ORTHOFIX INTERNATIONAL N V
Form 10-K
February 29, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

T ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2007
or
£ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File Number: 0-19961

ORTHOFIX INTERNATIONAL N.V.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

None

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes £ No 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 29, 2007, as reported by the Nasdaq Global Select Market, was approximately $730 million.

As of February 26, 2008, 17,086,856 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's Definitive Proxy Statement to be filed with the Commission in connection with the 2008 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 or escrow claim matters, risks relating to the protection of intellectual property, changes to the reimbursement policies of third parties, changes to governmental regulation of medical devices, the impact of competitive products, changes to the competitive environment, the acceptance of new products in the market, conditions of the orthopedic industry and the economy, currency or interest rate fluctuations, difficulties integrating newly acquired businesses or products, difficulties completing strategic acquisitions or dispositions and the other risks described in Item 1A under the heading "Risk Factors" in this Form 10-K.

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PART I

Item 1. Business

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

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, and to help them achieve a more active and mobile lifestyle. We design, develop, manufacture, market and distribute medical products used principally by musculoskeletal medical specialists for orthopedic applications. Our main products are invasive and minimally invasive spinal implant products and related human cellular and tissue based products (“HCT/P products”); non-invasive stimulation products designed to enhance the success rate of spinal fusions and to treat non-union fractures; external and internal fixation devices used in fracture treatment, limb lengthening and bone reconstruction; and bracing products used for ligament injury prevention, pain management and protection of surgical repair to promote faster healing. Our products also include a device designed to enhance venous circulation, cold therapy and 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 (“U.S.”) and Italy and manufacturing facilities in the United States, the United Kingdom, Italy and Mexico. We directly distribute our products in the U.S, the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Mexico, Brazil and Puerto Rico. In several 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 (the “SEC”), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, annual proxy statement on Schedule 14A and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information on our website or connected to our website is not incorporated by reference into this Form 10-K. Our Internet website is located at http://www.orthofix.com. Our SEC filings are also available on the SEC Internet website as part of the EDGAR database (http://www.sec.gov).

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Important Events

On or about July 23, 2007, Blackstone received a subpoena issued by the Department of Health and Human Services, Office of the Inspector General, under the authority of the federal healthcare anti-kickback and false claims statutes. The subpoena seeks documents for the period January 1, 2000 through July 31, 2006 which is prior to our acquisition of Blackstone. We believe that the subpoena concerns the compensation of physician consultants and related matters. Blackstone is cooperating with the government's request and is in the process of responding to the subpoena (See Item 3, Legal Proceedings).

On or about January 7, 2008, we received a federal grand jury subpoena from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks documents for the period January 1, 2000 through July 15, 2007. We believe that the subpoena concerns the compensation of physician consultants and related matters, and further believes that it is associated with Department of Health and Human Services, Office of Inspector General's investigation of such matters. We are cooperating with the government's request and are in the process of responding to the subpoena (See Item 3, Legal Proceedings).

On or about September 27, 2007, Blackstone received a federal grand jury subpoena from the United States Attorney's Office for the District of Nevada. This subpoena seeks documents for the period from January 1999 to the present. We believe that the subpoena concerns payments or gifts made by Blackstone to certain physicians. We are cooperating with the government's request and are in the process of responding to the subpoena (See Item 3, Legal Proceedings).

On Friday, February 29, 2008, Blackstone received a Civil Investigative Demand ("CID") from the Massachusetts Attorney General's Office, Public Protection and Advocacy Bureau, Healthcare Division. Management believes that the CID seeks documents concerning Blackstone's financial relationships with certain physicians and related matters for the period from March 2004 through the date of issuance of the CID (See Item 3, Legal Proceedings).

On February 21, 2008, we announced that we were exploring options related to the potential divestiture of the fixation assets in our Orthopedic business unit. We indicated that we have not yet identified a buyer for these fixation assets, and no definitive agreements have been signed. We anticipate that any proceeds realized from the divestiture of fixation assets would be used to reduce debt and strengthen the Company's balance sheet in anticipation of additional strategic opportunities in the Spine space.

