

WRIGHT MEDICAL GROUP INC

Form 10-K

March 01, 2005

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-K**

**FOR ANNUAL AND TRANSITION REPORTS  
PURSUANT TO SECTIONS 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

(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, 2004

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**  
(State or other jurisdiction of  
incorporation or organization)

**13-4088127**  
(I.R.S. Employer  
Identification No.)

**5677 Airline Road, Arlington, Tennessee**  
(Address of principal executive offices)

**38002**  
(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 whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☐ Yes ☐ No

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates 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 \$1,001,982,256.

As of February 22, 2005, there were 33,854,778 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, 2004, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 12, 2005.

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### **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 Management's Discussion and Analysis of Financial Condition and Results of Operations, Factors Affecting Future Operating Results 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.

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**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, 2004, we had net sales of \$297.5 million and net income of \$24.0 million.

**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 and the inception of Wright in its present form, reduced our debt and provided investment capital, thus allowing 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. 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 completed a secondary offering of 3,450,000 shares of common stock which generated \$49.5 million in net proceeds.

**Orthopaedic Industry**

It is estimated that the worldwide orthopaedic industry generated sales of approximately \$19 billion in 2004. We believe this figure will grow by 7% to 9% annually over the next three to four years. Six multinational companies currently dominate the orthopaedic industry, each with approximately \$1 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 Wright, 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.



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### *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 \$8 billion in 2004, 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 2004, with estimated sales of approximately \$4.0 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 \$3.7 billion in 2004.

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 polyethylene and ceramic-on-ceramic combinations, which exhibit improved wear characteristics and lead to longer implant life. In February 2003, we became one of only two companies cleared by the United States Food and Drug Administration (FDA) to market ceramic-on-ceramic hip systems in the United States. Since then, two additional competitors have entered the U.S. marketplace. 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 bone head 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 \$317 million worldwide in 2004. Major trends in extremity reconstruction include unique distal radius (wrist) and foot and ankle fixation devices.





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### *Biologics Market*

The biologics market is one of the fastest growing sectors of the orthopaedic market. These materials use both biological tissue-based and synthetic materials to regenerate damaged or diseased bone and to repair damaged tissue. The biologics sector includes products such as tissue-based bone grafts and bone graft substitute materials. 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. These materials 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 tissue. These products provide favorable microenvironments for quick revascularization and cell proliferation. It is estimated that the biologics market generated sales of approximately \$750 million worldwide in 2004.

## **Government Regulation**

### *United States*

Our products are strictly regulated by the 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 pre-clinical and clinical testing of our products, the manner of 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 regulation 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 study 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 studies support the safety and effectiveness of the device or warrant the

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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 study 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 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 November 2003, 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 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. 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.

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### *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 surgical instrumentation to accommodate surgeon preference.

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.

The ADVANCE® Unicompartamental Knee System is an innovative system of implants and instruments that allows for single compartment replacement with a minimally invasive surgical approach. This system is designed to reach the market for a unicompartamental knee that addresses injury or disease confined to the single compartment in the knee joint. We believe the simplified instrumentation utilized by the ADVANCE® Unicompartamental Knee System is a significant improvement over the instrumentation designs utilized in other unicompartamental knee systems on the market today.

Our ADVANCE® Double High Knee Tibial Insert design addresses an adverse phenomenon, known as paradoxical motion, that often occurs with other posterior cruciate ligament ( 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 and metal components, 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, minimally invasive 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

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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. By retaining the femoral head and neck and not invading the femoral canal, this procedure helps 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.

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.

In our hip replacement product lines, the LINEAGE® Acetabular System provides the surgeon with the option to interchangeably use either ceramic, metal or 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, which was designed in Europe, features a patented modular femoral neck, which allows the surgeon to make final adjustments 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 and PROFEMUR® T 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

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.



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### *Biologics*

We offer a broad line of biologics products that are used to replace damaged or diseased bone, to stimulate bone growth, and to provide other biological solutions for surgeons and their patients. These products focus on biological musculoskeletal repair by utilizing synthetic and human tissue-based materials. We were the first company to receive FDA market clearance for the use of resorbable synthetic bone graft substitutes for the spine, currently the largest application for this product.

