 2005 when a portion became ineffective. This termination resulted in a one-time gain of $0.4 million in 2005 recorded as a reduction of interest expense.

**12 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, 2006, 2005 and 2004 was approximately $4.2 million, $3.7 million and $3.5 million, respectively. Future minimum lease payments under operating leases as of December 31, 2006 are as follows:

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

**(In thousands)**

| | | |
|---|---|---|
| 2007 | $ | 4,388 |
| 2008 | | 3,393 |
| 2009 | | 2,855 |
| 2010 | | 2,290 |
| 2011 | | 1,780 |
| Thereafter | | 498 |
| Total | $ | 15,204 |

**13 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. Concurrent with the acquisition of Blackstone, the Company redefined its business segments and market sectors. All prior period information presented has been restated to conform to the new segments and market sectors. The Company is comprised of the following segments:

*Orthofix Domestic*
Orthofix Domestic ("Domestic") consists of operations in the United States of Orthofix Inc. which 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 biologic products. Blackstone's operating loss includes amortization of acquired intangible assets and inventory which has been stepped-up in value for the Blackstone acquisition.

*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.

*Orthofix International*
Orthofix 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 and Orthofix Holdings, Inc., the U.S. holding company's, operating expenses and identifiable assets.

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

The tables below present information by reportable segment:

| | External Sales | | | Intersegment Sales | | |
|---|---|---|---|---|---|---|
| **(In thousands)** | **2006** | **2005** | **2004** | **2006** | **2005** | **2004** |
| Domestic | $ 152,560 | $ 135,084 | $ 118,074 | $ 3,511 | $ 1,931 | $ 1,357 |
| Blackstone | 28,134 | - | - | 699 | - | - |
| Breg | 76,219 | 72,022 | 68,294 | 1,651 | 489 | 422 |
| International | 108,446 | 106,198 | 100,270 | 50,521 | 55,271 | 54,464 |
| Total | $ 365,359 | $ 313,304 | $ 286,638 | $ 56,382 | $ 57,691 | $ 56,243 |

**Operating Income (Expense)**

| **(In thousands)** | **2006** | **2005** | **2004** |
|---|---|---|---|
| Domestic | $ 36,560 | $ 34,513 | $ 28,841 |
| Blackstone | (39,268)* | - | - |
| Breg | 6,218 | 8,082 | 11,498 |
| International | 17,581 | 23,932 | 20,555 |
| Group Activities | (11,262) | (6,343) | (4,779) |
| Eliminations | (976) | (478) | 453 |
| Total | $ 8,853 | $ 59,706 | $ 56,568 |

* Includes $40.0 million of in-process research and development related to the acquisition of Blackstone.

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

**Identifiable Assets**

| **(In thousands)** | **2006** | **2005** |
|---|---|---|
| Domestic | $ 100,633 | $ 99,033 |
| Blackstone | 397,420 | - |
| Breg | 182,273 | 185,921 |
| International | 171,000 | 188,538 |
| Group activities | 24,612 | 13,126 |
| Eliminations | (13,653) | (12,757) |
| Total | $ 862,285 | $ 473,861 |

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

| (In thousands) | Depreciation and amortization | | | Income tax expense | | | Other income (expense) | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2006 | 2005 | 2004 | 2006 | 2005 | 2004 |
| Domestic | $ 2,934 | $ 3,021 | $ 3,360 | $ 14,444 | $ 13,680 | $ 12,155 | $ 300 | $ 2,522 | $ 267 |
| Blackstone | 2,011 | - | - | (1,710) | - | - | 199 | - | - |
| Breg | 8,154 | 7,786 | 7,328 | 125 | 961 | 2,242 | (24) | 56 | 22 |
| International | 3,347 | 4,060 | 3,708 | (1,042) | 4,791 | 2,052 | 1,190 | 32,999 | (6,506) |
| Group activities | 11 | - | - | 1,544 | 2,681 | (239) | (4,173) | 232 | 8 |
| Total | $ 16,457 | $ 14,867 | $ 14,396 | $ 13,361 | $ 22,113 | $ 16,210 | $ (2,508) | $ 35,809 | $ (6,209) |

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

| (In thousands) | 2006 | 2005 | 2004 |
|---|---|---|---|
| Domestic | $ 2,240 | $ 3,243 | $ 2,831 |
| Blackstone | 1,473 | - | - |
| Breg | 3,496 | 5,040 | 2,820 |
| International | 5,360 | 3,965 | 6,592 |
| Group | 44 | - | - |
| Total | $ 12,613 | $ 12,248 | $ 12,243 |

