WRIGHT MEDICAL GROUP INC
Form 10-K
March 01, 2006

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2005

OR

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

For the transition period from _____ to _____

Commission file number: 000-32883

WRIGHT MEDICAL GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4088127**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
5677 Airline Road, Arlington, Tennessee	**38002**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s telephone number, including area code: **(901) 867-9971**

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

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

Common Stock, par value $.01 per share

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

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

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. þ Yes o No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer þ Accelerated filer o Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes þ No

The aggregate market value of the voting and non-voting common equity held by nonaffiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as

of the last business day of the registrant s most recently completed second fiscal quarter was $814,239,980.
As of February 24, 2006, there were 34,202,268 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III is incorporated by reference from portions of the definitive proxy statement to be filed within 120 days after December 31, 2005, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 11, 2006.

WRIGHT MEDICAL GROUP, INC.
ANNUAL REPORT ON FORM 10-K
Table of Contents

Safe-Harbor Statement

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements made in this annual report, other than statements of historical fact, are forward-looking statements. Forward-looking statements reflect management s current knowledge, assumptions, beliefs, estimates, and expectations and express management s current views of future performance, results, and trends. We wish to caution readers that actual results might differ materially from those described in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including the factors discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A and elsewhere in this annual report), which could cause our actual

results to differ materially from those described in the forward-looking statements. Although we believe that the forward-looking statements are accurate, there can be no assurance that any forward-looking statement will prove to be accurate. A forward-looking statement should not be regarded as a representation by us that the results described therein will be achieved. We wish to caution readers not to place undue reliance on any forward-looking statement. The forward-looking statements are made as of the date of this annual report, and we assume no obligation to update any forward-looking statement after this date.

Table of Contents

PART I

Item 1. Business.

Overview

Wright Medical Group, Inc., through Wright Medical Technology, Inc. and other operating subsidiaries, is a global orthopaedic medical device company specializing in the design, manufacture and marketing of reconstructive joint devices and biologics products. Reconstructive joint devices are used to replace knee, hip and other joints that have deteriorated through disease or injury. Biologics are used to replace damaged or diseased bone, to stimulate bone growth, and to provide other biological solutions for surgeons and their patients. Within these markets, we focus on the higher-growth sectors of the orthopaedic industry, such as advanced bearing surfaces, modular necks, and bone conserving implants within the hip market, as well as on the integration of our biologics products into reconstructive joint procedures and other orthopaedic applications.

For the year ended December 31, 2005, we had net sales of $319.1 million and net income of $21.1 million. As of December 31, 2005, we had total assets of $371.8 million. Detailed information on our net sales by products line and our net sales, operating income and long-lived assets by geographic region can be found in Note 16 to the financial statements contained in Item 8 of this report.

History

We were incorporated on November 23, 1999, as a Delaware corporation (previously named Wright Acquisition Holdings, Inc.) and had no operations until an investment group led by Warburg, Pincus Equity Partners, L.P. acquired majority ownership of our predecessor company, Wright Medical Technology, Inc., on December 7, 1999. This transaction, which represented a recapitalization of our predecessor company, reduced our debt and provided investment capital, and allowed us to build on the predecessor company s respected brand name and strong relationships with orthopaedic surgeons developed during its 50-year history.

On December 22, 1999, we acquired Cremascoli Ortho Holding, S.A., based in Toulon, France, and shortly thereafter put a new management team in place at Cremascoli. This acquisition extended our product offerings, enhanced our product development capabilities, and expanded our European presence. As a result of combining Cremascoli s strength in hip reconstruction with the predecessor company s historical expertise in knee reconstruction and biologics, we offer a broad range of reconstructive joint devices and biologics to orthopaedic surgeons in over 60 countries.

In 2001, we sold 7,500,000 shares of common stock in our initial public offering, which generated $84.8 million in net proceeds. In 2002, we sold 3,450,000 shares of common stock in a secondary offering which generated $49.5 million in net proceeds.

Orthopaedic Industry

It is estimated that the worldwide orthopaedic industry generated sales of approximately $21 billion in 2005. We believe this figure will grow by 7% to 9% annually over the next three to four years. Seven multinational companies currently dominate the orthopaedic industry, each with approximately $1.5 billion or more in annual sales. The size of these companies often leads them to concentrate their marketing and research and development efforts on products that they believe will have a relatively high minimum threshold level of sales. As a result, there is an opportunity for a mid-sized orthopaedic company, such as us, to focus on smaller, higher-growth sectors of the orthopaedic market, while still offering a comprehensive product line to address the needs of its customers.

Orthopaedic devices are commonly divided into several primary sectors corresponding to the major subspecialties within the orthopaedic field: reconstruction, trauma, arthroscopy, spine and biologics. We specialize in reconstructive joint devices and biologics products.

Table of Contents

Reconstructive Joint Device Market

Most reconstructive joint devices are used to replace or repair joints that have deteriorated as a result of disease or injury. Despite the availability of non-surgical treatment alternatives such as oral medications, injections and joint fluid supplementation of the knee, severe cases of disease or injury often require reconstructive joint surgery. Reconstructive joint surgery involves the modification of the bone area surrounding the affected joint and the insertion of one or more manufactured components, and may also involve the use of bone cement.

The reconstructive joint device market is generally divided into the areas of knees, hips and extremities. It is estimated that the worldwide reconstructive joint device market had sales of approximately $9 billion in 2005, with hip reconstruction and knee reconstruction representing two of the largest sectors.

Knee Reconstruction. The knee joint involves the surfaces of three distinct bones: the lower end of the femur, the upper end of the tibia or shin bone, and the patella or kneecap. Cartilage on any of these surfaces can be damaged due to disease or injury, leading to pain and inflammation requiring knee reconstruction. Knee reconstruction was the largest sector of the reconstructive joint device market in 2005, with estimated sales of approximately $4.5 billion worldwide.

Major trends in knee reconstruction include the use of alternative, better performing surface materials to extend the implant s life and increase conservation of the patient s bone to minimize surgical trauma and accelerate recovery. Another significant trend in the knee reconstruction industry is the use of more technologically advanced knees, called advanced kinematic knees, which more closely resemble natural joint movement. Additionally, we believe that minimally invasive knee procedures, such as those for unicompartmental repair, which replaces only one femoral condyle, as well as minimally invasive surgical techniques and instrumentation are becoming more widely accepted.

Hip Reconstruction. The hip joint is a ball-and-socket joint which enables the wide range of motion that the hip performs in daily life. The hip joint is most commonly replaced due to degeneration of the cartilage between the head of the femur (the ball) and the acetabulum or hollow portion of the pelvis (the socket). This degeneration causes pain, stiffness and a reduction in hip mobility. It is estimated that the worldwide hip reconstruction market had sales of approximately $4 billion in 2005.

Similar to the knee reconstruction market, major trends in hip replacement procedures and implants are to extend implant life and to preserve bone stock for possible future procedures. New products have been developed that incorporate advances in bearing surfaces from the traditional polyethylene surface. Polyethylene surfaces may create wear debris that can lead to potential loosening of the implant. These alternative bearing surfaces include metal-on-metal, cross-linked polyethelene and ceramic-on-ceramic combinations, which exhibit improved wear characteristics and lead to longer implant life. In addition to advances in bearing surfaces, implants that preserve more natural bone have been developed in order to minimize surgical trauma and recovery time for patients. These implants, known as bone-conserving implants, leave more of the hip bones intact, which is beneficial given the likelihood of future revision replacement procedures as the average patient s lifetime increases. Bone-conserving procedures are intended to enable patients to delay their first total hip procedure and may significantly increase the time from the first procedure to the time when a revision replacement implant is required.

Extremity Reconstruction. Extremity reconstruction involves implanting devices to replace or reconstruct injured or diseased joints such as the finger, toe, wrist, elbow, foot, ankle and shoulder. It is estimated that the extremity reconstruction market had sales of approximately $400 million worldwide in 2005. Major trends in extremity reconstruction include unique distal radius (wrist) and foot and ankle fixation devices.

Biologics Market

The biologics market is one of the fastest growing sectors of the orthopaedic market. Biologics products use both biological tissue-based and synthetic materials to regenerate damaged or diseased bone and to repair damaged tissue. These products stimulate the body s natural regenerative capabilities to minimize or delay the need for invasive implant surgery, replace damaged or diseased bone, and provide other biological solutions for surgeons and their patients.

Table of Contents

Biologics products are used in spinal fusions, trauma fractures, joint replacements, and cranio-maxillofacial procedures and represent an alternative solution to autograft, a procedure that involves harvesting a patient s own bone or soft tissue. Currently, there are three main types of biological bone grafting products, which are osteoconductive, osteoinductive and combined osteoconductive/osteoinductive, that refer to the way in which the materials affect bone growth. Osteoconductive materials serve as a scaffold that supports the formation of bone but does not trigger new bone growth, whereas osteoinductive materials induce bone growth. Other biologics products enable the repair of soft tissue. These products provide favorable microenvironments for quick revascularization and cell proliferation. It is estimated that the biologics market generated sales of approximately $900 million worldwide in 2005.

Government Regulation

United States

Our products are strictly regulated by the United States Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act (FDC Act). Some of our products are also regulated by state agencies. FDA regulations and the requirements of the FDC Act affect the pre-clinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, recordkeeping, advertising and promotion of our medical device products. Our tissue-based products are subject to FDA regulations, the National Organ Transplant Act (NOTA), accreditation from the American Association of Tissue Banks (AATB), and various state agency regulations.

Generally, before we can market a new medical device, marketing clearance from the FDA must be obtained through a premarket notification under Section 510(k) of the FDC Act or the FDA s approval of a premarket approval (PMA) application. The FDA typically grants a 510(k) clearance if the applicant can establish that the device is substantially equivalent to a predicate device. It generally takes three months from the date of a 510(k) submission to obtain clearance, but it may take longer, particularly if a clinical trial is required. The FDA may find that a 510(k) is not appropriate or that substantial equivalence has not been shown and, as a result, will require a PMA application. PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of human clinical trials, bench tests and laboratory and animal studies. The PMA application must also contain a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission must include the proposed labeling and any training materials. The PMA application process can be expensive and generally takes significantly longer than the 510(k) process. Additionally, the FDA may never approve the PMA application. As part of the PMA application review process, the FDA generally will conduct an inspection of the manufacturer s facilities to ensure compliance with applicable quality system regulatory requirements, which include quality control testing, control documentation and other quality assurance procedures.

If human clinical trials of a medical device are required, either for a 510(k) submission or a PMA application, and the device presents a significant risk, the sponsor of the trial, usually the manufacturer or the distributor of the device, must file an investigational device exemption (IDE) application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and/or laboratory testing. If the IDE application is approved by the FDA and one or more institutional review boards (IRBs), human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a nonsignificant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA. Submission of an IDE does not give assurance that the FDA will approve the IDE and, if it is approved, there can be no assurance the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial must also comply with the FDA s IDE regulations and informed consent must be obtained from each subject. If the FDA believes we are not in compliance

Table of Contents

with the law, it can institute proceedings to detain or seize products, issue a market withdrawal, enjoin future violations and seek civil and criminal penalties against us and our officers and employees. If we fail to comply with these regulatory requirements, our business, financial condition and results of operations could be harmed.

