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BIOMET INC  
Form 10-K  
August 22, 2003

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

(Mark One)

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

For the fiscal year ended May 31, 2003.

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 No. 0-12515.

BIOMET INC.

(Exact name of registrant as specified in its charter)

INDIANA  
(State of incorporation)

35-1418342  
(IRS Employer  
Identification No.)

56 EAST BELL DRIVE, WARSAW, INDIANA  
(Address of principal executive offices)

46582  
(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  
(Title of class)

RIGHTS TO PURCHASE COMMON SHARES  
(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  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 an accelerated filer (as

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defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes [X] No [ ]

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 29, 2002, as reported by The Nasdaq National Market, was approximately \$6,520,022,987. As of August 7, 2003, there were 256,391,095 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 2003 Annual Meeting of Shareholders of the Registrant	Part III

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### 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 expressions, and 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; the Company's intent and ability to expand its operations; 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 intent and ability to consummate acquisitions; the Company's continued investment in new products and technologies; the ultimate success of the Company's strategic alliances and joint ventures; 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 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 impact of the transfer of marketing responsibility for the Company's internal fixation products; 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 "Risk Factors" section of this report for a description of

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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. 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., an Indiana corporation incorporated in 1977 ("Biomet" or the

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"Company"), and its subsidiaries design, manufacture and market products used primarily by musculoskeletal medical specialists in both surgical and non-surgical therapy, including reconstructive and fixation devices, electrical bone growth stimulators, orthopedic support devices, operating room supplies, general surgical instruments, arthroscopy products, spinal products, bone cements and accessories, bone substitute materials, craniomaxillofacial implants and instruments, and dental reconstructive implants and associated instrumentation. 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.; BioMer CV (the Biomet Merck joint venture); 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.

The Company's annual reports on Form 10-K (for the four 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 on or may be accessed through the Investors Section of the Company's Internet website at [www.biomet.com](http://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 devices, fixation products, spinal products and other products. The Company has three reportable geographic markets: United States, Europe and Rest of World. Reconstructive devices include knee, hip and extremity joint replacement systems, as well as dental reconstructive implants, bone cements and accessories and the procedure-specific instrumentation required to implant the Company's reconstructive systems. Fixation products 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 orthobiologicals. The other product sales category includes softgoods and bracing products, arthroscopy products, casting materials, general surgical instruments, operating room supplies, wound care products and other surgical products. Depending on the intended application, the Company reports sales of bone substitute materials in the reconstructive device, fixation product or spinal product group.

The following table shows the net sales and percentages of total net sales contributed by each of the Company's product groups for each of the three most recent fiscal years ended May 31, 2003.

YEARS ENDED MAY 31,  
(DOLLAR AMOUNTS IN THOUSANDS)

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	2003		2002	
	NET SALES	PERCENT OF TOTAL NET SALES	NET SALES	PERCENT OF TOTAL NET SALES
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NET SALES				

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Reconstructive Devices	\$ 867,602	63%	\$ 721,004	60%	\$ 614,3
Fixation Products	237,117	17%	215,544	18%	202,1
Spinal Products	143,607	10%	125,119	11%	91,1
Other Products	141,974	10%	130,235	11%	123,1
Total	\$1,390,300	100%	\$1,191,902	100%	\$1,030,6

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RECONSTRUCTIVE DEVICES

Orthopedic reconstructive devices 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 extremities, 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. The Company's orthopedic reconstructive devices are sold through its Biomet Orthopedics, Inc. ("Biomet Orthopedics") subsidiary. Additionally, dental reconstructive devices and associated instrumentation are used for oral rehabilitation through the replacement of teeth and repair of hard and soft tissues.

**KNEE SYSTEMS.** Total knee replacement procedures normally include a femoral component, a patellar component, a tibial tray and an articulating surface. Total knee replacement may occur as an initial joint replacement procedure, or as a revision procedure due to the need 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 Repicci II(R) 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 less bone removal, which may result in shorter recovery time and reduced blood loss. The Oxford(TM) Phase 3 Unicompartmental Knee, which is a mobile-bearing unicondylar knee that utilizes a minimally-invasive technique, continues to experience strong sales outside the United States. The Company is currently seeking clearance from the U.S. Food and Drug Administration ("FDA") to market the Oxford(TM) Phase 3 Knee. During fiscal year 2003, the Company introduced the Vanguard(TM) Series Unicompartmental Knee System. The Vanguard(TM) 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(TM) Phase 3 Minimally-Invasive Unicompartmental Knee System.

The Maxim(R) Complete Knee System incorporates cruciate retaining, posterior stabilized and constrained components, and competes in both the primary and

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revision knee market segments. The Maxim(R) System continues to be the Company's largest-selling knee system.

The Ascent(TM) 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(TM) System addresses the needs of both the primary and revision markets.

The Biomet(R) 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 or significant soft tissue instability as a result of multiple revision surgeries or oncological bone deficiencies.

During fiscal year 2003, the Company received clearance from the FDA for the fixed-bearing cruciate-retaining and posterior-stabilized versions of the Vanguard(TM) Complete Knee Replacement System. During fiscal year 2004 the Company plans to complete the instrument design for these two versions of Biomet's newest and most comprehensive knee system, and begin development focus on the mobile-bearing and revision aspects of this system. Biomet is also planning to launch the Maxim(R) MI (minimally-invasive) instruments during fiscal year 2004. These instruments are designed for utilization with the Maxim(R) and the AGC(R) Knee Systems to reduce incision size, 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.

HIP SYSTEMS. Total hip replacement procedures involve 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 due to the need 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 machined 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(R) polyethylene-lined or metal-on-metal acetabular components. Many of the femoral prostheses utilize the Company's proprietary porous plasma spray (PPS(TM)) coating, which enhances the attachment of bone cement to the stem or enables cementless fixation.

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The Alliance(R) family of hip systems is designed to address the demand from hospitals and surgeon groups toward standardization of total hip systems. The Alliance(R) hip family provides the largest selection in the marketplace of primary and revision stems available for implantation with a single set of instrumentation. The Alliance(R) family of hip systems includes the Answer(R), Bi-Metric(R), Bio-Groove(R), Hip Fracture(TM), Integral(R), Intrigue(TM), Osteocap RS(R), Progressive(TM), RX90(TM) and Vision(R) Hip Systems. The Alliance(R) family was further augmented by introducing Exact(TM) Instrumentation, an integrated instrument set developed to promote intraoperative flexibility and increase the efficiency, simplicity and consolidation of instrument use.

The Mallory-Head(R) Hip System is designed for both primary and revision total hip arthroplasty procedures. The primary femoral components feature a specific

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proximal geometry for cementless indications and a slightly different proximal ribbed geometry for those patients requiring fixation with bone cement. The Mallery-Head(R) revision calcar components provide innovative solutions for difficult revision cases, and have demonstrated excellent clinical results. The Mallery-Head(R) 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 Mallery-Head(R) System incorporates the Company's patented roller hardened technology, which dramatically increases the strength of the modular connection.

Biomet's 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(2)a-Taper(TM) Metal-on-Metal Articulation System may be utilized on most of Biomet's femoral components and has continued to evolve with the introduction of the M(2)a-38(TM) Hip Articulation System, which incorporates larger diameter metal-on-metal components designed to offer increased range of motion and decrease the likelihood of hip dislocation. The Company is also developing a ceramic-on-ceramic articulation system, which is currently being marketed outside the United States and is in the patient-enrollment phase of a clinical trial in the United States.

The Taperloc(R) 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(R) 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.

During the second quarter of fiscal year 2003, Biomet Orthopedics commenced the distribution of its RingLoc(R) 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 revision system that includes this option. The Freedom(TM) Constrained Liner, scheduled for release during fiscal year 2004, offers an enhanced range of motion of 110(degree) and a wide series of options. Additional new hip products scheduled for release during fiscal year 2004 include hip instruments for the Microplasty (TM) Minimally Invasive Hip Program (posterior approach), a non-flared version of the M(2)a-38(TM) Hip Articulation System and the Generation 4(TM) Polished Hip System, a smooth, tapered stem designed to help distribute bone cement evenly around the implant thereby enhancing fixation.

**EXTREMITY SYSTEMS.** The Company offers a variety of shoulder systems including the Absolute(R) Bi-Polar, Bi-Angular(R), Bio-Modular(R), Copeland(TM), Integrated(TM) and Mosaic(TM) Shoulder Systems, as well as uniquely-designed elbow replacement systems.