Our OSTEOSSET® bone graft substitute is a synthetic bone graft substitute made of surgical grade calcium sulfate. Our OSTEOSSET® bone graft substitute provides an attractive alternative to autograft, because it facilitates bone regeneration without requiring a painful, secondary bone-harvesting procedure. Additionally, being purely synthetic, OSTEOSSET® pellets are cleared for use in infected sites, an advantage over tissue-based material. The human body resorbs the OSTEOSSET® 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 OSTEOSSET® Resorbable Bead Kit, which is available in mixable powder form. OSTEOSSET® 2 DBM graft is a unique bone graft substitute incorporating demineralized bone matrix (DBM) into OSTEOSSET® 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 OSTEOSSET® T medicated pellets, which contain tobramycin sulfate, are currently one of the few resorbable bone void fillers available in international markets for the 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. The 115 in the product's name refers to the speed of the product application, which takes only one minute to mix, one minute to inject and five minutes to harden. MIIG® 115 graft combines the operative flexibility of an injectable substance with the clinically proven osteoconductive properties of OSTEOSSET® 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 a recent addition to the family of MIIG® products for the minimally invasive treatment of bone defects. It is a newly formulated, 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 a 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 extravasation (i.e., leakage).

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.

IGNITE<sup>®</sup> ICS Injectable Cellular Scaffold 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

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can offer: an osteoconductive scaffold with both osteoinductive and osteogenic capacity through the use of DBM and BMA, respectively. The IGNITE<sup>®</sup> ICS kit also provides specially-designed instrumentation both to procure BMA and to prepare the fracture site for the grafting procedure using minimally invasive techniques.

GRAFTJACKET<sup>®</sup> Regenerative Tissue Matrix is an onlay for repair or replacement of periosteum. This product provides a favorable microenvironment for bone repair by providing an environment for rapid revascularization, preventing scar tissue invasion into the bone graft area, and creating a protected environment for healing. In addition to bone repair, GRAFTJACKET<sup>®</sup> Regenerative Tissue Matrix is also useful in soft tissue applications, specifically rotator cuff and tendon repair.

GRAFTJACKET<sup>®</sup> 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<sup>®</sup> matrix for ulcer repair appears to be the first chronic wound graft to demonstrate the ability to repair deep foot wounds, which have a much higher risk of leading to amputation. When coupled with proper surgical technique and post-operative follow-up, successful repair with GRAFTJACKET<sup>®</sup> matrix for ulcer repair is achieved within twelve weeks based on clinical study results. The ulcer repair matrix integrates with the patient's own living soft tissue, thus speeding up new tissue growth and treatment time. Unlike other tissue engineered substitutes, GRAFTJACKET<sup>®</sup> matrix for ulcer repair generally requires only one application to treat the foot ulcer, reducing the time and cost associated with recovery. In January 2005, we received stand-alone reimbursement codes for the use of our GRAFTJACKET<sup>®</sup> matrix in the repair of diabetes-related foot ulcers and other complex wounds. We believe that this development presents a significant opportunity for us, which we are pursuing aggressively.

CELLPLEX<sup>®</sup> TCP Synthetic Cancellous Bone represents a new platform of bone graft substitutes. It is an osteoconductive, resorbable tricalcium phosphate ( TCP ) provided in granular form. It has been engineered with a highly porous, interconnected structure to facilitate the ingrowth of new bone throughout the implant. Compared to other commercially available TCP products, its benefits include a superior compressive strength and physical characteristics that more closely resemble that of cancellous bone. It is an excellent carrier of BMA with a demonstrated cellular affinity for mesenchymal stem cells. It is packaged in the INFILTRATE<sup>®</sup> Marrow Infusion Chamber to provide surgeons a simple option for combining BMA with the CELLPLEX<sup>®</sup> TCP, thereby adding an osteogenic component to the graft.