Most of our products are approved through the 510(k) premarket notification process. We have conducted clinical trials to support many of our regulatory approvals. Regulations regarding the manufacture and sale of our products are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition and results of operations. In particular, the FDA has statutory authority to regulate allograft-based products, processing and materials. The FDA has been working to establish a more comprehensive regulatory framework for allograft-based products, which are principally derived from human cadaveric tissue. The framework developed by the FDA establishes criteria for determining whether a particular human tissue-based product will be classified as human tissue, a medical device or biologic drug requiring premarket clearance or approval. All tissue-based products are subject to extensive FDA regulation, including a requirement that ensures that diseases are not transmitted to tissue recipients. The FDA has also proposed extensive additional regulations that would govern the processing and distribution of all allograft products. Consent to use the donor s tissue must also be obtained. If a tissue-based product is considered tissue, it does not require FDA clearance or approval before being marketed. If it is considered a device, or a biologic drug, then FDA clearance or approval may be required.

In addition to granting approvals for our products, the FDA and international regulatory authorities periodically inspect us for compliance with regulatory requirements that apply to medical devices marketed in the U.S. and internationally. These requirements include labeling regulations, manufacturing regulations, quality system regulations, regulations governing unapproved or off-label uses, and medical device regulations. Medical device regulations require a manufacturer to report to the FDA serious adverse events or certain types of malfunctions involving its products. The FDA periodically inspects device and drug manufacturing facilities in the U.S. in order to assure compliance with applicable quality system regulations. The FDA last inspected our Arlington, Tennessee manufacturing facility in March 2005, and our Toulon, France manufacturing facility in October 2003.

International

We obtain required regulatory approvals and comply with extensive regulations governing product safety, quality, manufacturing and reimbursement processes in order to market our products in all major foreign markets. These regulations vary significantly from country to country and with respect to the nature of the particular medical device. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in the U.S., and requirements for such approval may differ from FDA requirements.

All of our products sold internationally are subject to certain foreign regulatory approvals. In order to market our product devices in the member countries of the European Union, we are required to comply with the Medical Devices Directives and obtain CE mark certification. CE mark certification is the European symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. Under the Medical Devices Directives, all medical devices including active implants must qualify for CE marking. We also are required to comply with other foreign regulations such as obtaining MHLW (Ministry of Health Labor and Welfare) approval in Japan, HPB (Health Protection Branch) approval in Canada, and TGA (Therapeutic Goods Administration) approval in Australia as a few examples.

Products

We operate as one reportable segment, offering products in four primary market sectors: knee reconstruction, hip reconstruction, extremity reconstruction, and biologics.

Knee Reconstruction

Our knee reconstruction product portfolio strategically positions us in the areas of total knee reconstruction, revision replacement implants, and limb preservation products. These products provide the surgeon with a continuum of treatment options for improving patient care. We differentiate our products through innovative design features that reproduce movement and stability, resulting in products that more closely resemble a healthy knee. Additionally, we provide a broad array of Open and Minimally Invasive Surgery surgical instrumentation to accommodate surgeon

Table of Contents

and patient preference. Minimally Invasive Surgery (MIS) or Least Invasive Surgery (LIS) has gained momentum in recent history due to the smaller incision and minimal disruption of soft tissues, which can significantly reduce recovery times. Faster recovery and rehabilitation times are important to the growing market of younger, more active patients who want a quick return to their active lifestyles. The MIS surgical instrumentation is not only tissue sparing but more accurate and can perform traditional/open procedures as well. This is important for surgeons because not every patient clinically qualifies for the small incision surgical technique and they can standardize with one set of instruments regardless of open or MIS surgical technique.

The ADVANCE® Knee System is our primary knee product line offering. There are several innovative product offerings within the ADVANCE® Knee System product line, one of which is the ADVANCE® Medial Pivot Knee. The understanding of knee movement and function has advanced significantly over the past several years, and we believe the ADVANCE® Medial Pivot Knee is the first knee to be mass marketed that takes full advantage of the strides made in understanding the knee joint. The ADVANCE® Medial Pivot Knee is designed to approximate the movement and function of a healthy knee by using a unique spherical medial feature. Overall, we believe the ADVANCE® Medial Pivot Knee more closely approximates natural knee motion, improves clinical performance and provides excellent range of motion.

Our ADVANCE® Double High Knee Tibial Insert is designed to address the needs of surgeons that desire to retain the posterior cruciate ligament (PCL). The insert design addresses an adverse phenomenon, known as paradoxical motion, that often occurs with other PCL retaining knee systems. In general, total knee systems are designed to be used either with or without the patient s PCL. Most knee implant designs used with the PCL are based on the theory that the ligament will provide stability and increased flexion. Due to the phenomenon of paradoxical motion, however, small amounts of uncontrolled sliding can occur between the replaced femoral and tibial surfaces. This movement prevents the prosthetic knee from flexing in a stable, consistent manner like a normal knee and can result in abnormal gait and reduced flexion. The ADVANCE® Double-High Knee component can minimize paradoxical motion through an articulation designed to provide stability and maximize PCL function.

Our REPIPHYSIS® Technology allows for non-invasive expansion of any long bone where lengthening is needed. This technology, which we exclusively license, can be incorporated into a prosthetic implant and subsequently adjusted non-invasively when lengthening of the implant is needed. The most common application of this breakthrough technology is in the field of pediatric oncology, where growing children can have the bones attached to their hip or knee implant lengthened non-invasively, thus eliminating the need for more frequent surgeries and anesthesia.

Hip Reconstruction

We offer a comprehensive line of products for hip joint reconstruction. This product portfolio provides offerings in the areas of bone-conserving implants, total hip reconstruction, revision replacement implants, and limb preservation. Additionally, our hip products offer a combination of unique, innovative modular designs, a complete portfolio of advanced surface bearing materials, including ceramic-on-ceramic and metal-on-metal articulations, and innovative technology in surface replacement implants. We are therefore able to offer surgeons and their patients a full continuum of treatment options.

Our hip product portfolio includes our LIFETIME SOLUTIONS plan, a three-tiered lifetime solution for the surgical treatment of hip pain that incorporates our CONSERVE® family of products. Our CONSERVE® family of products work together to provide bone-conserving approaches to hip resurfacing and hip replacement. The first offering in our LIFETIME SOLUTIONS plan is a partial hip resurfacing procedure performed with the CONSERVE® Partial Resurfacing Implant. This procedure preserves the femoral head and neck and does not invade the femoral canal. In addition, the acetabulum is left completely intact. The CONSERVE® Partial Resurfacing Implant s conservative restoration provides a better solution for the patient by leaving maximum bone for future surgical procedures.

The second offering in our LIFETIME SOLUTIONS plan is a total hip resurfacing procedure using the CONSERVE® Plus Resurfacing Implant. This implant retains the femoral head and neck and resurfaces the acetabulum in a bone conserving manner, helping to preserve the patient s natural motion in the joint. Our CONSERVE® Plus Resurfacing Implant is available outside the U.S., but is pending FDA approval for the U.S. market.

Table of Contents

The third offering within LIFETIME SOLUTIONS is a primary total hip replacement. The CONSERVE® Total Implant with BFH Technology mimics the natural kinematics of the hip by replacing the natural femoral head with a large diameter femoral head implant. The result of this increased femoral head diameter is a significant reduction in the potential for dislocation. Coupled with our PROFEMUR® Hip System, we are able to provide surgeons and patients a minimally invasive option for their total hip replacement.

Following the creation of the CONSERVE® family of products, we launched our new A-Class Advanced Bearings Technology platform in 2005. The first offering from this platform is the new A-Class Metal for the CONSERVE® Total Implant with BFH Technology. Laboratory tests suggest that over the life of the implant, this new metal-on-metal bearing will result in significantly less wear than current metal-on-metal bearing surfaces. This new bearing is coupled with the BFH Technology for increased jump distance and low dislocation rates. In addition to the A-Class Metal, we also introduced our A-Class Poly cross-linked polyethylene acetabular bearing for the LINEAGE® Acebabular system. This advancement now gives us the only cup on the market with ceramic, metal and cross-linked poly inserts.

In our hip replacement product lines, the LINEAGE® Acetabular System provides the surgeon with the option to interchangeably use either ceramic-on-ceramic, metal-on-metal, or metal-on-cross-linked-polyethylene acetabular bearing surfaces for use with a common metal acetabular shell, thus offering maximum flexibility to the surgeon while minimizing inventory levels. The standard for replacement of the acetabulum, or socket, in the hip joint is a two-piece system consisting of a metal shell with a polyethylene liner. The polyethylene component serves as a bearing surface for the head of the femoral component, or ball. Alternative hard bearing materials, such as metal-on-metal and ceramic-on-ceramic, have been introduced in recent years. These options, ceramic-on-ceramic in particular, significantly reduce wear debris from articulation and therefore provide an optimal solution for young and active patients.

The ANCA-FIT Hip System, a traditional hip replacement system designed in Europe, has received clinical acceptance in Europe for eight years. The ANCA-FIT Hip System includes the femoral stem family of components as well as the acetabular shell family. The femoral stem is a non-cemented, anatomical stem with HA, or hydroxylapatite, coating. It features the patented modular interchangeable neck option found in other modular stems such as the PROFEMUR® Hip System. The acetabular shell is a titanium porous coated shell, designed to accept either ceramic or polyethylene liners.

The PROFEMUR® Hip System provides surgeons with modularity in hip implant procedures. Our PROFEMUR® Hip System features a patented modular femoral neck, which allows the surgeon to make final adjustments in leg length, offset and version to the implant as the last step in the procedure in order to accommodate each patient s unique anatomy. The PROFEMUR® Hip System is offered with a variety of femoral stem designs to provide a comprehensive implant system to appeal to any physician s preference in implant selection. Our principal PROFEMUR® stem offerings include our PROFEMUR® Z, PROFEMUR® Plasma Z, PROFEMUR® S PROFEMUR® Tapered and the PROFEMUR® Renaissance stems.

The PERFECTA® Hip System is the basic platform for our traditional hip stem product line. This system provides a full range of fixation options including press fit and cemented versions, and offers a wide selection of geometries in order to meet the needs of the patient s anatomical requirements as well as the surgeon s preferences. This product allows surgeons the flexibility to match the implant to each patient s unique requirements. The PERFECTA® Hip System has over ten years of clinical success worldwide.

The GUARDIAN® Limb Salvage System offers options for patients with significant bone loss due to cancer, trauma, or previous surgical procedures. This modular system, with an array of options in a multitude of sizes and complete inter-changeability, provides the surgeon with the ability to meet a variety of patient needs. The GUARDIAN® Proximal Tibial Implant was developed for patients with significant bone loss in the tibial bone. The GUARDIAN® Revision Hinge Implant, another of the products offered within the system, was developed for use in revision

Table of Contents

surgeries where both bone loss and ligament deficiencies are present. The GUARDIAN® Total Femur is used in rare cases where the entire femur must be replaced.

