BIOMET INC Form 424B3 August 21, 2009 Table of Contents

PROSPECTUS SUPPLEMENT

(to prospectus dated May 20, 2009 and the prospectus supplements dated

June 26, 2009, July 14, 2009 and August 7, 2009)

Filed Pursuant to Rule 424(b)(3) Registration No. 333-150655

BIOMET, INC.

\$775,000,000 10% Senior Notes due 2017

\$775,000,000 10³ /8%/11¹/8% Senior Toggle Notes due 2017

\$1,015,000,000 11⁵/8% Senior Subordinated Notes due 2017

This prospectus supplement updates and supplements the prospectus dated May 20, 2009 and the prospectus supplements dated June 26, 2009, July 14, 2009 and August 7, 2009.

See Risk Factors beginning on page 12 of the prospectus for a discussion of certain risks that you should consider before investing in the notes.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

This prospectus supplement and the accompanying prospectus have been prepared for and may be used by Goldman, Sachs & Co. and any affiliates of Goldman, Sachs & Co. in connection with offers and sales of the notes related to market-making transactions in the notes affected from time to time. Goldman, Sachs & Co. or its affiliates may act as principal or agent in such transactions, including as agent for the counterparty when acting as principal or as agent for both counterparties, and may receive compensation in the form of discounts and commissions, including from both counterparties, when it acts as agents for both. Such sales will be made at prevailing market prices at the time of sale, at prices related thereto or at negotiated prices. We will not receive any proceeds from such sales.

RECENT DEVELOPMENTS

We have attached to this prospectus supplement the Annual Report on Form 10-K of Biomet, Inc. dated August 21, 2009. The attached information updates and supplements Biomet, Inc. s Prospectus dated May 20, 2009 and the prospectus supplements dated June 26, 2009, July 14, 2009 and August 7, 2009.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not authorized any person to provide you with any information or represent anything about us or this offering that is not contained in this prospectus supplement and the accompanying prospectus. If given or made, any such other information or representation should not be relied upon as having been authorized by us. This prospectus supplement and the accompanying

prospectus does not offer to sell nor ask for offers to buy any of the securities in any jurisdiction where it is unlawful, where the person making the offer is not qualified to do so, or to any person who cannot legally be offered the securities. You should not assume that the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate as of any date other than the date on the front cover of this prospectus supplement and the accompanying prospectus or the date of any document incorporated by reference herein.

The date of this prospectus supplement is August 21, 2009.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended May 31, 2009.

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. 001-15601.

BIOMET, INC.

(Exact name of registrant as specified in its charter)

Indiana (State or other jurisdiction of

35-1418342 (I.R.S. Employer

incorporation or organization)

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: None

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

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

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 x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes "No"

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer " Accelerated filer " Accelerated filer " Smaller reporting company) Smaller reporting company "
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes " No x

As of November 30, 2008, the last business day of the registrant s most recently completed second fiscal quarter, there was no established public trading market for any of the common stock of the registrant. As of August 21, 2009, there were 1,000 shares of common stock of the registrant outstanding, all of which were owned by LVB Acquisition, Inc.

DOCUMENTS INCORPORATED BY REFERENCE

None.

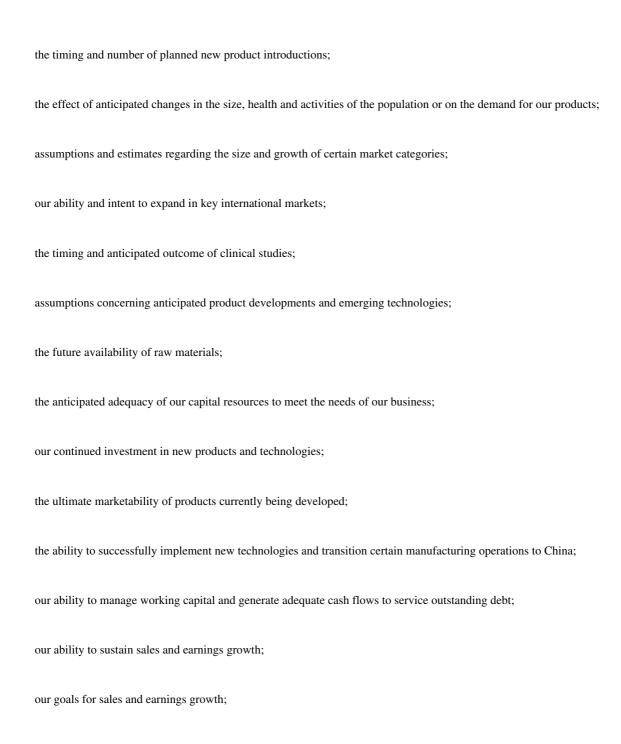
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FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of the U.S. federal securities laws. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. Forward-looking statements include statements generally preceded by, followed by or that include the words believe, could, expect, forecast, intend, may, anticipate, plan, predic project, potential, estimate, should, will or similar expressions. These statements include, but are not limited to, statements related to:



our success in achieving timely approval or clearance of our products with domestic and foreign regulatory entities; our success in implementing our value creation and operational improvement programs; the stability of certain foreign economic markets; the impact of anticipated changes in the musculoskeletal industry and our ability to react to and capitalize on those changes; our ability to successfully implement desired organizational changes; the impact of our managerial changes; and our ability to take advantage of technological advancements. Forward-looking statements reflect our current expectations and are not guarantees of performance. These statements are based on our management s beliefs and assumptions, which in turn are based on currently available information. Important assumptions relating to these forward-looking statements include, among others, assumptions regarding demand for our products, expected pricing levels, raw material costs, the timing and cost of planned capital expenditures, proposed regulatory reforms affecting the health care industry, expected outcomes of pending litigation and regulatory matters, the solvency of our insurers and the ultimate resolution of allocation and coverage issues with those insurers, competitive conditions and general economic conditions. Readers of this annual report are cautioned that reliance on any forward-looking statement involves risks and uncertainties. Although we believe 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 annual report will prove to be accurate. The inclusion of a forward-looking statement in this annual report should not be regarded as a representation by us that our objectives will be achieved. Forward-looking statements also involve risks and uncertainties, which could cause actual results to differ materially from those contained in any forward-looking statement. Many of these factors are beyond our ability to control or predict and could, among other things, cause actual results to differ from those contained in forward-looking statements made in this annual report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, financial condition, results of operations and cash flows and may include, but are not limited to, factors discussed under the heading Risk Factors and the following: changes in general economic conditions and interest rates; changes in the availability of capital and financing sources; changes in competitive conditions and prices in our markets; changes to the regulatory environment for our products, including national health care reform; the effects of incurring a substantial amount of indebtedness under our senior secured credit facilities, our senior notes, senior toggle notes and senior subordinated notes;

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senior notes, senior toggle notes and senior subordinated notes;

the effects upon us of complying with the covenants contained in our senior secured credit facilities and the indentures governing our

restrictions that the terms and conditions of our senior secured credit facilities may place on our ability to respond to changes in our business or take certain actions;

changes in the relationship between supply of and demand for our products;

fluctuations in costs of raw materials and labor;

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changes in other significant operating expenses; decreases in sales of our principal product lines; slow downs or inefficiencies in our product research and development efforts; increases in expenditures related to increased government regulation of our business; developments adversely affecting our sales activities outside the United States; decreases in reimbursement levels by our customers; difficulties in transitioning certain manufacturing operations to China; challenges in effectively implementing restructuring and cost saving initiatives; increases in cost-containment efforts by group purchasing organizations; loss of our key management and other personnel or inability to attract such management and other personnel; increases in costs of retaining existing independent sales agents of our products; unanticipated expenditures related to litigation, including investigations by the U.S. Department of Justice and the SEC; and failure to comply with the terms of the Corporate Integrity Agreement. We caution you not to place undue reliance on these forward-looking statements that speak only as of the date they were made. We do not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date of this annual report or to reflect the occurrence of unanticipated events.

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Part I.

Item 1. Business. General

Biomet, Inc., an Indiana corporation incorporated in 1977, is one of the largest orthopedic medical device companies in the United States and worldwide with operations in more than 50 locations throughout the world and distribution in approximately 90 countries. The Company s principal subsidiaries include Biomet Orthopedics, LLC; Biomet Manufacturing Corp.; Biomet Europe Ltd.; EBI, LLC; Biomet 3i, LLC; Biomet International Ltd.; Biomet Microfixation, LLC; Biomet Sports Medicine, LLC; and Biomet Biologics, LLC. Unless the context requires otherwise, the term Biomet, Company, we, our, or us refers to Biomet, Inc. and all of its subsidiaries. We design, manufacture and market a comprehensive range of both surgical and non-surgical products used primarily by orthopedic surgeons and other musculoskeletal medical specialists. For over 30 years, we have applied advanced engineering and manufacturing technology to the development of highly durable joint replacement systems.

Our reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge in, or may be accessed through, the Financial Information section of our website at www.biomet.com as soon as reasonably practicable after we file or furnish such material with or to the Securities and Exchange Commission, or the SEC. In addition, copies of these reports will be made available free of charge, upon written request to the Company s Investor Relations Department at 56 East Bell Drive, Warsaw, IN 46582.

The information on Biomet s website is not included as part of, nor incorporated by reference into, this Annual Report on Form 10-K.

Transactions with the Sponsor Group

On December 18, 2006, we entered into an Agreement and Plan of Merger with LVB Acquisition, LLC., a Delaware limited liability company, which was subsequently converted to a corporation, LVB Acquisition, Inc., or Parent, and LVB Acquisition Merger Sub, Inc., an Indiana corporation and a wholly-owned subsidiary of Parent, or Purchaser, which agreement was amended and restated as of June 7, 2007 and which we refer to, as may be amended and restated, supplemented or otherwise modified from time to time, as the Merger Agreement. Pursuant to the Merger Agreement, on June 13, 2007, Purchaser commenced a cash tender offer, or the Offer, to purchase all of our outstanding common shares, without par value, or the Shares, at a price of \$46.00 per Share (the Offer Price) without interest and less any required withholding taxes. The Offer was made pursuant to Purchaser s offer to purchase dated June 13, 2007 and the related letter of transmittal, each of which was filed with the SEC on June 13, 2007. The Offer expired at midnight, New York City time, on July 11, 2007, with approximately 82% of the outstanding Shares having been tendered to Purchaser. At our special meeting of shareholders held on September 5, 2007, more than 91% of our shareholders voted to approve the proposed Merger, and Parent acquired us on September 25, 2007 through a reverse subsidiary merger with Biomet, Inc. being the surviving company. Subsequent to the acquisition, we became a subsidiary of our Parent, which is controlled by LVB Acquisition Holding, LLC, or Holding, an entity controlled by a consortium of private equity funds affiliated with The Blackstone Group, Goldman, Sachs & Co., Kohlberg Kravis Roberts & Co., and Texas Pacific Group (each a Sponsor and collectively, the Sponsors), and their co-investors.

The Merger was completed on September 25, 2007 and was financed through:

the proceeds from the initial offering of the original notes;

initial borrowings under our senior secured credit facilities and our senior unsecured bridge facilities;

equity investments funded by direct and indirect equity investments from certain investment funds associated with or designated by the Sponsors, or the Sponsor Funds, certain investors who have agreed to co-invest with the Sponsor Funds, including investment funds affiliated with certain of the initial purchasers of the original notes, or the Co-Investors, and certain of our executive officers and members of our senior management, or the Management Participants, who rolled over existing equity interests and/or made cash

equity contributions; and

our cash on hand.