ADCON<sup>®</sup> Gel products are designed to reduce adhesion formation following lumbar spine (ADCON<sup>®</sup>-L Gel) and peripheral tendon/nerve (ADCON<sup>®</sup>-T/N Gel) procedures, which may cause post-operative pain. Both ADCON<sup>®</sup>-L Gel and ADCON<sup>®</sup>-T/N Gel are commercially available internationally, but are currently not available for sale in the U.S. Our ADCON<sup>®</sup>-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<sup>®</sup> 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<sup>®</sup>-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<sup>®</sup> Gel technology, to present the FDA with the clinical data intended to support the return of ADCON<sup>®</sup>-L Gel to the U.S. market. Since the submission of our ADCON<sup>®</sup>-L Gel PMA application to the FDA in December 2003, we have been working to satisfy additional requirements necessary to obtain FDA approval to market ADCON<sup>®</sup>-L Gel in the U.S. We will be required to conduct a separate clinical study to enter the U.S. market with ADCON<sup>®</sup>-T/N Gel.

### *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 finger and toe implants. The Swanson Hinge Finger has been used by surgeons for over 30 years.

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

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providing an alternative to the harvesting of the patient's own soft tissues as a spacer for the repaired joint, the ORTHOSPHERE® Carpometacarpal Implant reduces morbidity and operating time. We believe this product represents a significant improvement over conventional techniques.

Our EVOLVE® Modular Radial Head device addresses the market for modularity. The EVOLVE® Modular Radial Head device provides 150 different combinations of heads and stems allowing the surgeon to choose implant heads and stems that accommodate the patient's anatomy. The range of stem sizes permits minimal bone removal from the radial neck, thereby preserving bone stock. The stem design allows for rotational motion at the implant/bone interface and radiocapitellar articulation, potentially reducing capitellar wear. Additionally, the EVOLVE® Modular Radial Head device is easier to insert compared to single piece implants when assembled in patients.

The LOCON-T® and LOCON-D® Distal Radius Plating Systems provide surgeons with anatomically designed, stainless steel plating systems used in the repair of radial fractures. In designing both plating systems, we utilized thin, high-strength stainless steel with low profile screws in order to lessen tendon irritation and/or rupture, which are complications that result from this type of surgical repair.

Our MICRONAIL® intramedullary wrist fracture repair system is a next-generation, minimally invasive solution that provides immediate fracture stabilization utilizing fixed-angle locking screws. The MICRONAIL® system is targeted to become a viable alternative for many wrist fracture patients currently treated with a cast and is a patented and exclusively licensed product unique to the market.

In mid-February 2005, we launched our CHARLOTTE® Foot and Ankle System, a comprehensive offering of next-generation 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 replaces products supplied by a third party vendor pursuant to a distribution agreement that expired in the first quarter of 2005.

The OLYMPIA® Total Shoulder System is a comprehensive system that offers the surgeon many choices in terms of fixation and implant stability. This system offers two fixation options including press-fit stems for cementless applications and stems that are optimized for cemented applications. Most systems now available do not offer this level of versatility and surgeons must adjust their surgical technique to fit the available products. An additional advantage of the OLYMPIA® Total Shoulder System is that the humeral head is modular and asymmetric, allowing the surgeon to adjust joint tension as the final step of the surgical process.

## **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 \$18.4 million, \$16.2 million and \$10.4 million in 2004, 2003 and 2002, respectively. We are presently targeting an overall level of research and development spending in the range of 6% to 7% of net sales for 2005 and future years.

We have established several 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 surfaces that improve the clinical performance of reconstructive devices, including highly cross-linked polyethylene and low-wear metal-on-metal surfaces. Further, we provide minimally

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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. The first phase of this program combines a minimally invasive technique and instrumentation with our PROFEMUR® Hip System, which features our modular neck technology and is specially suited for use with a smaller surgical incision. In 2005, we anticipate that we will continue to focus on additional minimally invasive techniques and instrumentation for further surgical applications including the knee. Further, we announced in late 2004 a major initiative for the development of a next-generation knee that will build on the proprietary advanced kinematic features of our ADVANCE® Medial Pivot Knee as well as other significant technological improvements.

In the biologics area, we have a variety of research and development projects underway that are designed to further expand our presence in this rapidly growing 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. Additionally, in 2005 we plan to continue exploring investments in high-performance synthetic bone graft substitutes for opportunities within the trauma and spine segments of the orthopaedic market.