Extremity Reconstruction

We offer extremity products for the hand, wrist, elbow, shoulder, foot and ankle in a number of markets worldwide. Our small joint orthopaedic implants have many years of successful clinical history. We believe we are one of the recognized leaders in radial head repair and finger and toe implants.

Our EVOLVE® Modular Radial Head Replacement Prosthesis addresses the need for modularity in this anatomically highly-variable joint, and is the market leading radial head prosthesis. The EVOLVE® Modular Radial Head device provides 150 different combinations of heads and stems allowing the surgeon to choose implant heads and stems to accommodate the unpredictable anatomy of each patient. The smooth stem design allows for rotational motion at the implant/bone interface and radiocapitellar articulation, potentially reducing capitellar wear. In the first quarter of 2005, we released our EVOLVE® Radial Head Plating System for surgeons who wish to repair rather than replace the damaged radial head. With prosthesis and plating, we believe we have become the vendor of choice for repair of radial head fractures.

In mid-February 2005, we launched our CHARLOTTE Foot and Ankle System, a comprehensive offering of fixation products for foot and ankle surgery. The CHARLOTTE Foot and Ankle System includes six products that feature advanced design elements for simplicity, versatility, and high performance. The CHARLOTTE Foot and Ankle System offers a complete range of options for the most common foot and ankle surgical needs. The CHARLOTTE Foot and Ankle System replaced products supplied by a third party vendor pursuant to a distribution agreement that expired in the first quarter of 2005.

The LOCON-T® and LOCON-VLS® Distal Radius Plating Systems provide surgeons with anatomically designed, stainless steel plates used in the repair of distal radial fractures. In designing both plating systems, we utilized thin, high-strength stainless steel with low profile screws, which have been demonstrated clinically to lessen potential for tendon irritation and/or rupture, which are complications that historically have resulted from this type of surgical repair.

Our MICRONAIL intramedullary wrist fracture repair system is a next-generation, minimally invasive treatment for distal radius fractures that provides immediate fracture stabilization with minimal soft tissue disruption. The result is rapid recovery of hand and wrist functions as demonstrated by an initial clinical trial.

The ORTHOSPHERE® Carpometacarpal Implant for the repair of the basal thumb joint is constructed from implant-grade ceramic, which reduces wear and increases biocompatibility compared to other implant materials. By providing an alternative to the harvesting of the patient s own soft tissues as a spacer for the repaired carpometacarpal joint, the ORTHOSPHERE® Carpometacarpal Implant reduces morbidity and operating time in appropriately selected patients. We have received FDA 510(k) clearance to market this device in foot and ankle procedures such as the tarso-metatarsal joint.

Biologics

We offer a broad line of biologics products that are used to replace and repair damaged or diseased bone, tendons, soft tissues and other biological solutions for surgeons and their patients. These products focus on biological musculoskeletal repair by utilizing synthetic and human tissue-based materials. Internationally, we offer bone graft products incorporating antibiotic delivery and anti-adhesion products.

GRAFTJACKET® Regenerative Tissue Matrix is a soft tissue graft designed for augmentation of tendon and ligament repairs such as those of the rotator cuff (shoulder) and Achilles tendon in the ankle. By augmenting the strength of the tendon repair and incorporating biologically, GRAFTJACKET® increases surgeons confidence in the surgical outcome. GRAFTJACKET® Maxforce Extreme is a high strength form of GRAFTJACKET®, which provides maximum suture holding power for the most challenging of tendon and ligament repairs.

Table of Contents

GRAFTJACKET® matrix for ulcer repair is designed to repair challenging diabetic ulcers of the foot, the primary cause of hospital admissions for all individuals with diabetes. More than two-thirds of the amputations administered each year are performed on individuals with diabetes, often because of difficulties associated with diabetic foot ulcers. GRAFTJACKET® matrix for ulcer repair appears to be the first chronic wound graft to demonstrate the ability to reliably repair deep foot wounds, which have a much higher risk of leading to amputation. Unlike other diabetic foot ulcer products, GRAFTJACKET® matrix generally requires only one application to treat the foot ulcer, reducing the time and cost of treatment. In January 2005, we received stand-alone Medicare reimbursement codes for the use of our GRAFTJACKET® matrix in the repair of diabetes-related foot ulcers. We believe that this development presents a significant opportunity, which we are pursuing aggressively.

Our OSTEOSET® bone graft substitute is a synthetic bone graft substitute made of surgical grade calcium sulfate. OSTEOSET® bone graft provides an attractive alternative to autograft, because it facilitates bone regeneration without requiring a painful, secondary bone-harvesting procedure. Additionally, being purely synthetic, OSTEOSET® pellets are cleared for use in infected sites, an advantage over tissue-based material. The human body resorbs the OSTEOSET® material at a rate close to the rate that new bone grows. We offer surgeons the option of custom-molding their own beads in the operating room using the OSTEOSET® Resorbable Bead Kit, which is available in mixable powder form. OSTEOSET® 2 DBM graft is a unique bone graft substitute incorporating demineralized bone matrix (DBM) into OSTEOSET® surgical-grade calcium sulfate pellets. These two bone graft materials, each with a long clinical history, provide an ideal combination of osteoinduction and osteoconduction for guided bone regeneration. Our surgical grade calcium sulfate is manufactured using proprietary processes that consistently produce a high quality product. Our OSTEOSET® T medicated pellets, which contain tobramycin sulfate, are currently one of the few resorbable bone void fillers available in international markets for the prevention and treatment of osteomyelitis, an acute or chronic infection of the bone.

ALLOMATRIX® Injectable Putty combines a high content of DBM with our proprietary surgical grade calcium sulfate carrier. The combination provides an injectable putty with the osteoinductive properties of DBM as well as exceptional handling qualities. This product has been well received by surgeons. Another combination we offer is ALLOMATRIX® C bone graft putty, which includes the addition of cancellous bone granules. The addition of the bone granules increases the stiffness of the material and thereby improves handling characteristics, increases osteoconductivity scaffold, and provides more structural support. Our ALLOMATRIX® Custom bone graft putty allows surgeons to customize the amount of bone granules to add to the putty based on its surgical application. Most recently, we introduced ALLOMATRIX® DR Graft, which is ALLOMATRIX® putty that has been optimized for application in smaller fractures due to the smaller particle size of its cancellous bone granules and the application-specific volume in which it is marketed.

MIIG® 115 Minimally Invasive Injectable Graft is an injectable form of our surgical grade calcium sulfate paste that hardens in the body. MIIG® 115 graft combines the operative flexibility of an injectable substance with the clinically proven osteoconductive properties of our OSTEOSET® material. MIIG® 115 graft is ideally suited for use in non-loaded traumatic fractures such as the distal radius and tibial plateau.

MIIG® X3 High Strength Injectable Graft is an addition to the family of MIIG® products for the minimally invasive treatment of bone defects. It is an injectable calcium sulfate that hardens after placement, provides intraoperative support, and resorbs over time as it is replaced by new bone. Compared to the MIIG® 115 graft, the principle advantages of the MIIG® X3 graft is that it has 2.6 times greater compressive strength, easier injectability, and a longer working time. MIIG® X3 graft has several competitive advantages over injectable calcium phosphate products on the market, including its ability to be drilled or tapped for the placement of final hardware. Additionally, it poses less risk of damage to the joint cartilage upon extravasation (i.e., leakage into the joint space).

MIIG® X3 HiVisc graft is an advanced formulation of MIIG® X3 graft specially designed for management of complex compression fractures. The modified viscosity and extended working time of MIIG® X3 HiVisc graft reduces the potential for extravasation of material into joint spaces and provides greater operative flexibility to the surgeon for very challenging fractures.

Table of Contents

IGNITE® Power Mix is a bone repair stimulus that combines calcium sulfate, DBM and autologous bone marrow aspirate (BMA) for the treatment of problem fractures and delayed non-unions. This combination of materials provides the surgeon and patient with all three critical elements that a bone graft material can offer an osteoconductive scaffold with both osteoinductive and osteogenic capacity through the use of DBM and BMA, respectively. The IGNITE® ICS kit also provides specially-designed instrumentation both to procure BMA and to prepare the fracture site for the grafting procedure using a minimally invasive technique.

CELLPLEX TCP Synthetic Cancellous Bone is an osteoconductive, resorbable tricalcium phosphate (TCP) provided in granular form that simulates the structure of cancellous bone. It has been engineered with a highly porous, interconnected structure to facilitate the ingrowth of new bone throughout the material. Compared to other commercially available TCP products, its benefits include a superior compressive strength and physical characteristics that more closely resemble that of natural cancellous bone. It is an excellent carrier of BMA and is packaged in the INFILTRATE Marrow Infusion Chamber to provide surgeons a simple option for combining BMA with the CELLPLEX TCP, thereby adding an osteogenic component to the synthetic graft.

ADCON® Gel products are designed to reduce adhesion (scar) formation following lumbar spine (ADCON®-L Gel) and peripheral tendon/nerve (ADCON®-T/N Gel) procedures, which can cause post-operative pain and potentially lead to revision procedures (secondary surgery). Both ADCON®-L Gel and ADCON®-T/N Gel are commercially available internationally, but are currently not available for sale in the U.S. Our ADCON®-L Gel had previously received regulatory clearance with the FDA in 1998. In 2000, the FDA determined that the provisions of its Application Integrity Policy (AIP) would be applied to the prior owner of the ADCON® Gel technology due to its violations of Good Clinical Practices in the conduct, analysis, and reporting of data specific to the U.S. Clinical Study of ADCON®-L Gel. In 2003, the FDA lifted the AIP status of the prior owner, which subsequently allowed us, as the new owner of the ADCON® Gel technology, to present the FDA with the clinical data intended to support the return of ADCON®-L Gel to the U.S. market. In 2005, we withdrew our PMA application with the FDA for our ADCON® Gel product. Management is evaluating whether to continue to pursue re-submission for this product. If re-submitted, there can be no assurance that the FDA will accept another submission for filing in a timely manner or at all.

Product Development

Our research and development staff focuses on developing new products in the knee, hip and extremity reconstruction and biologics markets and on expanding our current product offerings and the markets in which they are offered. Realizing that new product offerings are a key to future success, we are committed to a strong research and development program. Research and development expenses totaled $22.3 million, $18.4 million and $16.2 million in 2005, 2004 and 2003, respectively. We are presently targeting an overall level of research and development spending, exclusive of non-cash stock-based compensation, of approximately 7.5% of net sales for 2006.

We continue to collaborate with surgeon advisory panels that provide advice on market trends and assist with the development and clinical testing of our products. We believe these surgeon advisors are prominent in the field of orthopaedics. We also partner periodically with other industry participants, particularly in the biologics area, to develop new products.