On November 6, 2007, we announced that Timothy M. Adams, 48, had been appointed Chief Financial Officer of the Company effective as of November 19, 2007. In conjunction with such responsibilities, Mr. Adams would also serve as Senior Vice President, Treasurer and Assistant Secretary of the Company. Mr. Adams succeeded Tom Hein, who remains with the Company as Executive Vice President of Finance. Mr. Adams joined the Company after three years as Chief Financial Officer for Cytyc Corporation, a global medical device and diagnostics company that was acquired in October 2007 by Hologic, Inc. Previously, Mr. Adams served as Chief Financial Officer for Modus Media International, Inc., a global supply chain management company and as Chief Financial Officer of Digex, Inc.

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 intend to 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.

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., which uses both direct and distributor sales representatives to sell Spine and Orthopedic products to hospitals, doctors, and other healthcare providers in the U.S. market. We have designated Blackstone Medical, Inc. ("Blackstone"), a company that we acquired on September 22, 2006, as a business segment. Blackstone specializes in the design, development and marketing of spinal implant and related HCT/P products. Blackstone uses both direct and 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 U.S. International uses both direct and distributor sales representatives to sell Spine, Orthopedic, Sports Medicine, Vascular, and Other products.

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Business Segment (a):

	Year ended December 31, (In US$ thousands)					
	2007		2006		2005	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Domestic	$ 166,727	34%	$ 152,560	42%	$ 135,084	43%
Blackstone	115,914	24%	28,134	8%	-	-
Breg	83,397	17%	76,219	21%	72,022	23%
International	124,285	25%	108,446	29%	106,198	34%
Total	$ 490,323	100%	$ 365,359	100%	$ 313,304	100%

(a) Prior to 2006, our operations in Mexico and Brazil were included within the Domestic segment. Conversely, in 2006 such operations are included within the International segment. 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 under the heading “Financial Statements and Supplementary Data”, as well as in Part II, Item 7 under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

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

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

Market Sector:

	Year ended December 31, (In US$ thousands)					
	2007		2006		2005	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Spine	$ 243,165	49%	$ 145,113	40%	$ 101,622	33%
Orthopedics	111,932	23%	95,799	26%	92,097	29%
Sports Medicine	87,540	18%	79,053	22%	72,970	23%
Vascular	19,866	4%	21,168	6%	23,887	8%
Other	27,820	6%	24,226	6%	22,728	7%
Total	$ 490,323	100%	$ 365,359	100%	$ 313,304	100%

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

Products

Our revenues are generally derived from the sales of products in four market sectors, Spine (49%), Orthopedics (23%), Sports Medicine (18%) and Vascular (4%), which together accounted for 94% of our total net sales in 2007. 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 2007.

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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®	Pulsed electromagnetic field (“PEMF”) non-invasive lumbar spine bone growth stimulator
Cervical-Stim®	PEMF non-invasive cervical spine bone growth stimulator
Origin™ DBM with Bioactive Glass	A bone void filler
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 designed 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 designed 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 that is designed to enhance the success of a spinal fusion procedure
Alloquent® Allografts	Interbody devices made of cortical bone that are designed to restore the space that has been lost between two or more vertebrae due to a degenerated disc

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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™, Contours VPS®, VeroNail® and Centronail®
Physio-Stim®	PEMF long bone non-invasive bone growth stimulator
Gotfried PC.C.P®	Percutaneous compression plating system for hip fractures
eight-Plate Guided Growth System®	Treatment for the bowed legs or knock knees of children
Cemex®	Bone cement
ISKD®	Internal limb-lengthening device
OSCAR	Ultrasonic bone cement removal
Sports Medicine Products	
Breg® Bracing	Bracing products which are designed to provide support and protection of limbs and extremities during healing and rehabilitation
Polar Care®	Cold therapy products that are designed to reduce swelling, pain and accelerate the rehabilitation process
Pain Care®	Pain therapy products that are designed to provide continuous post-surgical infusion of local anesthetic into surgical site
Vascular Products	
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 Guided Growth System®, 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 Guided Growth System® and Contours VPS® worldwide. We have U.S. distribution rights for Trinity® Bone Matrix for use in spinal and orthopedic applications.