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 LP® Great Toe Implant, the CONSERVE® Total Implant with BFH Technology, the MII® X3 HiVisc graft, OSTEOSET® 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, and the CHARLOTTE Foot and Ankle System.

## **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 2004 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.



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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.

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 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 and brochure mailings.

Our acquisition of Cremascoli provided an opportunity to cross-sell our predecessor company's products and legacy Cremascoli products in Europe, North America, Japan and certain other international markets. Because each market may have different product preferences, we believe that by utilizing our global sales and marketing teams understanding of surgeon preferences in their local markets, we can effectively modify and cross-sell existing products throughout the worldwide markets in which we compete.

We sell our products in the U.S. through a sales force of 318 people as of December 31, 2004. 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, Japan, Canada, and Germany 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, 2004, through a combination of our direct sales offices and 89 stocking distribution partners, we had approximately 400 international sales representatives that sell our products in over 60 countries.

Detailed information on our net sales and long-lived assets by geographic area can be found in Note 16 to the financial statements contained in Item 8 of this report.

## **Seasonal Nature of Business**

Our business is seasonal in nature. 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 during the summer months. 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.

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### **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;

- 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

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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 U.S., 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 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.

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.

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### **Employees**

As of December 31, 2004, we employed 899 people in the following areas: 368 in manufacturing, 292 in sales and marketing, 138 in administration and 101 in research and development. We do not have any active organized labor unions. 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](http://www.wmt.com). We make available free of charge through this website all of our Securities and Exchange Commission (SEC) filings, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as soon as reasonably practicable after they are electronically filed with the SEC.

### **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 the original portion of the administration building from the IDB under a lease agreement which expires on July 8, 2005. We may exercise an option to purchase the original portion of the administration building from the IDB at a price of \$101,000 at any time during the lease term. In 2004, we completed a 16,000 square foot expansion of the administration building which we own.

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 potential relocation in the Memphis metropolitan area or an expansion of our facilities at the current location. This relocation or expansion may include construction of new facilities.

Our international operations include warehouse, research, administrative and manufacturing facilities located in several countries. Our primary international manufacturing facility and warehouse are located in leased facilities 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.



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### **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. The claims in this case could impact a substantial portion of our knee product line. We believe, however, that we have strong defenses against the claims, and that the claims are, in part, covered by our patent infringement insurance. In 2004, a Markman hearing was held regarding interpretation of the patent claims that have been asserted by Howmedica in this lawsuit. The court has taken the issue of claim interpretation under advisement and both parties await the decision of the court on this issue. 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, 2004. However, 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 July 2002, pursuant to a purchase and royalty agreement with CERAbio LLC, 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 provided for in accrued expenses and is due once 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. We, believing that the contractual obligations for payment had not been met, disputed whether the second payment and royalties had been earned. In 2003, CERAbio and Phillips Plastics Corporation filed a lawsuit against us in the United States District Court for the Western District of Wisconsin for payment of the remaining \$1.5 million of the purchase price and the royalties earned to date. In November 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 our consolidated balance sheet. In 2004, we appealed the trial court's judgment to the United States Court of Appeals for the Seventh Circuit, briefs and oral arguments were submitted, and the appeal is pending. 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.**

None.

**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.

	<b>High</b>	<b>Low</b>
<b>Fiscal Year 2004</b>		
First Quarter	\$ 35.53	\$ 29.24
Second Quarter	\$ 36.99	\$ 29.56
Third Quarter	\$ 36.08	\$ 22.90
Fourth Quarter	\$ 30.10	\$ 20.75
<b>Fiscal Year 2003</b>		
First Quarter	\$ 17.85	\$ 14.02
Second Quarter	\$ 21.77	\$ 16.24
Third Quarter	\$ 26.75	\$ 18.80
Fourth Quarter	\$ 30.51	\$ 24.50

**Holders**

As of February 23, 2005, there were 172 stockholders of record and an estimated 9,834 beneficial stockholders.