In the knee, hip and extremity reconstruction areas, our research and development activities focus on expanding the continuum of products that span the life of implant patients, from early intervention, such as bone-conserving implants, to primary implants, revision replacement implants, and limb preservation implants. We continue to explore and develop advanced bearing and fixation surfaces that improve the clinical performance of reconstructive devices, including ceramic-on-ceramic and low-wear metal-on-metal surfaces. Further, we provide minimally invasive tissue sparing techniques that allow patients to quickly return to work and resume their daily activities. In 2004, we introduced the ODYSSEY Tissue Preserving Initiative, which is a minimally invasive surgery program for hip, knee, and total joint resurfacing procedures. In 2006, we anticipate that we will continue to focus on additional minimally invasive techniques and instrumentation for further surgical applications including the knee.

In the biologics area, we have a variety of research and development projects underway that are designed to further expand our presence in this market. Such projects include developing materials for new biologics applications as well as the integration of biologics products into reconstructive joint procedures and other orthopaedic applications.

Table of Contents

New products, procedures and techniques that we introduced across all product lines since 2003 include, but are not limited to, the MIIG® X3 High Strength Injectable Graft, the GRAFTJACKET® matrix for ulcer repair, the CELLPLEX TCP Synthetic Cancellous Bone, the CONSERVE® Total Implant with BFH Technology, the MIIG® X3 HiVisc graft, the OSTEOSET® 2 DBM Pellets, the ADVANCE® Double-High Knee Tibial Insert, the MICRONAIL intramedullary distal radius implant, the ODYSSEY Tissue Preserving Initiative for Hip and Knee procedures, the PROFEMUR® Tapered Stem Total Hip System, the CHARLOTTE Foot and Ankle System, the MIIG® HV Procedure Kit, the GRAFTJACKET® Regenerative Tissue Matrix Maxforce Extreme, the ODYSSEY Minimally Invasive Knee Instrument, the CONSERVE® Total A-Class Advanced Metal with BFH Technology hip system, and the PROFEMUR® Renaissance hip stem.

Manufacturing and Supply

We operate manufacturing facilities in Arlington, Tennessee, and Toulon, France. These facilities primarily produce orthopaedic implants and some of the related surgical instrumentation used to prepare the bone surfaces and cavities during the surgical procedure. The majority of our surgical instrumentation is produced to our specifications by qualified subcontractors who serve medical device companies.

During the past year, we have continued to modernize both production facilities through changes to the physical appearance and layout, and additions of new production and quality control equipment to meet the evolving needs of our product specifications and designs. In seeking to optimize our manufacturing operations, we have adopted many sophisticated manufacturing practices, such as lean manufacturing and Six Sigma quality programs, which are designed to lower lead times, minimize waste and reduce inventory. We have a wide breadth of manufacturing capabilities at both facilities, including skilled manufacturing personnel.

We rely on a limited number of suppliers for the components used in our products. Our reconstructive joint devices are produced from various surgical grades of titanium, cobalt chrome and stainless steel, various grades of high-density polyethylenes, silicone elastomer and ceramics. We rely on one supplier for the silicone elastomer used in our extremity products. We are aware of only two suppliers of silicone elastomer to the medical device industry for permanent implant usage. Additionally, we rely on one supplier of ceramics for use in our hip products. In addition, for our biologics products, we depend on a limited number of sources of DBM and cancellous bone matrix (CBM). Two not-for-profit tissue banks supplied us with all of the DBM and CBM that we used in 2005 in our allograft products. Further, we rely on one supplier for our GRAFTJACKET® family of soft tissue repair and graft containment products and one supplier for our ADCON® Gel products.

We maintain a comprehensive quality assurance and quality control program, which includes documentation of all material specifications, operating procedures, equipment maintenance and quality control methods. Our U.S. and European quality systems are based on the requirements of ISO 9001/ISO13485 and the applicable regulations imposed by the FDA on medical device manufacturers. We are accredited by the AATB, and we are an FDA-registered Tissue Bank. The FDA may audit our facilities at any time.

We believe that our manufacturing facilities have adequate room for our current production requirements. See Properties for an additional discussion of our facilities.

Sales and Marketing

Our sales and marketing efforts are focused on orthopaedic surgeons, who typically are the decision-makers in orthopaedic device purchases. We have established several surgeon advisory panels consisting of surgeons who we believe are leaders in their chosen orthopaedic specialties. We involve these surgeons and our marketing personnel in all stages of bringing a product to market from initial product development to product launch. As a result, we have a well educated, highly involved marketing staff and an established, global base of well respected surgeons, who serve as advocates to promote our products in the orthopaedic community.

Table of Contents

We offer clinical symposia and seminars, publish advertisements and the results of clinical studies in industry publications, and offer surgeon-to-surgeon education on our new products using our surgeon advisors in an instructional capacity. Additionally, approximately 16,000 practicing orthopaedic surgeons in the U.S. receive information on our latest products through our distribution network, our website, and brochure mailings.

We sell our products in the U.S. through a sales force of approximately 320 people as of December 31, 2005. This sales force primarily consists of independent, commission-based sales representatives and distributors engaged principally in the business of supplying orthopaedic products to hospitals in their geographic areas. Our U.S. field sales force is supported by our Tennessee-based sales and marketing organization. Our independent distributors and sales representatives are provided opportunities for product training throughout the year.

Our products are marketed internationally through a combination of direct sales offices in certain key international markets and distributors in other markets. We have sales offices in France, Italy, the United Kingdom, Belgium, Germany, the Netherlands, Japan, and Canada that employ direct sales employees and use independent sales representatives to sell our products in their respective markets. Our products are sold in other countries in Europe, Asia, Africa, South America and Australia using stocking distribution partners and other distribution arrangements. Stocking distributors purchase products directly from us for resale to their local customers, with product ownership generally passing to the distributor upon shipment. As of December 31, 2005, through a combination of our direct sales offices and approximately 100 stocking distribution partners, we had approximately 430 international sales representatives that sell our products in over 60 countries.

Seasonal Nature of Business

We traditionally experience lower sales volumes in the third quarter months than throughout the rest of the year as a result of the European holiday schedule. In addition, our first quarter selling, general and administrative expenses include additional expenses that we incur in connection with the annual meeting held by the American Academy of Orthopaedic Surgeons. This meeting, which is the largest orthopaedic meeting in the world, features the presentation of scientific papers and instructional courses for orthopaedic surgeons. During this 3-day event, we display our most recent and innovative products for these surgeons.

Competition

Competition in the orthopaedic device industry is intense and is characterized by extensive research efforts and rapid technological progress. Competitors include major companies in both the orthopaedic and biologics industries, as well as academic institutions and other public and private research organizations that continue to conduct research, seek patent protection and establish arrangements for commercializing products that will compete with our products.

The primary competitive factors facing us include price, quality, innovative design and technical capability, breadth of product line, scale of operations and distribution capabilities. Our current and future competitors may have greater resources, more widely accepted and innovative products, less invasive therapies, greater technical capabilities, and stronger name recognition than we do. Our ability to compete is affected by our ability to:

- develop new products and innovative technologies;
- obtain regulatory clearance and compliance for our products;
- manufacture and sell our products cost-effectively;
- meet all relevant quality standards for our products and their markets;
- respond to competitive pressures specific to each of our geographic markets, including our ability to enforce non-compete agreements;
- protect the proprietary technology of our products and manufacturing processes;
- market our products;

Table of Contents

attract and retain skilled employees and sales representatives; and

maintain and establish distribution relationships.

Intellectual Property

We currently own or have licenses to use more than 100 patents and pending patent applications throughout the world. We seek to aggressively protect technology, inventions and improvements that are considered important through the use of patents and trade secrets in the U.S. and significant foreign markets. We manufacture and market the products both under patents and license agreements with other parties.

Our knowledge and experience, creative product development, marketing staff, and trade secret information with respect to manufacturing processes, materials and product design, are as important as our patents in maintaining our proprietary product lines. As a condition of employment, we require all employees to execute a confidentiality agreement with us relating to proprietary information and patent rights.

There can be no assurances that our patents will provide competitive advantages for our products, or that competitors will not challenge or circumvent these rights. In addition, there can be no assurances that the United States Patent and Trademark Office (USPTO) will issue any of our pending patent applications. The USPTO may deny or require a significant narrowing of the claims in our pending patent applications and the patents issuing from such applications. Any patents issuing from the pending patent applications may not provide us with significant commercial protection. We could incur substantial costs in proceedings before the USPTO. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Additionally, the laws of some of the countries in which our products are or may be sold may not protect our intellectual property to the same extent as the laws in the U.S. or at all.

While we do not believe that any of our products infringe any valid claims of patents or other proprietary rights held by others, there can be no assurances that we do not infringe any patents or other proprietary rights held by them. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages or license fees to such party or cease production, marketing and distribution of those products. Litigation may also be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. We are currently involved in an intellectual property lawsuit with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation. See Legal Proceedings for an additional discussion of this lawsuit.

We also rely on trade secrets and other unpatented proprietary technology. There can be no assurances that we can meaningfully protect our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants. There can be no assurances, however, that the agreements will not be breached, adequate remedies for any breach would be available, or competitors will not discover or independently develop our trade secrets.

Third-Party Reimbursement

In the United States., as well as in foreign countries, government-funded or private insurance programs, commonly known as third-party payors, pay a significant portion of the cost of a patient s medical expenses. A uniform policy of reimbursement does not exist among all of these payors relative to payment of claims or enforcement of guidelines established by the Centers for Medicare and Medicaid Services (CMS). Therefore, reimbursement can be quite different from payor to payor as well as from one region of the country to another. We believe that reimbursement is an important factor in the success of any medical device. Consequently, we seek to obtain reimbursement for all of our products.

Reimbursement in the U.S. depends on our ability to obtain FDA clearances and approvals to market our products. Reimbursement also depends on our ability to demonstrate the short-term and long-term clinical and cost-effectiveness of our products from the results obtained from our clinical experience and formal clinical trials. We present these results at major scientific and medical meetings and publish them in respected, peer-reviewed medical journals.

Table of Contents

All U.S. and foreign third-party reimbursement programs, whether government funded or insured commercially, are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering health care. These types of programs can potentially limit the amount which health care providers may be willing to pay for medical devices.

CMS has adopted prospective payment systems with respect to U.S.-government funded patients for services performed in hospital settings and all approved procedures performed in ambulatory surgery centers. These prospective payment systems reimburse hospitals according to a system of groupings that classify patients into clinically cohesive groups based on similar diagnosis and consumption of hospital resources. The payment rate for each grouping is established by CMS based on the national average cost associated with each category of treatment. The prospective payment is intended to reimburse the facility for all costs associated with the patient s care, including all medical devices.

The majority of non-government funded payors have adopted payment systems based on the prospective payment methodology established by CMS. In some cases, however, particularly within the outpatient surgery center setting, providers continue to issue payments based on each component of the patient s care. In these situations, facilities charge payors separately for any medical devices used during treatment. Reimbursement is typically based on the cost of the device plus a small administrative fee.