*Geographical information*

Analysis of net sales by geographic destination:

| (In thousands) | 2006 | 2005 | 2004 |
|---|---|---|---|
| U.S. | $ 263,442 | $ 218,096 | $ 198,392 |
| Domestic | 263,442 | 218,096 | 198,392 |
| | | | |
| U.K. | 26,708 | 28,949 | 28,858 |
| Italy | 23,436 | 22,004 | 20,761 |
| Other | 51,773 | 44,255 | 38,627 |
| International | 101,917 | 95,208 | 88,246 |
| Total | $ 365,359 | $ 313,304 | $ 286,638 |

There are no sales in the Netherlands Antilles.

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

Analysis of long-lived assets by geographic area:

| **(In thousands)** | **2006** | **2005** |
|---|---|---|
| U.S. | $ 537,480 | $ 206,287 |
| Italy | 20,250 | 11,443 |
| U.K. | 30,461 | 22,379 |
| Cyprus | 5,277 | 13,426 |
| Others | 10,154 | 9,857 |
| Total | $ 603,622 | $ 263,392 |

**Sales by Market Sector for the year ended December 31, 2006**

| **(In 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 |

**Sales by Market Sector for the year ended December 31, 2005**

| **(In thousands)** | **Domestic** | **Blackstone** | **Breg** | **International** | **Total** |
|---|---|---|---|---|---|
| Spine | $ 101,470 | $ - | $ - | $ 152 | $ 101,622 |
| Orthopedics | 33,569 | - | - | 58,528 | 92,097 |
| Sports Medicine | - | - | 72,022 | 948 | 72,970 |
| Vascular | - | - | - | 23,887 | 23,887 |
| Other | 45 | - | - | 22,683 | 22,728 |
| Total | $ 135,084 | $ - | $ 72,022 | $ 106,198 | $ 313,304 |

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

**Sales by Market Sector for the year ended December 31, 2004**

| (In thousands) | Domestic | Blackstone | Breg | International | Total |
|---|---|---|---|---|---|
| Spine | $ 81,182 | $ - | $ - | $ 191 | $ 81,373 |
| Orthopedics | 36,874 | - | - | 53,238 | 90,112 |
| Sports Medicine | - | - | 68,294 | 194 | 68,488 |
| Vascular | - | - | - | 25,226 | 25,226 |
| Other | 18 | - | - | 21,421 | 21,439 |
| Total | $ 118,074 | $ - | $ 68,294 | $ 100,270 | $ 286,638 |

**14 Income taxes**

The Company and each of its subsidiaries are taxed at the rates applicable within each respective company's jurisdiction. The composite income tax rate will vary according to the jurisdictions in which profits arise. The components of the provision for income tax expense (benefit) are as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| (In thousands) | 2006 | 2005 | 2004 |
| Italy - Current | $ 5,030 | $ 3,011 | $ 2,727 |
| - Deferred | (6,167) | (310) | (241) |
| Cyprus - Current | 1,148 | 2,924 | 251 |
| - Deferred | 5 | 17 | - |
| U.K. - Current | 481 | 2,015 | 985 |
| - Deferred | - | - | (34) |
| U.S. - Current | 12,231 | 15,299 | 15,928 |
| - Deferred | (1,601) | (1,564) | (3,711) |
| Netherlands Antilles/Netherlands | | | |
| - Current | 6,772 | 506 | 25 |
| - Deferred | (4,852) | 892 | 134 |
| Other - Current | 314 | (4) | 168 |
| - Deferred | - | (673) | (22) |
| Total tax expense | $ 13,361 | $ 22,113 | $ 16,210 |

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

Income before minority interests and provision for income taxes consisted of:

| | Year ended December 31, | | |
|---|---|---|---|
| **(In thousands)** | **2006** | **2005** | **2004** |
| U.S. | $ (11,264) | $ 36,511 | $ 32,254 |
| Non-U.S. | 17,609 | 59,004 | 18,105 |
| | $ 6,345 | $ 95,515 | $ 50,359 |