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

Spine

Spine product sales represented 49% of our total net sales in 2007.

Neck and back pain is a common health problem for many people throughout the world and often requires surgical or non-surgical intervention for improvement. Neck and back problems are usually of a degenerative nature and are generally more prevalent among the older population. As the population ages, we believe physicians will see an increasing number of patients with degenerative spine issues who wish to have a better quality of life than that experienced by previous generations. Treatment options for spine disorders are expected to expand to fill the existing gap between conservative pain management and invasive surgical options, such as spine fusion.

We believe that our Spine products are positioned to address the needs of spine patients at many points along the continuum of care, offering non-operative, pre-operative, operative and post-operative products. Our products currently address the cervical fusion segment as well as the lumbar fusion segment which is the largest sub-segment of the spine market.

Blackstone offers a wide array of spine implants used during surgical procedures intended to treat a variety of spine conditions. Many of these surgeries are fusion procedures in the cervical and lumbar spine that utilize Blackstone's metal plates, rods and screws, its interbody devices or vertebral body replacements, and its HCT/P 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 mobile vertebrae encompass the thoracic and lumbar, or thoracolumbar, sections of the spine. The thoracic spine (12 vertebrae) helps to protect the organs of the chest cavity by attaching to the rib cage, and is the least mobile segment of the spine. The lumbar spine (five vertebrae) carries the greatest portion of the body's weight, allowing a degree of flexion, extension and rotation thus handling the majority of the bending movement. Additionally five fused vertebrae make up the sacrum (part of the pelvis) and four vertebrae make up the final part of the spine, the coccyx.

Spinal bending and rotation are accomplished through the vertebral discs located between each vertebra. Each disc is made up of a tough fibrous exterior, called the annulus, which surrounds a soft core called the nucleus. Excess pressure, deformities, injury or disease can lead to a variety of conditions affecting the vertebrae and discs that may ultimately require medical intervention in order to relieve patient pain and restore stability in the spine.

Spinal fusion is the permanent union of two or more vertebrae to immobilize and stabilize the affected portion of the spine. Most fusion surgeries involve the placement of a bone graft between the affected vertebrae, which is typically held in place by metal implants that also provide stability to the spine until the desired growth of new bone can

complete the fusion process. These implants typically consist of some combination of rods, screws and plates that are designed to remain in the patient even after the fusion has occurred.

Most fusion procedures performed on the lumbar area of the spine are done 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 ("PEEK") that are placed between the affected vertebrae to restore the space lost by the degenerated disc. The hollow spaces within these interbody devices are typically packed with some form of HCT/P material designed to accelerate the formation of new bone around the graft which ultimately results in the desired fusion.

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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 HCT/P 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. These specialty plates include the Newbridge® Laminoplasty Fixation System that is designed to expand the cervical vertebrae and relieve pressure on the spinal canal, as well as the Unity® plate which is used in anterior lumbar fusion procedures.

Blackstone also offers a variety of devices made of PEEK, including vertebral body replacements and interbody devices. Vertebral body replacements are designed to replace a patient's degenerated or deformed vertebrae. On the other hand, interbody devices, or cages, are designed to replace a damaged disc, restoring the space that had been lost between two vertebrae. Blackstone also offers interbody devices made of titanium metal.

Blackstone is also a distributor of human cellular and tissue based products ("HCT/P 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 that is intended to enhance a patient's ability to quickly grow new bone around a spinal fusion site. This product contains live adult stem cells harvested from human cadaveric donors and is intended to be a safer, simpler alternative to an autograft, which is commonly performed in connection with a spine fusion procedure. An autograft involves a separate surgical incision in the patient's hip area in order to harvest the patient's own bone to be used during the fusion procedure. An autograft procedure adds risk of an additional surgical procedure and related patient discomfort in conjunction with the spinal fusion.