The Copeland(TM) Humeral Resurfacing Head, was developed to minimize bone removal in shoulder procedures and has over 10 years of positive clinical results in the United Kingdom. The Discovery(TM) Elbow is a unique total elbow device that incorporates an ArCom(R) polyethylene molded bearing and condylar hinge mechanism designed to produce a more anatomic articulation than observed in simple-hinged elbow implants. The iBP(TM) (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. The modular Mosaic(TM) System is utilized to create a shoulder implant in complex revision and salvage/oncology procedures. During fiscal year 2003, Biomet introduced several new extremity products, including the Liverpool(TM) Radial Head Replacement implant for elbow reconstruction and

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the Comprehensive(TM) Shoulder System Fracture Stem, designed to repair and reconstruct the shoulder joint. Additionally, the AES(R) (Ankle Evolutive System) modular total ankle was launched in most European countries during fiscal year 2003.

**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(R) product line, features a patented micro-porous surface technology, which allows for earlier

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loading and improved bone integration to the surface of the implant compared to competitive dental implants. The OSSEOTITE NT(TM) (Natural Taper) Implant, introduced during fiscal year 2003, continues to gain increased market acceptance in the dental implant market. The tapered shape of the OSSEOTITE NT(TM) Implant, which resembles a natural root design, allows for immediate placement in extraction sockets and facilitates treatment of patients with convergent roots of adjacent teeth.

3i's offering of restorative treatment options also includes the GingiHue(TM) Post and the ZiReal(TM) Post. The GingiHue(TM) 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(TM) Post offers a highly aesthetic restorative option. This zirconia-based implant 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 crown and bridge techniques. Introduced during fiscal year 2003, the Calcigen(TM) Oral bone graft stabilizer is a resorbable calcium sulfate powder, which is designed for use with graft material as a binder or barrier in dental reconstructive applications.

**OTHER RECONSTRUCTIVE DEVICES.** Biomet's Patient-Matched Implant ("PMI(R)") 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(R) group utilizes a three-dimensional ("3-D") bone and soft tissue 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(R) 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(R) 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. The Company has successfully penetrated the domestic cement market with Palacos(R) Bone Cement, which is marketed primarily in conjunction with the Optivac(R) Vacuum Mixing System. During fiscal year 2003, Biomet Orthopedics introduced the Generation 4(R) Bone Cement with VacPac(R) Delivery System to the domestic market, where the product is experiencing excellent market acceptance.



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The VacPac(R) 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. During fiscal year 2003, Biomet submitted a 510(k) application to the FDA for Palacos(R) G Bone Cement with gentamicin antibiotic, which is currently marketed outside the United States.

Additional products and services for reconstructive indications include bone graft substitute materials and the distribution of allograft material. Calcigen(TM) S calcium sulfate bone graft substitute is a self-setting paste used to fill bone voids. The Calcigen(TM) PSI (Porous Synthetic Implant) Bone Graft System was introduced during fiscal year 2003, and is a porous, calcium phosphate bone substitute material. The Company also provides services related to the supply of allograft material procured through several tissue bank alliances. Biomet's VacPac(TM) System, initially designed for the vacuum mixing and delivery of bone cement, is also being utilized to package freeze-dried allografts. The flexible vacuum package allows rehydration with saline, blood or blood products inside the vacuum package. Markets being addressed by the distribution of the Company's allograft services include the orthopedic and dental reconstructive market segments, as well as the spinal and arthroscopy segments.

The GPS(TM) (Gravitational Platelet Separation) System, which is distributed by the Company's Cell Factor Technologies subsidiary, is a unique device that collects platelet concentrate (containing growth factors) from a small volume of the patient's blood using a fast, single spin process. The concentrate is then applied to the patient to promote acceleration of the body's natural healing process.

During fiscal year 2004, Biomet plans to introduce the Acumen(TM) Surgical Navigation System to the global market, enhancing visualization for minimally-invasive and traditional procedures. Procedure-specific software has been developed for reconstructive, fixation and spinal procedures. Clinical evaluations are scheduled to begin during fiscal year 2004.

### FIXATION PRODUCTS

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.

Palacos(R) is a registered trademark of Hereaus Kulzer GmbH.

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 EBI Bone Healing System(R) unit is a non-invasive option for the treatment of recalcitrant bone fractures (nonunions) which have not healed with conventional surgical and/or non-surgical methods. The non-invasive treatments sold by EBI generally provide an alternative to surgical intervention in the treatment of recalcitrant bone fractures, failed joint fusions and congenital pseudarthrosis. The EBI Bone Healing System(R) units produce low-energy pulsed electromagnetic field ("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

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bone cells. The EBI Bone Healing System(R) unit may be utilized over a patient's cast, incorporated into the cast or worn over the skin. In addition, the OrthoPak(R) Bone Growth Stimulation System offers a small, lightweight non-invasive bone growth stimulator using capacitive coupling technology. The OrthoPak(R) System provides greater ease of use and enhances access to fracture sites.

EBI also offers an implantable option when bone growth stimulation is required subsequent to surgical intervention. EBI's OsteoGen(TM) Totally Implantable Bone Growth Stimulator is an adjunct treatment when bone grafting and surgical intervention are required to treat a recalcitrant fracture.

**EXTERNAL FIXATION DEVICES.** External fixation is generally indicated to immobilize fractures when traditional casting is not a viable solution. The DynaFix(R) and DynaFix Vision(TM) Systems are patented devices for use in complicated trauma situations and in certain limb-lengthening and deformity correction applications. EBI also offers several other fixation systems addressing distal radius fractures and elbow fractures, as well as extensions to the DynaFix(R) and DynaFix Vision(TM) Systems designed to treat the varying and unique needs of practitioners and patients.

**INTERNAL FIXATION DEVICES.** The Company's internal fixation products include devices 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. They are intended as aids to healing and may be removed when healing is complete; they are not intended to replace normal body structures.

The VHS(R) Vari-Angle Hip Fixation System is a growing internal fixation product line for the Company. Its components can be adjusted intraoperatively, allowing the hospital to carry less inventory, while providing greater intraoperative selection of the optimum fixation angle. The Holland(TM) Nail System is a single universal nail designed to treat all types of femoral (hip or thigh) fractures. The Biomet(R) 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 Biomet(R) Ankle Arthrodesis Nail creates a solid fusion to correct ankle deformity.

During fiscal year 2003, the Company began to introduce the Quad 4(TM) Intramedullary Nail System to the domestic market. The Quad 4(TM) System requires approximately 50% less inventory than competitive systems and is uniquely designed to address the widest possible variety of femoral fractures.

**CRANIOMAXILLOFACIAL FIXATION SYSTEMS.** The Company manufactures and distributes craniomaxillofacial and neurosurgical titanium and resorbable implants, along with associated surgical instrumentation, principally marketed to craniomaxillofacial, neurosurgical and craniofacial surgeons through its subsidiary, Walter Lorenz Surgical, Inc. ("Lorenz Surgical"). Lorenz Surgical also offers specialty craniomaxillofacial surgical instruments, HTR-PMI(R) Hard Tissue Replacement material custom craniofacial implants and the Mimix(TM) Bone Substitute Material for use in craniomaxillofacial surgery.

Lorenz Surgical manufactures and markets the LactoSorb(R) Resorbable 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(R) 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(R) System is especially beneficial in pediatric reconstruction cases by eliminating the need for a second surgery to remove the plates and screws.

Mimix(TM) Bone Substitute Material is a synthetic tetra-calcium phosphate/tri-calcium phosphate material. This material is most commonly used

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for the repair of cranial defects, and is currently offered in putty form. Mimix(TM) QS, a quick-setting bone substitute material, was introduced during fiscal year 2003 to provide surgeons with a faster-setting formulation.

**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. During fiscal year 2003, the Company introduced Calcigen(TM) S (calcium sulfate) bone substitute material in granular and self-setting forms in the United States for orthopedic applications.

VHS(R) is a registered trademark of Implant Distribution Network, Ltd.

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### SPINAL PRODUCTS

The Company's spinal products include electrical stimulation devices for spinal applications, spinal fixation systems and bone substitute materials and allograft products for spinal applications.

**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's Spinal-Pak(R) Spine Fusion Stimulator utilizes capacitative coupling technology to encourage fusion incorporation. 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(R) System is patient friendly, enhancing comfort whether the patient is standing, sitting or reclining, and optimizing compliance with the treatment regimen to achieve fusion success. EBI's SpF(R) Implantable units each consist of a generator that provides a constant direct current to a titanium cathode placed where bone growth is required. EBI's implantable SpF(R)-PLUS Spinal Stimulation System, which was introduced during the fourth quarter of fiscal year 2003 and offers three times the current density at the cathode. The SpF(R) System has exhibited a 50% increase in fusion success rates over fusions with autograft alone.