On October 16, 2007, the borrowings under our senior unsecured cash pay bridge facility, our senior unsecured payment-in-kind (PIK)-option bridge facility and our senior subordinated unsecured bridge facility were repaid with the proceeds from the follow-on offering of the equal amounts of the additional original senior cash pay notes, original senior toggle notes and original senior subordinated notes, respectively.

We refer to these transactions, including the Merger and our payment of any fees and expenses related to these transactions, collectively as the Transactions .

In connection with the Transactions, we incurred significant indebtedness and became highly leveraged. See Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources. In addition, we allocated the purchase price to the fair value of the assets and liabilities of Biomet based on estimated fair value. The purchase accounting adjustments increased the carrying value of our property and equipment, inventory and established intangible assets (such as corporate and product names, core and completed technology, and customer relationships), among other things. Subsequent to the Transactions, interest expense and non-cash depreciation and amortization charges have significantly increased. As a result, our successor financial statements subsequent to the Transactions are not comparable to our predecessor financial statements.

Competitive Strengths

We believe we have a number of competitive strengths that will enable us to further enhance our position in the orthopedic medical device market.

Broad Market Leadership. We are the fourth largest player in the U.S. orthopedic reconstructive market and have maintained this position for over a decade. We have a large presence at U.S. hospitals, supplying products to over 60% of hospitals performing joint replacement surgery. In addition, we are the third largest manufacturer and marketer of dental reconstructive devices worldwide and maintain market leadership positions in the electrical stimulation and craniomaxillofacial fields.

Leading Research and Development Platform. We have a long history of innovation, engineering, quality and successful new product launches. Demonstrating our research and development leadership, we have launched approximately 900 new products in the past ten fiscal years and plan to introduce approximately 100 new products during fiscal 2010.

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Strong Relationships with Surgeon Customers. Based on their satisfaction with our products, we enjoy long-standing relationships with our surgeon customers, many of which commence during the surgeons residency training programs. Our support of medical education programs provides important training opportunities for orthopedic surgeons early in their careers. In fact, supporting hands-on training provides opportunities for residents, fellows and attending surgeons to experience the clinical benefits of our products. Surgeons have historically exhibited limited willingness to switch manufacturers, as successful patient outcomes are related to the practitioners familiarity with the procedural characteristics and instrumentation of certain implants.

Consistently Strong Operating Cash Flow Generation. Our business is characterized by consistently strong operating cash flows due to our robust operating history and moderate capital intensity. We have continually increased revenues and profitability, with fiscal 2009 representing our 31st consecutive year of year-over-year net sales growth. Over the last 20 years, from fiscal 1989 to fiscal 2009, we increased net sales at a compounded annual growth rate of approximately 16%. We have sustained growth through multiple macro-economic cycles, demonstrating a stable business profile. In addition, we have historically had modest capital expenditure and working capital requirements providing for strong operating cash flow conversion.

Experienced and Dedicated Management Team. We have a highly experienced management team at both the corporate and operational level. Our team is led by Jeffrey R. Binder, a 17-year veteran of the orthopedic medical device industry, who was appointed President and Chief Executive Officer in February 2007. Daniel P. Florin was appointed Senior Vice President and Chief Financial Officer in June 2007 and brings 18 years of financial officer/controller experience in the medical device industry and five years of public accounting and auditing experience to Biomet. Glen A. Kashuba was appointed Senior Vice President and President of Biomet Trauma and Biomet Spine, or BTBS, in April 2007, having previously served as Worldwide President of Cordis Endovascular, a division of Johnson & Johnson. Gregory W. Sasso, who has been with Biomet for 24 years, was appointed Senior Vice President and President of Biomet Strategic Business Unit (SBU) Operations in June 2007. In February 2008, Jon C. Serbousek was appointed President of Biomet Orthopedics, having spent 8 years with Medtronic and 13 years with DePuy, for a current total of 22 years in the medical device industry. Even though each of Messrs. Binder, Florin, Kashuba and Serbousek has been with us for less than three years, the members of our senior management team have an average tenure of 14 years with us and an average tenure of 19 years in the medical device industry. During fiscal 2008, certain members of our management team made a contribution of new equity through cash equity contributions and/or rollover of existing equity interests in the Transactions.

Premier Equity Sponsorship. The Blackstone Group, Goldman, Sachs & Co., Kohlberg Kravis Roberts & Co. and Texas Pacific Group are among the most well-known and respected financial sponsors in the world. The Sponsors have made investments in over 950 companies. The Sponsors and the Co-Investors contributed approximately \$5,387.5 million of equity in connection with the Transactions, representing 46% of the total funding for the Transactions, as part of one of the largest private equity investments in history. The Sponsors have considerable experience in the healthcare sector with investments in companies such as Accellent Inc., HCA Inc., IASIS Healthcare Corporation, Quintiles Transnational Corp., DJO Inc. (formerly ReAble Therapeutics, Inc.) and Vanguard Health Systems, Inc., among others.

Economic Uncertainties

Our results of operations could be substantially affected not only by global economic conditions, but also by local operating and economic conditions, which can vary substantially by market. Unfavorable conditions can depress sales in a given market and may result in actions that adversely affect our margins, constrain our operating flexibility or result in charges which are unusual or non-recurring. Certain macroeconomic events, such as the current crisis in the financial markets, could have a more wide-ranging and prolonged impact on the general business environment, which could also adversely affect us.

We believe the global uncertainty or recessionary environment has impacted the year over year market growth rates of the orthopedic reconstructive device industry from the historical rates in the high single digits to current market growth rates in the low single digits. Because of this, management is taking multiple precautionary measures to be able to manage expenses more conservatively, especially if our revenues were to decrease below those internally forecasted.

Unfavorable conditions in the economy have had an adverse effect on our dental reconstructive business during fiscal 2009 as compared to the prior fiscal year principally due to the elective nature of dental implant procedures, which are typically not reimbursed by private insurance plans or governmental agencies. While we have already undertaken and continue to undertake certain operating initiatives in connection with this business, we anticipate that the growth rate of our worldwide dental business will remain flat or have a low single digit decline during the current global recessionary environment, compared to reported double digit growth in fiscal 2008.

Regulatory and Other Uncertainties

In the United States, healthcare providers that purchase our products (*e.g.*, hospitals, physicians, dentists and other health care providers) 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 our musculoskeletal products. Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. In the Obama administration s fiscal year 2010 federal budget proposal, the administration emphasized maintaining patient choice, reducing inefficiencies and costs, increasing prevention programs, increasing coverage portability and universality, improving quality of care and maintaining fiscal sustainability. The Obama administration s fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes. In addition, members of Congress have proposed a single-payer healthcare system, a government health insurance option to compete with private plans and other expanded public healthcare measures. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially.

Outside of the United States, reimbursement systems vary significantly from country to country. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may decline. Many foreign markets, including Canada, and some European and Asian countries, have tightened reimbursement rates. Our ability to continue to sell certain products profitably in these markets may diminish if the government-managed healthcare systems continue to reduce reimbursement rates, which can decrease pricing and procedural volume.

Business Strategy

We intend to enhance our position as a leading orthopedic medical device company by pursuing the following strategic initiatives:

Continue to Develop and Launch New Products and Technologies. In May 2009, we launched our New Product Introduction, NPI, Process worldwide. The NPI Process is a global portfolio and project management approach that we believe will help bring visibility and control to all commercial aspects of new product development projects. The process breaks the project down into six stages of work and further divides these stages by formal review gates. We will have a single database of all of our development

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projects that is easily filtered and sorted to generate customized project roadmaps that serve as communication tools providing visibility to all functional teams. The database is designed to prioritize and focus the portfolio and also ensure that the workload is properly resourced and managed across the business. Projects will be assessed against pre-determined gate criteria. Functional teams, along with the global portfolio review teams, will select and prioritize projects that are expected to help deliver the growth target, meet strategic drivers, can be adequately resourced, provide a balanced portfolio, and meet specific hurdle rates.

Enhance Surgeon Customer Relationships through Product Performance and Innovation. We intend to continue to meet the needs of our surgeon customers and hospital customers by providing clinically superior and innovative products that offer a cost-effective means of treating patients. Our success has been built on responsiveness to the needs of the health care community, the clinical performance of our products and our ongoing commitment to continued product innovation.

Expand Our Global Reach. We intend to continue to increase the geographic presence of each of our business categories. We believe there are considerable opportunities for global expansion as healthcare spending increases in international markets the United States and Canada together accounted for approximately 60% of the global orthopedic market in 2008, but only approximately 5% of the world s population. We particularly plan to focus on deepening our position in under-penetrated regions where we believe there are attractive opportunities for growth, including Asia and Latin America, by deploying more resources to capture market opportunities, as well as by leveraging our established worldwide manufacturing facilities and salesforce. We believe we can successfully grow our presence in these regions by differentiating ourselves as a provider with a comprehensive portfolio of leading musculoskeletal products.

Focus on Operational Efficiency. We believe we have identified significant opportunities to streamline operations. We believe that the historically decentralized nature of our management and decision-making structure creates opportunities to improve operational efficiency as we centralize operations and increase focus, coordination and accountability throughout the organization. Plans include manufacturing footprint optimization, implementation of Six Sigma and Lean Manufacturing, procurement and offshoring initiatives, as well as reduction in overhead expenses. These changes were initiated during fiscal 2008 and will continue through 2010 and beyond, and we believe will enable us to maximize asset utilization, optimize working capital and increase cash flow, as well as accelerate product development and enhance customer service.

Maximize Operating Cash Flow. We are focused on maximizing our operating cash flow. Over the last 20 years, we have generated significant operating cash flow due to our business growth, strong operating margins and modest capital expenditure and other cash requirements. These business fundamentals will be supplemented by recently implemented initiatives expected to improve working capital, which historically has not been a primary focus area of management. In addition, we believe we will benefit from identified cost savings as we believe we expect to enhance operational efficiencies. We plan to use available cash after capital expenditures primarily to reduce leverage and strengthen our balance sheet.

Products

We operate in one business segment, musculoskeletal products, which includes the design, manufacture and marketing of products in four major categories: Reconstructive Products, Fixation Devices, Spinal Products and Other Products. We have three reportable geographic markets: United States, Europe and International.

The following charts set forth our net sales by product category and geographic markets for the fiscal year ended May 31, 2009. For certain financial information concerning our product categories and geographic markets, see Note 12 to our audited consolidated financial statements included elsewhere herein.

Reconstructive Products

Orthopedic reconstructive implants are used to replace joints that have deteriorated as a result of disease (principally osteoarthritis) or injury. Reconstructive joint surgery involves the modification of the area surrounding the affected joint and the implantation of one or more manufactured components, and may involve the use of bone cement. Our primary orthopedic reconstructive joints are knees, hips and shoulders, but we produce other joints as well. We also produce the associated instruments required by orthopedic surgeons to implant our reconstructive products, as well as bone cements and cement delivery systems. In addition, 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. A total knee replacement typically includes a femoral component, a patellar component, a tibial component and an articulating surface. Total knee replacement may occur as an initial joint replacement procedure, or as a revision procedure, which may be required to

replace, repair or enhance the initial implant. Partial, or unicompartmental, knee replacement is an option when only a portion of the knee requires replacement.