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

| **(In thousands)** | **2006** | **2005** |
|---|---|---|
| **Deferred tax liabilities** | | |
| Goodwill | $ 79 | $ (5) |
| Patents, trademarks and other intangible assets | (97,446) | (22,306) |
| Property, plant and equipment | (783) | (925) |
| Other | 3,131 | (2,416) |
| | $ (95,019) | $ (25,652) |
| **Deferred tax assets** | | |
| Other current | $ 202 | $ 111 |
| Inventories and related reserves | 1,968 | 1,781 |
| Accrued compensation | 1,555 | - |
| Allowance for doubtful accounts | 3,247 | 2,619 |
| Net operating loss carryforwards | 19,380 | 6,344 |
| Other long-term | 8,091 | 1,993 |
| | 34,443 | 12,848 |
| Valuation allowance | (9,428) | (6,324) |
| | 25,015 | 6,524 |
| Net deferred tax liability | $ (70,004) | $ (19,128) |

The valuation allowance as of December 31, 2006 and 2005 was $9.4 million and $6.3 million, respectively. The net increase in the valuation allowance was $3.1 million for the period ended December 31, 2006. 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 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, 2006.

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

As part of the acquisition of Blackstone, the Company acquired a net operating loss carryforward of $31.1 million which was subject to annual section 382 limitations of approximately $11.6 million per year. During 2006, the Company utilized $5.9 million of these net operating loss carryforwards. The Company has not established a valuation allowance for this net operating loss carryforward because management believes the net operating loss carryforwards will be utilized against future taxable income. The Company also has tax net operating loss carryforwards in other taxing jurisdictions of approximately $29.0 million 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.

In connection with the Company's European Restructuring in 2006 and a similar transaction in 2002, certain intangible assets were sold between subsidiaries in order to optimize the Company's supply chain. Such assets were sold at estimates of fair value based upon valuations provided by an independent third party. There can be no assurance that local tax authorities will not challenge such valuations. A successful challenge by the tax authorities could have a materially adverse effect on the Company's tax profile (including the ability to recognize the intended tax benefits from the transaction) or significantly increase the Company's future tax payments. The Company has not accrued any financial statement reserves in connection with these valuation matters.

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 thousands, except percentages)** | **2006** | | **2005** | | **2004** | |
|---|---|---|---|---|---|---|
| | **Amount** | **Percent** | **Amount** | **Percent** | **Amount** | **Percent** |
| Statutory U.S. federal income tax rate | $ 2,221 | 35% | $ 33,431 | 35.0% | $ 17,626 | 35.0% |
| Net effect of foreign tax | (3,089) | -48.7% | (3,513) | -3.7% | (3,068) | -6.1% |
| Net effect of KCI settlement | (113) | -1.8% | (11,366) | -11.9% | - | - |
| Change in valuation allowance | 2,875 | 45.3% | 238 | 0.2% | (391) | -0.8% |
| Tax holiday benefit – Seychelles | (566) | -8.9% | (986) | -1.0% | (918) | -1.8% |
| US-UK Tax Treaty | (1,543) | -24.3% | (664) | -0.7% | (1,880) | -3.7% |
| State taxes net of federal benefit | 1,394 | 22% | 1,314 | 1.4% | 1,132 | 2.2% |
| Net effect of non-deductible foreign losses | 42 | 0.7% | 3,119 | 3.3% | 2,950 | 5.9% |
| Blackstone purchased R&D | 14,000 | 220.6% | - | - | - | - |
| Italy brand revaluation * | (2,778) | -43.8% | - | - | - | - |
| European restructuring | (1,235) | -19.5% | - | - | - | - |
| Tax ruling Netherlands Antilles | 577 | 9.1% | 289 | 0.1% | - | - |
| Withholding tax | 765 | 12.1% | 622 | 1.9%- | - | - |
| Cyprus interest rate ruling | 460 | 7.2% | - | - | - | - |
| Domestic production deduction | (331) | -5.2% | (456) | -1.4%- | - | - |
| Other | 682 | 10.7% | 85 | - | 759 | 1.5% |
| | $ 13,361 | 210.5% | $ 22,113 | 23.2% | $ 16,210 | 32.2% |

| | |
|---|---|
| Income tax expense/effective rate | |

* The difference between the reported provision for income taxes and a provision computed by applying the statutory rates applicable to each subsidiary of the Company is attributable to the Company's election to adopt a new tax provision in Italy. The election allowed the Company to increase, for tax purposes only, the value of our trademarks in Italy by approximately $15.0 million. The Company incurred a tax liability of $2.7 million from applying a 19% tax rate to the revaluation of the trademark value. The Company expects to receive a future tax benefit of $5.6 million associated with amortization of that step-up in value which is based on the current Italian tax rates of approximately 37%. The net of the $5.6 million deferred tax asset and the $2.7 million tax liability resulted in a $2.9 million non-recurring discrete tax benefit.