If adequate levels of reimbursement from third-party payors outside of the U.S. are not obtained, international sales of our products may decline. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed health care systems that govern reimbursement for new medical devices and procedures. Canada and some European and Asian countries, in particular France, Japan, Taiwan, and Korea, have tightened reimbursement rates. Additionally, some foreign reimbursement systems provide for limited payments in a given period and, therefore, result in extended payment periods.

Employees

As of December 31, 2005, we employed approximately 990 people in the following areas: 410 in manufacturing, 310 in sales and marketing, 150 in administration, and 120 in research and development. We believe that we have an excellent relationship with our employees.

Environmental

Our operations and properties are subject to extensive federal, state, local and foreign environmental protection and health and safety laws and regulations. These laws and regulations govern, among other things, the generation, storage, handling, use and transportation of hazardous materials and the handling and disposal of hazardous waste generated at our facilities. Under such laws and regulations, we are required to obtain permits from governmental authorities for some of our operations. If we violate or fail to comply with these laws, regulations or permits, we could be fined or otherwise sanctioned by regulators. Under some environmental laws and regulations, we could also be held responsible for all of the costs relating to any contamination at our past or present facilities and at third-party waste disposal sites.

We believe our costs of complying with current and future environmental laws, regulations and permits, and our liabilities arising from past or future releases of, or exposure to, hazardous substances will not materially adversely affect our business, results of operations or financial condition, although there can be no assurances that they will not.

Available Information

Our website is located at www.wmt.com. We make available free of charge through this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission (SEC) pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC.

Table of Contents

Item 1A. Risk Factors.

Our business and its future performance may be affected by various factors, the most significant of which are discussed below.

We are subject to substantial government regulation that could have a material adverse effect on our business

The production and marketing of our products and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. See Business Government Regulation for further details on this process. U.S. and foreign regulations govern the testing, marketing and registration of new medical devices, in addition to regulating manufacturing practices, reporting, labeling and recordkeeping procedures. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot be assured that any of our products will be approved. Our failure to comply with applicable regulatory requirements could result in these governmental authorities:

imposing fines and penalties on us;

preventing us from manufacturing or selling our products;

bringing civil or criminal charges against us;

delaying the introduction of our new products into the market;

recalling or seizing our products; or

withdrawing or denying approvals or clearances for our products.

Even if regulatory approval or clearance of a product is granted, this could result in limitations on the uses for which the product may be labeled and promoted. Further, for a marketed product, its manufacturer and manufacturing facilities are subject to periodic review and inspection. Subsequent discovery of problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market or other enforcement actions.

We are currently conducting clinical studies of some of our products under an IDE. Clinical studies must be conducted in compliance with FDA regulations, or the FDA may take enforcement action. The data collected from these clinical studies will ultimately be used to support market clearance for these products. There is no assurance that the FDA will accept the data from these clinical studies or that it will ultimately allow market clearance for these products.

We are subject to various federal and state laws concerning health care fraud and abuse, including false claims laws, anti-kickback laws, and physician self-referral laws. Violations of these laws can result in criminal and/or civil punishment, including fines, imprisonment, and in the U.S., exclusion from participation in government health care programs. The scope of these laws and related regulations are expanding and their interpretation is evolving. There is very little precedent related to these laws and regulations. Increased funding for enforcement of these laws and regulations has resulted in greater scrutiny of marketing practices in our industry and resulted in several government investigations by various government authorities. If a governmental authority were to determine that we do not comply with these laws and regulations, then we and our officers and employees could be subject to criminal and civil sanctions, including exclusion from participation in federal health care reimbursement programs.

In order to market our product devices in the member countries of the European Union (EU), we are required to comply with the Medical Devices Directive and obtain CE mark certification. CE mark certification is the European symbol of adherence to quality assurance standards and compliance with applicable European Medical Device Directives. Under the Medical Devices Directive, all medical devices including active implants must qualify for CE marking. In August 2005, an EU Medical Devices Directive changed the classification of hip, knee, and shoulder implants from class IIb to class III. The transition period for these changes begins September 1, 2007. Upon reclassification to class III, manufacturers will be required to assemble significantly more documentation and submit it to their Notified Body for formal approval prior to affixing the CE mark to their product and packaging. We intend to

comply with the Medical Devices Directive for all of our products manufactured and sold in the EU. However, there can be no assurance that our products will be approved for CE marking in a timely manner or at all.

Table of Contents

Our biologics business is subject to emerging governmental regulations that can significantly impact our business

The FDA has statutory authority to regulate allograft-based products, processing and materials. The FDA has been working to establish a more comprehensive regulatory framework for allograft-based products, which are principally derived from cadaveric tissue. The framework developed by the FDA establishes criteria for determining whether a particular human tissue-based product will be classified as human tissue, a medical device or biologic drug requiring premarket clearance or approval. All tissue-based products are subject to extensive FDA regulation, including a requirement that ensures that diseases are not transmitted to tissue recipients. The FDA has also proposed extensive additional regulations that would govern the processing and distribution of all allograft products. Consent to use the donor s tissue must also be obtained. The regulations for allograft-based products are still developing. From time to time, the FDA reviews these products and may informally suggest to us how these products should be classified. If a human tissue-based product is considered human tissue, it does not require FDA clearance or approval before being marketed. If it is considered a medical device or biologic drug, then FDA clearance or approval may be required. Additionally, our biologics business involves the procurement and transplantation of allograft tissue, which is subject to federal regulation under NOTA. NOTA prohibits the sale of human organs, including bone and other human tissue, for valuable consideration within the meaning of NOTA. NOTA permits the payment of reasonable expenses associated with the transportation, processing, preservation, quality control and storage of human tissue. We currently charge our customers for these expenses. In the future, if NOTA is amended or reinterpreted, we may not be able to charge these expenses to our customers and, as a result, our business could be adversely affected.

Our principal allograft-based biologics offerings include ALLOMATRIX®, GRAFTJACKET®, and IGNITE® products.

Modifications to our marketed devices may require FDA regulatory clearances or approvals or require us to cease marketing or recall the modified devices until such clearances or approvals are obtained

When required, the products we market in the U.S. have obtained premarket notification under Section 510(k) of the FDC Act or were exempt from the 510(k) clearance process. We have modified some of our products and product labeling since obtaining 510(k) clearance, but we do not believe these modifications require us to submit new 510(k) notifications. However, if the FDA disagrees with us and requires us to submit a new 510(k) notification for modifications to our existing products, we may be the subject of enforcement actions by the FDA and be required to stop marketing the products while the FDA reviews the 510(k) notification. If the FDA requires us to go through a lengthier, more rigorous examination than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA application process. Products that are approved through a PMA application generally need FDA approval before they can be modified. See Business Government Regulation.

If we lose one of our key suppliers, we may be unable to meet customer orders for our products in a timely manner or within our budget

We rely on a limited number of suppliers for the components used in our products. Our reconstructive joint devices are produced from various surgical grades of titanium, cobalt chrome and stainless steel, various grades of high-density polyethylenes, silicone elastomer and ceramics. We rely on one supplier for the silicone elastomer used in our extremity products. We are aware of only two suppliers of silicone elastomer to the medical device industry for permanent implant usage. Additionally, we rely on one supplier of ceramics for use in our hip products.

In addition, for our biologics products, we presently depend upon a single supplier as our source for DBM and CBM, and any failure to obtain DBM and CBM from this source in a timely manner will deplete levels of on-hand raw materials inventory and could interfere with our ability to process and distribute allograft products. During 2006, we are expecting a single not-for-profit tissue bank to meet nearly all of our DBM and CBM order requirements, a key component in the allograft products we currently produce, market and distribute. We cannot be sure that our supply of DBM and CBM will continue to be available at current levels or will be sufficient to meet our needs, or that future

Table of Contents

suppliers of DBM and CBM will be free from FDA regulatory action impacting their sale of DBM and CBM. Since there is a small number of suppliers, if we cannot continue to obtain DBM and CBM from our current source in volumes sufficient to meet our needs, we may not be able to locate replacement sources of DBM and CBM on commercially reasonable terms, if at all. This could have the effect of interrupting our business, which could adversely affect our sales. Further, we rely on one supplier for our GRAFTJACKET® family of soft tissue repair and graft containment products, as well as one supplier for our ADCON® Gel products.

Suppliers of raw materials and components may decide, or be required, for reasons beyond our control to cease supplying raw materials and components to us. FDA regulations may require additional testing of any raw materials or components from new suppliers prior to our use of these materials or components and in the case of a device with a PMA application, we may be required to obtain prior FDA permission, either of which could delay or prevent our access to or use of such raw materials or components.

If we fail to compete successfully in the future against our existing or potential competitors, our sales and operating results may be negatively affected and we may not achieve future growth

The markets for our products are highly competitive and dominated by a small number of large companies. We may not be able to meet the prices offered by our competitors, or offer products similar to or more desirable than those offered by our competitors. See Business Competition.

If we are unable to continue to develop and market new products and technologies, we may experience a decrease in demand for our products or our products could become obsolete, and our business would suffer

We are continually engaged in product development and improvement programs, and new products represent a significant component of our growth rate. We may be unable to compete effectively with our competitors unless we can keep up with existing or new products and technologies in the orthopaedic implant market. If we do not continue to introduce new products and technologies, or if those products and technologies are not accepted, we may not be successful. Additionally, our competitors new products and technologies may beat our products to market, may be more effective or less expensive than our products, or may render our products obsolete. See Business Competition.

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors and be unable to operate our business profitably

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. See Business Intellectual Property. These legal means, however, afford only limited protection and may not adequately protect our rights. In addition, we cannot be assured that any of our pending patent applications will issue. The USPTO may deny or require a significant narrowing of the claims in our pending patent applications and the patents issuing from such applications. Any patents issuing from the pending patent applications may not provide us with significant commercial protection. We could incur substantial costs in proceedings before the USPTO. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. In addition, the laws of some of the countries in which our products are or may be sold may not protect our intellectual property to the same extent as U.S. laws or at all. We also may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries.

In addition, we hold licenses from third parties that are necessary to utilize certain technologies used in the design and manufacturing of some of our products. The loss of such licenses would prevent us from manufacturing, marketing and selling these products, which could harm our business.

We seek to protect our trade secrets, know-how and other unpatented proprietary technology, in part, with confidentiality agreements with our employees, independent distributors and consultants. We cannot be assured, however, that the agreements will not be breached, adequate remedies for any breach would be available, or our trade secrets, know-how, and other unpatented proprietary technology will not otherwise become known to or independently developed by our competitors.

Table of Contents

If we lose any existing or future intellectual property lawsuits, a court could require us to pay significant damages or prevent us from selling our products

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. We are currently involved in an intellectual property lawsuit with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation, where it is alleged that our ADVANCE® Knee product line infringes one of Howmedica s patents. See Legal Proceedings for more information regarding this lawsuit. If Howmedica were to succeed in obtaining the relief it claims, the court could award damages to Howmedica and impose an injunction against further sales of our product. If a monetary judgment is rendered against us, we may be forced to raise or borrow funds, as a supplement to any available insurance claim proceeds, to pay the damages award.