Our newest and most comprehensive total knee system, the Vanguard® Complete Knee System, accommodates up to 145 degrees of flexion and offers full interchangeability of the system s components to provide for a precise fit for each patient. The Vanguar® System may be implanted using our Premier Instrumentation for a conventional procedure or our Microplasty® Minimally Invasive Total Knee Instrumentation that is designed to reduce incision size and surrounding soft tissue disruption, to potentially allow for reduced blood loss, a shortened hospital stay, reduced postoperative pain and less time spent in rehabilitation, as compared to a conventional procedure. During fiscal 2009, we continued the development efforts for the rotating platform version of the Vanguard® Complete Knee System. We continued the introduction of the Signature Personalized Patient Care Program during fiscal 2009. The initial introduction was designed specifically for primary knee procedures. The Signature program uses a patient s MRI data to deliver patient-specific positioning guides to the surgeon for improved pre-operative planning and for implementation during the procedure. The Signature program was developed through a partnership with Materialise, a world leader in custom guides for the dental industry, and we believe this technology may be expanded to other orthopedic applications.

We introduced the Regenerex® Primary Tibial Tray during the second half of fiscal 2009. The Regenerex® Primary Tibial Tray combines advanced Regenerex® porous metal technology, which allows for biologic fixation, with a proven tibial tray design. In addition to Regenerex®, we introduced E1 Antioxidant Infused Technology Tibial Bearings during the second half of fiscal 2009. The E1 technology provides Vitamin E infused highly crosslinked polyethylene, which is designed to offer strength and oxidative stability for improved wear characteristics.

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We continue to be a market leader in addressing the increasing demand from practitioners and patients for procedures and products accommodating minimally-invasive knee techniques. The Oxford® Partial Knee, which is a mobile-bearing unicondylar knee that utilizes a minimally-invasive technique, continues to experience strong global sales. The Oxford® Partial Knee, which was introduced in the United States during fiscal 2005, is currently the only free-floating meniscal bearing unicompartmental knee system approved by the United States Food and Drug Administration, or FDA, for use in the United States. Our offering of minimally-invasive partial knee systems also includes the Alpina Unicompartmental Knee (which is not currently available in the United States); the Vanguard M Series Unicompartmental Knee System, a modified version of the Oxford® Partial Knee that incorporates a fixed-bearing tibial component as opposed to a free-floating tibial bearing; and the Repicci II® Knee System that is now being distributed by our sports medicine subsidiary.

Hip Systems. A total hip replacement involves the replacement of the head and neck of the femur and the acetabulum and may occur as an initial joint replacement procedure, or as a revision procedure, which may be required to replace, repair or enhance the initial implant. A femoral hip prosthesis consists of a femoral head and stem, which can be cast, forged or wrought, depending on the design and material used. Acetabular components include a prosthetic replacement of the socket portion, or acetabulum, of the pelvic bone. Because of variations in human anatomy and differing design preferences among surgeons, we manufacture femoral and acetabular prostheses in a variety of sizes and configurations. We offer a broad array of total hip systems, most of which utilize titanium or cobalt chromium alloy femoral components and our patented ArCom[®], ArComXL[®] or E1 polyethylene-lined, metal-on-metal or ceramic-on-ceramic acetabular components. Many of the femoral prostheses utilize our proprietary PPS[®] Porous Plasma Spray coating, which enables cementless fixation.

Out of our broad product platform of hip stem offerings, the Taperloc® Hip System has become our best-selling component. The Taperloc® Stem is marketed for non-cemented use in patients undergoing primary or revision hip replacement surgery as a result of noninflammatory degenerative joint disease. The Taperloc® femoral component is a collarless, flat, wedge-shaped implant designed to provide high levels of durability and stability in a design that is relatively simple to implant and is particularly well-suited for minimally-invasive procedures. We also offer the Taperloc® Microplasty® Stem that addresses the demand for a minimally-invasive, bone-conserving total hip implant. The shorter length of the Microplasty® Stem, compared to a traditional hip stem, allows for preservation of distal bone, while maintaining proximal femoral bone fixation.

Our comprehensive Microplasty[®] Minimally Invasive Hip Program includes proprietary products from our broad array of hip implants, as well as a distinctive training program and uniquely-designed instruments for a minimally-invasive approach. Our minimally-invasive hip development efforts have been focused on various surgical approaches, including an anterior supine approach, which is an intermuscular surgical approach.

During the second half of fiscal 2009, we launched the Echo® Bi-Metric® stem which is a cementless press-fit stem for the primary total hip procedures. The Echo® Bi-Metric® stem utilizes proven features of the Integral® and Bi-Metric® stems while integrating new design features to further enhance clinical performance accommodating a wider range of femoral canals, allowing for increased range of motion, and providing standard and lateralized offset options to restore biomechanics.

In our acetabular portfolio, our M^2 a-Magnum Articulation System incorporates large diameter metal-on-metal components designed to more closely resemble the natural anatomy, offering joint mechanic restoration with improved range of motion and joint stability. We continue to market $ArComXL^{\circledast}$, which is a second-generation highly crosslinked polyethylene bearing material based on our proven $ArCom^{\circledast}$ polyethylene. $ArComXL^{\circledast}$ polyethylene has demonstrated excellent wear characteristics without measurable oxidation after accelerated aging. During fiscal 2007, we received FDA clearance to market acetabular hip liners manufactured from E1 Highly Crosslinked Polyethylene. We believe E1 liners are the world s first Vitamin E stabilized highly crosslinked polyethylene products to be introduced to the market. Vitamin E is a natural antioxidant and is expected to provide optimal oxidation resistance for the implant bearings used in our total joint replacements.

The ReCap® Total Resurfacing System is a bone-conserving hip product currently used outside the United States for patients in the early stages of degenerative joint disease, including osteoarthritis, rheumatoid arthritis and avascular necrosis. We commenced a clinical study for the ReCap® Total Resurfacing System in the United States during fiscal 2006 and there were approximately 270 patients enrolled in the study as of May 31, 2009. The FDA recently accepted the concept of including European clinical data to support our U.S. Pre-Market Approval submission, subject to further review of the data after submission. We believe the potential exists to bring this product to the U.S. market during the calendar year 2011.

We introduced the Regenerex® RingLoc®+ Modular Acetabular System during fiscal 2008 and it continued to be a strong growth driver during fiscal 2009. The Regenerex® Construct provides design flexibility and solutions for difficult primary and revision cases. The advanced titanium scaffold structure of the Regenerex® Construct is a continuous three-dimensional matrix comprised of industry-standard Ti-6AL-4V. Titanium is a clinically proven material in the orthopedic market, with optimal biological fixation, and the Regenerex® construct is expected to be the material of choice for porous metal constructs.

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

The Copeland Humeral Resurfacing Head was developed to minimize bone removal in shoulder procedures and has approximately 20 years of positive clinical results in the United Kingdom. This system was expanded to include the Copeland EAS Extended Articular Surface Humeral Resurfacing Head designed to address rotator cuff arthropathy.

The initial release of the Comprehensive® Primary Shoulder occurred at the end of fiscal 2007. This initial release included the standard and mini length Comprehensive® Primary Stems and the Versa-Dial® Heads, as well as the hybrid glenoids. The Comprehensive® Primary System was fully released by the end of fiscal 2008 and received excellent market acceptance during fiscal 2009.

During the fourth quarter of fiscal 2009, we introduced the Comprehensive® Reverse Shoulder System which offers superior intraoperative flexibility. This is our first reverse shoulder introduction that will utilize the Comprehensive® platform stems, providing for cemented or cementless use. This system was designed to eliminate scapular notching by incorporating a more anatomic center of rotation utilizing our Versa-Dial® glenospheres.

Our T.E.S.S Total Evolutive Shoulder System continues to receive strong market acceptance in Europe. The T.E.S.S System, which is only available outside the United States, is a complete system that can be used in all indications of shoulder arthroplasty.

Dental Reconstructive Devices. Through our subsidiary, Biomet 3i, LLC (formerly Implant Innovations, Inc.), or Biomet 3i, we develop, manufacture and market products designed to enhance oral rehabilitation through the replacement of teeth and the repair of hard and soft tissues. These products include dental reconstructive devices and related instrumentation, bone substitute materials and regenerative products and materials. A dental implant is a small screw, normally constructed of titanium or titanium alloy, which 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.

Biomet 3i s historical flagship product, the OSSEOTITE product line, features a patented micro-roughened surface technology, which allows for early/immediate loading and improved bone integration to the surface of the implant compared to machined surfaced

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implants. In fiscal 2007, Biomet 3i further enhanced implant surface technology with the introduction of the NanoTite Implant. The surface features the application of nanometer scale crystals of calcium phosphate to the existing OSSEOTITE® surface. The NanoTite Implant was initially introduced in Certain® Implant configurations, which is an internal connection system that, through the use of the QuickSeat® connection, provides audible and tactile feedback when restorative abutments and ancillary components are seated into the implant. In addition, the 6 /12 point connection design of the Certain® Implant System offers enhanced flexibility in placing the implant when preangled abutments are used. In fiscal 2009, Biomet 3i continued to build on the fiscal 2008 introduction of the NanoTite Implant line by introducing the NanoTite Certain® Tapered PREVAIL® configuration. This implant is designed to enhance crestal bone preservation as a result of its integration of Platform Switching , a medialized Implant-Abutment-Junction that has been demonstrated to limit the reformation of soft and hard tissue at the bone crest. This is the first tapered geometry implant available from Biomet 3i that includes the platform switching concept.

In the site preparation category of the dental product portfolio, Biomet 3i completed beta evaluations of its Navigator® CT Guidance Instrumentation Kits, commercially launched this product during the third quarter of fiscal 2008. This open architecture instrumentation is designed to interface with the software and surgical guide solutions offered by existing entities in the marketplace. As planning and guide fabrication are based upon computed tomography scans, this can result in accurate implant placement when combined with the depth and rotational control offered by the Biomet 3i instrumentation. As implant placement position can be replicated as planned, this can also provide the opportunity for fabrication of a provisional prosthesis in advance of surgery thereby allowing for a complete implant restoration in one patient visit.

On the regenerative side of the site preparation portfolio, Biomet 3i has bolstered its bone grafting product and service offering. An exclusive agreement was signed with the University of Miami Tissue Bank for domestic representation of its dental allograft materials. The RegenerOss® Allograft Putty became available during the third quarter of fiscal 2008. This material features a demineralized bone matrix material in a non-toxic lecithin carrier conveniently offered in a syringe-based delivery system. In the fourth quarter of fiscal 2008, Biomet 3i introduced Endobon Xenograft Granules. This bovine-derived particulate bone grafting material is suitable for use in a wide range of dental related bone defects and offers improved handling characteristics and packaging versus some of the competitive products in this category.

During fiscal 2009, Biomet 3i launched its Encode® Complete patient-specific abutment technology. This enhancement of the baseline Encode® abutment offering will allow Biomet 3i to fabricate an abutment and orient implant body analogs into the proper position in a stone master model. This can allow for the complete fabrication of a restoration from one supragingival impression, which is significantly easier than present techniques and a potential opportunity to get more general dentists involved in implant therapy. The quality of these abutments and the ability to save significant chair time will also be of potential benefit to more experienced restorative dentists. Material choice for Encode® Complete abutment fabrication was expanded in fiscal 2009 to include Zirconia options for the fabrication of aesthetic, all-ceramic restorations.

