

BIOMET INC
Form 10-K
August 25, 2010
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended May 31, 2010.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-15601

BIOMET, INC.

(Exact name of registrant as specified in its charter)

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Indiana
(State or other jurisdiction of
incorporation or organization)

35-1418342
(I.R.S. Employer
Identification No.)

56 East Bell Drive, Warsaw, Indiana
(Address of principal executive offices)

46582
(Zip Code)

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

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

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

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

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

Indicate by check mark 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.

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. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of May 31, 2010, there was no established public trading market for any of the common stock of the registrant. As of May 31, 2010, there were 1,000 shares of common stock of the registrant outstanding, 100% of which were owned by LVB Acquisition, Inc.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents**TABLE OF CONTENTS**

	Page
<u>Part I.</u>	
Item 1. <u>Business</u>	5
Item 1A. <u>Risk Factors</u>	26
Item 1B. <u>Unresolved Staff Comments</u>	43
Item 2. <u>Properties</u>	44
Item 3. <u>Legal Proceedings</u>	45
Item 4. <u>Reserved</u>	46
<u>Part II.</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities</u>	47
Item 6. <u>Selected Financial Data</u>	48
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	49
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	74
Item 8. <u>Financial Statements and Supplementary Data</u>	76
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	123
Item 9A. <u>Controls and Procedures</u>	123
Item 9B. <u>Other Information</u>	124
<u>Part III.</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	125
Item 11. <u>Executive Compensation</u>	130
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	151
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	153
Item 14. <u>Principal Accounting Fees and Services</u>	154
<u>Part IV.</u>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	155
<u>Signatures</u>	156

Table of Contents

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, predict, project, potential, estimate, should, will or similar expressions. These statements include, but are not limited to, statements related to:

the timing and number of planned new product introductions;

the effect of anticipated changes in the size, health and activities of the population or on the demand for our products;

assumptions and estimates regarding the size and growth of certain market categories;

our ability and intent to expand in key international markets;

the timing and anticipated outcome of clinical studies;

assumptions concerning anticipated product developments and emerging technologies;

the future availability of raw materials;

the anticipated adequacy of our capital resources to meet the needs of our business;

our continued investment in new products and technologies;

the ultimate marketability of products currently being developed;

our ability to successfully implement new technologies and transition certain manufacturing operations to China;

our ability to manage working capital and generate adequate cash flows to service outstanding debt;

our ability to sustain sales and earnings growth;

our success in achieving timely approval or clearance of our products with domestic and foreign regulatory entities;

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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, future regulatory reforms affecting the healthcare 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

Table of Contents

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;

the effects upon us of complying with the covenants contained in our senior secured credit facilities and the indentures governing our senior notes, senior toggle notes and senior subordinated notes;

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;

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;

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developments adversely affecting our sales activities outside the United States;

decreases in reimbursement levels by our customers, including certain of our foreign government customers that are experiencing fiscal distress;

difficulties in transitioning certain manufacturing operations to China and other locations;

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

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. We intend to take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 regarding our forward-looking statements, and are including this sentence for the express purpose of enabling us to use the protections of the safe harbor with respect to all forward-looking statements.

Table of Contents**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. Our principal subsidiaries include Biomet Orthopedics, LLC; Biomet Manufacturing Corp.; Biomet Europe BV; 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.

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. (Parent), and LVB Acquisition Merger Sub, Inc., an Indiana corporation and a wholly-owned subsidiary of Parent, (Purchaser), which agreement was amended and restated as of June 7, 2007 and which we refer to as the Merger Agreement . Pursuant to the Merger Agreement, on June 13, 2007, Purchaser commenced a cash tender offer (the Offer) to purchase all of our outstanding common shares, without par value (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. In connection with the Offer, Purchaser entered into a credit agreement dated as of July 11, 2007 for a \$6,165.0 million senior secured term loan facility, (the Tender Facility), maturing on June 6, 2008, and pursuant to which it borrowed approximately \$4,181.0 million to finance a portion of the Offer and pay related fees and expenses. 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 (the Merger). Subsequent to the acquisition, we became a subsidiary of 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 TPG Capital (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 our 10% Senior Notes due 2017, which we refer to as our original senior cash pay notes, our 10³/8%/11¹/8% Senior Toggle Notes due 2017, which we refer to as our original senior toggle notes, and our 5¹/8% Senior Subordinated Notes due 2017, which we refer to as our original senior subordinated notes and collectively with our original senior cash pay notes and original senior toggle notes, our 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

cash on hand.

Table of Contents

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.