Spinal Bone Growth Stimulators

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

Spinal-Stim® is a non-invasive spinal fusion stimulator system commercially available in the U.S. 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 of not generating new bone around the damaged vertebrae after the operation. These patients typically have one or more risk factors such as smoking, obesity or diabetes, or their surgery involves the revision of a previously attempted fusion procedure that failed, or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical bone growth stimulation using Spinal-Stim® has been shown to increase the probability of fusion, without the need for additional surgery. According to internal sales data, more than 210,000 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 PEMF signal. Our approval from the U.S. Food and Drug Administration ("FDA") 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 FDA to market our Cervical-Stim® bone growth stimulator. Cervical-Stim® is an FDA-approved bone growth stimulator for use as an adjunct to cervical (upper) spine fusion in certain high-risk patients.

Orthopedics

Orthopedics products represented 23% of our total net sales in 2007.

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

Bone Fracture Management

Fixation

Our fracture management products consist of fixation devices designed to stabilize a broken bone until it can heal, as well as non-invasive post-surgical bone growth stimulation devices designed to accelerate the body's formation of new bone. Our fixation products come in two main types: external devices and internal devices. We initially focused on the production of external fixation devices for management of fractures that require surgery. External fixation devices are used to stabilize fractures from outside the skin with minimal invasion into the body. Our fixation devices use screws that are inserted into the bone on either side of the fracture site, to which the fixator body is attached externally. The bone segments are aligned by manipulating the external device using patented ball joints and, when aligned, are locked in place for stabilization. We believe that external fixation allows micromovement at the fracture site, which is beneficial to the formation of new bone. We believe that it is among the most minimally invasive and least complex surgical options for fracture management.

Internal fixation devices come in various sizes, depending on the bone which requires treatment, and consist of either long rods, commonly referred to as nails, or plates that are attached with the use of screws. A nail is inserted into the 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. Some 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 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.

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, we believe that the Sheffield fixator is more stable and stronger than most competing products – two critical concerns for a long-term limb reconstruction treatment. We believe other advantages of the Sheffield fixator over competing products include the rapid assembly, ease of use and the numerous possibilities for customization for each individual patient.

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Examples of our internal fixation devices include:

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

- The VeroNail® 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 we believe provides more stability than previous single screw designs.

- The Gotfried Percutaneous Compression Plating or Gotfried PC.C.P® System is a method of stabilization and fixation for hip-fracture surgery developed by Y. Gotfried, M.D. that we believe is minimally invasive. Traditional hip-fracture surgery can require a 5-inch-long incision down the thigh, but the Gotfried PC.C.P® System involves two smaller incisions, each less than one inch long. The Gotfried PC.C.P® System then allows a surgeon to work around most muscles and tendons rather than cutting through them. We believe that major benefits of this new approach to hip-fracture surgery include (1) a significant reduction of complications due to a less traumatic operative procedure; (2) reduced blood loss and less pain (important benefits for the typically fragile and usually elderly patient population, who often have other medical problems); (3) faster recovery, with patients often being able to bear weight a few days after the operation; and (4) improved post-operative results.

Bone Growth Stimulation

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

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

We believe that our systems offer portability, rechargeable battery operation, integrated component design, patient monitoring capabilities and the ability to cover a large treatment area without factory calibration for specific patient application. According to internal sales data, more than 132,000 patients have been treated using Physio-Stim® for long bone non-unions since the product was introduced.

Bone Deformity Correction

In addition to the treatment of bone fractures, we also design, manufacture and distribute devices that are intended to treat congenital bone conditions, such as limb length discrepancies, angular deformities (e.g., bowed legs in children), or degenerative diseases, as well as conditions resulting from a previous trauma. Examples of products offered in these areas include the eight-Plate Guided Growth System® and the Intramedullary Skeletal Kinetic Distractor, or ISKD®. The ISKD® system is a patented, internal limb-lengthening device that uses a magnetic sensor to monitor limb-lengthening progress on a daily basis. ISKD® is an expandable tubular device that is completely implanted

inside the bone to be lengthened. The ISCK® system is designed to lengthen the patient's bone gradually, and, after lengthening is completed stabilize the lengthened bone. ISKD® is an FDA-approved intramedullary bone lengthener on the market, and we have the exclusive worldwide distribution rights for this product.

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Sports Medicine

Sports Medicine product sales represented 18% of our total net sales in 2007.

We believe Breg, one of Orthofix's wholly-owned subsidiaries, is a market leader in the sale of orthopedic post-operative reconstruction and rehabilitative products to hospitals and orthopedic offices. Breg's products are grouped primarily into three product categories: Breg® Bracing, Polar Care® and Pain Care®. Approximately 60% of Breg's net revenues were attributable to the sale of bracing products in 2007, including: (1) functional braces for treatment and prevention of ligament injuries, (2) load-shifting braces for osteoarthritic pain management, (3) post-operative braces for protecting surgical repair and (4) foot and ankle supports that provide an alternative to casting. Approximately 30% of Breg's 2007 net revenues came from the sale of cold therapy products used to minimize the pain and swelling following knee, shoulder, elbow, ankle and back injuries or surgery. Approximately 5% of Breg's 2007 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 5% of Breg's 2007 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.

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

Post-operative braces are designed to limit a patient's range of motion after knee surgery and protect the repaired ligaments and/or joints from stress and strain. These braces are designed to promote a faster and healthier healing process. The products within this line provide both immobilization and/or a protected range of motion. The Breg post-operative family of braces, featuring the 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.

Osteoarthritic braces are used to treat patients suffering from osteoarthritis of the knee. Osteoarthritis ("OA") is a form of damage to, or degeneration of, the articular surface of a joint. This line of custom and off-the-shelf braces is designed to shift the load going through the knee, provide additional stability and reduce pain. In some cases, this type of brace may serve as a cost-efficient alternative to total knee replacement. Breg's CounterForce Plus, our newest bracing technology for patients suffering from OA, is based on a functional knee brace design that is intended to control both anterior/posterior and varus/valgus instabilities.

Polar Care®

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

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

Pain Care®

We manufacture, market and sell a line of pain therapy products called Pain Care®. This product line includes the Pain Care® 3200 and Pain Care® 4200 lines of disposable, pain management infusion pumps. These pain management systems are designed to 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.

Vascular

Vascular product sales represented 4% of our total net sales in 2007.

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, we believe that this product simulates the effect that would occur naturally during normal walking or hand flexion with a mechanical method and without the side effects and complications of medication.

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, calf or hand, as would occur naturally during normal walking or hand clenching. The A-V Impulse System® is distributed in the U.S. by Covidien Ltd. Outside the U.S., 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.

Other Products

Other product sales represented 6% of our total net sales in 2007.

Laryngeal Mask

The Laryngeal Mask, a product of The Laryngeal Mask Company Limited, is an anesthesia medical device designed to establish and maintain the patient's airway during an operation. We have exclusive distribution rights for the

Laryngeal Mask in the United Kingdom, Ireland and Italy.

Other

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

Product Development

Our research and development departments are responsible for new product development. We work regularly with certain institutions referred to below as well as with physicians and other consultants on the long-term scientific planning and evolution of our research and development efforts. Our primary research and development facilities are located in Wayne, New Jersey; Verona, Italy; McKinney, Texas; Vista, California; and Andover, United Kingdom.

We maintain interactive relationships with spine and orthopedic centers in the U.S., Europe, Japan and South and Central America, including research and development centers such as the Cleveland Clinic Foundation, Rutgers University, and the University of Verona in Italy. Several of the products that we market have been developed through these collaborations. In addition, we regularly receive suggestions for new products from the scientific and medical community, some of which result in Orthofix entering into assignment or license agreements with physicians and third-parties. We also receive a substantial number of requests for the production of customized items, some of which have resulted in new products. We believe that our policy of accommodating such requests enhances our reputation in the medical community.

In 2007 and 2005, we spent $24.2 million and $11.8 million, respectively, on research and development. In 2006, we spent $15.0 million on research and development and recorded a $40.0 million charge for In Process Research and Development as part of the purchase accounting for the Blackstone acquisition.

Patents, Trade Secrets, Assignments and Licenses

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

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

Government Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act, or the FDCA, as implemented and enforced by the

U.S. Food and Drug Administration, or the FDA. The regulations that cover our products and facilities vary widely from country to country. The amount of time required to obtain approvals or clearances from regulatory authorities also differs from country to country.

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

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

Class III medical devices are required to undergo the PMA approval process in which the manufacturer must establish the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will typically conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. By statute, the FDA has 180 days to review the PMA application, although, generally, review of the application can take between one and three years, or longer. Once approved, a new PMA or a PMA Supplement is required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Our bone growth stimulation products are classified as Class III by the FDA, and have been approved for commercial distribution in the U.S. through the PMA process. We also have under development, an artificial cervical disc product which is currently classified as FDA Class III and will require a human clinical trial and PMA approval. We also have under development other products designed to treat degenerative spinal disc disease but which allow greater post-surgical mobility than standard surgical approaches involving spinal fusion techniques. Certain of these products may be classified as FDA Class III products and may require PMA approval process including a human clinical trial.

In addition, Blackstone is a distributor of a product for bone repair and reconstruction under the brand name Trinity® Matrix which is an allogeneic bone matrix containing viable adult mesenchymal stem cells. We believe that Trinity® Matrix is properly classified under FDA's Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device or as a biologic or as a drug. We believe it is regulated under Section 361 of the Public Health Service Act and C.F.R. Part 1271. Blackstone also distributes certain surgical implant products known as "allograft" products which are derived from human tissues and which are used for bone reconstruction or repair and are surgically implanted into the human body. We believe that these products are properly classified by the FDA as minimally-manipulated tissue and are covered by FDA's "Good Tissues Practices" regulations, which cover all stages of allograft processing. There can be no assurance that our suppliers of the Trinity® Matrix and allograft products will continue to meet applicable regulatory requirements or that those requirements will not be changed in ways that could adversely affect our business. Further, there can be no assurance

that these products will continue to be made available to us or that applicable regulatory standards will be met or remain unchanged. Moreover, products derived from human tissue or bone are from time to time subject to recall for certain administrative or safety reasons and we may be affected by one or more such recalls. For a description of these risks, see Item 1A “Risk Factors.”

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The medical devices that we develop, manufacture, distribute and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining FDA clearance and other regulatory approvals to develop and market a medical device, particularly from the FDA, can be costly and time-consuming, and there can be no assurance that such approvals will be granted on a timely basis, if at all. While we believe that we have obtained all necessary clearances and approvals for the manufacture and sale of our products and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance. After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include: product listing and establishment registration; Quality System Regulation, or QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications; clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices; approval of product modifications that affect the safety or effectiveness of one of our PMA approved devices; Medical Device Reporting ("MDR") regulations, which require that manufacturers report to FDA if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; regulations pertaining to voluntary recalls; and notices of corrections or removals.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of those actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition and results of operations.

Moreover, governmental authorities outside the U.S have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. The European Commission, or EC, has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received CE certification from a "notified body" in order to be able to sell products within the member states of the European Union. Certification allows manufacturers to stamp the products of certified plants with a "CE" mark. Products covered by the EC regulations that do not bear the CE mark cannot be sold or distributed within the European Union. We have received certification for all currently existing manufacturing facilities and products.

Our products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid and Tricare, or private insurance plans and healthcare networks. Third-party payors may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the

policy holder's healthcare insurance benefits are limited. Also, third-party payors are increasingly challenging the prices charged for medical products and services. The Medicare program is expected to implement a new payment mechanism for certain items of durable medical equipment, or DME, for the competitive bidding program. This program is in the early stages of a gradual phase-in of implementation and payment rates for DME will be determined based on bid prices rather than the current Medicare DME fee schedule.

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

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

Sales, Marketing and Distribution

General Trends

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

Primary Markets

In 2007, Domestic accounted for 34% of total net sales; Blackstone accounted for 24% of total net sales; Breg accounted for 17% of total net sales; and International accounted for 25% 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 25 for a table of estimated revenue by payor type. For additional information about geographic areas, see Item 8 "Financial Statements and Supplementary Data."

Sales, Marketing and Distributor Network

We have established a broad distribution network comprised of direct sales representatives and distributors. This established distribution network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products through a sales and marketing force of approximately 593 direct sales and marketing representatives. Worldwide we also have approximately 288 independent distributors for our products in approximately 65 countries. The table below highlights the makeup of our sales, marketing and distribution network at December 31, 2007.