**Unregistered Sales of Equity Securities**

In 2004, we issued a total of 295,797 shares of common stock under warrants which were issued in connection with our 1999 recapitalization. Of this amount, we sold 7,754 shares of common stock to nine warrant holders upon the exercise of their warrants, and we received an aggregate of \$33,759 in cash from such sales. We issued another 288,043 shares of common stock to one warrant holder who elected to receive such lesser number of shares in lieu of paying the purchase price for the 345,455 shares that it was entitled to purchase. We did not register these transactions under the Securities Act of 1933 in reliance on the exemption from registration provided by Section 4(2) thereof. These transactions did not involve any public offering of common stock, and the warrant holders had adequate access to information about the Company through our public filings with the Securities and Exchange Commission.

**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 selected consolidated financial data of Wright Medical Group, Inc. for the periods indicated. The selected consolidated financial data as of December 31, 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 2000, and for the years then ended, was derived from our consolidated financial statements audited by Arthur Andersen LLP. The audited consolidated financial statements as of December 31, 2004, 2003 and 2002 and for the years then ended, are included elsewhere in this filing. The audited consolidated financial statements as of December 31, 2001 and 2000 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.

	<b>Year Ended December 31,</b>				
	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Statement of Operations:</b>					
Net sales	\$ 297,539	\$ 248,932	\$ 200,873	\$ 172,921	\$ 157,552
Cost of sales <sup>(1)</sup>	84,183	67,815	55,616	51,351	80,370
Gross profit	213,356	181,117	145,257	121,570	77,182
Operating expenses:					
Selling, general and administrative <sup>(2)</sup>	151,144	127,612	106,875	95,556	82,813
Research and development	18,421	16,151	10,357	10,108	8,390
Amortization of intangible assets <sup>(3)</sup>	3,889	3,562	3,946	5,349	5,586
Stock-based expense <sup>(4)</sup>	1,489	2,068	1,724	1,996	5,029
Acquired in-process research and development costs		4,558			
Arbitration settlement award			(4,200)		
Total operating expenses	174,943	153,951	118,702	113,009	101,818
Operating income (loss)	38,413	27,166	26,555	8,561	(24,636)
Interest expense, net	1,064	1,107	938	7,809	12,446
Other (income) expense, net	(74)	(1,060)	(1,277)	685	870
Income (loss) before income taxes	37,423	27,119	26,894	67	(37,952)
Provision for income taxes	13,401	9,722	1,834	1,574	1,541
Net income (loss)	\$ 24,022	\$ 17,397	\$ 25,060	\$ (1,507)	\$ (39,493)
<b>Net income (loss) per share: <sup>(5)</sup></b>					
Basic	\$ 0.72	\$ 0.53	\$ 0.79	\$ (0.31)	\$ (3,405.71)
Diluted	\$ 0.68	\$ 0.50	\$ 0.75	\$ (0.31)	\$ (3,405.71)
	\$ 33,391	32,857	31,870	13,195	17

Weighted-average number of common shares  
outstanding - basic

Weighted-average number of common shares outstanding - diluted	\$ 35,317	34,561	33,550	13,195	17
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	As of December 31,				
	2004	2003	2002	2001	2000
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 83,470	\$ 66,571	\$ 51,373	\$ 2,770	\$ 16,300
Working capital	189,466	147,255	127,557	47,546	54,020
Total assets	361,158	322,103	276,370	193,719	216,964
Long-term liabilities	19,533	20,516	25,939	30,967	141,514
Redeemable preferred stock					91,254
Stockholders' equity (deficit)	\$ 276,069	\$ 238,318	\$ 204,999	\$ 117,300	\$ (76,976)

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	<b>Year Ended December 31,</b>				
	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Other Data:</b>					
Cash flow provided by operating activities	\$ 37,365	\$ 40,065	\$ 21,950	\$ 818	\$ 18,151
Cash flow used in investing activities	(18,428)	(25,844)	(22,430)	(15,558)	(14,109)
Cash flow (used in) provided by financing activities	(2,305)	514	48,384	1,372	6,028
Depreciation	17,278	13,948	13,553	10,096	11,008
Amortization of intangible assets <sup>(3)</sup>	3,889	3,562	3,946	5,349	5,586
Capital expenditures	\$ 18,316	\$ 18,116	\$ 17,974	\$ 16,764	\$ 14,109