Other Reconstructive Products and Services. Our PMI® Patient-Matched Implant services group designs, manufactures and delivers custom reconstructive devices to orthopedic specialists. We believe this service continues to enhance our reconstructive sales by strengthening our relationships with orthopedic surgeons and augmenting our reputation as a responsive company committed to excellent product design. In order to assist orthopedic surgeons and their surgical teams in preoperative planning, our PMI® group utilizes a three-dimensional, or 3-D, bone reconstruction imaging system. We use computed tomography, or CT, data to produce 3-D reconstructions for the design and manufacture of patient-matched implants. With this imaging and model-making technology, our PMI® group is able to assist the physician prior to surgery by creating 3-D models. Within strict deadlines, the model is used by engineers, working closely with the surgeon, to create a PMI® design for the actual manufacturing of the custom implant for the patient.

We are involved in the ongoing development of bone cements and delivery systems. We have broadened the range of our internally developed and manufactured bone cement product offerings. Cobalt HV (High Viscosity) Bone Cement, which was introduced in the United States during fiscal 2006, is particularly well suited for use in minimally-invasive surgery, but may be used in all applicable joint replacement procedures. The excellent handling characteristics and high optical contrast of Cobalt HV Bone Cement are well suited to the current trends in orthopedic surgery. The patented SoftPac monomer packaging offers the only alternative to glass vial packaging, which is inherently less safe due to the necessity to break the glass vial to deliver the monomer. We offer our internally developed and manufactured bone cements with and without antibiotics.

Additional products and services for reconstructive indications include bone substitute materials and services related to allograft material. Our allograft services address several market segments, including the orthopedic and dental reconstructive segments, as well as the spinal, craniomaxillofacial and sports medicine segments.

We also offer the GPS® III Platelet Separation System, a device that collects platelet concentrate from a small volume of the patient s blood using a fast, single spin process. The GPS® III System is designed to provide a high percentage of platelet concentrate and we believe that this device has broad potential applications in the reconstructive and spine markets.

Fixation Devices

Our fixation products include electrical stimulation devices (excluding spine applications), external fixation devices, craniomaxillofacial fixation systems, internal fixation devices and bone substitute materials utilized in fracture fixation applications. Our craniomaxillofacial fixation products are marketed by our subsidiary, Biomet Microfixation, LLC, or Biomet Microfixation. All other fixation products are marketed primarily by Biomet Trauma.

Electrical Stimulation Systems. We are a market leader in the electrical stimulation segment of the fixation market. The FDA has acknowledged our extensive preclinical research documenting the Mechanism of Action for our pulsed electromagnetic field, or PEMF, capacitive coupling and direct current technologies. The Mechanism of Action for these technologies involves the stimulation of a cascade of bone morphogenic proteins (BMPs) as well as angiogenesis, chondrogenesis and osteogenesis.

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

The OrthoPak® 2 Bone Growth Stimulator, which is indicated for the treatment of recalcitrant (non-union) fractures, offers a small, lightweight, non-invasive device using capacitive coupling technology. The OrthoPak® 2 device delivers bone growth stimulation through wafer-thin electrodes that add virtually no extra weight on the non-union site. The Mechanism of Action behind our capacitive coupling stimulation technology involves the stimulation of osteopromotive factors involved in normal bone healing, such as TGF-\(\text{B}\)1 and PGE2. The OrthoPak® 2 product provides greater ease of use and enhances access to fracture sites that are normally hard to treat.

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We also offer an implantable option when bone growth stimulation is required in conjunction with, or subsequent to, surgical intervention. The Biomet® OsteoGen—surgically implanted bone growth stimulator is an adjunct treatment when bone grafting and surgical intervention are required to treat recalcitrant (non-union) fractures in long bones. The Mechanism of Action behind our direct current stimulation technology involves the stimulation of a number of osteoinductive growth factors including BMP-2, -6 and -7 and the BMP-2 receptor ALK2, which are normal physiological regulators of various stages of bone healing, including chondrogenesis and osteogenesis. In addition, electrochemical reactions at the cathode lower oxygen concentrations and increase pH.

The trauma hardware market can be segmented into two product classifications: External Fixation Devices and Internal Fixation Devices.

External Fixation Devices. External fixation devices are utilized to stabilize fractures when alternative methods of fixation are not suitable due to a variety of clinical indications including treatment of open fractures. We offer a complete line of systems that address the various segments of the trauma and reconstructive external fixation marketplace. The DynaFix® and DynaFix® Vision Systems are innovative, modular external fixation devices intended for use in complex trauma situations involving upper extremities, the pelvis and lower extremities.

A key driver in our external fixation portfolio is the Biomet® Vision FootRing System, which is a comprehensive system designed for the treatment of osteotomies, arthrodesis and fracture fixation indications. This system offers expanded indications for both trauma and reconstructive procedures. The simplified, snap-fit application of all components to the Biomet® Vision FootRing System can be configured into a multitude of constructs ranging from simple fractures to complex reconstruction. This system is made of lightweight, carbon fiber, which is radiolucent and also provides for increased patient comfort. Biomet Trauma also has a full line of external fixation products for certain reconstructive procedures involving limb lengthening, fusion, articulated fixation and deformity correction applications.

Internal Fixation Devices. Our internal fixation devices include products such as nails, plates, screws, pins and wires designed to stabilize traumatic bone injuries. These devices are used by orthopedic surgeons to provide an accurate means of setting and stabilizing fractures and for other reconstructive procedures. They are intended to aid in the healing process and may be removed when healing is complete. Internal fixation devices are not intended to replace normal body structures.

We develop, manufacture and/or distribute innovative products that fit into key segments of the fixation marketplace. Our flagship product used for the treatment of hip fractures is the Biomet[®] Peritrochanteric Nail System that incorporates an innovative single lag screw to minimize soft tissue impingement. In conjunction with the VHS[®] (a registered trademark of Implant Distribution Network, Ltd.) System, the Biomet[®] Peritrochanteric Nail System offers a choice of internal fixation options for the treatment of hip fractures.

Other innovative nailing products include the Biomet® Pediatric Locking Nail (PLN) and the Biomet® WIN Flexible Nail to complement our pediatric product line. The PLN, a customizable locking nail, was designed to provide stable fixation of femur fractures in children. The WIN Nail is manufactured of titanium alloy and is intended to treat a variety of long bone fractures.

In the area of locked plating designs, the OptiLock® Periarticular Plating System is a unique, pre-contoured plating system designed for fixation of periarticular lower extremity fractures. This system incorporates SphereLock technology that allows the surgeon to utilize locked or unlocked screws in various diameters through any hole in the plate, while incorporating minimally-invasive techniques. The OptiLock® System includes applications for the treatment of proximal tibial, distal femoral and distal tibial/fibular fractures. Often used in conjunction with our Biomet® Vision Pin-to-Bar System for temporizing fixation, the OptiLock® Periarticular Plating System provides surgeons with a comprehensive system to address a variety of simple and complex periarticular fractures.

During the first quarter of fiscal 2009, we introduced two innovative products targeted at the foot and ankle market segment, the Phoenix Ankle Arthrodesis Nail and the ForeRunner Mid-Foot Fusion Plating System. The Phoenix Ankle Arthrodesis Nail System is the only pan-talar ankle nail on the market that has a dual stage locking and compression capability. Through the innovative CoreLock technology, the Phoenix Ankle Arthrodesis Nail allows for internal talar compression, followed independently by locking of the calcaneal screws. The Forerunner Mid-Foot Fusion Plating System, is a low profile, comprehensive system that complements our current product offerings in the foot & ankle market segment. This is a low profile, comprehensive system designed for fixation in the foot and ankle. The Forerunner Plating System featuring SphereLock technology offers a wide range of plates with varying lengths between screw holes, as well as multiple screw diameters that provide for unlimited combinations for the unique and complicated structure of the foot. Both of these systems have been quickly embraced by foot and ankle surgeons with positive feedback related to intra-operative efficiencies and clinical experience.

As we refocused our efforts in the upper extremity market, Biomet Trauma initiated a limited release of the OptiLock® Proximal Humeral Plating System during the third quarter of fiscal 2009. The system is intended for fixation of fractures, osteotomies and non-unions of the humerus. Featuring SphereLock technology, this product offers an anatomically contoured, low profile plate with optimized bone screw trajectories that allow for minimal soft tissue impingement. Surgeon feedback continues to be positive with respect to clinical results, implant

design and instrumentation.

During the fourth quarter of fiscal 2009, Biomet Trauma released the PTN Lag Screws with OSSEOTITE surface treatment. The patented OSSEOTITE surface featured on the threads of the PTN lag screws is produced via a dual-acid etching process that creates a roughened titanium alloy surface. Since its original introduction by Biomet 3i for use in dental implants over a decade ago, the OSSEOTITE surface has demonstrated a significantly higher Bone-To-Implant-Contact (BIC) than standard titanium machined implants.

Craniomaxillofacial Fixation Systems. We manufacture and distribute craniomaxillofacial, neurosurgical, and thoracic titanium and resorbable implants, along with associated surgical instrumentation, which are principally marketed to craniomaxillofacial, neurosurgical, plastic, ear/nose/throat, pediatric and cardiothoracic surgeons through Biomet Microfixation. We offer HTR-PMI Hard Tissue Replacement implants for repair of severe cranial defects and bone substitute materials for use in craniomaxillofacial and neurosurgical applications. Innovative solutions are also offered for oral and maxillofacial surgeons with an off-the-shelf Total Mandibular Joint Replacement System and other new products to diagnose and treat temporomandibular joint syndrome, including in-office scope systems and arthrocentesis procedure products.

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

Biomet Microfixation introduced Allogenix Plus bone graft material during fiscal 2008. This material combines the lecithin-based Allogenix Demineralized Bone Matrix with Pro Osteon® granules, resulting in an improved bone graft material. 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. By combining a scaffold with an osteoinductive source, the need for a second procedure in order to harvest bone chips for use as a scaffold may be eliminated.

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Bone Substitute Materials. Bone substitute materials offer an alternative to the creation of a 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. We also provide the InterGro® line of DBM materials (InterGro® Paste, InterGro® Putty and InterGro® Plus). The InterGro® DBM materials use lecithin as a carrier, which is a natural lipid carrier that is resistant to breakdown by bodily fluids, temperature or aggressive irrigation.

Spinal Products

Our spinal products include electrical stimulation devices for spinal applications, spinal fixation systems and bone substitute materials, as well as allograft services for spinal applications. These products and services are primarily marketed in the United States under the Biomet Spine and Biomet Osteobiologics trade names.

Spine Fusion Stimulation Systems. Spinal fusions are surgical procedures undertaken to establish bony union between adjacent vertebrae. We distribute 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. We have assembled extensive preclinical research documenting the Mechanism of Action for the technology utilized in our spine fusion stimulation systems.

The SpinalPak® II Spine Fusion Stimulator utilizes capacitive coupling technology to enhance fusion incorporation. The Mechanism of Action behind the capacitive coupling stimulation technology involves the upregulation of osteopromotive factors that modulate normal bone healing, such as TGF-\(\textit{B}\)1 and PGE2. The device consists of a small, lightweight generator worn outside the body that is connected to wafer-thin electrodes applied over the fusion site. The SpinalPak® II System is patient-friendly, enhancing comfort whether the patient is standing, sitting or reclining, and optimizes compliance with the treatment regimen to enhance fusion success.