**SPINAL FIXATION SYSTEMS.** The Company distributes a traditional rod and plate system under the trademark EBI(R) Omega 21(TM) Spine System. EBI also manufactures and markets the SpineLink(R) 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 SpineLink(R)-II Spinal Fixation System is a second generation SpineLink(R) product launched during fiscal year 2003 that combines the independent, intrasegmental concept of the SpineLink(R) System with a low-profile design, which simplifies point-to-point fixation for the surgeon. EBI's VueLock(R) 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

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interference with anatomical soft tissue structures. In addition, the open design of the VueLock(R) System provides surgeons with enhanced visualization of the bone graft both during the actual surgical procedure and post-operatively on x-ray. During fiscal year 2003, EBI began its launch of the VuePASS(TM) Portal Access Surgical System, which offers a minimally-invasive spinal fusion procedure option for use with the SpineLink(R)-II System. EBI also released the EBI(R) Ionic(TM) Spine Spacer System during fiscal year 2003. The open design of this system allows for optimal bone graft placement and bone ingrowth, along with the additional benefit of excellent postoperative x-ray visualization. The Company recently secured nonexclusive licenses on three patents for top-loading spine systems from Interpore Cross, which will allow EBI to enter the spinal deformity market in January 2004. In addition, EBI co-owns the patent covering Interpore Cross' GEO Structure(TM) System and the Company plans to develop and release a competitive device.

**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(R) resorbable bone graft substitute material is a granular form of calcium phosphate that is resorbed and replaced with natural bone during the healing process. During fiscal year 2003, EBI introduced its EBI(R) OsteoStim(R) DBM (Demineralized Bone Matrix) Putty. Derived exclusively from human bone, the putty 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. In addition, EBI began the launch of the OsteoStim(R) Skelite(TM) Resorbable Bone Graft Substitute during fiscal year 2003. EBI plans to begin clinical trials for the implantable EBI(R) Restore(TM) vertebral motion restoration product during fiscal year 2004. The one-piece design of the EBI(R) Restore(TM) product is intended to help in the restoration of the patient's normal spine motion, as well as helping to simplify the implant procedure and permitting more minimally-invasive approaches.

### 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(R) Sports Medicine trade name. The Company manufactures and markets a line of arthroscopy products through its Arthrotek, Inc. ("Arthrotek") subsidiary.

Skelite is a trademark of Millenium Biologix, Inc.

**ORTHOPEDIC SUPPORT PRODUCTS.** EBI distributes a line of orthopedic support products under the EBI(R) 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. The Alliance(TM) Knee Brace is a lightweight product, anatomically designed for each patient. The MD (multi-dimensional) Elbow Brace, with its dual-hinge adjustment to control range of motion, accommodates various treatment and rehabilitation plans. EBI is committed to continuing to expand its line of orthopedic support devices and

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introduced the Quick Fit(TM) Post-Op Knee Brace and the EBI(R) Fracture Walker with Range-of-Motion Option during fiscal year 2003.

**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(R) Bone Tunneling System for the reattachment of soft tissue to bone, LactoSorb(R) resorbable arthroscopic fixation products, CuffPatch(TM) soft tissue reinforcement material for rotator cuff repair, and the Bone Mulch(TM) Screw/WasherLoc(TM) Device for anterior cruciate ligament repair.

### 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, including the relationships forged with Organogenesis, Inc. and Z-KAT, Inc. during fiscal year 2002. The Company is working with Organogenesis to market orthopedic products incorporating Organogenesis' FortaFlex(TM) bio-engineered matrix technology, such as the CuffPatch(TM) rotator cuff repair product marketed by the Company's Arthrotek subsidiary. The Company is collaborating with Z-KAT to co-develop and distribute image-guided software and intelligent instrumentation for various musculoskeletal applications and techniques, including minimally-invasive procedures.

For the years ended May 31, 2003, 2002 and 2001, the Company expended approximately \$55,309,000, \$50,750,000, and \$43,020,000, 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, gene therapy technologies and image-guided software in the musculoskeletal products field.

The Company's research and development efforts have produced approximately 340 new products and services during the last four fiscal years, including the following new products and services introduced during fiscal year 2003: GPS(TM) Gravitational Platelet Separation System, ReCap(TM) Hemi Hip Resurfacing System, Mallory-Head(R) HA Coated Primary Stem, Microplasty Minimally Invasive Hip Program, RingLoc(R) II Constrained Liner, Ascent(TM) Anterior Stabilized Bearing Knee, Generation 4(R) Bone Cement with VacPac(R) Delivery System, Vanguard(TM) Series Unicompartmental Knee System, Quad 4(TM) Intramedullary Nail System, Comprehensive(TM) Fracture Stem, Liverpool(TM) Radial Head, Mosaic(TM) Humeral Replacement System, DynaFix(R) Hip Distractor, DynaFix(R) Radiolucent Rail, OptiROM(R) Posterior Approach System, EBI(R) Ionic(TM) Spine Spacer System, EBI(R) Osteo-Stim(R) ALIF Allograft Spacer System, EBI(R) OsteoStim(R) Demineralized Bone Matrix Putty, EBI(R) OsteoStim(R) Lordotic Cervical Allograft

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Spacer System, EBI(R) OsteoStim(R) PLIF Allograft Spacer System, EBI(R) VuePASS(TM) Portal Access Surgical System, SpF(R)-PLUS(TM) Spinal Fusion Stimulator, EBI(R) Fracture Walker with Range of Motion Option, Quick Fit(TM) Post-Op Knee Brace, Universal Wrist Splint, Allograft Cross Pin, CuffPatch(TM) Soft Tissue Reinforcement, LactoSorb(R) L-15 Cross Pin, Howell(TM) 65(degree) Tibial Guide with Coronal Rod, Mimix(TM) QS (Quick Set) Bone Substitute Putty, Calcigen(TM) PSI Bone Graft System, Calcibon(TM) Bone Substitute Granules, Calcibon(TM) Bone Substitute Paste, Mesofol(TM) Resorbable Anti-Adhesion Foil, PMI Beads (antibiotic carrier), Septodrain(R) Surgical Drain, Optigun(TM) Bayonet, Optigun(TM) Ratchet, Osteopal(R) V Vertebroplasty Cement, F40(TM) Hip Stem, Petroch(TM) Hip Stem, Performance(R) CrCo Tibia, Performance(R) Modular Tibial Tray, Performance(R) Tibial Stems with Offset, TMK(TM) Knee (Total Meniscal Knee), Cemento(TM) Vertebroplasty Cement Delivery System, OSSEOTITE NT(TM) Natural-Taper Implant and Calcigen(TM) Oral bone graft stabilizer.

FortaFlex is a trademark of Organogenesis, Inc.

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During fiscal year 2004, the Company intends to release other new products, including, but not limited to, the following products: Total Mandibular System, a top-loading universal spine system, a rod and coupler-based spine system, fixed-bearing cruciate-retaining and posterior-stabilized versions of the Vanguard(TM) Complete Knee Replacement System, Maxim(R) MI instruments, Freedom(TM) Constrained Liner, instruments for the Microplasty(TM) Minimally Invasive Hip Program (posterior approach), non-flared version of the M2a-38(TM) Hip Articulation System, Generation 4(TM) Polished Hip System, and the Acumen(TM) Surgical Navigation System.

### 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 conduct 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 conduct. 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. 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, 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.

The Company believes it is well-positioned to face the changing international regulatory environment. The International Standards Organization ("ISO") has an

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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 health care 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, 2002, certain reimbursements for DRG payment were adjusted. The payments for DRG 209, 471 and 491 increased 6.9% 5.8% and 6.7%, respectively. The average DRG payments for spinal and trauma procedures increased 5.7% and 5.8%, respectively. Additional increases in DRG reimbursement rates will also take effect on October 1, 2003. The payments for DRG 209, 471 and 491 will increase 1.6%, 2.3% and 4.0%, respectively. The average DRG payments for spinal and trauma procedures will increase 4.5% and 4.7%, 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 74.7 million by the year 2023. 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

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Company has also observed a trend toward a demand for technologically-advanced products that are simple to use and cost effective, while incorporating state-of-the-art solutions to the demands of the increasingly active patient. The Company has firmly positioned itself as the advocate of the surgeon 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 2,000 sales representatives throughout the world.

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 holiday seasons, with the exception of some elective pediatric procedures scheduled to coincide with school breaks.

The Company's customers are the hospitals, surgeons, other physicians and healthcare providers who employ 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, 2003, 2002 and 2001, the Company's foreign sales aggregated \$423,662,000, \$335,527,000 and \$308,292,000, respectively, or 30%, 28% 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 2003, foreign sales were positively impacted by \$16.4 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 K of the Notes to Consolidated Financial Statements included in Item 8 of this report and are incorporated herein by reference.

The Company consigns inventory throughout the world to its customers and to its distributors and direct salespersons for their use in marketing its products and in filling customer orders. As of May 31, 2003, inventory of approximately \$137,992,000 was consigned to 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 Howmedica Osteonics, a subsidiary of Stryker Corp.; Zimmer, Inc., a subsidiary of Zimmer Holdings, Inc.; Smith & Nephew plc and Centerpulse Orthopedics, a division of Centerpulse AG. Management believes these five companies, together with Biomet Orthopedics, have the predominant share of



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the 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.

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EBI's spinal fixation systems compete with those of Medtronic/Sofamor Danek, Inc., a subsidiary of Medtronic, Inc.; DePuy AcroMed Corporation, a subsidiary of Johnson & Johnson; Synthes, Inc.; Stryker Spine, a division of Stryker Corp.; Centerpulse Spine-Tech, Inc., a division of Centerpulse AG; Interpore International, 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 Corp.; Synthes, Inc. and Orthofix, Inc., a subsidiary of Orthofix International N.V. The Company's internal fixation product lines compete with those of DePuy ACE, a Johnson & Johnson company; Zimmer, Inc., a subsidiary of Zimmer Holdings, Inc.; Smith & Nephew plc; and Synthes, Inc.

EBI's electrical stimulation devices primarily compete with those offered by Orthofix, Inc., a subsidiary of Orthofix International N.V.; OrthoLogic Corp.; and Exogen, Inc., a subsidiary of Smith & Nephew plc. Competition in the electrical stimulation market is on the basis of product design, service 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 Straumann AG; Nobel Biocare AB and Centerpulse Dental, Inc., a subsidiary of Centerpulse AG.

Lorenz Surgical primarily competes in the craniomaxillofacial fixation and specialty surgical instrumentation and neurosurgical cranial flap fixation markets. Its competitors include Synthes, Inc.; Stryker-Leibinger, a subsidiary 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; Arthrex, Inc.; and Bionx Implants, Inc.

### 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

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Company believes that its inventory of raw materials is sufficient to meet any short-term supply shortages of metallic alloys.

EBI purchases all components of its electrical stimulators from approximately 250 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.

3i purchases all materials to produce its products from approximately 82 suppliers, approximately 21 of whom are the single source of supply for the particular product. 3i believes that, in the event of a shortage, there are alternative sources of supply for all products, and maintains an inventory of materials sufficient to meet any short-term shortages of supply. The results of the Company's operations are not materially dependent on raw material costs.

### EMPLOYEES

As of May 31, 2003, the Company's domestic operations (including Puerto Rico) employed approximately 3,400 persons, of whom approximately 1,770 were engaged in production and approximately 1,630 in research and development, sales, marketing, administrative and clerical efforts. The Company's international subsidiaries employed approximately 1,720 persons, of whom approximately 815 were engaged in production and approximately 905 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.

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The establishment of Biomet's domestic 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), which is material to its operations. The Company is not aware of any single patent, the loss or invalidity of which would be material to its consolidated revenues or earnings.

BIOMET, EBI, W'. LORENZ, 3i and ARTHROTEK are the Company's principal registered trademarks in the United States, and federal registration has been obtained or

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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.

### 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 update publicly 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 be not 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 63% of the Company's net sales for the year ended May 31, 2003. 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 legislation in the United States, such as the Sarbanes-Oxley Act of 2002.

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 actions against the Company can result in various actions that could adversely impact the Company's operations, including:

- o the recall or seizure of products;
- o the suspension or revocation of the authority necessary for the production or sale of a product;
- o the imposition of fines and penalties;
- o the delay of the Company's ability to introduce new products into the market; and
- o other civil or criminal sanctions against the Company.

THE COMPANY IS SUBJECT TO RISKS ARISING FROM CURRENCY EXCHANGE RATE FLUCTUATIONS, WHICH COULD INCREASE THE COMPANY'S COSTS AND MAY CAUSE THE COMPANY'S PROFITABILITY TO DECLINE.

During fiscal year 2003, sales of the Company's products in foreign markets approximated \$423,662,000, or 30% of the Company's total revenues. Accordingly,

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the U.S. dollar value of the Company's foreign-generated revenues varies with currency exchange rate fluctuations. Measured in local currency, the majority of the Company's foreign-generated revenues was generated in Europe. Significant increases in the value of the U.S. dollar relative to foreign currencies could have an adverse effect on the Company's results of operations. The Company's consolidated net sales were favorably affected by 3.2% during fiscal year 2003, and adversely impacted by 0.7% during fiscal year 2002 as a result of the impact of foreign currency translations. At the present time, the Company does not engage in hedging transactions to protect against uncertainty in future exchange rates between any particular foreign currency and the U.S. dollar.

SALES MAY DECLINE IF THE COMPANY'S CUSTOMERS DO NOT RECEIVE ADEQUATE LEVELS OF REIMBURSEMENT FROM THIRD-PARTY PAYORS FOR THE COMPANY'S PRODUCTS AND IF CERTAIN TYPES OF HEALTH CARE PROGRAMS ARE ADOPTED IN THE COMPANY'S KEY MARKETS.

In the United States, health care providers that purchase the Company's products generally rely on payments from third-party payors (principally federal Medicare, state Medicaid and private health insurance plans) to cover all or a portion of the cost of the Company's musculoskeletal products. In the event that third-party payors deny coverage or reduce their current levels of reimbursement, the Company may be unable to sell certain of its products on a profitable basis, thus adversely impacting the Company's results of operations. Further, third-party payors are continuing to carefully review their coverage policies with respect to existing and new therapies and can, without notice, deny coverage for treatments that may include the use of the Company's products.

In addition, some health care providers in the United States have adopted or are considering the adoption of a managed care system in which the providers contract to provide comprehensive health care for a fixed cost per person. Health care providers in a managed care system may attempt to control costs by authorizing fewer elective surgical procedures, including joint reconstructive surgeries, or by requiring the use of the least expensive implant available. In response to these, and other, pricing

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pressures, the Company's competitors may lower the prices for their products. The Company may not be able to match the prices offered by the Company's competitors, thus adversely impacting the Company's results of operations and prospects. Further, in the event that the United States considers the adoption of a national health care system in which prices are controlled and patient care is managed by the government, such regulation could have a material adverse effect on the Company's business, results of operations and financial condition.

Outside of the United States, reimbursement systems vary significantly from country to country. In the majority of the international markets in which the company's products are sold, government-managed health care systems mandate the reimbursement rates and methods for medical devices and procedures. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of the Company's products may decline. Many foreign markets, including Canada, and some European and Asian countries, have tightened reimbursement rates. The ability of the Company to continue to sell certain of its products profitably in these markets may diminish if the government-managed health care systems continue to reduce reimbursement rates.

THE COMPANY'S BUSINESS MAY BE HARMED AS A RESULT OF LITIGATION.

The Company's involvement in the manufacture and sale of medical devices creates exposure to significant risk of product liability claims, particularly in the United States. In the past, the Company has received product liability claims

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relating to the Company's products and anticipates that it will continue to receive claims in the future, some of which could have a negative impact on the Company's business. Additionally, the Company could experience a material design or manufacturing failure in its products, a quality system failure, other safety issues, or heightened regulatory scrutiny that would warrant a recall of some of the Company's products. The Company's existing product liability insurance coverage may be inadequate to satisfy liabilities the Company might incur. If a product liability claim or series of claims is brought against the Company for uninsured liabilities or in excess of the Company's insurance coverage limits, the Company's business could suffer and its results could be materially impacted.

In addition, the musculoskeletal products industry is highly litigious with respect to the enforcement of patents and other intellectual property rights. In some cases, intellectual property litigation may be used to gain a competitive advantage. The Company has in the past and may in the future become a party to lawsuits involving patents or other intellectual property. A legal proceeding, regardless of the outcome, could put pressure on the Company's financial resources and divert the time and effort of the Company's management.

A NATURAL OR MAN-MADE DISASTER COULD HAVE A MATERIAL ADVERSE EFFECT ON THE COMPANY'S BUSINESS.

The Company has nearly twenty manufacturing operations located throughout the world. However, a significant portion of the Company's products are produced at and shipped from its facility in Warsaw, Indiana. In the event that this facility were severely damaged or destroyed as a result of a natural or man-made disaster, the Company would be forced to shift production to its other facilities and/or rely on third-party manufacturers. Although the Company believes that it is adequately insured, such an event could have a material adverse effect on the Company's business, results of operations and financial condition.

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### EXECUTIVE OFFICERS OF THE REGISTRANT

The name, age, business background, positions held with the Company and tenure as an executive officer of each of the Company's executive officers are set forth below. No family relationship exists among any of the executive officers. Except as otherwise stated, each executive officer has held the position indicated during the last five years. Executive officers are elected annually by the Board of Directors to serve for one year and until their successors are elected, subject to resignation, retirement or removal.

Name, Age and Business Experience -----	Served as Executive Officer Since -----	Current P with the -----
DANE A. MILLER, PH.D., 57 President and Chief Executive Officer of the Company. Director of the Company since 1977.	1977	President Executive Director
NILES L. NOBLITT, 52 Chairman of the Board of the Company. Director of the Company since 1977.	1978	Chairman and Direc

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<p>CHARLES E. NIEMIER, 47 Senior Vice President - International Operations of the Company. Director of the Company since 1987.</p>	1984	Senior Vice President - International Operations and Director of the Company.
<p>GARRY L. ENGLAND, 49 Senior Vice President - Warsaw Operations of the Company.</p>	1987	Senior Vice President - Warsaw Operations of the Company.
<p>DANIEL P. HANN, 48 Senior Vice President, General Counsel and Secretary of the Company since June 1999; prior thereto, Vice President, General Counsel and Secretary of the Company. Director of the Company since 1989.</p>	1989	Senior Vice President, General Counsel and Secretary of the Company.
<p>JOEL P. PRATT, 49 Senior Vice President of the Company since June 1999 and President of Walter Lorenz Surgical, Inc. since January 2002; prior thereto, President of Arthrotek, Inc.</p>	1990	Senior Vice President of the Company and President of Walter Lorenz Surgical, Inc.
<p>GREGORY D. HARTMAN, 46 Senior Vice President - Finance and Chief Financial Officer of the Company since June 1999; prior thereto, Vice President - Finance and Chief Financial Officer of the Company.</p>	1991	Senior Vice President - Finance and Chief Financial Officer of the Company.
<p>JAMES W. HALLER, 46 Controller of the Company and Vice President - Finance of Biomet Orthopedics, Inc. since June 2001; prior thereto, Controller of the Company.</p>	1991	Controller of the Company and Vice President - Finance of Biomet Orthopedics, Inc.
<p>JERRY L. FERGUSON, 62 Vice Chairman of the Board of the Company since December 1997. Director of the Company since 1977.</p>	1994	Vice Chairman of the Board of the Company and Director of the Company.
<p>JAMES R. PASTENA, 52 Vice President of the Company since September 1998 and President of EBI, L.P.</p>	1998	Vice President of the Company and President of EBI, L.P.

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### ITEM 2. PROPERTIES.

The following are the principal properties of the Company:

FACILITY	LOCATION
<p>Corporate headquarters of Biomet, Inc.; manufacturing and research and development facility of Biomet Manufacturing Corp.; and distribution center and offices of Biomet Orthopedics, Inc.</p>	<p>Warsaw, Indiana</p>
<p>Administrative, manufacturing and distribution facility of EBI, L.P. and administrative offices of Electro-Biology, Inc.</p>	<p>(1) Parsippany, New Jersey (2) Parsippany, New Jersey</p>

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Manufacturing facility of EBI, L.P. and administrative offices of Biolectron, Inc.	Allendale, New Jersey
Manufacturing facility of EBI, L.P.	Marlow, Oklahoma
Administrative, manufacturing and distribution facility of Lorenz Surgical	Jacksonville, Florida
Office, manufacturing and distribution facility of Implant Innovations, Inc.	(1) Palm Beach Gardens, (2) Palm Beach Gardens,
Office and manufacturing facilities of Arthrotek, Inc.	(1) Ontario, California (2) Redding, California
Manufacturing facility of Biomet Fair Lawn L.P.	Fair Lawn, New Jersey
Office and manufacturing facility of Electro-Biology, Inc.	Guaynabo, Puerto Rico
Office, manufacturing and warehouse facility of Catheter Research, Inc.	Indianapolis, Indiana
Office, manufacturing and warehouse facility of Biomet Merck France Sarl	Valence, France
Office, manufacturing and warehouse facilities of Biomet Merck Deutschland GmbH	(1) Berlin, Germany (2) Berlin, Germany
Office and research and development facility of Biomet Merck Biomaterials GmbH	Darmstadt, Germany
Administrative offices of Biomet Merck and office and warehouse facility of Ortomed BV	Dordrecht, The Netherlands

- (1) Operations at this facility have ceased and the facility is being leased to other parties.
- (2) Includes 46,000 square feet of space in this facility that is subleased to other parties.

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FACILITY	LOCATION
Office and manufacturing facility of IQL	Valencia, Spain
Office, manufacturing and warehouse facilities of Biomet Merck Cementing Technologies AB	Sjoberg, Sweden
Manufacturing and administrative facilities of Biomet Merck Ltd.	(1) Bridgend, South Wales (2) Swindon, England

In addition, the Company maintains more than 30 offices and warehouse facilities in various countries, including Canada, Europe, Asia Pacific and Latin America. The Company believes that all of its facilities are adequate, well-maintained



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and suitable for the development, manufacture, distribution and marketing of all its products.

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### ITEM 3. LEGAL PROCEEDINGS.

In January 1996, a jury returned a verdict in a patent infringement matter against the Company and in favor of Raymond G. Tronzo ("Tronzo"), which in August 1998 was subsequently reversed and vacated by the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). The Federal Circuit then remanded the case to the District Court for the Southern District of Florida (the "District Court") for further consideration on state law claims only. On August 27, 1999, the District Court entered a final judgment of \$53,530 against the Company. Tronzo then appealed the District Court's final judgment with the Federal Circuit and in January 2001 the Federal Circuit reinstated a \$20 million punitive damages award against the Company while affirming the compensatory damage award of \$520. The Federal Circuit's decision was based principally on procedural grounds, and in March 2001 it denied the Company's combined petition for panel rehearing and petition for rehearing en banc. On November 13, 2001, the United States Supreme Court ("Supreme Court") denied the Company's petition to review the \$20 million punitive damage award against the Company given to Tronzo. The Company had previously recorded a one-time special charge during the third quarter of fiscal year 2001 of \$26.1 million, which represents the total damage award plus the maximum amount of interest that, as calculated by the Company, may be due under the award and related expenses. The Company has paid \$20.2 million out of escrow. On February 12, 2003 the Federal Circuit ruled that the Company does not owe post-judgment interest in connection with the damage award paid in this case. As a result of this favorable ruling, the Company recorded a pre-tax gain of approximately \$5.8 million in the third quarter of fiscal year 2003. Management considers this matter fully to be concluded.

In October 1997 and April 2000 the Company received subpoenas from the United States Department of Health and Human Services, Office of Inspector General ("HHS/OIG"), and the United States Attorney's Office for the Eastern District of Pennsylvania ("USAO") in conjunction with an investigation of a physician group, with which the Company had a relationship, under the Medicare laws. The subpoenas sought the production of documents referring or relating to Pennsylvania Hospital and Thomas Jefferson Hospital, (two of the Company's major hospital customers at that time in Philadelphia), a physician group practicing under the name Orthopaedic Reconstructive Associates and The Rothman Institute. The Company also is aware that its distributor servicing the hospitals received a similar subpoena. The Company does not itself submit claims to or receive reimbursements from Medicare with respect to its orthopedic reconstructive products, but the laws with respect to Medicare reimbursement prohibit any person from paying or offering to pay any direct or indirect remuneration intended to induce the purchase of products or services. Those laws are complex and can be broadly construed to cover a wide range of financial and business activities. During the time period covered by the subpoenas, the Company had research, product development, physician training, clinical follow-up and data collection relationships with The Rothman Institute. The Company has not been advised of the precise subject matter of the USAO and HHS/OIG investigation, but was advised by the USAO in May 2003 that it is not a target of the investigation. As a result, the Company believes it is unlikely that this matter will have a material impact on the Company's financial position or business operations.

There are various other claims, lawsuits, disputes with third parties,

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investigations and pending actions involving various allegations against the Company incident to the operation of its business, principally product liability and intellectual property cases. Each of these matters is subject to various uncertainties, and it is possible that some of these matters may be resolved unfavorably to the Company. The Company does not anticipate that the adverse outcome of these matters will result in a material loss. The Company establishes accruals for losses that are deemed to be probable and subject to reasonable estimate. Based on the advice of counsel to the Company in these matters, management believes that the ultimate outcome of these matters and any liabilities in excess of amounts provided will not have a material adverse impact on the Company's consolidated financial position or on its future business operations.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

Not Applicable.

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## PART II

### ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The following table shows the quarterly range of high and low sales prices for the Company's Common Shares as reported by The Nasdaq National Market for each of the three most recent fiscal years ended May 31. The approximate number of shareholders of record as of August 7, 2003 was 6,389.

	High	Low
2003		
Fourth	\$ 33.50	\$ 26.74
Third	30.50	26.42
Second	31.87	25.69
First	29.28	21.75
2002		
Fourth	32.68	25.18
Third	33.26	26.77
Second	33.74	24.33
First	34.36	25.06
2001		
Fourth	30.67	23.67
Third	27.83	20.46
Second	26.92	19.08
First	23.50	14.97

The Company paid cash dividends of \$0.10, \$0.09 and \$0.07 per share on July 15, 2002; July 27, 2001 and July 17, 2000, respectively.

On July 2, 2003, the Company announced a cash dividend of \$0.15, payable July 18, 2003, to shareholders of record at the close of business on July 11, 2003.

All market prices and dividend information have been adjusted to give

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retroactive effect to the three-for-two stock splits announced July 9, 2001 and July 6, 2000.

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### ITEM 6. SELECTED FINANCIAL DATA.

#### INCOME STATEMENT DATA

Years ended May 31,

(in thousands, except per share amounts)

	2003	2002	2001
Net sales .....	\$1,390,300	\$1,191,902	\$1,030,000
Cost of sales .....	407,295	332,727	290,000
<hr/>			
Gross profit .....	983,005	859,175	739,000
Selling, general and administrative expenses .....	501,191	437,731	370,000
Research and development expense .....	55,309	50,750	40,000
Other charges/(credits) .....	(5,800)	-	20,000
<hr/>			
Operating income .....	432,305	370,694	299,000
Other income, net .....	19,438	5,421*	10,000
<hr/>			
Income before income taxes and minority interest .....	451,743	376,115	310,000
Provision for income taxes .....	156,961	127,665	100,000
<hr/>			
Income before minority interest .....	294,782	248,450	210,000
Minority interest .....	8,081	8,710	10,000
<hr/>			
Net income .....	\$ 286,701	\$ 239,740	\$ 199,000
<hr/>			
Earnings per share:			
Basic .....	\$ 1.10	\$ .89	\$ .75
Diluted .....	1.10	.88	.75
<hr/>			
Shares used in the computation of earnings per share:			
Basic .....	259,493	268,475	268,475
Diluted .....	261,394	271,245	271,245
<hr/>			
Cash dividends paid per common share .....	\$ .10	\$ .09	\$ .09

#### BALANCE SHEET DATA

At May 31,

(in thousands)

	2003	2002	2001
Working capital .....	\$ 845,101	\$ 715,245	\$ 720,000

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Total assets .....	1,672,169	1,521,723	1,48
Long-term obligations, including redeemable preferred stock ...	-	-	
Shareholders' equity .....	1,286,134	1,176,479	1,14

o All share and per share data have been adjusted to give retroactive effect to the three-for-two stock splits declared on July 9, 2001 and July 6, 2000.

\* Other income, net for fiscal 2002 was adversely impacted by a \$9 million charge as a result of equity write-downs in marketable securities and other investments.

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### ITEM 7. MANAGEMENT'S DISCUSSION & ANALYSIS OF FINANCIAL CONDITION & RESULTS OF OPERATIONS.

#### OVERVIEW

This discussion should be read in conjunction with the Company's consolidated financial statements and the corresponding notes contained herein. The Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that are subject to certain risk factors, as described in this report under "Risk Factors" in Part I, Item 1 - "Business". The Company is engaged in the research, development, manufacturing and marketing of products used primarily by musculoskeletal medical specialists. The Company's primary products include reconstructive devices, dental reconstructive implants, bone cements and accessories, electrical bone growth stimulators, fixation devices, craniomaxillofacial implants, bone substitute materials, spinal products, softgoods and bracing products, arthroscopy products, operating room supplies and instruments. The Company has operations in over 30 countries and distributes its products in over 100 countries throughout the world. The solid growth experienced by the Company during fiscal year 2003 in both domestic and international markets is attributable to the Company's emphasis on technological advances through line extensions and new product introductions. In addition, growth in the patient population (as a result of increases in both the size of the elderly population and the expansion of the traditional age bracket of musculoskeletal patients) has contributed to this growth.

The following table shows the percentage relationship to net sales of items derived from the Consolidated Statements of Income and the percentage change from year to year.

	Percentage of Net Sales			P Incre 200 VS. 20
	2003	2002	2001	
Net sales .....	100.0%	100.0%	100.0%	17%
Cost of sales .....	29.3	27.9	28.7	22
-----				
Gross profit .....	70.7	72.1	71.3	14
Selling, general and administrative expenses .....	36.0	36.7	36.3	14
Research and development expense .....	4.0	4.3	4.2	9
Other charges/(credits) .....	(0.4)	-	2.5	n/m
-----				
Operating income .....	31.1	31.1	28.3	17

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Other income, net .....	1.4	0.5	1.9	258
-----				
Income before income taxes and minority interest ....	32.5	31.6	30.2	20
Provision for income taxes .....	11.3	10.8	10.3	23
-----				
Income before minority interest .....	21.2	20.8	19.9	19
Minority interest .....	0.6	0.7	0.7	(7)
-----				
Net income .....	20.6%	20.1%	19.2%	20%
=====				

n/m - Not Meaningful

### FISCAL 2003 COMPARED TO FISCAL 2002\*

Net Sales - Net sales increased 17% during the current fiscal year to \$1,390,300,000 from \$1,191,902,000 in 2002. Excluding the positive impact of foreign currency translation adjustments (3.2%), net sales increased 14%. Worldwide sales of reconstructive devices increased 20% to \$867,602,000 in fiscal year 2003 compared to \$721,004,000 in 2002. Contributing to this increase was approximately 4% due to currency translation, 3% from pricing and 13% from incremental volume and product mix. Worldwide hip and bone cement sales increased 23% during the current year, while knee sales increased 18%, extremities sales increased 16% and dental reconstructive product sales increased 19%.

Fixation sales increased 10% during fiscal 2003 to \$237,117,000 from \$215,544,000 in 2002. Contributing to this increase was approximately 1% due to currency translation, 1% from pricing and 8% from incremental volume and product mix. Worldwide sales of internal fixation devices increased 13%, external fixation devices increased 7%, electrical stimulation devices increased 6%, and craniomaxillofacial products including bone substitutes increased 21%.

Spinal sales increased 15% to \$143,607,000 in fiscal 2003 compared to \$125,119,000 in 2002. Contributing to this increase was approximately 1% due to currency translation, 2% from pricing and 12% from incremental volume and product mix. Worldwide sales of spinal stimulation products increased 13%, while spinal hardware including bone substitutes increased 18%.

Sales of the Company's other products increased 9% to \$141,974,000 in fiscal 2003 from \$130,235,000 in 2002. Contributing to this increase was approximately 2% due to currency translation, 1% from pricing and 6% from incremental volume and product mix. Worldwide sales of arthroscopy products increased 16%, softgoods and bracing products increased 8% and general surgical instrumentation increased 12%.

Sales in the United States increased 13% to \$966,638,000 during the current fiscal year compared to \$856,375,000 last year. Components of this increase were incremental volume and product mix (9%) and positive pricing environment (4%). European sales increased 28% to

\* For purposes of this Management's Discussion and Analysis, the fiscal period is June 1 - May 31.

### MANAGEMENT'S DISCUSSION & ANALYSIS OF FINANCIAL CONDITION & RESULTS OF OPERATIONS (CONTINUED)

\$332,053,000 during the current fiscal year from \$260,420,000 in 2002.

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Components of this increase were positive currency translation (13%), incremental volume and product mix (13%) and positive pricing environment (2%). The Company anticipates foreign currency translations to positively influence sales during fiscal 2004. Sales in Rest of World increased 22% to \$91,609,000 this year from \$75,107,000 last year. Components of this increase were incremental volume and product mix (18%) and positive pricing environment (4%). The Company commenced direct sales of its products in Japan during fiscal 2002 which accounted for about half of this increased product demand.

Gross Profit - The Company's gross profit increased 14% to \$983,005,000 in fiscal 2003 from \$859,175,000 in 2002. The gross profit margin decreased to 70.7% of sales in fiscal 2003 compared to 72.1% in 2002. On a country-by-country basis, the Company improved gross margins through higher selling prices, improved manufacturing efficiencies and general cost controls, but due to the lower margins received on international sales and the higher growth rate on international sales compared to domestic sales, the consolidated gross margin decreased.

Selling, General and Administrative Expenses - Selling, general and administrative expenses increased 14% in fiscal 2003 to \$501,191,000 compared to \$437,731,000 last year. This increase is primarily a result of increased commission expense on higher sales compared to last year. As a percent of sales, selling, general and administrative expenses were 36.0% in fiscal 2003 compared to 36.7% in 2002. Factors contributing to this decrease include eliminating the amortization of goodwill (approximately \$7.2 million) and an overall slower growth rate for expenditures, partially offset by increased liability insurance premiums. Due to tighter insurance markets, the Company anticipates its cost for liability insurance coverage to increase during fiscal 2004.

Other charges/(credits) - On February 12, 2003, the United States Court of Appeals for the Federal Circuit ruled that the Company did not owe post-judgment interest in connection with the damage award paid in the Tronzo case. As a result of this favorable ruling, the Company recorded a pre-tax gain of approximately \$5.8 million during the third quarter (See Note L in the Notes to Consolidated Financial Statements).

Research and Development Expense - Research and development expense increased 9% during the current year to \$55,309,000 compared to \$50,750,000 in 2002. This increase reflects the Company's continued emphasis on new product development, enhancements and additions to existing product lines and technologies, and clinical outcomes research related to the safety, efficacy and clinical performance of the Company's products. As a percent of sales, research and development expenses were 4.0% in fiscal 2003 compared to 4.3% in 2002.

Operating Income - Operating income increased 17% during fiscal 2003 to \$432,305,000 from \$370,694,000 in 2002. U.S. operating income increased 19% to \$388,841,000 from \$326,906,000, reflecting solid sales growth for higher-margin product lines. European operating income increased 7% to \$41,924,000 compared to \$39,152,000 in 2002. This growth reflects solid sales growth in Europe, lower gross margins, higher selling expenses and improved foreign currency translation. Rest of World operating income decreased to \$1,540,000 in fiscal 2003 from \$4,636,000 in 2002 due to start up expenses associated with establishing direct operations in Japan and Brazil for the orthopedic and dental reconstructive businesses, respectively.

Other Income, Net - Other income, net increased during the current year to \$19,438,000 from \$5,421,000 in 2002. During the fourth quarter of last year, the Company recorded a pre-tax charge of \$9 million as a result of equity write-downs in Selective Genetics, Inc. and other marketable securities. The loss in value of these investments was considered other than temporary. Excluding these write-downs, other income, net increased 35% as a result of higher cash and investment balances, partially offset by lower investment

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yields.

Provision for Income Taxes - The provision for income taxes increased to \$156,961,000, or 34.7% of income before income taxes for fiscal 2003 compared to \$127,665,000 or 33.9% of income before income taxes last year. This increase is due to income growing faster in countries with higher tax rates, changes in the U.S. tax code which, over time reduce the historical U.S. tax benefits from operating in Puerto Rico and various state tax rate increases. The Company expects these tax increases to continually increase its effective rate in future years and anticipates its effective rate to be 34.8% in 2004.

Net Income - The factors mentioned above resulted in a 20% increase in net income to \$286,701,000 for fiscal 2003 from \$239,740,000 in 2002. These factors and the reduction in the shares used in the computation of earnings per share through the Company's share repurchase programs resulted in a 24% increase in basic earnings per share for 2003 to \$1.10 compared to \$0.89 in 2002.

### FISCAL 2002 COMPARED TO FISCAL 2001

Net Sales - Net sales increased 16% during fiscal 2002 to \$1,191,902,000 from \$1,030,663,000 in 2001. Excluding the negative impact of foreign currency translation (0.7%) and discontinued products (1.3%) and the positive impact of acquisitions (2.6%), net sales increased 15% during fiscal 2002. Worldwide sales of reconstructive devices increased 17% to \$721,004,000 in fiscal 2002 compared to \$614,308,000 in 2001 (16% excluding acquisitions). Worldwide hip sales increased 16% during fiscal 2002. Worldwide knee sales increased 18% in fiscal 2002. The Company's 3i division experienced a 17% increase in dental reconstructive implant sales.

Fixation sales increased 7% during fiscal 2002 to \$215,544,000 from \$202,152,000 in 2001. Fixation sales growth was positively influenced by 2% from the inclusion of Bioelectron's OrthoPak(R) Stimulation System for the whole fiscal year compared to eight months for fiscal 2001. Worldwide sales of internal fixation devices increased 8% and external fixation devices increased 6% in fiscal 2002. Worldwide sales of electrical stimulation systems increased 14%. Sales of Lorenz Surgical's craniomaxillofacial products experienced a 14% decrease compared to fiscal 2001.

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### MANAGEMENT'S DISCUSSION & ANALYSIS OF FINANCIAL CONDITION & RESULTS OF OPERATIONS (CONTINUED)

Spinal sales increased to \$125,119,000 in fiscal 2002 compared to \$91,103,000 in fiscal 2001, an increase of 37%. Spinal sales growth was positively influenced by 13% from the inclusion of Bioelectron's SpinalPak(R) Fusion Stimulation System for the full fiscal year compared to eight months for fiscal 2001. In addition, Biomet Merck discontinued distributing a spinal product line that resulted in a 3% decrease in spinal sales. Excluding the effect of these events, spinal product sales increased 27% for fiscal 2002.

Sales of the Company's other products increased 6% to \$130,235,000 in fiscal 2002 from \$123,100,000 in 2001. These results include discontinued general surgery products distributed in Portugal through Biomet Merck. Excluding the effects of this discontinuation, other product sales increased 14% during the year. Products posting sales growth include EBI's softgoods and bracing products, and Arthrotek's procedure-specific products. Products experiencing sales decreases include Lorenz Surgical's surgical instrumentation.

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Sales in the United States increased 19% to \$856,375,000 during fiscal 2002 compared to \$722,372,000 in 2001. This is due largely to increased product demand and continued market penetration (14%) and positive pricing environment (5%). Foreign sales increased 9% to \$335,527,000 in fiscal 2002 from \$308,291,000 in 2001. Excluding the effect of currency translation, foreign sales increased 11%. Foreign sales continued to be negatively influenced by the expiration and non-renewal of the distribution agreement with the Company's Japanese distributor of Biomet products during fiscal 2001. However, the Company commenced direct sales in Japan during fiscal 2002.

Gross Profit - The Company's gross profit increased 17% to \$859,175,000 in fiscal 2002 from \$734,600,000 in 2001. The gross profit margin increased to 72.1% of sales in fiscal 2002 compared to 71.3% in 2001. The improved gross margin was attributable to increased sales of higher margin reconstructive and spinal products worldwide and improved manufacturing efficiencies and general cost controls at the Company's European operations.

Selling, General and Administrative Expenses - Selling, general and administrative expenses increased 17% in fiscal 2002 to \$437,731,000 compared to \$374,793,000 in 2001. This increase was a result of increased commission expense on higher sales compared to the previous year. As a percent of sales, selling, general and administrative expenses were 36.7% in fiscal 2002 compared to 36.3% in 2001. Factors contributing to this increase include reorganization costs at Lorenz Surgical (approximately \$2 million); costs associated with a direct selling operation and expanded marketing presence in Japan (approximately \$3 million); inclusion of Bioelectron operations for a full fiscal year, including amortization of goodwill (approximately \$1.5 million); and continued expansion of the Company's worldwide salesforces.

Research and Development Expense - Research and development expense increased 18% during fiscal 2002 to \$50,750,000 compared to \$43,020,000 in 2001. As a percent of sales, research and development expenses were 4.3% in fiscal 2002 compared to 4.2% in 2001. This increase reflects the Company's continued emphasis on new product development, enhancements and additions to existing product lines and technologies, and clinical outcomes research related to the safety, efficacy and clinical performance of the Company's products.