- (1) In connection with our recapitalization and acquisition of Cremascoli, we recorded inventory step-ups pursuant to Accounting Principles Board (APB) Opinion No. 16. This accounting treatment required a \$31.1 million step-up of inventories above manufacturing costs. The step-up was charged to cost of sales over the following twelve months, reflecting the estimated period over which the inventory was sold. Cost of sales was charged \$29.1 million in the year ended December 31, 2000.
- (2) In accordance with the provisions of 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.
- (3) Amortization of intangible assets in 2004, 2003, and 2002 excludes amortization of goodwill in accordance with SFAS No. 142. See Note 6 to the financial statements contained in Item 8 of this report.
- (4) Amounts presented as stock-based expense consist of; cost of sales totaling \$68, \$107, \$108, \$89 and \$8 for the years ended December 31, 2004, 2003, 2002, 2001 and 2000, respectively; selling, general and administrative expenses of \$1,364, \$1,875, \$1,506, \$1,807 and \$4,901 for the years ended December 31, 2004, 2003, 2002, 2001 and 2000, respectively; and research and development expenses of \$57, \$86, \$110, \$100 and \$120 for the years ended December 31, 2004, 2003, 2002, 2001 and 2000, respectively.
- (5) Net income (loss) applicable to common stockholders includes preferred stock dividends of \$2.5 million for the year ended December 31, 2001, preferred stock dividends of \$4.4 million and the beneficial conversion feature of the series C preferred stock of \$13.1 million for the year ended December 31, 2000.

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**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.

*Factors affecting future operating results.* This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to the factors that are described in the MD&A captions discussed above and elsewhere in 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 Europe. We market our products in over 60 countries through a global distribution system that consists of a sales force of approximately 700 individuals who promote our products to orthopaedic surgeons and hospitals. At the end of 2004, we have 318 exclusive independent distributors and sales associates in the U.S., and approximately 400 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 and the inception of Wright in its present form. 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, hips and extremities. Our biologics sales



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encompass a broad portfolio of products designed to stimulate and augment the natural regenerative capabilities of the human body. We also sell various orthopaedic products not considered to be part of our knee, hip, extremity or biologics product lines.

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 PERFECT® Hip System. In 2003, the FDA granted us approval to market our ceramic-on-ceramic bearing as part of the LINEAGE® Acetabular System, placing us among the first companies to market ceramic-on-ceramic total hip solutions in the U.S.

Our biologics products focus on biological musculoskeletal repair and include synthetic and human tissue-based materials. Our principal biologics products include the ALLOMATRIX® line of injectable tissue-based bone graft substitutes, the GRAFTJACKET® tissue repair and containment membranes, the OSTEOSET® synthetic bone graft substitute, the MIIG® family of minimally invasive injectable synthetic bone grafts, and in our international markets, the ADCON® 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 Swanson line of finger and toe joint replacement products, the ORTHOSPHERE® Carpometacarpal Implant for repair of the basal thumb joint, the EVOLVE® Modular Radial Head device, the LOCON-T® Distal Radius Plating System, the MICRONAIL intramedullary wrist fracture repair system, and the CHARLOTTE Foot and Ankle System, a line of comprehensive foot and ankle implants.

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.*** The significant growth of our business that we experienced in 2003 continued into 2004, with considerable expansion of all of our principal product line sales. Net sales grew 20% in 2004, totaling \$297.5 million, compared to \$248.9 million in 2003. 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 and the integration of biologics products into reconstructive joint procedures and other orthopaedic applications, combined with new product development focused on specific surgical issues, continues to drive our success. Our hip and biologics product lines contributed significantly to our performance in 2004, achieving 27% and 24% growth rates, respectively.

A significant development in the hip market over the past two years has been advances in bearing surfaces, including ceramic-on-ceramic. In 2003, the FDA granted us approval to market our ceramic-on-ceramic bearing as part of the LINEAGE® Acetabular System, placing us among the first companies to market ceramic-on-ceramic total hip solutions in the U.S. While we encountered additional competition in the ceramic-on-ceramic hip market in 2004, we sustained a considerable growth rate throughout the year, ending 2004 with an overall growth rate of 27%. We anticipate further competition in the ceramic-on-ceramic hip market in 2005; however, we believe that our full continuum of hip products will position us for continued success in 2005.