The SpF® PLUS-Mini Spine Fusion Stimulator offers the highest current density available in one-third of the size of the original SpF® PLUS Spine Fusion Stimulator. The surgically-implanted SpF® PLUS-Mini Spine Fusion Stimulator consists of a generator that provides a constant direct current to titanium cathodes placed where bone growth is required. The Mechanism of Action behind our direct current stimulation technology involves the upregulation of a number of osteoinductive growth factors including BMP-2, -6 and -7 and the BMP-2 receptor ALK2, which are normal physiological regulators of various stages of bone healing, including chondrogenesis and osteogenesis. The SpF® Stimulator has exhibited a 50% increase in fusion success rates compared to fusions with autograft alone.

Spinal Fixation Systems. We market spinal fixation devices for various spinal fusion applications. In the thoracolumbar market segment, we offer several systems. The Array® System is available in titanium or stainless steel, provides a single locking setscrew featuring V-Force Thread Vertical Vector Technology designed to enhance the intraoperative ease of use for the surgeon. During fiscal 2006, we launched the Array® Deformity Spine System, which includes various styles of screws, hooks and rods for scoliosis correction. A more recent product offering is the Polaris Spine System, a low profile, top-loading, thoracolumbar system utilizing a patented Helical Flang® (a registered trademark of Roger P. Jackson) closing mechanism. This feature minimizes the potential for cross-threading and seat splay, simplifying the implant closing procedure for the surgeon. The Polaris System is available in titanium or stainless steel and in 6.35mm or 5.5mm rod diameters, with various screw, hook and rod options.

We also offer a variety of spacer products for the thoracolumbar market segment. The Solitaire Anterior Spinal System is a stand-alone device with numerous implantation options for intraoperative flexibility. This system is available with implants manufactured from titanium or PEEK-OPTIMA® (a registered trademark of Invibio, Limited) polymer, an implant option for increased radiographic fusion assessment. Another spacer offering is, the TPS -TL System, which features a patented telescoping plate design, allowing the surgeon to fit the implant to the defect, while integrating the functions of an anterior plate and vertebral column spacer. We also offer the ESL® (Elliptically Shaped Lumbar), C-Thru and Ibex thoracolumbar spacers. All three of these spacers feature open designs to permit ample space for bone graft placement. The ESL® System has an elliptical shape, offering optimal surface contact with the vertebral body endplates. The Ibex System is curved to conform to the anterior shape of the adjacent vertebral body. The ESL®, C-Thru and Ibex thoracolumbar spacers are available in PEEK-OPTIMA registered trademark of Invibio, Limited) polymer for increased radiographic fusion assessment.

For cervical applications, the open design of the VueLock® Anterior Cervical Plate System provides surgeons with enhanced visualization of the bone graft both during the actual surgical procedure and postoperatively on x-ray. We also offer the C-TEK® Anterior Cervical Plate, which provides a non-constrained, semi-constrained or a completely rigid construct, depending on the surgeon s preference. Made of titanium, the C-TEK® Plate offers both fixed and variable screws in a wide variety of diameters and lengths and features a unique locking mechanism to prevent screw back out. In fiscal 2009, we introduced the C-Tek® MaxAn—Anterior Cervical Plate System, which incorporates technology developed by Gary K. Michelson, M.D. This unique design allows for maximum angulation of the screws, permitting the surgeon to utilize a shorter plate, which helps optimize plate placement to potentially prevent impingement of the adjacent healthy disc.

For cervical and upper thoracic procedures, we offer the Altius M-INI Occipito-Cervico-Thoracic Spinal Fixation System, which features top-loading screws and a 3.5mm rod for maximum strength. This system also incorporates Helical Flange® (a registered trademark of Roger P. Jackson) Locking Technology. Occipital fixation is also available with the Altius M-INI System, featuring a low-profile plate that is placed independently from the rod, allowing for easier assembly and less rod contouring.

Minimally-invasive surgery is of growing interest in the practice of many spine surgeons. A minimally-invasive approach to spine surgery has demonstrated the potential for less morbidity, decreased blood loss and less time in rehabilitation. In the minimally-invasive surgery market, we offer the Ballista Percutaneous Pedicle Screw Placement System and the AccuVision Minimally Invasive Access System. Both systems were launched in the United States during fiscal 2009.

To address the vertebral body compression fracture market, we offer two systems designed for the delivery of materials to weakened bone structures, including the CDV and LP2 Delivery Systems. Through a series of dilating cannulae and various instruments, the systems allow the surgeon to access the anatomy through a percutaneous approach and safely deliver high viscosity material under low, controlled pressure. The CDV Delivery System offers the ability to biopsy before delivery.

Bone Substitute and Allograft Materials. Traditional spinal fusion 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. Pro Osteon® 200R and Pro Osteon® 500R are bone graft substitutes made from marine coral. Both are a resorbable combination of hydroxyapatite and calcium carbonate that is intended to be replaced with natural bone during the healing process. Pro Osteon® 200R is available as

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granules, while Pro Osteon® 500R is available in granules and blocks. The Biomet® PlatFORM Demineralized Bone Matrix, or DBM, derived exclusively from human bone, is an osteoconductive, osteoinductive and osteogenic matrix. This material consists of freeze-dried flexible and pliable sheets of demineralized bone matrix putty for use as a bone void filler. The Biomet ® PlatFORM DBM can be utilized alone or in combination with autologous bone or other forms of allograft and can be rehydrated with bone marrow aspirate for use in posterolateral spine fusions. Since this matrix has no synthetic additives, this eliminates any surgeon concern regarding toxicity of certain carriers currently used in other DBMs. We also have available the InterGro® line of DBM materials (InterGro® Paste, InterGro® Putty and InterGro® Plus). The InterGro® DBM materials use lecithin as a carrier, which is a natural lipid carrier that is resistant to breakdown by bodily fluids, temperature or aggressive irrigation.

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

Motion Preservation Products. We have suspended our Investigational Device Exemption pilot study for the Regain® Lumbar Artificial Disc. We will continue to follow the patients as required. The Company has made a decision to refocus our organic development efforts in next generation, non-anterior MIS approaches, leveraging our domain knowledge of the space and our unique MIS portfolio and access instruments. As such, we have also suspended further development on the Min-T total lumbar ceramic, artificial disc, which was also based on an anterior surgical approach. In order to address the cervical artificial disc opportunity, the Company is continuing to develop next generation designs utilizing innovative materials and geometries.

Other Products

We also manufacture and distribute numerous 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.

Arthroscopy Products. We manufacture and market a line of arthroscopy products through our subsidiary, Biomet Sports Medicine, LLC, or Biomet Sports Medicine. 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. Our principal products consist of the EZLoc Femoral Fixation Device, the WasherLoc Tibial Fixation Device, LactoSorb resorbable arthroscopic fixation products, the ALLthread Suture Anchor, the MaxFire Meniscal Repair Device with ZipLoop Technology and ToggleLoc with ZipLoop Technology, and the InnerVue Diagnostic Scope system, which utilizes a needle scope to diagnose knee and shoulder conditions in a physician s office.

Orthopedic Support Products. We distribute a line of orthopedic support products under the Biomet Bracing name, including back braces, knee braces and immobilizers, wrist and forearm splints, cervical collars, shoulder immobilizers, slings, abdominal braces, ankle supports and a variety of other orthopedic splints.

Product Development

Our 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. Evolutionary developments are driven primarily by the individual subsidiaries and include product line extensions and improvements.

We continue to aggressively conduct internal research and development efforts to generate new marketable products, technologies and materials. In addition, we believe we are well positioned to take advantage of external acquisition and development opportunities. An important component of our strategy has been the formation of strategic alliances to enhance the development of new musculoskeletal products.

For fiscal 2009, for the period July 12, 2007 through May 31, 2008, for the period June 1, 2007 through July 11, 2007, and for fiscal 2007, we expended \$93.5 million, \$82.2 million, \$34.0 million and \$85.6 million, respectively, on research and development. It is expected that ongoing research and development expenses will continue to increase. Our principal research and development efforts relate to our orthopedic reconstructive devices, spinal fixation products, revision orthopedic reconstructive devices, dental reconstructive devices, arthroscopy products,

resorbable technology, biomaterial products and autologous therapies.

We have launched approximately 900 new products during the past ten fiscal years and plan to introduce approximately 100 new products during fiscal 2010.

Patents and Trademarks

We believe that patents and other intellectual property will continue to be of importance in the musculoskeletal industry. Accordingly, we continue to protect technology developed internally and to acquire intellectual property rights associated with technology developed outside the Company. We enforce our intellectual property rights consistent with our strategic business objectives. We do not believe that we have any single patent or license (or series of patents or licenses) that is material to our operations, consolidated revenues, or earnings. We currently have more than 1,300 patents and in excess of 680 pending patent applications.

BIOMET is our principal registered trademark throughout the world, and registrations have been obtained or are in process with respect to various other trademarks associated with our products. Unless otherwise noted in this annual report, all trademarks contained herein are owned by Biomet, Inc. or one of its affiliates and subsidiaries.

Government Regulation

Most aspects of our business are subject to some degree of government regulation in the countries in which our operations are conducted. It has always been our practice to comply with all regulatory requirements governing our products and operations and to conduct our affairs in an ethical manner. This practice is reflected in our Code of Business Conduct and Ethics, various other compliance policies and through the responsibility of the Audit Committee of the Board of Directors to review our systems of internal control, our process for monitoring compliance with laws and regulations and our process for monitoring compliance with our Code of Business Conduct and Ethics. For some products, and in some areas of the world such as the United States, Canada, Japan and Europe, government regulation is significant and, in general, there appears to be a trend toward more stringent regulation throughout the world, as well as global harmonization of various regulatory requirements. We devote significant time, effort and expense to addressing the extensive government and regulatory requirements applicable to our 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. We believe that we are no more or less adversely affected by existing government regulations than are our competitors.

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

We believe that we are well positioned to face the changing international regulatory environment. The International Standards Organization, or the ISO, has an internationally recognized set of standards aimed at ensuring the design and manufacture of quality products. A company that has passed an ISO audit and obtained ISO certification applicable to its activity sector is internationally recognized as having quality manufacturing processes. The European Union (EU) legislation requires that medical devices bear a CE mark. The CE mark is a European Union and European Free Trade Association 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 our products. Each of our principal manufacturing facilities has been certified to ISO 13485:2003. Each of our products sold in Europe bears the CE mark, with the exception of custom-made implants that do not require a CE mark. The EU has recently reclassified our total joint products to Class III via Directive 2005/50/EC and we are in the process of complying with this Directive.

In addition, governmental bodies in the United States and throughout the world have expressed concern about the costs relating to healthcare and, in some cases, have focused attention on the pricing of medical devices. Government regulation regarding pricing of medical devices already exists in some countries and may be expanded in the United States and other countries in the future. We are 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. Other factors affecting a specific hospital s reimbursement rate include the size of the hospital, its teaching status and its geographic location.

While we are unable to predict the extent to which our business may be affected by future regulatory developments, we believe that our substantial experience in dealing with governmental regulatory requirements and restrictions throughout the world, our emphasis on efficient means of distribution and our ongoing development of new and technologically-advanced products should enable us to continue to compete effectively within this increasingly regulated environment.