Exchange Offer

On May 21, 2008, we commenced an exchange offer for all of our outstanding original notes for an equal principal amount of our 10% Senior Notes due 2017, which we refer to as our exchange senior cash pay notes, our 10 3/8%/11 1/8% Senior Toggle Notes due 2017, which we refer to as our exchange senior toggle notes, and our 11 1/8% Senior Subordinated Notes due 2017, which we refer to as our exchange senior subordinated notes, which notes were registered under the Securities Act of 1933, as amended, and which we refer to collectively as our exchange notes. On July 1, 2008, we announced the completion of the exchange offer, pursuant to which \$775,000,000 of the \$775,000,000 aggregate principal amount of original senior cash pay notes, \$774,999,500 of the \$775,000,000 aggregate principal amount of original senior toggle notes and \$1,014,999,500 of the \$1,015,000,000 aggregate principal amount of our original senior subordinated notes were tendered and accepted for exchange. We refer to the original senior cash pay notes and the exchange senior cash pay notes as the senior cash pay notes, the original senior toggle notes and the exchange senior toggle notes as the senior toggle notes, the original senior subordinated notes and the exchange senior subordinated notes as the senior subordinated notes and the original notes and the exchange notes collectively as the notes. We also refer to the senior cash pay notes and the senior toggle notes as the senior notes.

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.

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. 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.

Table of Contents

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 2010 representing our 32nd consecutive year of year over year net sales growth. Over the last 20 years, from fiscal 1990 through fiscal 2010, we increased net sales at a compounded annual growth rate of approximately 15%. We have sustained growth through multiple macro-economic cycles, demonstrating a stable business profile. In addition, we have historically had modest capital expenditures 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, an 18-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 19 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 25 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 total of 23 years in the medical device industry. Even though each of Messrs. Binder, Florin, Kashuba and Serbousek has been with us for less than four years, the members of our senior management team have an average tenure of 15 years with us and an average tenure of 20 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 TPG Capital 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 adverse conditions in the global economy, 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 mid single digits. Because of this, management has taken, and will continue to take, 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 and fiscal 2010 as compared to prior fiscal years principally due to the elective nature of dental implant procedures, which are typically not reimbursed by private insurance plans or governmental

Table of Contents

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 could remain flat during the current global economic environment, compared to reported double digit growth in fiscal 2008. Dental sales decreased 2% worldwide and in the United States during the year ended May 31, 2010; however, we believe the dental market has begun to stabilize and showed signs of improvement during the last half of fiscal 2010.

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. In March 2010, comprehensive health care reform legislation was enacted through the passage of the Patient Protection and Affordable Health Care Act (H.R. 3590) and the Health Care and Education Reconciliation Act (H.R. 4872). Among other initiatives, these laws impose a 2.3% excise tax on domestic sales of medical devices following December 31, 2012, which is estimated to contribute approximately \$27 billion to healthcare reform. Various healthcare reform proposals have also emerged at the state level. Outside of the excise tax, which will impact our results of operations and cash flows following December 31, 2012, we cannot predict with certainty what healthcare initiatives, if any, will be implemented at the state level, or what the ultimate effect of federal health care reform or 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, results of operations and cash flows, 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.

We continue to monitor economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and our business, especially in light of the global economic downturn and the European sovereign debt crisis. We believe the credit and economic conditions within Greece, Spain, Italy and Portugal, among other members of the European Union, have deteriorated over the past twelve months. These conditions have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect on our accounts receivable outstanding in these countries.

As of May 31, 2010, our orthopedic net accounts receivable in Greece, Italy, Spain and Portugal totaled over \$100.0 million. To date, we have not experienced any significant cash losses with respect to the collection of our accounts receivable related to sales within these countries. However, during fiscal 2010 we did recognize \$9.3 million of expense to adjust our public accounts receivable in Greece to its expected net realizable value based upon the recent proposal by the Greek government to settle certain past due healthcare liabilities with long-term zero coupon bonds. We classified \$38.9 million of our Greece receivables as a long-term asset based on the Greek government proposal.

We have expanded the factoring of our accounts receivable in Spain, Italy and Portugal. Control and risk of those trade receivables are fully transferred and accounted for as a sale. We factored approximately \$39.7 million of receivables under these factoring arrangements during fiscal 2010, which serve to reduce our collection risk in these countries.

Table of Contents

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, or NPI, process worldwide. The NPI process is a global portfolio and project management approach that helps 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 have a single database of all of our development 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 are assessed against pre-determined gate criteria. Functional teams, along with the global portfolio review teams, 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 accounted for approximately 57% of the global orthopedic market in 2009, 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 2011 and beyond, and we believe these changes 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 had not been a primary focus area of management. In addition, we believe we will benefit from identified cost savings as we enhance operational efficiencies. We plan to use available cash after capital expenditures primarily to reduce leverage, strengthen our balance sheet and for strategic acquisitions.