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 $191.1 million, $232.1 million and $201.9 million at December 31, 2006, 2005 and 2004, 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.

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

15 **Related parties**

The following related party balances and transactions as of and for the three years ended December 31, 2006, 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 System, purchases quality control and logistic services and buys the Laryngeal Mask from companies in which a former board member has a beneficial minority interest.

| | Year ended December 31, | | |
|---|---|---|---|
| **(In thousands)** | **2006** | **2005** | **2004** |
| Sales | $ 404 | $ 573 | $ 987 |
| Purchases | $ 16,733 | $ 17,411 | $ 16,986 |
| Accounts payable | $ 2,474 | $ 1,711 | $ 1,386 |
| Accounts receivable | $ 86 | $ 126 | $ 198 |
| Due from officers (included in other long-term assets) | $ 208 | $ 370 | $ 356 |

**16 Contingencies**

*Litigation*

The Company, in the normal course of its business, is involved in various lawsuits from time to time. In addition, the Company is subject to certain other contingencies discussed below:

The Company's subsidiary, Blackstone Medical, is a defendant in 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. The plaintiffs allege that (i) they are 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 Medical's making, selling, offering for sale, and using within the United States its Blackstone Anterior Cervical Plate, 3º Anterior Cervical Plate, Hallmark Anterior Cervical Plate and Construx Mini PEEK VBR System products is infringing and has infringed the Patents, and that such infringement has been willful. The Complaint requests both damages and an injunction against further alleged infringement of the Patents. The Complaint does not specifically state an amount of damages. Blackstone Medical has denied infringement and asserts that the Patents are invalid.

Novamedix, a subsidiary of the Company, filed an action on February 21, 1992 against Kinetic Concepts Inc. (“KCI”) alleging infringement of the patents relating to Novamedix’s A-V Impulse System foot pump product, breach of contract, unfair competition and was seeking damages. On September 30, 2005 KCI, Novamedix and the Company announced a settlement had been reached under which KCI agreed to pay Novamedix $75.0 million and to give Novamedix an option to receive a limited assignment of certain KCI foot pump patent rights. The Company had contractual obligations to distribute a portion of the settlement proceeds to certain former owners of Novamedix and the original patents. The final settlement amounts to be paid to these former owners and patent holders was not concluded at December 31, 2005. The Company recorded a gain of $40.1 million and the related tax amount of $2.7 million and accrued $26.2 million for contractual obligations. Further, the Company agreed to indemnify KCI against certain tax liabilities that might arise out of the settlement. Management believes the risk that any such claims might arise under this indemnity to be remote.

In management's opinion, the Company is not currently involved in any other legal proceeding, individually or in the aggregate, that will have a material effect on the financial position, liquidity or operating results of the Company.

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

*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 individuals 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 10% or more of net sales in 2006, 2005 or 2004.

**17 Pensions and deferred compensation**

Orthofix Inc. sponsors a defined contribution benefit plan (the "401(k) Plan") covering substantially all full time employees. This 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 401(k) Plan. During the years ended December 31, 2006, 2005 and 2004, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $945,000, $962,000 and $760,000, respectively. Breg also sponsors a 401(k) plan. This 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 $750 deferred. During the years ended December 31, 2006, 2005 and 2004, expenses incurred relating to the Breg 401(k) Plan, including matching contributions were $102,000, $101,000 and $111,000, respectively. Blackstone also sponsors a 401(k) plan. This 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 fourth quarter of 2006, expense incurred relating to the Blackstone 401(k) Plan including matching contributions were $38,000.

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 2006, 2005 and 2004 were approximately $489,000, $450,000 and $468,000, 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 2006, 2005 and 2004 was approximately $352,000, $316,000 and $292,000, respectively. Deferred compensation payments of $274,000, $215,000 and $207,000 were made in 2006, 2005 and 2004, respectively. The balance as of December 31, 2006 of $1.4 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.