In the future, we may become a party to other lawsuits involving patents or other intellectual property. A legal proceeding, regardless of the outcome, could drain our financial resources and divert the time and effort of our management. If we lose one of these proceedings, a court, or a similar foreign governing body, could require us to pay significant damages to third parties, require us to seek licenses from third parties and pay ongoing royalties, require us to redesign our products, or prevent us from manufacturing, using or selling our products. In addition to being costly, protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

If product liability lawsuits are brought against us, our business may be harmed

The manufacture and sale of medical devices exposes us to significant risk of product liability claims. In the past, we have had a number of product liability claims relating to our products, none of which either individually, or in the aggregate, have resulted in a material negative impact on our business. In the future, we may be subject to additional product liability claims, some of which may have a negative impact on our business. Additionally, 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 protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

Fluctuations in insurance expense could adversely affect our profitability

We hold a number of insurance policies, including product liability insurance, directors and officers liability insurance, property insurance and workers compensation insurance. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted.

If we cannot retain our key personnel, we will not be able to manage and operate successfully and we may not be able to meet our strategic objectives

Our continued success depends, in part, upon key managerial, scientific, sales and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. We compete for such personnel with other companies, academic institutions, governmental entities and other organizations. There can be no assurance that we will be successful in retaining our current personnel or in hiring or retaining qualified personnel in the future. Loss of key personnel or the inability to hire or retain qualified personnel in the future could have a material adverse effect on our ability to operate successfully. Further, any inability on our part to enforce non-compete arrangements related to key personnel who have left the business could have a material adverse effect on our business.

Table of Contents

We derive a significant portion of our sales from operations in international markets that are subject to political, economic and social instability

We derive a significant portion of our sales from operations in international markets. Our international distribution system consists of 8 direct sales offices and approximately 100 stocking distribution partners, which combined employ approximately 430 sales representatives who sell in over 60 countries. Most of these countries are, to some degree, subject to political, social and economic instability. For the years ended December 31, 2005 and 2004, approximately 38% and 39%, respectively, of our net sales were derived from our international operations. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional foreign governmental controls or regulations on orthopaedic implants and biologics products;
- new export license requirements, particularly related to our biologics products;
- economic instability, including currency risk between the U.S. dollar and foreign currencies, in our target markets;
- a shortage of high-quality international salespeople and distributors;
- loss of any key personnel who possess proprietary knowledge or are otherwise important to our success in international markets;
- changes in third-party reimbursement policy that may require some of the patients who receive our implant products to directly absorb medical costs or that may necessitate our reducing selling prices for our products;
- changes in tariffs and other trade restrictions, particularly related to the exportation of our biologics products;
- work stoppages or strikes in the health care industry, such as those that have previously affected our operations in France, Canada, Korea and Finland in the past;
- a shortage of nurses in some of our target markets, particularly affecting our operations in France; and
- exposure to different legal and political standards due to our conducting business in over 60 countries.

Any material decrease in our foreign sales would negatively impact our profitability. Our international sales are predominately generated in Europe. In Europe, health care regulation and reimbursement for medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries.

Our business could suffer if the medical community does not continue to accept allograft technology

New allograft products, technologies and enhancements may never achieve broad market acceptance due to numerous factors, including:

- lack of clinical acceptance of allograft products and related technologies;
- the introduction of competitive tissue repair treatment options that render allograft products and technologies too expensive and obsolete;
- lack of available third-party reimbursement;
- the inability to train surgeons in the use of allograft products and technologies;
- the risk of disease transmission; and
- ethical concerns about the commercial aspects of harvesting cadaveric tissue.

Table of Contents

Market acceptance will also depend on the ability to demonstrate that existing and new allografts and technologies are attractive alternatives to existing tissue repair treatment options. To demonstrate this, we rely upon surgeon evaluations of the clinical safety, efficacy, ease of use, reliability and cost effectiveness of our tissue repair options and technologies. Recommendations and endorsements by influential surgeons are important to the commercial success of allograft products and technologies. In addition, several countries, notably Japan, prohibit the use of allografts. If allograft products and technologies are not broadly accepted in the marketplace, we may not achieve a competitive position in the market.

If adequate levels of reimbursement from third-party payors for our products are not obtained, surgeons and patients may be reluctant to use our products and our sales may decline

In the U.S., health care providers that purchase our products generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to pay for all or a portion of the cost of joint reconstructive procedures and products utilized in those procedures. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement. Our sales depend largely on governmental health care programs and private health insurers reimbursing patients medical expenses. Surgeons, hospitals and other health care providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products.

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

If adequate levels of reimbursement from third-party payors outside of the U.S. are not obtained, international sales of our products may decline. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed health care systems that govern reimbursement for medical devices and procedures. Canada, and some European and Asian countries, in particular France, Japan, Taiwan, and Korea, have tightened reimbursement rates. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. See Business Third-Party Reimbursement for more information regarding reimbursement in the U.S. and abroad.

If market clearance is not obtained for the re-launch of the ADCON ® Gel products and the launch of the CONSERVE® Plus implant in the U.S., growth of our biologics and hip product lines could be impacted

Our ADCON® Gel products and our CONSERVE® Plus Resurfacing Implant are available outside the U.S.. There can be no assurance that the sale of our ADCON® Gel or CONSERVE® Plus products in the U.S. will be cleared by the FDA in a timely manner or at all, which could have a significant impact on the future growth of our biologics and hip product lines, respectively.

In 2005, our PMA application with the FDA for our ADCON® Gel product was withdrawn by management. Management is evaluating whether to continue to pursue re-submission for this product. If re-submitted, there can be no assurance that the FDA will accept another submission for filing in a timely manner or at all.

If surgeons do not recommend and endorse our products, our sales may decline or we may be unable to increase our sales and profits

In order for us to sell our products, surgeons must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from surgeons. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, clinical efficacy and cost-effectiveness of our products compared to products of our competitors and on training surgeons in the proper application of our products.

Table of Contents

If a natural or man-made disaster strikes our manufacturing facilities, we could be unable to manufacture our products for a substantial amount of time and our sales could decline

We have principally relied to date on our manufacturing facilities in Arlington, Tennessee, and Toulon, France. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. In the event one of our facilities was affected by a disaster, we would be forced to rely on third-party manufacturers or shift production to our other manufacturing facility. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms or at all.

Our business plan relies on certain assumptions about the market for our products, which, if incorrect, may adversely affect our profitability

We believe that the aging of the general population and increasingly active lifestyles will continue and that these trends will increase the need for our orthopaedic implant products. The projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize, or if non-surgical treatments gain more widespread acceptance as a viable alternative to orthopaedic implants.

Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings

Since a majority of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign exchange rates. Our international net sales were favorably affected by the impact of foreign currency fluctuations totaling approximately $400,000 in 2005 and $8.1 million in 2004. We currently employ a derivative program using 30-day foreign currency forward contracts to mitigate the risk of currency fluctuations on our intercompany receivable and payable balances that are denominated in foreign currencies. These forward contracts are expected to offset the transactional gains and losses on the related intercompany balances. These forward contracts are not designated as hedging instruments under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities.* Accordingly, the changes in the fair value and the settlement of the contracts are recognized in the period incurred.

Table of Contents

Efforts to acquire and integrate other companies or product lines could adversely affect our operations and financial results

We may pursue acquisitions of other companies or product lines. Our ability to grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. Even if we complete acquisitions, we may also experience:

- difficulties in integrating any acquired companies, personnel and products into our existing business;
- delays in realizing the benefits of the acquired company or products;
- diversion of our management s time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated; or
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions.

In addition, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize acquisition expenses and acquired assets.

Our quarterly operating results are subject to substantial fluctuations and you should not rely on them as an indication of our future results

Our quarterly operating results may vary significantly due to a combination of factors, many of which are beyond our control. These factors include:

- demand for products, which historically has been lowest in the third quarter;
- our ability to meet the demand for our products;
- increased competition;
- the number, timing and significance of new products and product introductions and enhancements by us and our competitors;
- our ability to develop, introduce and market new and enhanced versions of our products on a timely basis;
- changes in pricing policies by us and our competitors;
- changes in the treatment practices of orthopaedic surgeons;
- changes in distributor relationships and sales force size and composition;
- the timing of material expense- or income-generating events and the related recognition of their associated financial impact;
- the timing of significant orders and shipments;
- availability of raw materials;
- work stoppages or strikes in the health care industry;
- changes in FDA and foreign governmental regulatory policies, requirements and enforcement practices;

Table of Contents

changes in accounting policies, estimates, and treatments; and
general economic factors.

We believe that our quarterly sales and operating results may vary significantly in the future and that period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indications of future performance. We cannot assure you that our sales will increase or be sustained in future periods or that we will be profitable in any future period. Any shortfalls in sales or earnings from levels expected by securities or orthopaedic industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period.

We rely on our independent sales distributors and sales representatives to market and sell our products

Our success depends largely upon marketing arrangements with independent sales distributors and sales representatives, in particular their sales and service expertise and relationships with the customers in the marketplace. Independent distributors and sales representatives may terminate their relationships with us or devote insufficient sales efforts to our products. We do not control our independent distributors and they may not be successful in implementing our marketing plans. Our failure to maintain our existing relationships with our independent distributors and sales representatives could have an adverse effect on our operations. Similarly, our failure to recruit and retain additional skilled independent sales distributors and sales representatives could have an adverse effect on our operations. We have experienced turnover with some of our independent distributors in the past which adversely affected short-term financial results while we transitioned to new independent distributors. While we believe these transitions have been managed effectively, similar occurrences could happen in the future with different results which could have a greater adverse effect on our operations than we have previously experienced.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters and U.S. operations consist of a 74,000 square foot manufacturing facility, a 40,000 square foot warehouse, and a 60,000 square foot administration building located on 31 acres in Arlington, Tennessee. We lease the manufacturing facility from the Industrial Development Board of the Town of Arlington (IDB) under a lease agreement which is automatically renewable through 2049. We may exercise an option to purchase the manufacturing facility from the IDB at a nominal price at any time during the lease term. We lease the warehouse from the IDB under a lease agreement which has no predetermined expiration date. We may exercise an option to purchase the warehouse from the IDB at a nominal price at any time during the lease term. We lease a 44,000 square foot portion of the administration building from the IDB under a lease agreement that expires on July 8, 2008. We may exercise an option to purchase the leased portion of the administration building from the IDB at a price of $101,000, which we have pre-paid, at any time during the lease term. We own another 16,000 square foot portion of the administrative building that was built in 2004.

We believe that our U.S. manufacturing facility has adequate room to meet our current production requirements. However, based on our anticipated future needs for space at our corporate headquarters, we are currently conducting an analysis of our facility needs, which could result in an expansion of our facilities at the current location, or the construction of new facilities.

Our international operations include manufacturing, warehouse, sales, research and development, and administrative facilities located in several countries. Our primary international warehouse is located in a leased facility in Toulon, France. Our primary international research and development facility is located in leased facilities in Milan, Italy. Our sales offices in France, Italy, the United Kingdom, Belgium, Japan, and Canada also include warehouse and administrative space.