Operating Income - Operating income increased 28% during fiscal 2002 to \$370,694,000 from \$290,687,000 in 2001. Excluding the \$26.1 million charge in 2001 for the Tronzo litigation, operating income increased 17%. U.S. operating income increased 30% to \$326,906,000 from \$251,927,000, reflecting solid sales growth for higher-margin product lines. Non-U.S. operating income increased 13% to \$43,788,000 compared to \$38,760,000 in 2001. This growth reflects solid foreign sales growth, effective cost controls and improved foreign currency translation.

Other Income, Net - Other income, net decreased 73% during fiscal 2002 to \$5,421,000 from \$19,989,000 in 2001. During the fourth quarter of fiscal 2002, the Company recorded a pre-tax charge of \$9 million as a result of equity write-downs in Selective Genetics, Inc. and other marketable securities. The loss in value of these investments was considered other than temporary. Excluding these write-downs, other income, net declined 28% as a result of lower interest rates on lower cash balances during fiscal 2002.

Provision for Income Taxes - The provision for income taxes increased to \$127,665,000, or 33.9% of income before income taxes in fiscal 2002 compared to \$105,906,000 or 34.1% of income before income taxes in 2001. This percentage decrease was due to income growing faster in countries with a lower tax rate. These benefits are partially offset by changes in the Puerto Rican local tax structure, which, over time reduce the historical U.S. tax benefits from operating in Puerto Rico. As a result of various state tax law changes, the Company expects its effective rate to increase in future years.



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Net Income - The factors mentioned above resulted in a 21% and 20% increase in net income and basic earnings per share, respectively, for 2002 compared to 2001. Net income increased to \$239,740,000 from \$197,546,000 and basic earnings per share increased to \$.89 from \$.74.

### LIQUIDITY & CAPITAL RESOURCES

The Company's cash and investments increased to \$418,594,000 at May 31, 2003, from \$386,517,000 at May 31, 2002. Net cash from operating activities was \$310,277,000 in fiscal 2003 compared to \$184,237,000 in 2002. The principal sources of cash from operating activities were net income of \$286,701,000 and non-cash charges of depreciation and amortization of \$45,659,000. The principal uses of cash include increases in accounts and notes receivable of \$35,144,000. Accounts receivable balances continue to increase as the Company continues to expand its direct selling operations in countries where it traditionally sold to distributors, and as it experiences sales growth.

Cash flows used in investing activities were \$19,697,000 in fiscal 2003 compared to \$77,419,000 in 2002. The primary uses of cash for investing activities were purchases of investments, offset by sales and maturities of investments, and capital expenditures. Major capital expenditures for the year were expansion of facilities at key manufacturing sites in Indiana and Florida, as well as a new office building for the joint venture operations in Europe.

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### MANAGEMENT'S DISCUSSION & ANALYSIS OF FINANCIAL CONDITION & RESULTS OF OPERATIONS (CONTINUED)

Cash flows used in financing activities were \$222,808,000 in fiscal 2003 compared to \$188,923,000 in 2002. The primary uses of funds during the current year were the share repurchase programs, in which \$219,184,000 was used to purchase 8,127,000 Common Shares of the Company, and a cash dividend of \$0.10 per share was paid on July 15, 2002 to shareholders of record on July 8, 2002. The source of funds from financing activities was proceeds on the exercise of stock options. On July 2, 2003, the Company's Board of Directors announced a cash dividend of \$0.15 per share payable on July 18, 2003 to shareholders of record at the close of business on July 11, 2003. Additionally, the Board of Directors authorized the purchase of up to an additional \$100 million and 2,000,000 shares of the outstanding Common Shares of the Company in two separate repurchase programs. The Company maintains its cash and investments in money market funds, certificates of deposit, corporate bonds, debt instruments, mortgage-backed securities and equity securities. The Company's investments are generally liquid and investment grade. The Company is exposed to interest rate risk on its corporate bonds, debt instruments, fixed rate preferred equity securities and mortgage-backed securities.

Pursuant to the terms of the Joint Venture Agreement with Merck KGaA ("Merck"), the Company granted Merck a put option whereby Merck has the right to elect to require the Company to purchase all, but not less than all, of Merck's interest in the BioMer C.V. ("BioMer"). Merck may exercise the put option by giving notice to the Company at any time during (a) the period beginning on May 1, 2001, and ending on May 10, 2008, or (b) a period of 180 days following receipt by Merck of notice from the Company that a "change of control" of the Company (as defined in the Joint Venture Agreement) has occurred prior to May 1, 2023.

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The put exercise price, which is payable in cash, is the greater of (i) a formula based on earnings of BioMer and multiples of comparative public companies, as defined in the Joint Venture Agreement, or (ii) the net book value of all the assets of BioMer less all liabilities of BioMer multiplied by Merck's 50% ownership percentage in BioMer. The put option formula is a mechanism whereby the Company would pay a fair market purchase price for Merck's 50% ownership interest in BioMer. If Merck chooses to exercise its put option in the future, at the time of exercise the transaction could be deemed a material transaction for the Company; however, management believes that the transaction could be funded out of the Company's current operations and, given the Company's current cash position and the strength of its balance sheet, the transaction should not negatively impact the financial strength of the Company or its ongoing operations. As of the close of the Company's most recently completed fiscal quarter, the net book value purchase price of BioMer would be approximately \$110 million, which may or may not reflect the fair market purchase price at the time of closing the put transaction, should it occur.

The Company anticipates that its use of cash for capital expenditures in fiscal 2004 will be at least as high as 2003 and 2002. The Company is currently expanding its EBI manufacturing site, as well as its Japanese and European operations. The Company intends to pursue strategic acquisition candidates. The Company is confident about the growth prospects in these areas and intends to invest in an effort to improve its worldwide market position. The Company expects to spend in excess of \$230 million over the next two fiscal years for capital expenditures and research and development costs, including the research projects with Z-Kat, Selective Genetics and Organogenesis to develop products and technologies that further enhance musculoskeletal procedures. Funding of these and other activities is expected to come from currently available funds and cash flows generated from future operations. The Company has no off-balance sheet financial arrangements and no material long-term contractual financial obligations.

### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of its financial position and results of operations are based upon the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. The Company's significant accounting policies are discussed in Note B of the Notes to Consolidated Financial Statements. In management's opinion, the Company's critical accounting policies include allowance for doubtful accounts, excess and obsolete inventories, non-marketable securities, goodwill and intangible assets and accrued insurance.

**Allowance for Doubtful Accounts** - The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required which would affect our future operating results.

**Excess and Obsolete Inventory** - In our industry, consigned inventory is routinely used to provide the healthcare provider with the appropriate product when needed. Because of the bell curve of product used, larger and smaller sizes of inventory are provided but infrequently used. In addition, the musculoskeletal market is highly competitive with new products, raw materials and procedures being introduced continually, which may obsolete products currently on the market. The Company must make estimates regarding the future use of these products and provides a provision for excess and obsolete inventories. If actual product life-cycles, product demand or market conditions

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are less favorable than those projected by management, additional inventory write-downs may be required which would affect future operating results.

Non-Marketable Securities - Periodically, the Company makes strategic investments in companies whose stock is not currently traded on a major stock exchange. The cost method of accounting is used to account for these investments as the Company holds a non-material ownership percentage and does not participate in management of such companies. Each quarter the Company assesses the value of these investments by using information acquired from industry trends, the management of these companies

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### MANAGEMENT'S DISCUSSION & ANALYSIS OF FINANCIAL CONDITION & RESULTS OF OPERATIONS (CONCLUDED)

and other external sources. Based on the information acquired, the Company records an investment impairment charge when it is believed an investment has experienced a decline in value that is other than temporary. In the fourth quarter of fiscal 2002, the Company recorded an impairment charge of \$5.5 million for its investment in Selective Genetics (current carrying value of \$0.5 million). Future adverse changes in market conditions or poor operating results of underlying investments could result in losses or an inability to recover the carrying value of the investments that may possibly require additional impairment charges in the future.

Goodwill and Other Intangible Assets - In assessing the recoverability of the Company's intangibles, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. If these estimates or their related assumptions change in the future, the Company may be required to record impairment charges for these assets.

Accrued Insurance - As noted in Note L of the Notes to Consolidated Financial Statements, the Company has a self-insured retention against product liability claims with insurance coverage over and above the retention. There are various other claims, lawsuits, disputes with third parties, investigations and pending actions involving various allegations against the Company. Product liability claims are routinely reviewed by the Company's insurance carrier and management routinely reviews other claims for purposes of establishing ultimate loss estimates. In addition, management must determine estimated liability for claims incurred but not reported. Such estimates and any subsequent changes in estimates may result in adjustments to our operating r