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

18 **Share option plans**

**Option and stock purchase plans**

At December 31, 2006, the Company had three stock-based compensation 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 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. Awards generally vest on years of service with all awards fully vesting within five years of the grant date. Awards can be in the form of an option, 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. At December 31, 2006, there were 1,530,186 awards outstanding under the 2004 LTIP Plan of which 308,222 were exercisable.

*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 date of grant. There are no options left to be granted under the Staff Plan. At December 31, 2006, there were 346,675 options outstanding under the Staff Plan of which 331,675 are exercisable.

*Performance Accelerated Stock Option Agreement*

On June 29, 2000, the Company's shareholders approved, the grant to certain executive officers of the Company of performance accelerated stock options ("PASOs"), which it administers as a sub-plan of the Staff Plan, to purchase up to 1,000,000 shares of the Company's common stock, subject to the terms summarized below. The option to purchase the Company's common stock under the PASOs was granted effective January 1, 2000 (the "Grant Date") at an exercise price equal to $17.875 per share, the price of the Company's common stock on the date shareholders approved the reservation of 1,000,000 shares for issuance under the PASO plan.

The PASOs include both service-based and performance-based vesting provisions. Under the service-based provisions, subject to the continued employment of the executive, the PASOs became 100% non-forfeitable and exercisable on the fifth anniversary of the Grant Date. Vesting under the PASOs would be accelerated, however, if certain stock price targets are achieved. The performance-based vesting provisions provide for the vesting of one-eighth of the PASO grant for each $5.00 increase in the price of the Company's common stock above $15.00 per share. The total number of shares eligible for the accelerated vesting on an annual basis was limited to 20% of the number of shares subject to the PASO with a cumulative carryover for the unvested portion of shares eligible for accelerated vesting for each of the prior years. During the period ended December 31, 2006, 200,000 stock options were exercised and none were forfeited. As of December 31, 2006, 187,500 options remain outstanding under the option agreements. Under the initial agreement, all options expire on January 1, 2009. Due to the resignation from the Board of Directors of the only remaining option holder on December 5, 2006, under the terms of this option agreement, his outstanding options will expire on December 5, 2007.

*Performance Accelerated Stock Option Inducement Agreements*

On December 30, 2003, the Company granted inducement stock option awards to two key executives of Breg, Inc, in conjunction with the acquisition of Breg, Inc. 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, Inc. The inducement grants include both service-based and performance-based vesting provisions. Under the service-based provisions, subject to the continued employment of the executive, the inducement grants become 100% non-forfeitable and exercisable on the fourth anniversary of the grant date. Vesting of a portion of the options under the inducement agreement will be accelerated if certain stock price targets are achieved. The performance-based vesting provisions generally provide for the vesting of one-fifth of the inducement grants for each $5.00 increase in the price of the Company's common stock above $40.00 per share. The total number of shares eligible for the accelerated vesting on an annual basis is limited to 25% of the number of shares subject to the inducement grants with a cumulative carryover for the unvested portion of shares eligible for accelerated vesting for each of the prior years. Prior to the expiration of the term of the options, only one-half of the vested options can be exercised in any one year. As of December 31, 2006, 200,000 options remain outstanding under the inducement grants, of which 30,000 were exercisable.

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

*Employee Stock Purchase Plan*

The Employee Stock Purchase Plan provides for the issuance of shares of the Company's common stock. During each purchase period, eligible employees may designate between 1% and 25% of their cash compensation to be deducted from their cash compensation for the purchase of common stock under the plan. The purchase price of the shares under the plan is equal to 85% to the fair market value on the first day of the plan year (July 1st to June 30th). The purchase price for the Company's officers is equal to 100% of the fair market value on the first day of each plan year. The aggregate number of shares reserved for issuance under the Employee Stock Purchase Plan in 2006 was 450,000 shares. As of December 31, 2006, 308,977 shares had been issued under the Employee Stock Purchase Plan.

Summaries of the status of the Company's stock option and warrant plans as of December 31, 2006, 2005 and 2004 and changes during the years ended on those dates are presented below:

| | 2006 | | 2005 | | 2004 | |
|---|---|---|---|---|---|---|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at beginning of year | 1,944,199 | $ 32.02 | 1,783,693 | $ 27.36 | 2,051,502 | $ 21.62 |
| Granted | 816,950 | $ 39.70 | 508,500 | $ 43.15 | 434,000 | $ 37.18 |
| Exercised | (406,225) | $ 25.54 | (246,374) | $ 19.45 | (698,428) | $ 16.41 |
| Forfeited | (90,563) | $ 39.29 | (101,620) | $ 34.55 | (3,381) | $ 30.40 |
| Outstanding at end of year | 2,264,361 | $ 35.67 | 1,944,199 | $ 32.02 | 1,783,693 | $ 27.36 |
| | | | | | | |
| Options exercisable at end of year | 857,397 | | 777,225 | | 834,593 | |
| Weighted average fair value of options granted during the year at market value | | $ 13.78 | | $ 15.09 | | $ 13.03 |
| Weighted average fair value of options granted during the year 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, 2006**

| | 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 |
| $ 7.50 - $17.00 | 127,475 | 1.81 | $ 12.36 | 127,475 | $ 12.53 |
| $ 17.87 - $25.00 | 225,150 | 1.58 | $ 19.07 | 225,150 | $ 19.07 |
| $ 26.72 - $36.57 | 209,550 | 6.55 | $ 32.43 | 195,217 | $ 32.25 |
| $ 36.58 - $41.33 | 1,171,051 | 8.54 | $ 38.44 | 200,920 | $ 38.12 |
| $ 41.34 - $46.33 | 531,135 | 9.03 | $ 43.42 | 108,635 | $ 43.67 |
| | 2,264,361 | 7.40 | $ 35.67 | 857,397 | $ 28.68 |

The weighted average remaining contractual life of exercisable options was 4.6 years at December 31, 2006. The total intrinsic value of options exercised was $1.9 million, $2.8 million and $9.3 million for the years ended December 31, 2006, 2005 and 2004, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2006 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 $50.00 closing price of the Company's stock on December 31, 2006. The aggregate intrinsic value of options outstanding was $26.5 million, $8.4 million and $9.9 million for the years ended December 31, 2006, 2005 and 2004, respectively. The aggregate intrinsic value of options exercised was $11.9 million, $5.4 million and $6.3 million for the years ended December 31, 2006, 2005 and 2004, respectively.

**19 Earnings per share**

For each of the three years in the period ended December 31, 2006, there were no adjustments to net income for purposes of calculating basic and diluted net income per common share. The following is a reconciliation of the weighted average shares used in the basic and diluted net income per common share computations.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2006 | 2005 | 2004 |
| Weighted average common shares-basic | 16,165,540 | 15,913,475 | 15,396,540 |
| Effect of diluted securities: | | | |
| Stock options | -- | 375,500 | 578,405 |
| Weighted average common share-diluted | 16,165,540 | 16,288,975 | 15,974,945 |

The Company did not include in the diluted shares outstanding calculation 763,564 options in 2006, 392,400 options in 2005 and 200,000 options in 2004 because their inclusion would be anti-dilutive.

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

**20 Quarterly financial data (unaudited)**

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

| | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter | Year |
|---|---|---|---|---|---|
| **2006** | | | | | |
| Net sales | $ 81,116 | $ 84,735 | $ 83,368 | $ 116,140 | $ 365,359 |
| Gross profit | 59,657 | 63,536 | 62,361 | 86,180 | 271,734 |
| Net income | 8,246 | 12,728 | (35,417) | 7,403 | (7,042) |
| Net income per common share: | | | | | |
| Basic | 0.51 | 0.79 | (2.19) | 0.45 | (0.44) |
| Diluted | 0.51 | 0.79 | (2.19)[1] | 0.44 | (0.44) |
| **2005** | | | | | |
| Net sales | $ 77,688 | $ 79,540 | $ 75,812 | $ 80,264 | $ 313,304 |
| Gross profit | 56,792 | 58,765 | 55,619 | 58,340 | 229,516 |
| Net income | 10,779 | 9,405 | 46,020 | 7,198 | 73,402 |
| Net income per common share: | | | | | |
| Basic | 0.68 | 0.59 | 2.88 | 0.45 | 4.61 |
| Diluted | 0.67 | 0.58 | 2.81 | 0.44 | 4.51 |

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.

(1) The Company formerly reported $2.17 which has been adjusted to exclude the antidilutive effect of options.