Table of Contents

Item 3. Legal Proceedings.

From time to time, we are subject to lawsuits and claims which arise out of our operations in the normal course of business. We are the plaintiff or defendant in various litigation matters in the ordinary course of business, some of which involve claims for damages that are substantial in amount. We believe that the disposition of claims currently pending, including the matters discussed below, will not have a material adverse effect on our financial position or results of operations.

Howmedica Osteonics Corp. v. Wright Medical Technology, Inc.

In 2000, Howmedica Osteonics Corp., a subsidiary of Stryker Corporation, filed a lawsuit against us in the United States District Court for the District of New Jersey alleging that we infringed Howmedica s U.S. Patent No. 5,824,100 related to our ADVANCE® Knee product line. The lawsuit seeks an order of infringement, injunctive relief, unspecified damages and various other costs and relief and could impact a substantial portion of our knee product line. We believe, however, that we have strong defenses against Howmedica s claims and thus are vigorously defending this lawsuit. In November 2005, the court issued a Markman ruling on claim construction holding that our products do not literally infringe the claims of Howmedica s patent. No trial date has been set in this matter. We are unable to estimate the potential liability, if any, with respect to the claims, and accordingly, no provision has been made for this contingency as of December 31, 2005. We believe that the claims are covered in part by our patent infringement insurance. We do not believe that the outcome of this lawsuit will have a material adverse effect on our financial position or results of operations.

CERAbio, LLC and Phillips Plastics Corporation v. Wright Medical Technology, Inc.

In 2002, pursuant to a purchase and royalty agreement with CERAbio LLC (CERAbio), we purchased assets consisting primarily of completed technology for $3.0 million and recorded this entire amount as an intangible asset. Of this purchase price, $1.5 million was paid upon signing the purchase agreement. The remaining $1.5 million is recorded in Accrued expenses and other current liabilities in the consolidated balance sheet and is payable if certain conditions under the agreement are satisfied. The agreement also provides for specified future royalties contingent upon sales of products related to the acquired technology. Believing that the contractual obligations for payment had not been met, we disputed whether the second payment and royalties had been earned. In 2003, CERAbio and Phillips Plastics Corporation filed a lawsuit against the Company in the United States District Court for the Western District of Wisconsin for payment of the remaining $1.5 million purchase price and the royalties earned to date. In 2003, the trial court ruled in favor of CERAbio and ordered us to pay the remaining purchase price and the royalties earned to date. The royalties earned to date have been recorded within Accrued expenses and other current liabilities in the consolidated balance sheet. In 2004, we appealed the trial court s judgment to the United States Court of Appeals for the Seventh Circuit. In June 2005, the appeals court upheld the trial court s ruling granting CERAbio summary judgment on certain of our counterclaims, but overruled the trial court s ruling limiting our evidence that we could present at trial. The effect of this ruling was to grant us a new trial in this dispute, the date for which has been set as May 8, 2006. We do not believe that the outcome of this lawsuit will have a material adverse effect on our financial position or results of operations.

Item 4. Submission of Matters to a Vote of Security Holders.

Not applicable.

Table of Contents

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq National Market under the symbol WMGI. The following table sets forth, for the periods indicated, the high and low bid prices per share of our common stock as reported on the Nasdaq National Market.

	High	Low
Fiscal Year 2005		
First Quarter	$ 27.62	$ 24.00
Second Quarter	$ 27.97	$ 22.98
Third Quarter	$ 28.40	$ 23.93
Fourth Quarter	$ 24.39	$ 18.30
Fiscal Year 2004		
First Quarter	$ 35.53	$ 29.24
Second Quarter	$ 36.99	$ 29.56
Third Quarter	$ 36.08	$ 22.90
Fourth Quarter	$ 30.10	$ 20.75

Holders

As of February 24, 2006, there were 191 stockholders of record and an estimated 7,201 beneficial owners of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all future earnings for the operation and expansion of our business. We do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on our common stock will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors. In addition, our current credit facility prohibits us from paying any cash dividends without the lenders consent.

Table of Contents

Item 6. Selected Financial Data.

The following tables set forth certain of our selected consolidated financial data as of the dates and for the years indicated. The selected consolidated financial data as of December 31, 2005, 2004, 2003 and 2002, and for the years then ended, was derived from our consolidated financial statements audited by KPMG LLP. The selected consolidated financial data as of December 31, 2001, and for the year then ended, was derived from our consolidated financial statements audited by Arthur Andersen LLP. The audited consolidated financial statements as of December 31, 2005, 2004 and 2003, and for the years then ended, are included elsewhere in this filing. The audited consolidated financial statements as of December 31, 2002 and 2001, and for the years then ended, are not included in this filing. Historical results are not necessarily indicative of the results to be expected for any future period. These tables are presented in thousands, except per share data.

	Year Ended December 31,				
	2005	**2004**	**2003**	**2002**	**2001**
Statement of Operations:					
Net sales	$ 319,137	$ 297,539	$ 248,932	$ 200,873	$ 172,921
Cost of sales	91,740	84,183	67,815	55,616	51,351
Gross profit	227,397	213,356	181,117	145,257	121,570
Operating expenses:					
Selling, general and administrative [1]	166,916	151,144	127,612	106,875	95,556
Research and development	22,283	18,421	16,151	10,357	10,108
Amortization of intangible assets [2]	4,250	3,889	3,562	3,946	5,349
Stock-based expense [3]	467	1,489	2,068	1,724	1,996
Acquired in-process research and development costs			4,558		
Arbitration settlement award				(4,200)	
Total operating expenses	193,916	174,943	153,951	118,702	113,009
Operating income	33,481	38,413	27,166	26,555	8,561
Interest (income) expense, net	(176)	1,064	1,107	938	7,809
Other expense (income), net	237	(74)	(1,060)	(1,277)	685
Income before income taxes	33,420	37,423	27,119	26,894	67
Provision for income taxes	12,355	13,401	9,722	1,834	1,574
Net income (loss)	$ 21,065	$ 24,022	$ 17,397	$ 25,060	$ (1,507)
Net income (loss) per share: [4]					
Basic	$ 0.62	$ 0.72	$ 0.53	$ 0.79	$ (0.31)
Diluted	$ 0.60	$ 0.68	$ 0.50	$ 0.75	$ (0.31)
Weighted-average number of common shares outstanding - basic	33,959	33,391	32,857	31,870	13,195
Weighted-average number of common shares outstanding - diluted	35,199	35,317	34,561	33,550	13,195

	As of December 31,				
	2005	**2004**	**2003**	**2002**	**2001**
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 51,277	$ 83,470	$ 66,571	$ 51,373	$ 2,770
Working capital	196,126	189,803	147,255	127,557	47,546
Total assets	371,810	361,158	322,103	276,370	193,719
Long-term liabilities	15,547	19,870	20,516	25,939	30,967
Stockholders equity	$ 292,008	$ 276,069	$ 238,318	$ 204,999	$117,300

Table of Contents

	Year Ended December 31,				
	2005	2004	2003	2002	2001
Other Data:					
Cash flow provided by operating activities	$ 5,291	$ 37,365	$ 40,065	$ 21,950	$ 818
Cash flow used in investing activities	(31,583)	(18,428)	(25,844)	(22,430)	(15,558)
Cash flow (used in) provided by financing activities	(5,379)	(2,305)	514	48,384	1,372
Depreciation	17,895	17,278	13,948	13,553	10,096
Amortization of intangible assets [(2)]	4,250	3,889	3,562	3,946	5,349
Capital expenditures	$ 30,356	$ 18,316	$ 18,116	$ 17,974	$ 16,764

(1) In accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections,* our $1.6 million loss on early retirement of debt in 2001, which was originally presented as an extraordinary loss on debt extinguishment, does not meet the criteria to be classified as extraordinary. Consequently, pursuant to this newly adopted standard, this amount has been reclassified to selling, general and administrative expense.

(2) Amortization of intangible assets in 2005, 2004, 2003 and 2002 excludes amortization of goodwill in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*. See Note 6 to the financial statements contained in Item 8 of this report.

(3) Amounts presented as non-cash stock-based expense consist of: cost of sales totaling $12, $68, $107, $108, and $89 for the years ended December 31, 2005, 2004, 2003, 2002, and 2001, respectively; selling, general and administrative expenses of $449, $1,364, $1,875, $1,506, and $1,807 for the years ended December 31, 2005, 2004, 2003, 2002, and 2001, respectively; and research and development expenses of $6, $57, $86, $110, and $100 for the years ended December 31, 2005, 2004, 2003, 2002, and 2001, respectively.

(4) Net income (loss) applicable to common stockholders includes preferred stock dividends of $2.5 million for the year ended December 31, 2001.

Table of Contents

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following management s discussion and analysis of financial condition and results of operations (MD&A) describes the principal factors affecting the results of our operations, financial condition, and changes in financial condition, as well as our critical accounting estimates. MD&A is organized as follows:

Executive overview. This section provides a general description and history of our business, a brief discussion of our principal product lines, significant developments in our business, and the opportunities, challenges and risks we focus on in the operation of our business.

Net sales and expense components. This section provides a description of the significant line items on our consolidated statement of operations.

Results of operations. This section provides our analysis of and outlook for the significant line items on our consolidated statement of operations.

Seasonal Nature of Business. This section describes the effects of seasonal fluctuations in our business.

Liquidity and capital resources. This section provides an analysis of our liquidity and cash flow and a discussion of our outstanding debt and commitments.

Critical accounting estimates. This section discusses the accounting estimates that are considered important to our financial condition and results of operations and require us to exercise subjective or complex judgments in their application. All of our significant accounting policies, including our critical accounting estimates, are summarized in Note 2 to our consolidated financial statements in Item 8 of this report.

Executive Overview

Company Description. We are a global orthopaedic medical device company specializing in the design, manufacture and marketing of reconstructive joint devices and biologics products. Reconstructive joint devices are used to replace knee, hip and other joints that have deteriorated through disease or injury. Biologics are used to replace damaged or diseased bone, to stimulate bone growth, and to provide other biological solutions for surgeons and their patients. We have been in business for over 50 years and have built a well-known and respected brand name and strong relationships with orthopaedic surgeons.

Our corporate headquarters and U.S. operations are located in Arlington, Tennessee, where we conduct our domestic research and development, manufacturing, warehousing, and administrative activities. Outside the U.S., we have research and development, manufacturing, and administrative facilities in Toulon, France; research, distribution and administrative facilities in Milan, Italy; and sales and distribution offices in Canada, Japan and throughout Europe. We market our products in over 60 countries through a global distribution system that consists of a sales force of approximately 750 individuals who promote our products to orthopaedic surgeons and hospitals. At the end of 2005, we have approximately 320 exclusive independent distributors and sales associates in the U.S., and approximately 430 sales representatives internationally who are employed through a combination of our stocking distribution partners and direct sales offices.