Sales and Marketing

We have diligently worked to attract and retain qualified, well-trained and motivated sales representatives. The breadth of our product offering and the quality of our salesforces collaborate to create synergies that we believe uniquely position us to continue to efficiently penetrate the musculoskeletal market. In the United States, our products are marketed by a combination of independent commissioned sales agents and direct sales representatives, based on the specific product group being represented. In an effort to ensure the continuity of our relationships with the independent third-party distributors who represent Biomet Orthopedics and as a result of a competitor s efforts to try and hire our existing distributors and sales representatives, we incurred \$2.0 million in fiscal year 2009, \$24.0 million for the period from July 12, 2007 through May 31, 2008, \$18.0 million for the period from June 1, 2007 through July 11, 2007, and \$39.0 million in fiscal 2007, which negatively affected our results of operations for these periods. In Europe, our products are promoted by sales representatives employed by subsidiaries, independent third-party distributors, and some independent commissioned sales agents, based primarily on the geographic location. In the rest of the world, we maintain direct selling organizations in ten countries, as well as independent commissioned sales agents and independent third-party distributors in other key markets. In aggregate, our products are marketed by approximately 3,000 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 declines during the summer months and the winter holiday season.

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

We have inventory located throughout the world with our customers, our distributors and direct salespersons for their use in marketing our products and in filling customer orders. As of May 31, 2009, inventory of approximately \$223.3 million was located with these distributors, salespersons and customers. We maintain trade accounts receivable balances based on credit terms that are generally consistent with industry and local market practices.

Distribution

We operate distribution facilities domestically in Warsaw, Indiana; Irvine, California; Palm Beach Gardens, Florida; Parsippany, New Jersey; Jacksonville, Florida; Fair Lawn, New Jersey; Ontario, California and internationally in Valence, France; Berlin, Germany; Dordrecht, The Netherlands; Valencia, Spain; Sjobo, Sweden; Bridgend, South Wales; Swindon, England; Tokyo, Japan; Seoul, Korea; North Ryde, Australia; Jinhua, China; and Changzou, China. We generally ship our orders via expedited courier service. Our backlog of firm orders is not considered material to an understanding of our business.

Competition

Our business is highly competitive. 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. Major competitors in our four product categories are set forth below by market category.

Reconstructive Products

Our orthopedic reconstructive devices compete with those offered by DePuy, Inc. (a Johnson & Johnson company), Smith & Nephew plc, Stryker Orthopaedics (a division of Stryker Corp.) and Zimmer, Inc. (a subsidiary of Zimmer Holdings, Inc.). Management believes these four companies, together with Biomet, have the predominant share of the global orthopedic reconstructive device market. We believe that our prices for orthopedic reconstructive devices are competitive with those in the industry. We believe that our future success will depend upon, among other things, our service and responsiveness to our distributors and orthopedic specialists, the continued excellent clinical results of our products, and upon our ability to design and market innovative and technologically-advanced products that meet the needs of the marketplace.

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Our dental reconstructive devices compete in the areas of dental reconstructive implants and related products. The primary competitors in the dental implant market include Nobel Biocare AB, Straumann AG, Zimmer Dental (a subsidiary of Zimmer Holdings, Inc.) and Astra Tech (part of the AstraZeneca Group).

Fixation Devices

Our electrical stimulation devices primarily compete with those offered by Orthofix, Inc. (a subsidiary of Orthofix International N.V.), DJO Inc. (formerly ReAble Therapeutics, Inc.) and Smith & Nephew plc. Competition in the electrical stimulation market is on the basis of product design, service, price and success rates of various treatment alternatives.

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

Spinal Products

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

Other Products

Our craniomaxillofacial fixation products, specialty surgical instrumentation and neurosurgical cranial flap fixation products compete with those offered by Synthes, Inc., Stryker Leibinger Micro Implants (a division of Stryker Corp.), KLS-Martin, L.P., Osteomed Corp., Aesculap, Inc., Medtronic, Inc. and Codman (a Johnson & Johnson company).

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

Our orthopedic support products consist primarily of back braces, knee braces and immobilizers, wrist and forearm splints, cervical collars, shoulder immobilizers, slings, abdominal braces and ankle supports that compete with those offered by Orthofix, Inc. (a subsidiary of Orthofix International N.V.), DJO Inc. (formerly DJ Orthopedics, Inc.) and Ossur. Competition in the bracing market is on the basis of product design, service and price.

Raw Materials and Supplies

The raw materials used in the manufacture of our 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 our raw material requirements are limited to any material extent by critical supply or single origins. The demand for certain raw materials used by us, such as cobalt-chromium 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, we could experience complications in obtaining these raw materials. However, based on our current relationship with our suppliers, we do not anticipate a material shortage in the foreseeable future. Further, we believe that our inventory of raw materials is sufficient to meet any short-term supply shortages of metallic alloys. The results of our operations are not materially dependent on raw material costs.

We purchase all components of our electrical stimulators from approximately 190 outside suppliers, approximately 40 of which are the single source of supply for the particular product. In most cases, we believe 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 our orders could be filled.

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

We purchase the materials to produce our dental products from approximately 69 suppliers, approximately 58 of which are the single source of supply for the particular product. We believe that, in the event of a shortage, there are readily available alternative sources of supply for single-source products, and we maintain an inventory of materials sufficient to meet any short-term shortages of supply.

Environmental Matters

We are subject to various federal, state and local laws and regulations regulating the discharge of materials into the environment and otherwise relating to the protection of the environment. We do not believe that we will be required to expend any material amounts in order to comply with these laws and regulations or that compliance with such laws and regulations will materially affect our capital expenditures, results of operations or financial condition.

Employees

As of May 31, 2009, our domestic operations (including Puerto Rico) employed 3,548 persons, of whom 1,903 were engaged in production and 1,645 in research and development, sales, marketing, administrative and clerical efforts. Our international subsidiaries employed 3,559 persons, of whom 1,821 were engaged in production and 1,738 in research and development, sales, marketing, administrative and clerical efforts. None of our principal domestic manufacturing employees is represented by a labor union. The production employees at our Bridgend, South Wales facility are organized. Employees working at the facilities in Berlin and Dieburg, Germany; Valence, France; Swindon, United Kingdom; Sjöbo, Sweden; and Valencia, Spain are represented by Workers Councils. We believe that our relationship with our employees is satisfactory.

The establishment of our domestic orthopedic reconstructive manufacturing operations in north central Indiana, near other members of the orthopedic industry, provides access to the highly skilled machine operators required for the manufacture of our products. Our European manufacturing locations in South Wales, England, France, Spain, Sweden and Germany also provide good sources for skilled manufacturing labor. Our Puerto Rican operations principally involve the assembly of purchased components into finished products using a skilled labor force. Our manufacturing operations in Jinhua, Zhejiang Province, and Changzhou, Jiangsu Province, China are growing and currently include approximately 600 persons which are included in the numbers above.

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Item 1A. Risk Factors

The following factors, among others, could cause our 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 our business, financial condition, results of operations and cash flows. The risks identified in this section are not exhaustive. We operate in a dynamic and competitive environment. New risk factors affecting us 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 our 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. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business or results of operations in the future. In addition, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. The following discussion of our risk factors speaks only as of the date on which they were made and should be read in conjunction with the consolidated financial statements and related notes included herein. Because of these and other factors, past financial performance should not be considered an indication of future performance. Any of the following risks could materially adversely affect our business, financial condition, results of operations or cash flows.

Risks Relating to Our Business

Our future profitability depends on the success of our reconstructive products.

Sales of our reconstructive products accounted for approximately 74% of our net sales for the year ended May 31, 2009 and for the period July 12, 2007 to May 31, 2008, and 71% of our net sales for the period June 1, 2007 to July 11, 2007 and for fiscal 2007. We expect sales of reconstructive products to continue to account for a significant portion of our aggregate sales. Any event adversely affecting the sale of reconstructive products may, as a result, adversely affect our business, financial condition, results of operations and cash flows.

If we are unable to continue to develop and market new products and technologies in a timely manner or at all, the demand for our products may decrease or our products could become obsolete, and our revenue and profitability may decline.

The market for our products is highly competitive and dominated by a small number of large companies. We are continually engaged in product development, research and improvement efforts. New products and line extensions of existing products represent a significant component of our growth rate. Our ability to continue to grow sales effectively depends on our capacity to keep up with existing or new products and technologies in the musculoskeletal products market. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time consuming and approvals and clearances might not be granted for future products on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals and clearances for future products could result in delayed realization of product revenues or in substantial additional costs which could have a material adverse effect on our business or results of operations. In addition, if our competitors—new products and technologies reach the market before our products, they may gain a competitive advantage or render our products obsolete. See Business Competition—elsewhere in this annual report for more information about our competitors. The ultimate success of our product development efforts will depend on many factors, including, but not limited to, our ability to create innovative designs and materials, provide innovative 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 we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. Even in the event that we are 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 our competitors of products embodying new technologies or features.

Our business, financial condition, results of operations and cash flows could be significantly and negatively affected by substantial government regulations.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Overall, there appears to be a trend toward more stringent regulation throughout the world, and we do not anticipate this trend to dissipate in the near future.

In general, the development, testing, manufacturing and marketing of our 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, we are required to implement and maintain stringent reporting, labeling and record keeping procedures. The medical device industry also is subject to a myriad of complex laws and regulations governing Medicare and Medicaid

reimbursement and health care fraud and abuse laws, with these laws and regulations being subject to interpretation. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. In certain public statements, governmental authorities have taken positions on issues for which little official interpretation was previously available. Some of these positions appear to be inconsistent with common practices within the industry but have not previously been challenged.

Various federal and state agencies have become increasingly vigilant in recent years in their investigation of various business practices. Governmental and regulatory actions against us can result in various actions that could adversely impact our operations, including:

the recall or seizure of products;
the suspension or revocation of the authority necessary for the production or sale of a product;
the suspension of shipments from particular manufacturing facilities;
the imposition of fines and penalties;
the delay of our ability to introduce new products into the market;
the exclusion of our products from being reimbursed by federal and state health care programs (such as Medicare, Medicaid, Veterans Administration health programs and Civilian Health and Medical Program Uniformed Service, or CHAMPUS); and

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other civil or criminal sanctions against us.

Any of these actions, in combination or alone, or even a public announcement that we are being investigated for possible violations of these laws, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In many of the foreign countries in which we market our products, we are subject to regulations affecting, among other things: clinical efficacy, product standards, packaging requirements, labeling requirements, import/export restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our devices and products in these countries, such as the European Medical Devices Directive, are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our products to be qualified before they can be marketed with the benefit of reimbursement eligibility. Failure to receive or delays in the receipt of relevant foreign qualifications also could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As both the U.S. and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Our products and operations are also often subject to the rules of industrial standards bodies, such as the International Standards Organization. If we fail to adequately address any of these regulations, our business will be harmed.

We, like other companies in the orthopedic industry, are involved in ongoing governmental investigations, the results of which may adversely impact our business and results of operations.

In May 2007, we received a subpoena from the U.S. Department of Justice through the U.S. Attorney for the Southern District of West Virginia requesting documents generally relating to a certain number of products manufactured, marketed and sold by the EBI subsidiary for the period from January 1999 through the present. In June 2007, we received a second administrative subpoena from the U.S. Attorney for the Southern District of West Virginia requesting documents relating to a specific physician s assistant. We understand that the Department of Justice is conducting a civil investigation of EBI s sales and marketing practices relating to certain spinal products. We are fully cooperating with the request of the Department of Justice. We can make no assurances as to the time or resources that will be needed to devote to this inquiry or its final outcome.

In April 2009, we became aware of a qui tam complaint originally filed in March 2005 by an individual plaintiff against the principal manufacturers of bone growth stimulation devices, including us, our parent, LVB Acquisition, Inc., and our subsidiary, EBI. The U.S. District Court for the District of Massachusetts ordered that the complaint be unsealed on March 24, 2009, but we have not been notified that a summons and complaint have been served on any registered agent of us, our parent or EBI. The complaint alleges a cause of action under the False Claims Act and appears to focus on alleged reimbursement-related false claims associated primarily with the sale versus the rental of those devices. We believe that this complaint is related to the subpoena issued by the Department of Justice requesting documentation relating to EBI s osteogenesis and bone growth stimulation devices, as described below. We are currently in the process of evaluating the complaint. We can make no assurances as to the time or resources that will be needed to devote to this inquiry or its final outcome.

In April 2009, we received a subpoena from the U.S. Department of Justice through the U.S. Attorney for the District of Massachusetts requesting various documents purportedly relating to EBI s osteogenesis and bone growth stimulation devices. We are currently in the process of evaluating the scope of the subpoena and intend to fully cooperate with the request of the Department of Justice. We can make no assurances as to the time or resources that will be needed to devote to this inquiry or its final outcome.

We received a Civil Investigative Demand (CID) issued by the Commonwealth of Massachusetts Office of the Attorney General (Massachusetts AG) on or about November 19, 2007. The CID requested documents for the period November 1, 2003 to the present concerning certain physicians and provider groups, including, among other things, documents concerning any contracts or agreements with, and any payments made to, those physicians or provider groups. We have produced documents in response to the CID, and intend to continue to cooperate with the Massachusetts AG. It is not possible at this time to predict the likely outcome of this inquiry or its financial impact should the outcome be adverse to us.

On May 7, 2009, we received a subpoena from the Attorney General of New Jersey requesting various documents relating to the financial interests and arrangements of physicians conducting clinical trials for or on our behalf for which financial forms were submitted to the FDA. We are currently in the process of evaluating the scope of the subpoena and our response. According to a news release issued by the Attorney General of New Jersey, subpoenas have also been issued to other major medical device manufacturing companies seeking similar information. We can make no assurances as to the time or resources that will be needed to devote to this inquiry or its final outcome.

From time to time, we have been, and may be in the future, the subject of additional investigations. If, as a result of these investigations, we are found to have violated one or more applicable laws, our business, financial condition, results of operations and cash flows could be materially adversely affected. If some of our existing business practices are challenged as unlawful, we may have to change those practices, which could

have a material adverse effect on our business, financial condition, results of operations and cash flows.

Sales may decline if our customers do not receive adequate levels of reimbursement from third-party payors for our products and if certain types of healthcare reform programs are adopted in our key markets and other administration proposals.

In the United States, healthcare providers that purchase our products (*e.g.*, hospitals, physicians, dentists and other health care providers) 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 our musculoskeletal products. These third-party payors may deny reimbursement if they determine that a device used in a procedure was not in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors may also decline to reimburse for experimental procedures and devices. In the event that third-party payors deny coverage or reduce their current levels of reimbursement, we may be unable to sell certain products on a profitable basis, thereby materially adversely impacting our 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 our products.

Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. In the Obama administration s fiscal year 2010 federal budget proposal, the administration emphasized maintaining patient choice, reducing inefficiencies and costs, increasing prevention programs, increasing coverage portability and universality, improving quality of care and maintaining fiscal sustainability. The Obama administration s fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes. In addition, members of Congress have proposed a single-payer healthcare system, a government health insurance option to compete with private plans and other expanded public healthcare measures. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially.

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Outside of the United States, reimbursement systems vary significantly from country to country. In the majority of the international markets in which our products are sold, government-managed healthcare 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 our products may decline. Many foreign markets, including Canada, and some European and Asian countries, have tightened reimbursement rates. Our ability to continue to sell certain products profitably in these markets may diminish if the government-managed healthcare systems continue to reduce reimbursement rates.

In May 2009, President Obama s administration announced proposed future tax legislation that could substantially modify the rules governing the U.S. taxation of certain non-U.S. subsidiaries. These potential changes include, but are not limited to; 1) limitations on the deferral of U.S. taxation of foreign earnings; 2) limitations on the ability to claim and utilize foreign tax credits; and 3) deferral of various tax deductions until non-U.S. earnings are repatriated to the U.S. Each of these proposals would be effective for taxable years beginning after December 31, 2010. Many details of the proposal remain unknown, and any legislation enacting such modifications would require Congressional approval. However, if any of these proposals are enacted into law, they could impact the Company s effective tax rate.

Compliance with the terms of the Corporate Integrity Agreement requires cooperation by many employees and others and may divert substantial financial and human resources from our other business activities.

On September 27, 2007 we entered into a Deferred Prosecution Agreement with the U.S. Attorney s Office for the District of New Jersey. The agreement concluded the government s investigation into whether consulting agreements between the largest orthopedic manufacturers and orthopedic surgeons who use joint reconstruction and replacement products may have violated the federal Anti-Kickback Statute. Through the agreement, the U.S. Attorney s Office agreed not to prosecute Biomet, Inc. and our wholly-owned subsidiary Biomet Orthopedics, Inc. in connection with this matter, provided that we satisfied our obligations under the agreement for 18 months subsequent to September 27, 2007. The agreement called for the appointment of an independent monitor to review our compliance with the agreement, particularly in relation to our consulting agreements. The independent monitor filed a final report with the U.S. Attorney s Office for the period from September 27, 2007 through March 1, 2009. On March 27, 2009, the Deferred Prosecution Agreement expired and the complaint was dismissed with prejudice.

As part of the resolution of this matter, we entered into a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, or OIG-HHS. The agreement requires us for 5 years subsequent to September 27, 2007 to continue to adhere to our Code of Business Conduct and Ethics and certain other provisions, including reporting requirements.

We are committed to continuing to devote sufficient resources to meet our obligations under the Corporate Integrity Agreement. Compliance with this agreement requires substantial cooperation of our employees, distributors and sales agents and the healthcare professionals with whom they interact. These efforts not only involve expense, but also require management and other key employees to focus extensively on these matters.

The ongoing informal investigation by the United States Securities and Exchange Commission and the United States Department of Justice regarding potential violations of the Foreign Corrupt Practices Act in the sale of medical devices in a number of foreign countries by companies in the medical device industry could have a material adverse effect on our business, financial condition, results of operations and cash flows.

On September 25, 2007, we received a letter from the SEC informing us that it is conducting an informal investigation regarding possible violations of the Foreign Corrupt Practices Act in the sale of medical devices in certain foreign countries by companies in the medical devices industry. The Foreign Corrupt Practices Act prohibits U.S. companies and their officers, directors, employees, shareholders acting on their behalf and agents from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad or otherwise obtaining favorable treatment and this law requires companies to maintain records which fairly and accurately reflect transactions and to maintain internal accounting controls. In many countries, hospitals and clinics are government-owned and healthcare professionals employed by such hospitals and clinics, with whom we regularly interact, may meet the definition of a foreign official for purposes of the Foreign Corrupt Practices Act. If we are found to have violated the Foreign Corrupt Practices Act, we may face sanctions including fines, criminal penalties, disgorgement of profits and suspension or debarment of our ability to contract with government agencies or receive export licenses. On November 9, 2007, we received a letter from the Department of Justice requesting any information provided to the SEC be provided to the Department of Justice on a voluntary basis. We continue to fully cooperate with both requests and we are in the process of conducting our own review relating to these matters in certain countries in which we and our distributors conduct business and have met and expect to continue to meet with the SEC and the DOJ to update them on the status of our review.

We could be subject to further governmental investigations or actions by other third parties as a result of our recent settlement with the Department of Justice and OIG-HHS.

As discussed in Business-Government Regulation , we are subject to various federal and state laws concerning healthcare fraud and abuse, including false claims laws and anti-kickback laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration (VA) health programs. These laws are administered by, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services and state attorneys general. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years.

As discussed in Legal Proceedings, the SEC has commenced an informal investigation into sales by us and other companies of medical devices in foreign countries. In addition, we are in the process of conducting our own review relating to these matters and are also cooperating with the U.S. Department of Justice and at least one state attorney general. While we believe that the pending state investigations are not likely to have a material adverse effect on our business or financial condition, additional claims or investigations by private plaintiffs or other states or governmental agencies are possible. We intend to review and take appropriate actions with respect to any such investigations or proceedings; however, we cannot assure that the costs of defending or fines imposed in resolving those civil or criminal investigations or proceedings would not have a material adverse effect on our financial condition, results of operations and cash flows.

The current economic uncertainties may adversely affect our results of operations.

Our results of operations could be substantially affected not only by global economic conditions, but also by local operating and economic conditions, which can vary substantially by market. Unfavorable conditions can depress sales in a given market and may result in actions that adversely affect our margins, constrain our operating flexibility or result in charges which are unusual or non-recurring. Certain macroeconomic events, such as the current crisis in the financial markets, could have a more wide-ranging and prolonged impact on the general business environment, which could also adversely affect us.

We believe the global uncertain or recessionary environment has impacted the market growth rates of the orthopedic business from the historical rates in the high single digits to current market growth rates in the low single digits. Because of this, management is taking multiple precautionary measures to be able to manage expenses more conservatively, especially if our revenues were to decrease below those internally forecasted.

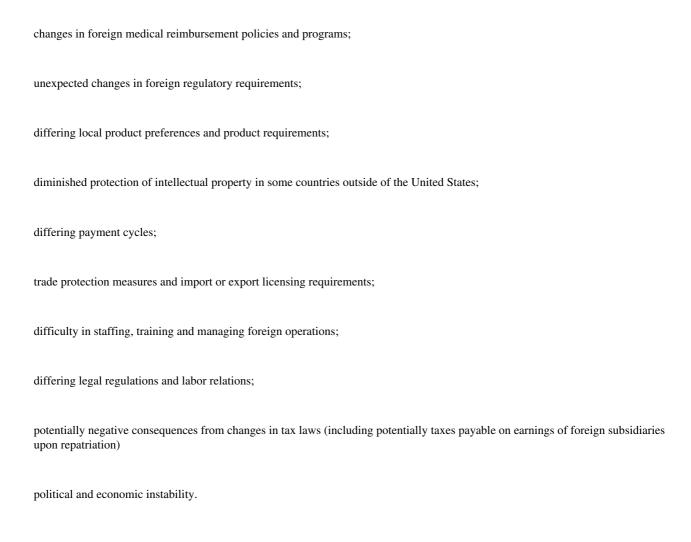
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We are subject to cost-containment efforts of group purchasing organizations, which may have a material adverse effect on our financial condition, results of operations and cash flows.