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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 thousand) | December 31, 2006 | December 31, 2005 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,745 | $ 6,240 |
| Prepaid expenses and other current assets | 718 | 548 |
| Total current assets | 11,463 | 6,788 |
| Other long term assets | 292 | 372 |
| Investments in and amounts due from subsidiaries and affiliates | 384,711 | 363,855 |
| Total assets | $ 396,466 | $ 371,015 |
| **Liabilities and shareholders' equity** | | |
| Current liabilities | $ 1,911 | $ 975 |
| Long-term liabilities | 1,920 | 1,155 |
| Shareholders' equity | | |
| Common stock | 1,645 | 1,602 |
| Additional paid in capital | 128,297 | 106,746 |
| Accumulated earnings | 248,433 | 255,475 |
| Accumulated other comprehensive income | 14,260 | 5,062 |
| | 392,635 | 368,885 |
| Total liabilities and shareholders' equity | $ 396,466 | $ 371,015 |

*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, 2006 | December 31, 2005 | December 31, 2004 |
|---|---|---|---|
| (Expenses) Income | | | |
| General and administrative | $ (8,774) | $ (5,115) | $ (4,599) |
| Equity in earnings of investments in subsidiaries and affiliates | 692 | 79,603 | 38,571 |
| Other, net | 2,800 | 204 | 336 |
| Income (loss) before income taxes | (5,282) | 74,692 | 34,308 |
| Income tax expense | (1,760) | (1,290) | (159) |
| Net income (loss) | $ (7,042) | $ 73,402 | $ 34,149 |

*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, 2006 | December 31, 2005 | December 31, 2004 |
|---|---|---|---|
| Net income (loss) | $ (7,042) | $ 73,402 | $ 34,149 |
| Equity in earnings of investments in subsidiaries and affiliates | (692) | (79,603) | (38,571) |
| Cash used in other operating activities | (1,066) | (39,486) | (6,234) |
| Net cash used in operating activities | (8,800) | (45,687) | (10,656) |
| Cash flows from investing activities: | | | |
| Investments and advances made in subsidiaries and affiliates | - | - | (6,400) |
| Distributions and amounts received from subsidiaries | 24,468 | 38,538 | 7,547 |
| Cash provided by other investing activities | - | - | 1,300 |
| Net cash provided by investing activities | 24,468 | 38,538 | 2,447 |
| Cash flows from financing activities: | | | |
| Net proceeds from issuance of common stock | 11,507 | 6,471 | 12,247 |
| Dividends to subsidiaries and affilliates | (24,845) | - | - |
| Tax benefit on exercise of stock options | 2,175 | - | - |
| Net cash provided by financing activities | (11,163) | 6,471 | 12,247 |
| Net (decrease) increase in cash and cash equivalents | 4,505 | (678) | 4,038 |
| Cash and cash equivalents at the beginning of the year | 6,240 | 6,918 | 2,880 |
| Cash and cash equivalents at the end of the year | $ 10,745 | $ 6,240 | $ 6,918 |

*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 it 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, 2006 is approximately $247.2 million. 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 Long Term Debt and Note 12 Commitments and Note 16 Contingencies of the Company's consolidated financial statements.

### 4 Dividends From Subsidiaries

Cash dividends paid to Orthofix International N.V. from its consolidated subsidiaries accounted for by the equity method were $24.5 million, $38.5 million and $7.5 million for the periods ended December 31, 2006, 2005 and 2004, respectively.

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**Schedule 2 – Valuation and Qualifying Accounts**

For the years ended December 31, 2006, 2005 and 2004:

| **(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** |
| **2006** | | | | | | |
| Allowance for doubtful accounts receivable | 4,155 | 5,475 | 41 | (3,634) | 228 | 6,265 |
| Inventory provisions | 3,334 | 3,042 | 242 | (1,309) | 1,905 | 7,213 |
| Deferred tax valuation allowance | 6,324 | 3,024 | 80 | - | - | 9,428 |
| **2005** | | | | | | |
| Allowance for doubtful accounts receivable | 4,195 | 5,124 | 40 | (5,204) | - | 4,155 |
| Inventory provisions | 4,010 | 1,234 | - | (1,910) | - | 3,334 |
| Deferred tax valuation allowance | 138 | 238 | 5,948 | - | - | 6,324 |
| **2004** | | | | | | |
| Allowance for doubtful accounts receivable | 4,314 | 4,266 | 47 | (4,432) | - | 4,195 |
| Inventory provisions | 3,656 | 667 | (48) | (265) | - | 4,010 |
| Deferred tax valuation allowance | 529 | 138 | - | (529) | - | 138 |