Company History. We were incorporated in November 1999 as a Delaware corporation, and had no operations until December 7, 1999, when we were reorganized by an investment group through the acquisition of our predecessor company, Wright Medical Technology, Inc. This transaction represented a recapitalization of our predecessor company. On December 22, 1999, we acquired Cremascoli Ortho Holding, S.A., an orthopaedic medical device company headquartered in Toulon, France. In 2001, we completed our IPO of 7,500,000 shares of common stock, which generated $84.8 million in net proceeds. In 2002, we completed a secondary offering of 3,450,000 shares of common stock which generated $49.5 million in net proceeds.

Principal Products. We primarily sell reconstructive joint devices and biologics products. Our reconstructive joint device sales are derived from three primary product lines: knees and hips, collectively referred to as our reconstructive large joint business, and extremities. Our biologics sales are derived from a broad portfolio of products designed to stimulate and augment the natural regenerative capabilities of the human body. We also sell orthopaedic products not considered to be part of our knee, hip, extremity or biologics product lines.

Table of Contents

Our hip joint reconstruction product portfolio provides offerings in the areas of bone-conserving implants, total hip reconstruction, revision replacement implants, and limb preservation. Our hip joint products include the CONSERVE® family of products, the PROFEMUR® Hip System, the LINEAGE® Acetabular System, the ANCA-FIT Hip System, and the PERFECTA® Hip System.

Our biologics products focus on biological musculoskeletal repair and include synthetic and human tissue-based materials. Our principal biologics products include the GRAFTJACKET® soft tissue repair and containment membranes, the ALLOMATRIX® line of injectable tissue-based bone graft substitutes, the OSTEOSET® synthetic bone graft substitute, the MIIG® family of minimally invasive injectable synthetic bone grafts, and in certain of our international markets, the ADCONÒ Gel anti-adhesion product.

We offer extremity products for the hand, wrist, elbow, shoulder, foot and ankle in a number of markets worldwide. Our principal extremity products include the EVOLVE® Modular Radial Head device, the CHARLOTTE Foot and Ankle System, the LOCON-T® and LOCON VLS Distal Radius Plating Systems, and the MICRONAIL intramedullary wrist fracture repair system. We also sell the Swanson line of finger and toe joint replacement products and the ORTHOSPHERE® Carpometacarpal Implant for repair of the basal thumb joint.

Our knee reconstruction products position us well in the areas of total knee reconstruction, revision replacement implants, and limb preservation products. Our principal knee products include the ADVANCE® Knee System and the ADVANCE® Unicompartmental Knee System.

Significant Business Developments. Net sales grew 7.3% in 2005, totaling $319.1 million, compared to $297.5 million in 2004. Our success is attributable to our focus on the high growth sectors of the orthopaedic industry, such as advanced bearing surfaces, modular necks and bone conserving implants within the hip market. Our hip, knee and extremity product lines contributed significantly to our performance in 2005, achieving 10%, 8%, and 11% growth rates, respectively.

During 2005, our domestic biologics business declined by approximately 2% year-over-year. This decline was driven by the continued downward trend in sales of our DBM containing ALLOMATRIX® family of products due to competitive pressures in the mature market for DBM containing products. We anticipate that domestic sales of these products will continue to decline in 2006; however, we expect that these declines will be offset by sales growth of our GRAFTJACKET® soft tissue repair and containment membranes.

During 2005, our international sales increased by approximately 4% as compared to 2004. This slower rate of growth is attributable to our markets in France and Italy, both of which declined year-over-year. These declines began in the fourth quarter of 2004 as a result of the transition of certain management and distribution personnel in Southern Europe. We anticipate that sales in France and Italy will continue to decline year-over-year in the first half of 2006. However, we believe that sales in these markets will grow in the latter half of 2006 as the personnel now in place successfully complete this transitional period. Sales in our other international markets increased by 17% in total during 2005 as compared to prior year.

In mid-February 2005, we launched our internally-developed CHARLOTTE Foot and Ankle System and transitioned our foot and ankle business from a line of products supplied by a third party vendor pursuant to a distribution agreement that expired in the first quarter of 2005. The CHARLOTTE Foot and Ankle System offers a complete range of options for the most common foot and ankle surgical needs and includes six products that feature advanced design elements for simplicity, versatility, and high performance. During the fourth quarter of 2004, we incurred approximately $2.9 million of costs as a result of this transition to write down our distributed foot and ankle implant inventory to its estimated net realizable value and accelerated depreciation on the related surgical instrumentation. The success of our CHARLOTTE Foot and Ankle system contributed significantly to the success of our extremity product line in 2005.

In June 2005, our premarket approval (PMA) application with the United States Food and Drug Administration (FDA) for our ADCON® Gel product was withdrawn by management. Based on the progress of the review to date, management determined that in order to adequately address all of the requests made by the FDA in connection with their review of this application, withdrawal of the filing at this time was appropriate. Management is evaluating whether to continue to pursue re-submission for this product. If re-submitted, there can be no assurance that the FDA will accept another submission for filing in a timely manner or at all.

28

Table of Contents

In November 2005, we received marketing clearance from the FDA for our IGNITE® Bone Void Filler kits. This clearance was obtained based on satisfaction of the FDA s requirements pursuant to a 510(k) premarket notification process that began with our submission of a 510(k). This submission was in response to the FDA s clarification to all known manufacturers of DBM-containing products including us, that such products should be regulated under the medical device premarket notification provisions of the Food, Drug, and Cosmetic Act. As of December 31, 2005, all of the Company s DBM-containing products currently produced and sold in the U.S. have received regulatory clearance.

Significant Industry Factors. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearance and compliance for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, respond to competitive pressures specific to each of our geographic markets, including our ability to enforce non-compete agreements, and successfully market and distribute our products in a profitable manner. We, and the entire industry, are subject to extensive governmental regulation, primarily by the FDA. Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and has recently experienced increased pricing pressures, specifically in the areas of reconstructive joints and biologic bone repair products. We devote significant resources to assessing and analyzing competitive, regulatory and economic risks and opportunities. A detailed discussion of these and other factors is provided in Item 1A of this report.

Net Sales and Expense Components

Net sales. We derive our net sales primarily from the sale of reconstructive joint devices and biologics products. An overview of our principal product lines is provided in Executive Overview.

Cost of sales. Our cost of sales consists primarily of direct labor, allocated manufacturing overhead, raw materials and components, charges incurred for excess and obsolete inventories, royalty expenses associated with licensing technologies used in our products or processes, and certain other period expenses.

Selling, general and administrative. Our selling, general and administrative expenses consist primarily of salaries, sales commissions, royalty and consulting expenses associated with our medical advisors, marketing costs, facility costs, legal costs, other general business and administrative expenses, and depreciation expense associated with surgical instruments required by surgeons to use when implanting our products.

Research and development. Research and development expense includes costs associated with the design, development, testing, deployment, enhancement and regulatory approval of our products.

Amortization of intangible assets. Our intangible assets consist of purchased intangibles related to completed technology, distribution channels and trademarks primarily resulting from our 1999 acquisition of Cremascoli, as well as distribution and product licenses, and non-compete agreements. We amortize intangible assets over periods ranging from 1 to 15 years.

Stock-based expense. We incur non-cash stock-based expenses as a result of the amortization of non-cash deferred compensation that is recorded in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees.* This deferred compensation resulted following the issuance of stock options to employees and the sale of equity securities prior to the completion of our IPO when the estimated fair value of the securities was deemed, for financial reporting purposes, to have exceeded their respective exercise or sales price. Additionally, for stock-based incentives granted to consultants, we defer and amortize the fair value of such grants

Table of Contents

as calculated pursuant to Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation.* Deferred compensation is amortized on a straight-line basis over the respective vesting periods of the stock-based incentives, which is generally four years, and we immediately expense all non-cash stock-based compensation associated with the issuance of equity where no vesting restrictions apply.

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), *Share Based Payment* (SFAS No. 123R), which requires the recognition of compensation expense for the fair value of share-based transactions. The fair value must be determined as of the date of grant using a valuation model such as Black-Scholes or a lattice model. The resulting compensation will be recognized over the service period. In April 2005, the SEC amended Rule 4-01(a) of Regulation S-X regarding the compliance date for SFAS No. 123R. This amendment modified the effective date of SFAS No. 123R, requiring adoption of this standard on the first interim or annual reporting period of the first fiscal year beginning on or after June 15, 2005. Accordingly, we adopted SFAS No. 123R effective January 1, 2006. Although management s evaluation of SFAS No. 123R is not complete, we estimate that the amount of non-cash stock-based compensation that we will record in 2006 pursuant to the adoption of SFAS No. 123R will be significant. The effect on our historical results of operations of expensing the fair value of stock options using the Black-Scholes model and the provisions of SFAS No. 123 is presented in Note 2 to our consolidated financial statements in Item 8 of this report.

Interest (income) expense, net. Interest (income) expense, net, consists primarily of interest on borrowings outstanding under our senior credit facility, capital lease agreements, and certain of our factoring agreements, as well as non-cash expenses associated with the amortization of deferred financing costs resulting from the origination of our senior credit facility. These expenses are offset by income generated by our invested cash balances and investments in marketable securities.

Provision for income taxes. We record provisions for income taxes on earnings generated by both our domestic and international operations. Historically, our effective tax rates have varied from our statutory tax rates primarily due to research and development credits and changes in estimates related to our valuation allowances recorded against our net deferred tax assets.

Table of Contents

Results of Operations

Comparison of the year ended December 31, 2005 to the year ended December 31, 2004

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands) and as percentages of net sales:

	Year Ended December 31,			
	2005		2004	
	Amount	% of Sales	Amount	% of Sales
Net sales	$ 319,137	100.0%	$ 297,539	100.0%
Cost of sales	91,740	28.7%	84,183	28.3%
Gross profit	227,397	71.3%	213,356	71.7%
Operating expenses:				
Selling, general and administrative	166,916	52.3%	151,144	50.8%
Research and development	22,283	7.0%	18,421	6.2%
Amortization of intangible assets	4,250	1.3%	3,889	1.3%
Stock-based expense	467	0.1%	1,489	0.5%
Total operating expenses	193,916	60.8%	174,943	58.8%
Operating income	33,481	10.5%	38,413	12.9%
Interest (income) expense, net	(176)	(0.1)%	1,064	0.4%
Other expense (income), net	237	0.1%	(74)	0.0%
Income before income taxes	33,420	10.5%	37,423	12.6%
Provision for income taxes	12,355	3.9%	13,401	4.5%
Net income	$ 21,065	6.6%	$ 24,022	8.1%

The following table sets forth our net sales by product line for the periods indicated (in thousands) and the percentage of year-over-year change:

	Year Ended December 31, 2005	Year Ended December 31, 2004	% Change
Hip products	$ 109,267	$ 99,133	10.2%
Knee products	94,073	87,408	7.6%
Biologics products	62,358	62,070	0.5%
Extremity products	40,594	36,433	11.4%
Other	12,845	12,495	2.8%
Total net sales	$ 319,137	$ 297,539	7.3%

Table of Contents

The following graphs illustrate our product line sales as a percentage of total net sales for the years ended December 31, 2005 and 2004: