BIOMET INC
Form 10-K
August 10, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended May 31, 2005.

OR

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

For the transition period from _____ to _____.

Commission file No. **0-12515.**

(Exact name of registrant as specified in its charter)

Indiana	**35-1418342**
(State of incorporation)	*(IRS Employer Identification No.)*
56 East Bell Drive, Warsaw, Indiana	**46582**
(Address of principal executive offices)	*(Zip Code)*

(574) 267-6639
(Registrant s telephone number, including area code)

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

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

Common Shares	**Rights to Purchase Common Shares**
(Title of class)	*(Title of class)*

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes þ No o

The aggregate market value of the Common Shares held by non-affiliates of the registrant, based on the closing price of the Common Shares on November 30, 2004, as reported by The Nasdaq National Market, was approximately $10,981,817,686. As of July 26, 2005, there were 249,564,889 Common Shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Identity of Document	Parts of Form 10-K Into Which Document Is Incorporated
Proxy Statement with respect to the 2005 Annual Meeting of Shareholders of the Registrant	Part III

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of federal securities laws. Those statements are often indicated by the use of words such as will, intend, anticipate, estimate, expect, plan and similar expressi include, but are not limited to, statements related to the timing and number of planned new product introductions; the effect of anticipated changes in the size, health and activities of population on demand for the Company s products; assumptions and estimates regarding the size and growth of certain market segments; the Company s ability and intent to expand in key international markets; the timing and anticipated outcome of clinical studies; assumptions concerning anticipated product developments and emerging technologies; the future availability of raw materials; the anticipated adequacy of the Company s capital resources to meet the needs of its business; the Company s continued investment in new products and technologies; the ultimate success of the Company s strategic alliances; the ultimate marketability of products currently being developed; the ability to successfully implement new technology; future declarations of cash dividends; the Company s ability to sustain sales and earnings growth; the Company s goals for sales and earnings growth; the future value of the Company s Common Stock; the ultimate effect of the Company s Share Repurchase Programs; the Company s success in achieving timely approval or clearance of its products with domestic and foreign regulatory entities; the stability of certain foreign economic markets; the impact of anticipated changes in the musculoskeletal industry and the ability of the Company to react to and capitalize on those changes; the ability of the Company to integrate the operations of acquired businesses; and the Company s ability to take advantage of technological advancements. Readers of this report are cautioned that reliance on any forward-looking statement involves risks and uncertainties. Although the Company believes that the assumptions on which the forward-looking statements contained herein are based are reasonable, any of those assumptions could prove to be inaccurate given the inherent uncertainties as to the occurrence or nonoccurrence of future events. There can be no assurance that the forward-looking statements contained in this report will prove to be accurate. The inclusion of a forward-looking statement herein should not be regarded as a representation by the Company that the Company s objectives will be achieved. Readers of this report should carefully read the factors set forth under the caption Risk Factors beginning on page 14 of this report for a description of certain risks that could, among other things, cause actual results to differ from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon the Company s business, financial condition and results of operations. The Company undertakes no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Accordingly, the reader is cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made.

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PART I

Item 1. Business.

General

Biomet, Inc. (Biomet or the Company), an Indiana corporation incorporated in 1977, and its subsidiaries design, manufacture and market products used primarily by musculoskeletal medical specialists in both surgical and non-surgical therapy. The Company s product portfolio encompasses reconstructive products, fixation devices, spinal products and other products. Biomet has corporate headquarters in Warsaw, Indiana, and manufacturing and/or office facilities in more than 50 locations worldwide.

The Company s principal subsidiaries include Biomet Orthopedics, Inc.; Biomet Manufacturing Corp.; EBI, L.P.; Biomet Europe B.V.; Implant Innovations, Inc.; Walter Lorenz Surgical, Inc. and Arthrotek, Inc. Unless the context requires otherwise, the term Company as used herein refers to Biomet and all of its subsidiaries.

On June 18, 2004, the Company completed the merger of Interpore International, Inc., now known as Interpore Spine Ltd. (Interpore), with a wholly-owned subsidiary of Biomet. As a result of the merger, Interpore shareholders were entitled to receive $14.50 per share in cash, representing an aggregate purchase price of approximately $266 million. Interpore s primary products include spinal implants, orthobiologics and minimally-invasive surgery products used by surgeons in a wide variety of applications.

The Company s annual reports on Form 10-K (for the five most recent fiscal years), quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge in, or may be accessed through, the Investors Section of the Company s Internet website at www.biomet.com as soon as reasonably practicable after the Company files or furnishes such material with or to the Securities and Exchange Commission.

Products

The Company operates in one business segment, musculoskeletal products, which includes the design, manufacture and marketing of four major market segments: reconstructive products, fixation devices, spinal products and other products. The Company has three reportable geographic markets: United States, Europe and Rest of World. Reconstructive products include knee, hip and extremity joint replacement systems, as well as dental reconstructive implants, bone cements and accessories, the GPS® System and the procedure-specific instrumentation required to implant the Company s reconstructive systems. Fixation devices include internal and external fixation devices, craniomaxillofacial fixation systems and electrical stimulation devices that do not address the spine. Spinal products include electrical stimulation devices addressing the spine, spinal fixation systems and orthobiologics. The other product sales category includes, arthroscopy products, softgoods and bracing products, casting materials, general surgical instruments, operating room supplies and other surgical products. Depending on the intended application, the Company reports sales of bone substitute materials in the reconstructive product, fixation device or spinal product segment.

The following table shows the net sales and percentages of total net sales contributed by each of the Company s product segments for each of the three most recent fiscal years ended May 31, 2005.

	Years Ended May 31, (Dollar amounts in thousands)					
	2005		2004		2003	
	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Reconstructive Products	$ 1,254,234	67%	$ 1,052,865	65%	$ 867,602	63%
Fixation Devices	246,730	13%	248,821	15%	237,117	17%
Spinal Products	214,039	11%	159,927	10%	143,607	10%

Other Products	164,947	9%	153,640	10%	141,974	10%
Total	$ 1,879,950	100%	$ 1,615,253	100%	$ 1,390,300	100%

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Reconstructive Products

Orthopedic reconstructive implants are used to replace joints that have deteriorated as a result of disease (principally osteoarthritis) or injury. Reconstructive joint surgery involves the modification of the area surrounding the affected joint and the implantation of one or more manufactured components, and may involve the use of bone cement. The Company s primary orthopedic reconstructive joints are knees, hips and shoulders, but it produces other joints as well. The Company also produces the associated instruments required by orthopedic surgeons to implant the Company s reconstructive devices, as well as bone cements and delivery systems. Additionally, dental reconstructive implants and associated instrumentation are used for oral rehabilitation through the replacement of teeth and repair of hard and soft tissues.

Knee Systems. A total knee replacement typically includes a femoral component, a patellar component, a tibial component and an articulating surface. Total knee replacement may occur as an initial joint replacement procedure, or as a revision procedure, which may be required to replace, repair or enhance the initial implant. Partial, or unicondylar, knee replacement is an option when only a portion of the knee requires replacement.

The Company continues to be a market leader in addressing the increasing demand from practitioners and patients for procedures and products accommodating minimally-invasive knee techniques. The Oxford® Unicompartmental Knee, which is a mobile-bearing unicondylar knee that utilizes a minimally-invasive technique, continues to experience strong global sales. The Oxford® Knee, which was introduced in the United States during fiscal year 2005, is currently the only free-floating meniscal unicompartmental system approved for use in the United States. The Company s offering of minimally-invasive unicondylar knee systems also includes the Alpina® Unicompartmental Knee, which is not currently available in the United States, and the Vanguard M Series Unicompartmental Knee System. The Vanguard M System is designed to accommodate surgeons who prefer a fully-instrumented, minimally-invasive unicondylar system, and incorporates a fixed-bearing tibial component to accompany the femoral component and instruments of the Oxford® Unicompartmental Knee System. The Repicci II® Unicondylar Knee System is specifically designed to accommodate a minimally-invasive knee arthroplasty procedure. This system incorporates self-aligning metal and polyethylene components. This innovative procedure can often be performed on an outpatient basis and requires a smaller incision and minimal bone removal, which may result in shorter recovery time and reduced blood loss.

During fiscal year 2005, the Company continued the global launch of primary components of Biomet s newest and most comprehensive knee system, the Vanguard Complete Knee System. The Vanguard System accommodates up to 145 degrees of flexion, while conserving more bone than competitive high-flex systems. The Vanguard System was launched in conjunction with Biomet s Microplasty® Minimally Invasive Total Knee Instrumentation, and will continue throughout fiscal year 2006. Microplasty® Total Knee Instruments also may be used in conjunction with the AGC®, Maxim® and Ascent Knee Systems. The Microplasty® Instrumentation is designed to reduce incision size and surrounding soft tissue disruption, which may provide reduced blood loss, a shortened hospital stay, reduced postoperative pain and less time spent in rehabilitation, as compared to a conventional procedure.

During fiscal year 2006, the Company intends to continue to focus development efforts on the completion of the rotating platform and revision options of the Vanguard Complete Knee System, as well as expansion of the Microplasty® Minimally Invasive instrument platform to include less invasive posterior referencing, anterior referencing, and image-guided options. In addition, the general launch of the Premier Instrumentation, as well as the introduction of the Vanguard Revision SSK (Super Stabilized Knee) System are planned to begin during fiscal year 2006. In Europe, the Company plans to continue the rollout of the ROCC (ROtating Concave Convex) Knee, a mobile-bearing total knee system.

The Maxim® Complete Knee System incorporates cruciate retaining, posterior stabilized and constrained components, and competes in both the primary and revision knee market segments. The Maxim® Knee System was the Company s largest-selling knee system during fiscal year 2005.

The Ascent Total Knee System incorporates an open box posterior stabilized femoral component with a swept-back anterior flange that can accept either a posterior stabilized or constrained tibial bearing. This system is designed with a deepened patella groove to enhance patellar tracking and contribute to reduced lateral release rates. The Ascent System addresses the needs of both the primary and revision markets. The Ascent Knee System also features an option

with a cruciate retaining primary series for those patients who do not require a posterior stabilized femoral component. The Biomet® Orthopaedic Salvage System (OSS) continues to gain market acceptance. This system provides modular flexibility while reducing overall inventory demands. The OSS System is used mainly in instances of severe bone loss and/or significant soft tissue instability as a result of multiple revision surgeries or oncological bone deficiencies.

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Hip Systems. A total hip replacement involves the replacement of the head of the femur and the acetabulum, and may occur as an initial joint replacement procedure, or as a revision procedure, which may be required to replace, repair or enhance the initial implant. A femoral hip prosthesis consists of a femoral head and stem, which can be cast, forged or wrought, depending on the design and material used. Acetabular components include a prosthetic replacement of the socket portion, or acetabulum, of the pelvic bone. Because of variations in human anatomy and differing design preferences among surgeons, femoral and acetabular prostheses are manufactured by the Company in a variety of sizes and configurations. The Company offers a broad array of total hip systems, most of which utilize titanium or cobalt chromium alloy femoral components and the Company s patented ArCom® and ArComXL polyethylene-lined or metal-on-metal acetabular components. Many of the femoral prostheses utilize the Company s proprietary porous plasma spray (PPS®) coating, which enables cementless fixation.

The Alliance® family of hip systems is designed to address the demand from hospitals and surgeon groups toward standardization of total hip systems. The Alliance® hip family provides the largest selection in the marketplace of primary and revision stems available for implantation with a single set of instruments. The Alliance® family of hip systems includes the Answer®, Bi-Metric®, Hip Fracture, Integral®, Intrigue , Reach® and Rx 90® Hip Systems. The Alliance® family was further augmented by introducing Exact Instrumentation, an integrated instrument set developed to promote intraoperative flexibility and increase the efficiency, simplicity and consolidation of instrument use.

The Mallory/Head® Hip System is designed for both primary and revision total hip arthroplasty procedures. The primary femoral components feature a specific proximal geometry for cementless indications and a slightly different proximal ribbed geometry for those patients requiring fixation with bone cement. The Mallory/Head® Revision Calcar components provide innovative solutions for difficult revision cases and have demonstrated excellent clinical results. The Mallory/Head® Calcar replacement prosthesis is offered in both a one-piece and modular geometry, which allows for individual customization at the time of surgical intervention, even in cases of severe bone deficiency. The modular version of the Mallory/Head® System incorporates the Company s patented roller hardened technology, which dramatically increases the strength of the modular connection.

The Company continues to explore the development of innovative articulation technologies and materials. Biomet s M^2a Metal-on-Metal Hip System combines a cobalt chrome head with a cobalt chrome liner and has demonstrated a 20- to 100-fold reduction in volumetric wear in simulator studies compared to traditional metal-polyethylene articulation systems. The M^2a-Taper Metal-on-Metal Articulation System may be utilized on all of Biomet s femoral components and has continued to evolve with the introduction of the M^2a-Magnum Hip Articulation System, which incorporates larger diameter metal-on-metal components designed to more closely resemble the natural anatomy, offering improved range of motion and joint stability. The C^2a-RingLoc Ceramic-on-Ceramic Articulation System, being sold in markets outside the United States, is currently in clinical studies within the United States. The Company is also developing the C^2a-Taper Ceramic-on-Ceramic Articulation System, which may be introduced during calendar year 2005, pending regulatory clearance. In addition, the Company is pursuing the development of a diamond-on-diamond hip articulation system through its relationship with Diamicron, Inc., a global leader in the research, development and manufacture of polycrystalline diamond composite technology for biomedical applications.

During fiscal year 2005, the Company introduced ArComXL , which is a second-generation highly crosslinked polyethylene bearing material based on the Company s proven ArCom® polyethylene. ArComXL polyethylene has demonstrated superior wear characteristics without measurable oxidation after accelerated aging. Biomet was the first orthopedic company to sell a second-generation highly crosslinked polyethylene material.

The Taperloc® Hip System is marketed for non-cemented use in patients undergoing primary hip replacement surgery as a result of noninflammatory degenerative joint disease. The Taperloc® femoral component is a collarless, flat, wedge-shaped implant that provides excellent durability and stability in a design that is relatively simple and predictable to implant. The incorporation of standard and lateralized offset options provides the surgeon with the ability to reconstruct a stable joint with proper leg length in virtually all patient anatomies.

Biomet s Microplasty® Minimally Invasive Hip Program is a comprehensive program including proprietary products from Biomet s broad array of hip products, as well as implants specifically designed for the Microplasty® Minimally Invasive Hip Program, a distinctive training program, and uniquely-designed instruments for a minimally-invasive approach. During the fourth quarter of fiscal year 2005, Biomet received regulatory clearance for the Balance®

Microplasty® Femoral Stem, the Company s first hip implant designed specifically for the Microplasty® Minimally Invasive Hip Program. In addition, the Company received clearance in July 2005 for a second porous femoral stem designed specifically for the Microplasty® Minimally Invasive Hip Program. During fiscal year 2005, the Taperloc® Hip System was the cornerstone of the Company s Microplasty® Minimally Invasive Hip Program. During fiscal years 2005 and 2004, more than 1,100 surgeons in the United States completed the Microplasty® Minimally Invasive Hip Training Program.

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The Company continues to enhance the development of the Microplasty® Minimally Invasive Hip Instruments. Biomet s minimally-invasive hip development efforts have been focused on various surgical approaches. Instruments relating to the posterior and anterior lateral approaches were introduced during fiscal year 2004 and instruments relating to additional approaches are scheduled for introduction during fiscal year 2006.

During fiscal year 2005, the ReCap® Total Resurfacing System was launched in 16 countries throughout Europe. The ReCap® Total Resurfacing System is a bone-conserving approach indicated for patients in the early stages of degenerative joint disease, including osteoarthritis, rheumatoid arthritis and avascular necrosis. The Company intends to commence a clinical study for the ReCap® Total Resurfacing System in the United States during fiscal year 2006.

The Company also provides constrained hip liners, which are indicated for patients with a high risk of hip dislocation. While the percentage of patients requiring a constrained liner is relatively small, surgeons often prefer to utilize a primary and revision system that includes this option.

The Company intends to continue development of several new hip products during fiscal year 2006, including porous metal technology and the Selex® Acetabular System. Biomet s porous metal technology provides design flexibility and solutions for difficult primary and revision cases. The Selex® Acetabular System is designed to continue the Company s heritage in creating bearing surfaces to optimize design features with a broad selection for all bearing materials. During fiscal year 2006, the Company intends to continue to develop implants related to the Microplasty® Minimally Invasive Hip Program.

Extremity Systems. The Company offers a variety of shoulder systems including the Absolute® Bi-Polar, Bi-Angular®, Bio-Modular®, Comprehensive®, Copeland , Integrated and Mosaic Shoulder Systems, as well as uniquely-designed elbow replacement systems.

The Copeland Humeral Resurfacing Head was developed to minimize bone removal in shoulder procedures and has over 17 years of positive clinical results in the United Kingdom. The modular Mosaic System is utilized to create a shoulder implant in complex revision and salvage/oncology procedures. The Discovery Elbow is a unique total elbow device that incorporates an ArCom® polyethylene molded bearing and condylar hinge mechanism designed to produce a more anatomic articulation than observed in simple hinged elbow implants. The iBP (Instrumented Bone Preserving) Elbow System is marketed in Europe and is designed to closely resemble the natural anatomy of the elbow to allow for a more complex pattern of movement than simple hinged implants.

During fiscal year 2006, the Company plans to roll out the ExploR Modular Radial Head Hemi-Elbow, a two-piece device comprised of a tapered stem paired with a head designed to articulate with the patient s natural bone. Also, in selected European markets, the Company plans to continue the introduction of T.E.S.S. (Total Evolutive Shoulder System), a complete shoulder system that can be used in all indications of a shoulder arthroplasty. The T.E.S.S. System allows for maximum preservation of bone due to its anatomical design and requires only one instrumentation system for implantation of all designs included in the system, regardless of the prosthesis used.

Dental Reconstructive Implants. Through its subsidiary, Implant Innovations, Inc. (3i), the Company develops, manufactures and markets products designed to enhance oral rehabilitation through the replacement of teeth and the repair of hard and soft tissues. These products include dental reconstructive implants and related instrumentation, bone substitute materials and regenerative products and materials. A dental implant is a small screw or cylinder, normally constructed of titanium, that is surgically placed in the bone of the jaw to replace the root of a missing tooth and provide an anchor for an artificial tooth. 3i s flagship product, the OSSEOTITE® product line, features a patented micro-porous surface technology, which allows for earlier loading and improved bone integration to the surface of the implant compared to competitive dental implants. The OSSEOTITE® Certain® implant system, which continued its rollout during fiscal year 2005, is an internally connected system that, through the use of the QuickSeat® connection, provides audible and tactile feedback when abutments and copings are seated into the implant. In addition, the 6/12 point connection design of the OSSEOTITE® Certain® implant system offers enhanced flexibility in placing the implant and abutment. 3i also offers the DIEM Immediate Occlusal Loading Guidelines as a reference for the use of specially-designed components and surgical tools that allows clinicians to offer the convenience of one-visit implant therapy to appropriate patients.

During fiscal year 2005, 3i launched the Provide Abutment Restoration System, which is designed to be more widely accepted by general dentists due to its ease of use.

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3i s offering of restorative treatment options also includes the GingiHue Post and the ZiReal Post. The GingiHue Post is a gold-colored titanium nitride coated abutment, which optimizes the projection of natural color to approximate the appearance of natural teeth. The ZiReal Post offers a highly aesthetic restorative option. This zirconia-based abutment provides the natural translucence of ceramic material, but with greater strength, durability and resistance to cracking than conventional aluminum oxide ceramic abutments. Both of these products may be used with conventional implant therapy.

Other Reconstructive Devices. Biomet s Patient-Matched Implant (PMI®) services group expeditiously designs, manufactures and delivers one-of-a-kind reconstructive devices to orthopedic specialists. The Company believes this service continues to enhance Biomet s reconstructive sales by strengthening its relationships with orthopedic surgeons and augmenting its reputation as a responsive company committed to excellent product design. In order to assist orthopedic surgeons and their surgical teams in preoperative planning, Biomet s PMI® group utilizes a three-dimensional (3-D) bone reconstruction imaging system. The Company uses computed tomography (CT) data to produce 3-D reconstructions for the design and manufacture of patient-matched implants. Biomet also provides anatomic physical models based on patient CT data. With this imaging and model-making technology, Biomet s PMI® group is able to assist the physician prior to surgery by creating 3-D models. Within strict deadlines, the model is used by engineers to create a PMI® design for the actual manufacturing of the custom implant for the patient.

The Company is involved in the ongoing development of bone cements and delivery systems. During fiscal year 2005, the Company continued to penetrate the domestic and European bone cement markets. The Generation 4® Bone Cement with VacPac® Delivery System is a proprietary, self-contained system designed to promote consistency and integrity of the cement, eliminate exposure to fumes during mixing, and reduce operating room time due to ease of the mixing and delivery process. The Company intends to globally broaden the range of its internally developed and manufactured bone cement product offering. For example, Cobalt Bone Cement, which was specifically developed for use in minimally-invasive surgery, is scheduled to be introduced in the United States during fiscal year 2006. The superior handling characteristics and high optical contrast of Cobalt Bone Cement are well suited to the current trends in orthopedic surgery. The Company intends to offer its internally developed and manufactured bone cements with and without antibiotic and intends to market them in conjunction with Biomet s patented Optivac® Vacuum Mixing System.

The Company is working to reduce its dependence on external suppliers of bone cements. Since June 1, 2000, the Company s primary supplier of bone cement, including Palacos® bone cement and Palacos® G bone cement, has been Heraeus Kulzer GmbH (Kulzer). Kulzer is obligated to supply the Company with bone cement in the United States through the end of calendar year 2005. On January 28, 2005, the Company announced the initiation of the development of its own advanced cement systems to retain its position as a market leader in the bone cement and accessories product category. During fiscal year 2005, the Company s sales of bone cement products supplied by external suppliers represented approximately 3% of the Company s consolidated sales.

Additional products and services for reconstructive indications include bone graft substitute materials and services related to allograft material. Calcigen® S calcium sulfate bone graft substitute is a self-setting paste used to fill bone voids. The Calcigen® PSI (Porous Synthetic Implant) Bone Graft System is a porous, calcium phosphate bone substitute material used as a bone void filler. The Company also provides services related to the supply of allograft material procured through several tissue bank alliances. Markets addressed by the Company s allograft services include the orthopedic and dental reconstructive market segments, as well as the spinal, craniomaxillofacial and arthroscopy segments.

The GPS® (Gravitational Platelet Separation) System, which is distributed by the Company s Cell Factor Technologies subsidiary, is a unique device that collects platelet concentrate from a small volume of the patient s blood using a fast, single spin process. The GPS® System offers a high quality platelet concentrate and has broad potential applications in the reconstructive and spine markets. The GPS® System is marketed in conjunction with the Biomet® Rapid Recovery Program, a comprehensive approach to patient education, a minimally-invasive surgical approach and pain management that was developed in conjunction with leading orthopedic surgeons in the United States.

During fiscal year 2005, Biomet continued the introduction of the Acumen® Surgical Navigation System to the global market, enhancing visualization for minimally-invasive and traditional procedures. During fiscal year 2005, the

Company received clearances from the FDA for the Acumen® Surgical Navigation System software for use with the Taperloc® Total Hip System and the Repicci II® Unicondylar Knee System. Procedure-specific software continues to be developed for the reconstructive and spinal markets. The Company anticipates receiving clearances from the FDA during fiscal year 2006 for the Acumen® Navigation System software for use with the Vanguard®, AGC® Performance®, Ascent® and Alpina® Total Knee Systems, as well as the Array®, Polaris®, EBI® Omega 21® and Synergy® Spinal Fixation Systems.

Palacos® is a registered trademark of Heraeus Kulzer GmbH.

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Fixation Devices

The Company s fixation products include electrical stimulation devices (that do not address the spine), external fixation devices, craniomaxillofacial fixation systems, internal fixation devices and bone substitute materials utilized in fracture fixation applications.

Electrical Stimulation Systems. The Company s subsidiary, EBI, L.P. (EBI), is the market leader in the electrical stimulation segment of the fixation market. The FDA has acknowledged EBI s extensive preclinical research documenting the Mechanism of Action for its pulsed electromagnetic field (PEMF), capacitative coupling and direct current technologies. The Mechanism of Action for these technologies involves the stimulation of a cascade of bone morphogenic proteins (BMPs), as well as angiogenesis, chondrogenesis and osteogenesis.

The EBI Bone Healing System® unit is a non-invasive bone growth stimulation device indicated for the treatment of recalcitrant bone fractures (nonunions), failed fusions and congenital pseudarthrosis that have not healed with conventional surgical and/or non-surgical methods. The non-invasive bone growth stimulation devices sold by EBI generally provide an alternative to surgical intervention in the management of these bony applications. The EBI Bone Healing System® units produce low-energy PEMF signals that induce weak pulsing currents in living tissues that are exposed to the signals. These pulses, when suitably configured in amplitude, repetition and duration, affect living bone cells to differentiate, migrate and proliferate. The Mechanism of Action behind the PEMF technology involves the stimulation of growth factors involved in normal bone healing. EBI s preclinical research demonstrates that PEMF signals increase a number of growth factors, such as TGF-ß, BMP-2 and BMP-4, which are normal physiological regulators of the various stages of bone healing, including angiogenesis, chondrogenesis and osteogenesis. The EBI Bone Healing System® unit may be utilized over a patient s cast, incorporated into the cast or worn over the skin.

The OrthoPak® Bone Growth Stimulation System, which is indicated for the treatment of recalcitrant (nonunion) fractures, offers a small, lightweight, non-invasive bone growth stimulator using capacitive coupling technology. The OrthoPak® System delivers bone growth stimulation through wafer-thin electrodes that add virtually no extra weight on the nonunion site. The Mechanism of Action behind EBI s capacitive coupling stimulation technology involves the stimulation of osteopromotive factors involved in normal bone healing, such as TGF-ß1 and PGE2. The OrthoPak® System provides greater ease of use and enhances access to fracture sites that are normally hard to treat.

EBI also offers an implantable option when bone growth stimulation is required subsequent to surgical intervention. The EBI OsteoGen® Surgically Implanted Bone Growth Stimulator is an adjunct treatment when bone grafting and surgical intervention are required to treat recalcitrant (nonunion) fractures in long bones. The Mechanism of Action behind EBI s direct current stimulation technology involves the stimulation of a number of osteoinductive growth factors including BMP-2, -6 and -7 and the BMP-2 receptor ALK2, which are normal physiological regulators of various stages of bone healing, including chondrogenesis and osteogenesis. In addition, electrochemical reactions at the cathode lower oxygen concentrations and increase pH.

During fiscal year 2005, a private company petitioned the U.S. Food & Drug Administration to reclassify noninvasive bone growth stimulators from Class III to Class II medical devices. The petition is directed at products, like those described above, that utilize electromagnetic fields to stimulate bone growth. Although the success of the petition is uncertain, the Company has registered its opposition to the petition. The outcome of the petition will most likely not be known for several years.

External Fixation Devices. External fixation is utilized for stabilization of fractures when alternative methods of fixation are not suitable. The Company s EBI subsidiary offers a complete line of systems that address the various segments of the trauma and reconstructive external fixation marketplace. The DynaFix® and DynaFix® Vision Systems are patented, modular external fixation devices intended for use in complex trauma situations involving upper extremities, the pelvis and lower extremities. EBI also has a full line of external fixation products for certain reconstructive procedures involving limb lengthening, fusion, articulated fixation and deformity correction applications.

Internal Fixation Devices. The Company s internal fixation devices include products such as nails, plates, screws, pins and wires designed to temporarily stabilize traumatic bone injuries. These devices are used by orthopedic surgeons to provide an accurate means of setting and stabilizing fractures and for other reconstructive procedures.

They are intended as aids to healing and may be removed when healing is complete. Internal fixation devices are not intended to replace normal body structures. During fiscal year 2004, the Company transferred its internal fixation business from Biomet Orthopedics to EBI, allowing the Company s full range of orthopedic fixation products to be distributed by EBI. The full implementation of this transition is expected to continue through fiscal year 2006.

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EBI develops, manufactures and distributes innovative products that fit into key segments of the fixation marketplace. The VHS® Vari-Angle Hip Fixation System is used primarily in the treatment of hip fractures. The components of the VHS® Vari-Angle Hip Fixation System can be adjusted intraoperatively, allowing the hospital to carry less inventory, while providing greater intraoperative flexibility to achieve the optimum fixation angle. The Holland Nail System is a single, universal trochanteric nail designed to treat all types of femoral (hip or thigh) fractures.

During fiscal year 2005, the Company introduced the EBI® Peritrochanteric Nail System, which incorporates an innovative single lag screw concept and is delivered through a trochanteric entry point. In conjunction with the VHS® System and the Holland Nail System, the EBI® Peritrochanteric Nail System will further augment the Company s product portfolio for hip fracture fixation treatment.

The EBI® Low Profile Tibial Nail, used to treat fractures between the knee and ankle, is primarily indicated in the treatment of unstable or nonunion fractures. The EBI® Ankle Arthrodesis Nail is designed for reconstructive procedures where internal fixation is the desired fixation option to achieve solid fusion of the ankle joint.

The Company has also implemented several projects in the area of locked plating designs. During fiscal year 2005, the Company introduced the OptiLock Distal Radius Plating System. The OptiLock System was designed using state-of-the-art locking technology and incorporates plates and screws that address volar, radial and dorsal plating applications. The Company intends to introduce the OptiLock Periarticular Plating System for lower extremity application during fiscal year 2006. Similar to the OptiLock Distal Radius Plating System, the OptiLock Periarticular System will incorporate anatomically designed plates with locking technology for femoral and tibial fracture and reconstructive procedures. During fiscal year 2006, the Company intends to continue to make innovate improvements in hip fracture, locked plating, external fixation and intramedullary fixation devices to enhance the Company s portfolio of fixation implants for the trauma marketplace.

Craniomaxillofacial Fixation Systems. The Company manufactures and distributes craniomaxillofacial, neurosurgical, and thoracic titanium and resorbable implants, along with associated surgical instrumentation, principally marketed to craniomaxillofacial, neurosurgical, plastic, ENT, pediatric and cardiothoracic surgeons through its subsidiary, Walter Lorenz Surgical, Inc. (Lorenz Surgical). Lorenz Surgical also offers specialty craniomaxillofacial surgical instruments, HTR-PMI® Hard Tissue Replacement material custom craniofacial implants and the Mimix® Bone Substitute Material for use in craniomaxillofacial and neurosurgical applications.

Lorenz Surgical manufactures and markets the LactoSorb® Fixation System of resorbable plates and screws comprised of a copolymer of poly-L-lactic acid and polyglycolic acid. As a result of its innovative design, the LactoSorb® System is comparable in strength to titanium plating systems at its initial placement and is resorbed within 9 to 15 months after implantation. The LactoSorb® System is especially beneficial in pediatric reconstruction cases by eliminating the need for a second surgery to remove the plates and screws.

Mimix® Bone Substitute Material is a synthetic tetra-calcium phosphate/tri-calcium phosphate material. This material is most commonly used for the repair of cranial defects and is currently offered in putty form. Mimix® QS, a quick-setting bone substitute material, provides surgeons with a faster-setting formulation. The Company intends to introduce the Mimix® MP (malleable putty) during fiscal year 2006. This version of the Mimix® material in malleable putty form is designed to improve handling properties of this self-setting bone void filling material.

Bone Substitute Materials. When presented with a patient demonstrating a bone defect, such as a fractured bone or bone loss due to removal of a tumor, the treating surgeon may remove a portion of bone from the patient at a second site to use as a graft to induce healing at the site of the defect. Bone substitute materials can eliminate the pain created at the graft site, as well as the costs associated with this additional surgical procedure. Depending on the specific use of the bone substitute material, it can have reconstructive, fixation or spinal applications.

Spinal Products

The Company s spinal products include electrical stimulation devices for spinal applications, spinal fixation systems, bone substitute materials and allograft services for spinal applications and the development of artificial disc replacement products.

Spinal Fusion Stimulation Systems. Spinal fusions are surgical procedures undertaken to establish bony union between adjacent vertebrae. EBI distributes both non-invasive and implantable electrical stimulation units that surgeons can use as options to provide an appropriate adjunct to surgical intervention in the treatment of spinal fusion

applications. EBI has assembled extensive preclinical research documenting the Mechanism of Action for the technology utilized in its spinal fusion stimulation systems.

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The EBI SpinalPak® Spine Fusion Stimulator utilizes capacitive coupling technology to encourage fusion incorporation. The Mechanism of Action behind the capacitive coupling stimulation technology involves the stimulation of osteopromotive factors that modulate normal bone healing, such as TGF-ß1 and PGE2. The unit consists of a small, lightweight generator worn outside the body that is connected to wafer-thin electrodes applied over the fusion site. The SpinalPak® System is patient friendly, enhancing comfort whether the patient is standing, sitting or reclining, and optimizes compliance with the treatment regimen to achieve fusion success.

EBI s surgically implanted SpF® Spinal Fusion Stimulator consists of a generator that provides a constant direct current to titanium cathodes placed where bone growth is required. The Mechanism of Action behind EBI s direct current stimulation technology involves the stimulation of a number of osteoinductive growth factors including BMP-2, -6 and -7 and the BMP-2 receptor ALK2, which are normal physiological regulators of various stages of bone healing, including chondrogenesis and osteogenesis. The SpF® Stimulator has exhibited a 50% increase in fusion success rates over fusions with autograft alone. A new, smaller SpF® Stimulator designed to enhance patient comfort and physician pre-implant testing and implantation is scheduled for launch during fiscal year 2006.

Spinal Fixation Systems. The Company markets fixation products for a variety of spinal fusion applications. The Array® Spinal System has a single, locking setscrew featuring spinal V-Force Thread Technology designed to enhance the intraoperative ease of use for the surgeon during system locking. In fiscal year 2005, EBI launched the Array® Deformity Spine System, which includes various styles of screws, hooks and rods for scoliosis correction. In the thoracolumbar fusion area, EBI markets the EBI® Omega 21 Spine System. This system features a unique multidirectional coupler and expandable screw. EBI also markets the SpineLink®-II Spinal Fixation System, which addresses many of the inherent limitations of traditional rod and plate systems by linking each spine segment individually for intrasegmental control. Through the use of a modular titanium link and polydirectional screw, this unique system provides an intrasegmental solution to spine fixation, enabling the surgeon to tailor the segmental construction to the patient s anatomy. The Company also offers a variety of spacer products for the thoracolumbar market segment. The Ionic® Spine Spacer System features an open design that allows for optimal bone graft placement and bone ingrowth, along with the additional benefit of excellent postoperative x-ray visualization. New products in this area include the ESL and Ibex Spine Systems. Both of these titanium implants are endplate-sparing designs reducing the risk of subsidence. In addition, both the ESL and Ibex Spine Systems are open to permit ample space for bone graft placement and growth. The ESL System, introduced during fiscal year 2005, features an elliptical shape offering optimal surface contact with the vertebral body endplates. The Ibex implant, which is scheduled for launch during fiscal year 2006, is curved to conform to the anatomical shape of the vertebral body. Additionally, the beveled corners of the Ibex implant facilitate ease of use for the surgeon during implantation.

For cervical applications, EBI s VueLock® Anterior Cervical Plate System offers surgeons several important benefits, including a one-step locking mechanism featuring a pre-attached expansive ring that eliminates the need for additional locking components, as well as a low profile that minimizes interference with anatomical soft tissue structures. In addition, the open design of the VueLock® System provides surgeons with enhanced visualization of the bone graft both during the actual surgical procedure and postoperatively on x-ray.

The Company also offers the C-Tek® Anterior Cervical Plate System, which offers a constrained, semi-constrained or a completely rigid construct, depending on the surgeon s preference. Made from titanium, the C-Tek® Anterior Cervical Plate System offers both fixed and variable screws in a wide variety of diameters and lengths. This System also features a unique locking mechanism to prevent screw back out. The C-Thru System is scheduled for release during fiscal year 2006 as a new and improved version of the C-Tek® Anterior Cervical Plate System. The C-Thru System offers the same basic design as the C-Tek® System, with the addition of viewing windows manufactured into the front of the plate for improved visualization both intraoperatively and postoperatively. For posterior cervical procedures, the Company offers the Altius M-INI System, which offers top loading, inner tightening, polyaxial screws as well as hooks for the cervico-thoracic spine. The Altius M-INI System features a 3.5mm rod and a wide variety of screws ranging in diameter from 3.5mm to 4.5mm. Occipital fixation is also available with the Altius M-INI System, featuring a low profile plate that is placed independently from the rod, allowing for easier assembly and less rod contouring.

Minimally-invasive spine surgery is of growing interest in the practice of many spine surgeons. Traditional, open surgical approaches to the spine for discectomy, fusion and fixation have brought with them lengthy postoperative healing and rehabilitation issues. A minimally-invasive approach to spine surgery has demonstrated less morbidity, minimal blood loss and further benefits such as a shorter hospital stay. In the minimally-invasive surgery market, EBI markets the VuePASS Portal Access Surgical System, which offers spine surgeons an optimized balance between the current limitations of competitive percutaneous systems and traditional successful open techniques. Under direct visualization for a posterior lumbar approach, the VuePASS system allows for traditional open techniques through a minimally-invasive access cannula system.

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The Synergy® Spinal System is a complete system, capable of addressing both low back and deformity indications. It is available in both stainless steel and titanium, offering 4.75mm and 6.35mm rod diameters, as well as a full complement of screws ranging from 4.0mm to 8.0mm in both fixed and polyaxial styles. The Synergy® Spinal System also contains a full offering of hooks in a wide variety of styles and sizes. The Company recently introduced the Polaris Spinal System, which is a top-loading, inner tightening thoracolumbar system utilizing a patented closing mechanism known as a helical flange. The helical flange feature helps prevent cross threading and seat splay, simplifying the implant closing procedure for the surgeon. Currently, the Polaris system is available in titanium in a 6.35mm rod diameter, with both fixed and polyaxial screws, ranging in size from 4.0mm to 7.0mm. The Company also markets the Structure System, which utilizes various kinds of fixation washers, used to secure screws to the vertebral body for an anterior screw/rod construct.

The Company also offers a variety of spine spacer products directed toward the thoracolumbar segment. The Geo Structure® Vertebral Body Replacement features various sizes and shapes, including ovals, straight rectangles and bent rectangles. The Geo Structure® implant is produced from cast titanium, offering a maximum amount of space inside the implant, with a minimum amount of material, resulting in excellent strength characteristics and imaging capabilities. The Vanguard Spinal System is a stand-alone device for anterior indications. The TPS System is a unique implant indicated for trauma and tumor pathologies of the thoracolumbar spine. The TPS System is designed as a combination of a plate and spacer that is expandable, allowing the surgeon to fit the implant to the defect.

The Osteoplasty System is designed to facilitate the delivery of materials into the bone through small incisions. The Osteoplasty System includes several different configurations, including the CDO , LP2 and DCD systems, each featuring a low-pressure system designed to deliver high viscosity material.

Bone Substitute Materials. Traditional spinal fixation surgery includes the use of a spinal fixation device in conjunction with a bone substitute or bone graft material to increase the likelihood of successful bone fusion. The OsteoStim® Resorbable Bone Graft Substitute material is a granular form of calcium phosphate that is resorbed and replaced with natural bone during the healing process. Pro Osteon® 200R and Pro Osteon® 500R are bone graft substitutes made from marine coral. Both are a resorbable combination of hydroxyapatite and calcium carbonate. Pro Osteon® 200R is available as granules. Pro Osteon® 500R is available in granules and blocks. The EBI® OsteoStim® DBM (Demineralized Bone Matrix) Putty, derived exclusively from human bone, can be used with a variety of substances, such as bone substitute material, machined allograft, autograft and platelet rich plasma, to enhance the surgeon s treatment options. EBI also has available the InterGro® line of DBM products (InterGro® Paste, InterGro® Putty and InterGro® Plus). The InterGro® DBM products use lecithin as a carrier. Lecithin is an entirely natural carrier that can be easily absorbed by the body. EBI also markets the OsteoStim® Skelite® Resorbable Bone Graft Substitute.

Precision Machined Allograft. Many spinal fusion procedures, in both the lumbar and cervical spine, involve interbody spinal fusion. Surgeons often utilize precision machined allograft spacers to fuse the interbody space. EBI provides services related to the OsteoStim® Cervical Allograft Spacer for anterior cervical interbody fusions, the OsteoStim® ALIF Allograft Spacer for anterior lumbar interbody fusions, and the OsteoStim® PLIF Allograft Spacer for posterior lumbar interbody fusions. All three systems are lordotic in shape, have serrated teeth on the top and bottom for added stability, are offered in various heights and have specific instrumentation to facilitate implantation.

Artificial Disc Replacement Products. The international clinical study for the lumbar version of EBI s Regain Artificial Disc, a one-piece pyrocarbon artificial disc nucleus replacement began during fiscal year 2005. The pyrocarbon material has a high level of strength, is biocompatible and extremely resistant to wear. An IDE study for the lumbar version of the Regain Disc is planned to begin in the United States during fiscal year 2006. The clinical study for the cervical version of Regain Artificial Disc is also scheduled to begin during fiscal year 2006. In addition, EBI is developing lumbar and cervical versions of the Rescue Total Disc Replacement product. The Company s development efforts in the artificial disc market are augmented as a result of the acquisition of Interpore and its Min T Artificial Disc project.

Other Products

The Company also manufactures and distributes several other products, including orthopedic support products (also referred to as softgoods and bracing products), arthroscopy products, operating room supplies, casting materials, general surgical instruments, wound care products and other surgical products. EBI manufactures and distributes an

extensive line of orthopedic support products under the EBI® Sports Medicine trade name. The Company manufactures and markets a line of arthroscopy products through its Arthrotek, Inc. (Arthrotek) subsidiary.

Skelite® is a registered trademark of Millenium Biologix, Inc.

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Arthroscopy Products. Arthroscopy is a minimally-invasive orthopedic surgical procedure in which an arthroscope is inserted through a small incision to allow the surgeon direct visualization of the joint. This market is comprised of five product categories: power instruments, manual instruments, visualization products, soft tissue anchors, and procedure-specific instruments and implants. Arthrotek s principal products consist of the CurvTek® Bone Tunneling System for the reattachment of soft tissue to bone, LactoSorb® resorbable arthroscopic fixation products, MaxBraid PE high strength suture material and the EZLoc Femoral Fixation Device for one-step passage and fixation of graft material. During fiscal year 2005, Arthrotek introduced the InnerVue Diagnostic Scope System, which utilizes a needle scope to diagnose knee and shoulder conditions in a physician s office.

Orthopedic Support Products. EBI distributes a line of orthopedic support products under the EBI® Sports Medicine name, including traction framing equipment, back supports, wrist and forearm splints, cervical collars, shoulder immobilizers, slings, abdominal binders, knee braces and immobilizers, rib belts, ankle supports and a variety of other orthopedic splints. Sales of these softgoods and bracing products are assisted by the Support-on-Site (S.O.S.SM) stock and bill program, which efficiently handles the details of product delivery for the healthcare provider. During fiscal year 2005, EBI introduced the Alliance OTS (off the shelf) Functional Knee Brace, a convenient choice for the post anterior cruciate ligament (ACL) reconstruction or ACL deficient patient. EBI also launched the Apex Shoulder Wedge, V-Loc Back Brace, Universal Hand Splint, and the Ascend® Stabilizer Ankle Brace. EBI is committed to continuing to expand its line of orthopedic support devices and intends to launch a variety of products during fiscal year 2006.

Product Development

The Company s research and development efforts are essentially divided into two categories: innovative new technology and evolutionary developments. Most of the innovative new technology development efforts are focused on biomaterial products, and are managed at the corporate level and take place primarily in Warsaw, Indiana and Darmstadt, Germany. Evolutionary developments are driven primarily by the individual subsidiaries and include product line extensions and improvements.

The Company continues to aggressively conduct internal research and development efforts to generate new marketable products, technologies and materials. In addition, the Company is well positioned to take advantage of external acquisition and development opportunities. An important component of the Company s strategy has been the formation of strategic alliances to enhance the development of new musculoskeletal products.

For the years ended May 31, 2005, 2004 and 2003, the Company expended approximately $79,676,000, $63,636,000, and $55,309,000, respectively, on research and development. It is expected that ongoing research and development expenses will continue to increase. The Company s principal research and development efforts relate to its reconstructive devices, electrical stimulation products, spinal fixation products, revision orthopedic reconstructive devices, dental reconstructive implants, arthroscopy products, resorbable technology, biomaterial products and image-guided software in the musculoskeletal products field.

The Company s research and development efforts have produced more than 500 new products and services during the last six fiscal years. During fiscal year 2006, the Company intends to release several new products, product line extensions and improvements.

Government Regulation

Most aspects of the Company s business are subject to some degree of government regulation in the countries in which its operations are conducted. It has always been the practice of the Company to comply with all regulatory requirements governing its products and operations and to conduct its affairs in an ethical manner. This practice is reflected in the Company s Code of Business Conduct and Ethics and the responsibility of the Audit Committee of the Board of Directors to review the Company s systems of internal control, its process for monitoring compliance with laws and regulations and its process for monitoring compliance with its Code of Business Conduct and Ethics. For some products, and in some areas of the world such as the United States, Canada, Japan and Europe, government regulation is significant and, in general, there appears to be a trend toward more stringent regulation throughout the world, as well as global harmonization of various regulatory requirements. The Company devotes significant time, effort and expense addressing the extensive government and regulatory requirements applicable to its business. Governmental regulatory actions can result in the recall or seizure of products, suspension or revocation of the

authority necessary for the production or sale of a product, and other civil and criminal sanctions. The Company believes that it is no more or less adversely affected by existing government regulations than are its competitors.

In the United States, the development, testing, marketing and manufacturing of medical devices are regulated under the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, the Safe Medical Devices Act of 1990, the FDA Modernization Act of 1997, the Medical Device User Fee and Modernization Act of 2002 and additional regulations promulgated by the FDA and various other federal, state and local agencies. In general, these statutes and regulations require that manufacturers adhere to certain standards designed to ensure the safety and efficacy of medical devices and related medical products.

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The Company believes it is well positioned to face the changing international regulatory environment. The International Standards Organization (ISO) has an internationally recognized set of standards aimed at ensuring the design and manufacture of quality products. A company that has passed an ISO audit and obtained ISO registration is internationally recognized as having quality manufacturing processes. The European Union requires that medical products bear a CE mark. The CE mark is an international symbol, which indicates that the product adheres to European Medical Device Directives. Compliance with ISO quality systems standards is one of the requirements for placing the CE mark on the Company s products. Each of the Company s products sold in Europe bears the CE mark.
In addition, governmental bodies in the United States and throughout the world have expressed concern about the costs relating to healthcare and, in some cases, have focused attention on the pricing of medical devices. Government regulation regarding pricing of medical devices already exists in some countries and may be expanded in the United States and other countries in the future. The Company is subject to increasing pricing pressures worldwide as a result of growing regulatory pressures, as well as the expanding predominance of managed care groups and institutional and governmental purchasers. Under Title VI of the Social Security Amendments of 1983, hospitals receive a predetermined amount of Medicare reimbursement for treating a particular patient based upon the patient s type of illness identified with reference to the patient s diagnosis under one or more of several hundred diagnosis-related groups (DRGs). Other factors affecting a specific hospital s reimbursement rate include the size of the hospital, its teaching status and its geographic location. The Company s orthopedic reconstructive products are primarily covered by DRG 209 (Major Joint and Limb Reattachment Procedures Lower Extremities), DRG 471 (Bilateral Major Procedures of the Lower Extremity) and DRG 491 (Major Joint and Limb Reattachment Procedures Upper Extremities), and have also received approval for pass-through coding under the Hospital Outpatient Prospective Payment System. Effective October 1, 2004, certain reimbursements for DRG payment were adjusted by the Center for Medicare and Medicaid Services (CMS). The payments for DRG 209, 471 and 491 increased 2.7%, 2.5% and 2.5%, respectively. The average DRG payments for spinal and trauma procedures increased 4.9% and 3.9%, respectively. On August 1, 2005, CMS announced the revised DRG rates, which will go into effect on October 1, 2005, as well as the creation of separate DRG categories for primary and revision procedures for the hip and knee. DRG 209 will be replaced by DRG 544 (Major joint replacement or reattachment of lower extremity) and DRG 545 (Revision of hip or knee replacement). The new reimbursement rates for DRG 544 and DRG 545 represent an increase of 0.1 % and 26.5%, respectively, over the previous DRG 209 rate. The reimbursement rates for DRG 471 and 491 are scheduled to increase 6.6% and 2.1%, respectively. In addition, the average reimbursement rates for spinal and trauma procedures are proposed to increase 5.0% and 4.5%, respectively.
While the Company is unable to predict the extent to which its business may be affected by future regulatory developments, it believes that its substantial experience in dealing with governmental regulatory requirements and restrictions throughout the world, its emphasis on efficient means of distribution and its ongoing development of new and technologically-advanced products should enable it to continue to compete effectively within this increasingly regulated environment.

Sales and Marketing

The Company believes that sales of its products are currently affected and will continue to be positively affected by favorable demographic trends and a shift toward a preference for technologically-advanced products. The demand for musculoskeletal products continues to grow, in part, as a result of the aging of the baby boomer population in the United States. The U.S. Census Bureau projections indicate that the population aged 55 to 75 years is expected to grow to approximately 66 million people by the year 2015. Moreover, the age range of potential patients is expanding outside the traditional 55 to 75 year range, as procedures are now being recommended for younger patients and as elderly patients are remaining healthier and more active than in past generations. The Company has also observed a trend toward a demand for technologically-advanced products that are simple to use and cost effective, while applying state-of-the-art solutions to the demands of the increasingly active patient. The Company believes it has firmly positioned itself as a surgeon advocate and has worked to promote the right of the surgeon to prescribe the medical treatment best suited to the needs of the individual patient.
The Company has diligently worked to attract and retain qualified, well-trained and motivated sales representatives. The breadth of the Company s product offering and the quality of its salesforces collaborate to create synergies that

uniquely position the Company to continue to efficiently penetrate the musculoskeletal market. In the United States, the Company s products are marketed by a combination of independent commissioned sales agents and direct sales representatives, based on the specific product group being represented. In Europe, the Company s products are promoted by a mixture of direct sales representatives, independent third-party distributors, and some independent commissioned sales agents, based primarily on the geographic location. In the rest of the world, the Company maintains direct selling organizations in approximately ten countries, as well as independent commissioned sales agents and independent third-party distributors in other key markets. In aggregate, the Company s products are marketed by more than 2,400 sales representatives throughout the world.

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Elective surgery-related products appear to be influenced to some degree by seasonal factors, as the number of elective procedures decline during the summer months and the winter holiday season.

The Company s customers are the hospitals, surgeons, other physicians and healthcare providers who use its products in the course of their practices. The business of the Company is dependent upon the relationships maintained by its distributors and salespersons with these customers, as well as the Company s ability to design and manufacture products that meet the physicians technical requirements at a competitive price.

For the fiscal years ended May 31, 2005, 2004 and 2003, the Company s foreign sales aggregated $641,223,000, $535,721,000 and $423,662,000, respectively, or 34%, 33% and 30% of net sales, respectively. Major international markets for the Company s products are Western Europe, Asia Pacific, Australia, Canada and Latin America. The Company s business in these markets is subject to pricing pressures and currency fluctuation risks. During fiscal year 2005, foreign sales were positively impacted by $36.6 million due to foreign currency translations. As the Company continues to expand in key international markets, it faces obstacles created by competition, governmental regulations and regulatory requirements. Additional data concerning net sales to customers, operating income, long-lived assets, capital expenditures and depreciation and amortization by geographic areas are set forth in Note L of the Notes to Consolidated Financial Statements included in Item 8 of this report and are incorporated herein by reference.

The Company has inventory located throughout the world with its customers, its distributors and direct salespersons for their use in marketing its products and in filling customer orders. As of May 31, 2005, inventory of approximately $162,464,000 was located with these distributors, salespersons and customers.

Competition

The business of the Company is highly competitive. Major competitors in the orthopedic reconstructive device market include DePuy, Inc., a subsidiary of Johnson & Johnson; Stryker Orthopaedics, a division of Stryker Corp.; Zimmer, Inc., a subsidiary of Zimmer Holdings, Inc.; and Smith & Nephew plc. Management believes these four companies, together with Biomet Orthopedics, have the predominant share of the global orthopedic reconstructive device market. Competition within the industry is primarily based on service, clinical results, and product design, although price competition is an important factor as healthcare providers continue to be concerned with costs. The Company believes that its prices for orthopedic reconstructive devices are competitive with those in the industry. The Company believes its future success will depend upon its service and responsiveness to its distributors and orthopedic specialists, the continued superior clinical results of its products, and upon its ability to design and market innovative and technologically-advanced products that meet the needs of the marketplace.

EBI s spinal fixation systems compete with other spinal fixation systems primarily on the basis of breadth of product line, product recognition and price. EBI s principal competitors in this area are Medtronic Sofamor Danek, Inc., a subsidiary of Medtronic, Inc.; DePuy Spine, a Johnson & Johnson company; Synthes, Inc.; Stryker Spine, a division of Stryker Corp.; Zimmer Spine, a subsidiary of Zimmer Holdings, Inc.; and others.

EBI s external fixation devices compete with other external fixation devices primarily on the basis of price, ease of application and clinical results. EBI s principal competitors in the external fixation market are Smith & Nephew plc; Stryker Trauma, a division of Stryker Corp.; Synthes, Inc.; and Orthofix, Inc., a subsidiary of Orthofix International N.V. The Company s internal fixation product lines compete with those of Synthes, Inc., DePuy, Inc., a Johnson & Johnson company; Zimmer, Inc., a subsidiary of Zimmer Holdings, Inc.; Smith & Nephew plc; and Stryker Trauma, a division of Stryker Corp.

EBI s electrical stimulation devices primarily compete with those offered by Orthofix, Inc., a subsidiary of Orthofix International N.V.; dj Orthopedics, LLC, a subsidiary of dj Orthopedics, Inc.; and Smith & Nephew plc. Competition in the electrical stimulation market is on the basis of product design, service, price and success rates of various treatment alternatives.

3i products compete in the areas of dental reconstructive implants and related products. Its primary competitors in the dental implant market include Nobel Biocare AB; Straumann AG; and Zimmer Dental, a subsidiary of Zimmer Holdings, Inc.

Lorenz Surgical primarily competes in the craniomaxillofacial fixation, specialty surgical instrumentation and neurosurgical cranial flap fixation markets. Its competitors include Synthes, Inc.; Stryker Leibinger Micro Implants, a division of Stryker Corp.; KLS-Martin, L.P.; and Osteomed Corp.

Arthrotek products compete primarily in the areas of procedure-specific implants and instruments, manual instruments and power instruments. Competitors include Smith & Nephew Endoscopy, a division of Smith & Nephew plc; Stryker Corp; Linvatec Corp., a subsidiary of CONMED Corporation; Mitek, a division of Ethicon, a Johnson & Johnson Company; Arthrocare Corp., and Arthrex, Inc.

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Raw Materials and Supplies

The raw materials used in the manufacture of the Company s orthopedic reconstructive devices are principally nonferrous metallic alloys, stainless steel and polyethylene powder. With the exception of limitations on the supply of polyethylene powder, none of the Company s raw material requirements are limited to any material extent by critical supply or single origins. The demand for certain raw materials used by the Company, such as cobalt alloy and titanium may vary. The primary buyers of these metallic alloys are in the aerospace industry. If the demands of the aerospace industry should increase dramatically, the Company could experience complications in obtaining these raw materials. However, based on its current relationship with its suppliers, the Company does not anticipate a material shortage in the foreseeable future. Further, the Company believes that its inventory of raw materials is sufficient to meet any short-term supply shortages of metallic alloys. The results of the Company s operations are not materially dependent on raw material costs.

EBI purchases all components of its electrical stimulators from approximately 120 outside suppliers, approximately 15 of whom are the single source of supply for the particular product. In most cases, EBI believes that all components are replaceable with similar components. In the event of a shortage, there are alternative sources of supply available for all components, but some time would likely elapse before EBI s orders could be filled.

Coral is the primary raw material utilized to manufacture certain of the Company s Pro Osteon® products. The coral used in Pro Osteon® products is sourced from two genera located in a variety of geographic locations. The Company s primary source of coral has historically been the tropical areas of the Pacific and Indian Oceans. Although the Company obtains its coral from a single source supplier, for which an alternate supplier has not been identified, the Company believes that it has an adequate supply of coral for the foreseeable future.

3i purchases all materials to produce its products from approximately 82 suppliers, approximately 26 of whom are the single source of supply for the particular product. 3i believes that, in the event of a shortage, there are readily available alternative sources of supply for all products, and maintains an inventory of materials sufficient to meet any short-term shortages of supply.

Employees

As of May 31, 2005, the Company s domestic operations (including Puerto Rico) employed approximately 4,060 persons, of whom approximately 2,060 were engaged in production and approximately 2,000 in research and development, sales, marketing, administrative and clerical efforts. The Company s international subsidiaries employed approximately 2,040 persons, of whom approximately 970 were engaged in production and approximately, 1070 in research and development, sales, marketing, administrative and clerical efforts. None of the Company s principal domestic manufacturing employees is represented by a labor union. The production employees at its Bridgend, South Wales facility are organized. Employees working at the facilities in Darmstadt and Berlin, Germany; Valence, France; and Valencia, Spain are represented by statutory Workers Councils which negotiate labor hours and termination rights. The Workers Councils do not directly represent such employees with regard to collective bargaining of wages or benefits. The Company believes that its relationship with all of its employees is satisfactory.

The establishment of Biomet s domestic reconstructive manufacturing operations in north central Indiana, near other members of the orthopedic industry, provides access to the highly skilled machine operators required for the manufacture of Biomet products. The Company s European manufacturing locations in South Wales, England, France, Spain, Sweden and Germany also provide good sources for skilled manufacturing labor. EBI s Puerto Rican operations principally involve the assembly of purchased components into finished products using a skilled labor force.

Patents and Trademarks

The Company believes that patents and other intellectual property will continue to be of importance in the musculoskeletal industry. Accordingly, management continues to protect technology developed internally and to acquire intellectual property rights associated with technology developed outside the Company. Management enforces its intellectual property rights consistent with the Company s strategic objectives. The Company does not believe that it has any single patent or license (or series of patents or licenses) that is material to its operations. The Company is not aware of any single patent, that if lost or invalidated, would be material to its consolidated revenues or earnings.

BIOMET, EBI, W . LORENZ, 3i, ARTHROTEK and INTERPORE CROSS are the Company s principal registered trademarks in the United States, and federal registration has been obtained or is in process with respect to various

other trademarks associated with the Company s products. The Company holds or has applied for registrations of various trademarks in its principal foreign markets. Unless otherwise noted in this report, all trademarks contained herein are owned by Biomet, Inc. or one of its affiliates.

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Risk Factors

The following factors, among others, could cause the Company s future results to differ from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect on the Company s business, financial condition and results of operations. The risks identified in this section are not exhaustive. The Company operates in a dynamic and competitive environment. New risk factors affecting the Company emerge from time to time and it is not possible for management to predict all such risk factors. Further, it is not possible to assess the impact of all risk factors on the Company s business or the extent to which any single factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Given these inherent risks and uncertainties, investors are cautioned not to place undue reliance on forward-looking statements as a prediction of actual results. In addition, the Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. The following discussion of the Company s risk factors speaks only as of the date on which they were made and should be read in conjunction with the consolidated financial statements and related notes included herein. Because of these and other factors, past financial performance should not be considered an indication of future performance.

The Company s future profitability depends on the success of the Company s principal product lines.

Sales of the Company s reconstructive products accounted for approximately 67% of the Company s net sales for the year ended May 31, 2005. The Company expects sales of reconstructive products to continue to account for a significant portion of the Company s aggregate sales. Any event adversely affecting the sale of reconstructive products may, as a result, adversely affect the Company s business, results of operations and financial condition.

If the Company is unable to continue to develop and market new products and technologies in a timely manner, the demand for the Company s products may decrease, or the Company s products could become obsolete, and the Company s revenue and profitability may decline.

The market for the Company s products is highly competitive and dominated by a small number of large companies. The Company is continually engaged in product development, research and improvement efforts, and new products and line extensions of existing products represent a significant component of the Company s growth rate. The Company s ability to continue to grow sales effectively depends on its capacity to keep up with existing or new products and technologies in the musculoskeletal products market. In addition, if the Company s competitors new products and technologies reach the market before the Company s products, they may gain a competitive advantage or render the Company s products obsolete. See Competition in Item 1 Business of this Form 10-K for more information about the Company s competitors. The ultimate success of the Company s product development efforts will depend on many factors, including, but not limited to, the Company s ability to create innovative designs, materials and surgical techniques; accurately anticipate and meet customers needs; commercialize new products in a timely manner; and manufacture and deliver products and instrumentation in sufficient volumes on time.

Moreover, research and development efforts may require a substantial investment of time and resources before the Company is adequately able to determine the commercial viability of a new product, technology, material or other innovation. Even in the event that the Company is able to successfully develop innovations, they may not produce revenue in excess of the costs of development and may be quickly rendered obsolete as a result of changing customer preferences or the introduction by the Company s competitors of products embodying new technologies or features.

The Company is subject to substantial government regulation that could have a material adverse effect on the Company s business.

Most aspects of the Company s business are subject to some degree of government regulation in the countries in which its operations are conducted. As discussed under the heading Government Regulation in Item 1 Business of this Form 10-K, for some products and in some areas of the world, such as the United States, Canada, Japan and Europe, government regulation is significant. Overall, there appears to be a trend toward more stringent regulation throughout the world. The Company does not anticipate this trend to dissipate in the near future. In addition, the medical device industry is subject to a myriad of complex laws governing Medicare and Medicaid reimbursements, and the U.S. Department of Health and Human Services has become increasingly vigilant in recent years with respect to investigations of various business practices. Further, as a publicly-traded company, the Company is subject to

increasingly demanding corporate and financial legislation in the United States, such as the Sarbanes-Oxley Act of 2002, which requires the time and attention of management and creates additional costs and expenses.

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In general, the development, testing, manufacture and marketing of the Company s products are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. The regulatory process requires the expenditure of significant time, effort and expense to bring new products to market. In addition, the Company is required to implement and maintain stringent reporting, labeling and record keeping procedures. The Company cannot assure that the relevant authorities will approve any of its products. Furthermore, governmental and regulatory act