Table of Contents

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, 2010. 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 Vanguard[®] Complete Knee System is supported by five instrumentation platforms: Microplasty[®], Premier[®], Microplasty[®] Elite, Vanguard[®] Tensor and Vanguard[®] Anterior Referencing, accommodating a number of workflows and techniques. During fiscal 2010, we continued the development efforts for the rotating platform version of the Vanguard[®] Complete Knee System.

Also during fiscal 2010, the Signature[®] System, initially designed for use in primary knee procedures, was under development for use in unicompartmental knee applications. The Signature[®] System uses a patient's MRI or CT data to deliver patient-specific positioning guides to the surgeon for improved pre-operative planning and for implementation during the procedure. The Signature[®] System 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.

The Regenerex[®] Primary Patella was introduced during fiscal 2010. When utilized with our clinically successful Regenerex[®] Tibial Tray, the Regenerex[®] Primary Patella complements our broad cementless product portfolio. This portfolio combines advanced Regenerex[®] porous metal technology, which allows for biologic fixation, with proven tibial tray and patella designs. Additionally, the E1[®] Antioxidant Infused Technology Tibial Bearings continued to receive strong market demand. The E1[®] technology provides Vitamin E infused highly crosslinked polyethylene, which is designed to offer strength and oxidative stability for improved wear characteristics.

Table of Contents

We continue to be a market leader for products accommodating minimally-invasive knee techniques. 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 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. Many of the femoral prostheses utilize our proprietary PPS® Porous Plasma Spray coating, which enables cementless fixation.

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.

From 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 device 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 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 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 by 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 M²a-Magnum Articulation System incorporates large diameter metal-on-metal components to more closely resemble the natural anatomy, offering joint mechanic restoration designed to improve range of motion and joint stability. We market ArComXL® polyethylene, which is a highly crosslinked polyethylene bearing material based on our proven ArCom® polyethylene. ArComXL® 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 material. 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 marketed outside the United States for patients in the early stages of degenerative joint disease, including osteoarthritis, rheumatoid

Table of Contents

arthritis and avascular necrosis. We commenced a clinical study for the ReCap® Total Resurfacing System in the United States during fiscal 2006 and as of May 31, 2010, patient enrollment had been completed with 272 patients enrolled in the study. The FDA accepted the inclusion of 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 and fiscal 2010. The Regenerex® Construct unites the proven clinical history of titanium with an enhanced interconnecting pore structure, resulting in an innovative material that provides for high levels of biologic fixation and provides design flexibility and solutions for difficult primary and revision procedures. 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 and 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 continued to receive high levels of market acceptance during fiscal 2009 and fiscal 2010.

During the fourth quarter of fiscal 2009, we introduced the Comprehensive® Reverse Shoulder System which offers excellent 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 continued to receive strong market acceptance in Europe during fiscal 2010. 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, 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 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

Table of Contents

QuickSeat® connection, provides audible and tactile feedback when restorative abutments and ancillary components are seated into the implant. In addition, the $\frac{6}{12}$ point connection design of the Certain® Implant System offers enhanced flexibility in placing the implant when pre-angled abutments are used. In fiscal 2009, Biomet 3i continued to expand 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 and 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 in a non-toxic lecithin carrier, which is 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 allows 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 for more general dentists to become 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.

In July 2010, Biomet 3i announced its offering of comprehensive digital solutions to dental implant professionals worldwide through an innovative collaboration with Renishaw plc, a manufacturer of in-lab dental scanning systems. This new relationship provides laboratories using Renishaw Contact Scanners and *3i incise* CAD software broader access to a wide range of dental milling options including *3i incise* Copings and Frameworks in Zirconia and Cobalt Chrome (only available in Europe) and the ability to scan precision copy milled bar patterns (not available for sale in the United States; there is a 510(k) premarketing notification to the FDA pending for precision copy milled bars scanned on Renishaw systems). Laboratories utilizing the ProceraForte® Scanner (Nobel Biocare Services AG is the owner of the ProceraForte mark) can also benefit from all of these options by using the *3i incise* CAD software.

With *3i incise*, Biomet 3i and Renishaw plc are providing solutions for natural tooth restorations such as copings and frameworks. These options are available through dental laboratories, are patient specific and designed to result in beautifully crafted new smiles.

Other Reconstructive Products and Services. Our PMI® Patient-Matched Implant services group designs, manufactures and delivers patient-specific reconstructive devices to orthopedic specialists. We believe this

Table of Contents

service continues to enhance our reconstructive sales by strengthening our business 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 implant for each specific patient.

We are involved in the on