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	Direct Sales & Marketing Headcount			Distributors		
	United States	International	Total	United States	International	Total
Domestic	322	-	322	27	1	28
Blackstone	51	6	57	45	27	72
Breg	62	3	65	38	66	104
International	6	143	149	1	83	84
Total	441	152	593	111	177	288

In our largest market, the U.S., our sales, marketing and distribution network is separated between several distinct sales forces addressing different market sectors. The Spine market sector is addressed primarily by a direct sales force for spinal bone growth stimulation products and Blackstone HCT/P products and a distribution network for Blackstone spinal implant products. The Orthopedic market sector is addressed by a hybrid distribution network of predominately direct sales supplemented by distributors. The Sports Medicine market sector is addressed primarily by a distribution network for Breg products.

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

Marketing and Product Education

We seek to market our products principally to medical professionals and group purchasing organizations (“GPOs”) 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. We believe 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 GPOs 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 2007 were attended by over 760 surgeons and over 310 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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Competition

Our bone growth stimulation products compete principally with similar products marketed by Biomet Spine a business unit of Biomet, Inc, DJO Incorporated, and Exogen, Inc., a subsidiary of Smith & Nephew plc. Our Blackstone spinal implant and HCT/P products compete with products marketed by Medtronic, Inc., De Puy, a division of Johnson and Johnson, Synthes AG, Stryker Corp., Zimmer, Inc., Biomet Spine and various smaller public and private companies. For external and internal fixation devices, our principal competitors include Synthes AG, Zimmer, Inc., Stryker Corp., Smith & Nephew plc and Biomet Orthopedics, a business unit of Biomet, Inc. The principal non-pharmacological products competing with our A-V Impulse System® are manufactured by Huntleigh Technology PLC and Kinetic Concepts, Inc.

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

We believe that we enhance our competitive position by focusing on product features such as innovation, ease of use, versatility, cost and patient acceptability. We attempt to avoid competing based solely on price. Overall cost and medical effectiveness, innovation, reliability, after-sales service and training are the most prevalent methods of competition in the markets for our products, and we believe that we compete effectively.

Manufacturing and Sources of Supply

We generally design, develop, assemble, test and package our stimulation and orthopedic products, and subcontract the manufacture of a substantial portion of the component parts. We design and develop our Blackstone spinal implant and Alloquent® Allograft HCT/P products but subcontract their manufacture and packaging. Through subcontracting, we attempt to maintain operating flexibility in meeting demand while focusing our resources on product development, education and marketing as well as quality assurance standards. In addition to designing, developing, assembling, testing and packaging its products, Breg also manufactures a substantial portion of the component parts used in its products. Although certain of our key raw materials are obtained from a single source, we believe that alternate sources for these materials are available. Further, we believe that an adequate inventory supply is maintained to avoid product flow interruptions. We have not experienced difficulty in obtaining the materials necessary to meet our production schedules.

We generally source for distribution HCT/P products including Trinity® Matrix, our adult stem-cell based bone growth matrix product. Trinity® Matrix Multipotential Cellular Bone Matrix is a single source product obtained under an exclusive distribution agreement. 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 the Trinity® Matrix as well as the Alloquent® Allograft implants are made from human tissue and thus availability is subject to supply of human donors. During 2007, we believe that our revenue growth for Trinity® Bone Matrix was impacted by lower than expected levels of product from our suppliers available for sale. Our distribution agreement with our supplier for the Trinity product expires on December 31, 2008. There can be no assurance that we will be able to renew that agreement or otherwise ensure access to that product by that date.

Our products are currently manufactured and assembled in the U.S., Italy, the United Kingdom, and Mexico. We believe that our plants comply in all material respects with the requirements of the FDA and all relevant regulatory authorities outside the United States. For a description of the laws to which we are subject, see Item 1 – “Business – 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.