Many customers of our products have joined group purchasing organizations in an effort to contain costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization s affiliated hospitals and other members. If we are not one of the providers selected by a group purchasing organization, affiliated hospitals and other members may be less likely to purchase our products, and if the group purchasing organization has negotiated a strict compliance contract for another manufacturer s products, we may be precluded from making sales to members of the group purchasing organization for the duration of the contractual arrangement. Our failure to respond to the cost-containment efforts of group purchasing organizations may cause us to lose market share to our competitors and could have a material adverse effect on our sales, financial condition, results of operations and cash flows.

We conduct a significant amount of our sales activity outside of the United States, which subjects us to additional business risks and may adversely affect our results due to increased costs.

During the year ended May 31, 2009, the period July 12, 2007 to May 31, 2008, the period June 1, 2007 to July 11, 2007, and fiscal 2007, we derived approximately \$976.2 million, or 39% of our net sales, \$883.1 million, or 41% of our net sales, \$92.6 million, or 37% of our net sales, and \$800.9 million, or 38% of our net sales, respectively, from sales of our products outside of the United States. We intend to continue to pursue growth opportunities in sales internationally, which could expose us to additional risks associated with international sales and operations. Our international operations are, and will continue to be, subject to a number of risks and potential costs, including:



In addition, we are subject to risks arising from currency exchange rate fluctuations, which could increase our costs and may adversely affect our results. The U.S. dollar value of our foreign-generated revenues varies with currency exchange rate fluctuations. Measured in local currency, the majority of our foreign-generated revenues were generated in Europe. Significant increases in the value of the U.S. dollar relative to foreign currencies could have a material adverse effect on our results of operations. Our consolidated net sales were negatively affected by approximately 3% during the year ended May 31, 2009 as a result of the impact of foreign currency translation.

Any of these factors may, individually or as a group, have a material adverse effect on our business, financial condition, results of operations and cash flows.

We conduct manufacturing operations outside of the United States and are in the process of transitioning certain manufacturing operations to China, which will expose us to additional business risks.

In addition to our principal executive offices, we maintain more than 50 other manufacturing facilities, offices and warehouse facilities in various countries, including Canada, Europe, Asia Pacific and Latin America.

We currently conduct operations in Jinhua, Zhejiang Province, China and Changzhou, Jiangsu Province, China. Our future business strategy may involve the operation of other manufacturing facilities in China. As a result of this initiative, we will be exposed to all the risks inherent in operating in an emerging market like China. In recent years the Chinese economy has undergone various developments, including beginning the transition from a more heavily government influenced-planned economy to a more market-oriented economy. Despite this transition, the Chinese government continues to own significant production assets and exercises significant control over economic growth. Our international operations, including our planned expansion in China, may be subject to greater or new political, legal and economic risks than those faced by our operations in the United States, including such risks as those arising from:

unexpected changes in foreign or domestic legal, regulatory or governmental requirements or approvals, such as those related to taxation, lending, import and tariffs, environmental regulations, land use rights, intellectual property and other matters;
unexpected increases in taxes, tariffs and other assessments;
diminished protection of intellectual property;
trade protection measures and import or export licensing requirements;
difficulty in staffing, training and managing foreign operations;
differing legal and labor regulations;
political and economic instability; and

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Due to these inherent risks, there can be no assurance that we will achieve any anticipated benefits from transitioning manufacturing operations to China and any of these factors may, individually or as a group, have a material adverse effect on our business, financial condition, results of

operating in a market with a less developed supply chain, transportation and distribution infrastructure.

operations and cash flows.

Our business and financial performance may be adversely affected by our inability to effectively implement restructuring and cost saving initiatives.

As of the second quarter of fiscal 2008, we commenced plans for a global cost savings program targeting pre-tax savings of \$65.0 million on an annualized basis. The program includes the transition of certain manufacturing operations to China, the restructuring of our domestic and international corporate structure and improvements to operating processes (including manufacturing footprint optimization, implementation of Six Sigma and Lean Manufacturing, procurement and offshoring initiatives, as well as reduction in overhead expenses). Projected costs and savings associated with these initiatives are subject to a variety of risks, including:

contemplated costs to effect these initiatives may exceed estimates;

initiatives we are contemplating may require consultation with various employees, labor representatives or regulators, and such consultations may influence the timing, costs and extent of expected savings;

initiatives will also require close coordination with customers with respect to the transfer of existing business to other Company locations, and certain business may not ultimately be retained as a result of the possible transition of certain operations;

the loss of skilled employees in connection with the initiatives; and

projected savings contemplated under this program may fall short of targets.

While we have begun and expect to continue to implement these strategies, there can be no assurance that we will be able to do so successfully or that we will realize the projected benefits of these and other restructuring and cost saving initiatives. If we are unable to realize these anticipated cost reductions, our business may be adversely affected. Moreover, our continued implementation of restructuring and cost saving initiatives integration may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our business may be harmed as a result of product liability litigation.

Our 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, we have received product liability claims relating to our products and anticipate that we will continue to receive claims in the future, some of which could have a material adverse impact on our business. In addition, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. Our existing product liability insurance coverage may be inadequate to satisfy liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or is in excess of our insurance coverage limits, our business could suffer and our financial condition, results of operations and cash flow could be materially adversely impacted.

We may be subject to intellectual property litigation and infringement claims, which could cause us to incur significant expenses or prevent us from selling our products.

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. We have 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 our financial resources and divert the time, energy and efforts of our management.

A successful claim of patent or other intellectual property infringement against us could adversely affect our growth and results of operations, in some cases materially. From time to time, we receive notices from third parties of potential infringement and receive claims of potential infringement. We may be unaware of intellectual property rights of others that may cover some of our technology. If someone claims that our products infringed their intellectual property rights, any resulting litigation could be costly and time consuming and would divert the attention of management and key personnel from other business issues.

The complexity of the technology involved and the uncertainty of intellectual property litigation increase these risks. Claims of intellectual property infringement also might require us to enter into costly royalty or license agreements. However, we may be unable to obtain royalty or license agreements on terms acceptable to us or at all. We also may be subject to significant damages or an injunction preventing us from manufacturing, selling or using some of our products in the event of a successful claim of patent or other intellectual property infringement. Any of these adverse consequences could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The conditions of the U.S. and international capital markets may adversely affect our ability to draw on our current revolving credit facilities as well as the value of certain of our investments.

We believe that our cash, other liquid assets and operating cash flow, together with available borrowings and potential access to credit and capital markets, will be sufficient to meet our operating expenses, research and development costs and capital expenditures and service our debt requirements as they become due. However, our ongoing ability to meet our substantial debt service and other obligations will be dependent upon our future performance, which will be subject to business, financial and other factors. We will not be able to control many of these factors, such as economic conditions in the markets where we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt, support our operations and meet our other obligations. If we do not have enough money, we may be required to refinance all or part of our existing debt, sell assets or borrow more money. We cannot guarantee that we will be able to do so on terms acceptable to us, if at all. In addition, the terms of existing or future debt agreements may restrict us from pursuing any of these alternatives.

If financial institutions that have extended credit commitments to us are adversely affected by the conditions of the U.S. and international capital markets, they may become unable to fund borrowings under their credit commitments to us, which could have a material and adverse impact on our financial condition and our ability to borrow additional funds, if needed, for working capital, capital expenditures, acquisitions, research and development and other corporate purposes.

Loss of our key management and other personnel, or an inability to attract such management and other personnel, could impact our business.

We depend on our senior managers and other key personnel to run our business and on technical experts to develop new products and technologies. The loss of any of these senior managers or other key personnel could adversely affect our operations. Competition for qualified employees is intense, and the loss of qualified employees or an inability to attract, retain and motivate additional highly skilled employees required for the management, operation and expansion of our business could hinder our ability to expand, conduct research and development activities successfully and develop marketable products.

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If we fail to retain our existing relationships with our independent sales agents and distributors or establish relationships with different agents and distributors, our results of operations may be negatively impacted.

Our revenues and profitability depend largely on the ability of independent sales agents and distributors to sell our products to customers. Typically, these agents and distributors have developed long-standing relationships with our customers and provide our customers with the necessary training and product support relating to our products. The average tenure of our independent sales agents and distributors within our subsidiary Biomet Orthopedics, LLC, or Biomet Orthopedics, is ten years. If we fail to retain our existing relationships with these agents and distributors or establish relationships with different agents and distributors, our results of operations may be negatively impacted.

A natural or man-made disaster could have a material adverse effect on our business.

We have approximately 16 manufacturing operations located throughout the world. However, a significant portion of our products are produced at and shipped from our facility in Warsaw, Indiana. In the event that this facility is severely damaged or destroyed as a result of a natural or man-made disaster, we would be forced to shift production to our other facilities and/or rely on third-party manufacturers. Such an event could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Any expansion or acquisition may prove risky for us.

We may, from time to time, consider and take advantage of selected opportunities to grow by acquiring businesses whose operations or product lines fit well within our existing businesses or whose geographic location or market position would enable us to expand into new markets. Our ability to implement this expansion strategy will, however, depend on whether any suitable businesses are available at suitable valuations, how much money we can spend and maintaining our customer base. Any acquisition that we make could be subject to a number of risks, including, failing to discover liabilities of the acquired company for which we may be responsible as a successor owner or operator despite any investigation we may make before the acquisition, our inability to assimilate the operations and personnel of the acquired company, the loss of key personnel in the acquired company and any adverse impact on our financial statements from the amortization of acquired intangible assets or the creation of reserves or write-downs. We may not be able to adequately meet these challenges, and any failure to do so could adversely affect our business, financial condition, results of operations and cash flows. In addition, if we incur additional indebtedness to finance these acquisitions, the related risks we face from our already substantial level of indebtedness could intensify.

Risks Related to Our Indebtedness

Our substantial level of indebtedness could materially adversely affect our ability to generate sufficient cash to fulfill our obligations under the notes, our ability to react to changes in our business and our ability to incur additional indebtedness to fund future needs.

We are highly leveraged. As of May 31, 2009, we had total indebtedness of \$6,212.7 million. The following chart shows our level of indebtedness as of May 31, 2009:

(6)		
(\$ in millions)		
European facilities	\$	52.6
Senior secured term loan facilities		3,524.7
Senior secured cash flow revolving credit facility		
Senior secured asset-based revolving credit facility		65.2
Senior cash pay notes		775.0
Senior toggle notes		775.0
Senior subordinated notes		1,015.0
Premium on debt		5.2
Total	\$	6,212.7

As of May 31, 2009, we had outstanding approximately \$3,589.9 million in aggregate principal amount of indebtedness under our senior secured credit facilities that would bear interest at a floating rate. We have entered into a series of interest rate swap agreements to fix the interest rates on approximately 81% of the borrowings under our senior secured credit facilities. See Management s Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures about Market Risk Interest Rate Risk. Based on our overall interest rate exposure at May 31, 2009, including variable rate debt, a hypothetical 10% increase or decrease in interest rates applied to the fair value of

the financial instruments discussed above as of May 31, 2009, would cause a \$2.7 million increase in or savings in interest expense, respectively.

Our substantial level of indebtedness increases the possibility that we may be unable to generate cash sufficient to pay, when due, the principal of, interest on or other amounts due in respect of our indebtedness. Our substantial indebtedness, combined with our other financial obligations and contractual commitments, could have important consequences. For example, it could:

make it more difficult for us to satisfy our obligations with respect to our indebtedness, including the notes, and any failure to comply with the obligations under any of our debt instruments, including restrictive covenants, could result in an event of default under the indentures governing the notes and the agreements governing such other indebtedness;