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Capital Expenditures

We had tangible and intangible capital expenditures in the amount of $27.2 million, $12.6 million and $12.2 million in 2007, 2006 and 2005, respectively, principally for computer software and hardware, patents, licenses, plant and equipment, tooling and molds and product instrument sets. In 2007, we invested $27.2 million in capital expenditures of which $7.9 million were related to acquisition of InSWing™ interspinous process spacers at Blackstone. We currently plan to invest approximately $20.0 million in capital expenditures during 2008 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, 2007, we had 1,406 employees worldwide. Of these, 482 were employed at Domestic, 166 were employed at Blackstone, 432 were employed at Breg and 326 were employed at International. Our relations with our Italian employees, who numbered 104 at December 31, 2007, 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 1,406 employees, 593 were employed in sales and marketing functions, 254 in general and administrative, 460 in production and 99 in research and development.

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.

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Our acquisition of Blackstone could present challenges for us.

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

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

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

Failure to overcome these risks or any other problems encountered in connection with the acquisition of Blackstone could adversely affect our business, prospects and financial condition. In addition, if Blackstone's operations and financial results 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.

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.

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

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

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

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

For example, our subsidiary, Blackstone, maintains a license agreement with Cross Medical, Inc./Biomet Spine ("Cross/Biomet") covering certain pedicle screw products currently sold by Blackstone. Prior to the completion of its acquisition by us, Blackstone requested that Cross/Biomet consent to the assignment of the license agreement to the extent Blackstone's acquisition by the Company constituted an assignment thereunder. 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 by independent sales representatives to customers or to our independent distributors and purchased by hospitals, doctors and other healthcare providers. These products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid and Tricare, or private insurance plans and healthcare networks. Third-party payors may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the policy holder's healthcare insurance benefits are limited. Also, third-party payors are increasingly challenging the prices charged for medical products and services. Limits put on reimbursement could make it more difficult for people to buy our products and reduce, or possibly eliminate, the demand for our products. In addition, should governmental authorities enact additional legislation or adopt regulations that affect third-party coverage and reimbursement, demand for our products may be reduced with a consequent material adverse effect on our sales and profitability.

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

The Centers for Medicare and Medicaid Services ("CMS"), in its ongoing implementation of the Medicare program has obtained 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 of the FDA-approved devices could lead to changes in coverage policies regarding off-label uses by TriCare, Medicare and/or Medicaid. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Our products are sold in many countries, such as the United Kingdom, France, and Italy, with publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales.

As required by law, CMS is expected to implement a competitive bidding program for durable medical equipment paid for by the Medicare program. The initial implementation of the competitive bidding program is expected to begin with a few products in limited areas in 2008. The Company's products are not yet included in the competitive bidding process. We believe that the competitive bidding process will principally affect products sold by our Sports Medicine business. We cannot predict which products from any of our businesses will ultimately be affected or when the competitive bidding process will be extended to our businesses. It is projected to be expanded further in 2009, and fully implemented sometime 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.

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We estimate that revenue by payor type is:

- Independent Distributors 21%
- Third Party Insurance 20%
- International Public Healthcare Systems 12%
- Direct (hospital) 38%
- U.S. Government – Medicare, Medicaid, TriCare 7%
- Self pay 2%

We and certain of our suppliers may be subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products.

The medical devices we manufacture and market are subject to rigorous regulation by the Food and Drug Administration, or FDA, and numerous other federal, state and foreign governmental authorities. These authorities regulate the development, approval, classification, testing, manufacturing, labeling, marketing and sale of medical devices. Likewise, our use and disclosure of certain categories of health information may be subject to federal and state laws, implemented and enforced by governmental authorities that protect health information privacy and security. For a description of these regulations, see Item 1 – “Business – Government Regulation.”

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The approval or clearance by governmental authorities, including the FDA in the United States, is generally required before any medical devices may be marketed in the United States or other countries. We cannot predict whether in the future, the U.S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition or results of operations. The process of obtaining FDA clearance and other regulatory clearances or approvals to develop and market a medical device can be costly and time-consuming, and is subject to the risk that such approvals will not be granted on a timely basis if at all. The regulatory process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices. The FDA has the ability to change the regulatory classification of a cleared or approved device from a higher to a lower regulatory classification which could materially adversely impact our ability to market or sell our devices.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of those actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition and results of operations.