In March 2004, our PMA application for our CONSERVE® Plus Hip System was accepted for filing by the FDA. Our CONSERVE® Plus Resurfacing Implant is available outside the U.S. and is pending FDA clearance for the U.S. market. With our CONSERVE® Plus Resurfacing Implant, the surface of the patient's femoral head and the acetabular surface are replaced with minimal bone loss. In May 2004, we received a warning letter from the FDA regarding the CONSERVE® Plus Resurfacing Implant investigational device exemption. We responded in June 2004, addressing

the issues cited in the warning letter, and in reply, the FDA informed us that our corrective actions had been accepted. We continue to work with the FDA as it reviews this PMA.

In March 2004, we received marketing clearance from the FDA for our ALLOMATRIX® Injectable Putty. 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) in March 2002. This submission was in response to the FDA's

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clarification to all allograft putty providers, including us, that such products should be regulated under the medical device premarket notification provisions of the Food, Drug, and Cosmetic Act. Further, in July 2004, we received marketing clearance from the FDA for our ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR putty products following our submission of a 510(k) in April 2004, completing the clearance process for our entire ALLOMATRIX® family of products.

In August 2004, we introduced our MICRONAIL intramedullary wrist fracture repair system, a next-generation, minimally invasive solution that provides immediate fracture stabilization utilizing fixed-angle locking screws. The MICRONAIL system is targeted to become a viable alternative for many wrist fracture patients currently treated with a cast and is the only one of its kind on the market.

In September 2004, we announced a voluntary market withdrawal of a limited number of metal acetabular hip cups intended for use in our CONSERVE® hip systems, as these components may not have met our product specifications due to the presence of a small ridge on the cup's non-articulating inside bearing surface. We notified the FDA of this action and removed from commercial availability all unused components covered by the market withdrawal. In connection with this market withdrawal, we incurred approximately \$800,000 of expenses for probable costs related to the market withdrawal. We did not experience any supply issues as a result of this market withdrawal, and this market withdrawal has not had a significant impact on our sales. Further discussion of our voluntary market withdrawal is included in Note 15 to our consolidated financial statements in Item 8 of this report.

During the fourth quarter of 2004, we incurred approximately \$2.9 million of costs as a result of the transition from certain of our foot and ankle implant offerings to an innovative, next-generation line of internally developed products, collectively referred to as the CHARLOTTE Foot and Ankle System, replacing products supplied by a third party vendor pursuant to a distribution agreement that expired in the first quarter of 2005. These charges resulted from the write down of our distributed foot and ankle implant inventory to its estimated net realizable value and accelerated depreciation on the related surgical instrumentation. We launched our CHARLOTTE Foot and Ankle System in mid-February 2005.

**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 our success is dependent on our ability to compete successfully against our competitors. 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 under the heading, Factors Affecting Future Operating Results, within MD&A.

## **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 under the heading, Executive Overview, within MD&A.

**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.

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

**Stock-based expense.** We incur 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. This deferred compensation resulted following the issuance of stock options to employees and the sale of equity securities when the estimated fair value of the securities was deemed, for financial reporting purposes, to have exceeded their respective exercise or sales price. The substantial majority of our stock-based expense relates to the issuance of shares and options prior to the completion of our IPO in 2001. Additionally, for stock-based incentives granted to consultants, we defer and amortize the fair value of such grants as calculated pursuant to Statement of Financial Accounting Standards (SFAS) No. 123. 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 stock-based compensation associated with the issuance of equity where no vesting restrictions apply.

**Interest expense, net.** Interest expense, net, consists primarily of interest on borrowings outstanding under our senior credit facility 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 earned on our invested cash balances.

**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.

**Results of Operations**

**Introduction.** 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,					
	2004	% of	2003	% of	2002	% of
	Amount	Sales	Amount	Sales	Amount	Sales
Net sales	\$ 297,539	100.0%	\$ 248,932	100.0%	\$ 200,873	100.0%
Cost of sales	84,183	28.3%	67,815	27.2%	55,616	27.7%
Gross profit	213,356	71.7%	181,117	72.8%	145,257	72.3%
Operating expenses:						
Selling, general and administrative	151,144	50.8%	127,612	51.3%	106,875	53.2%
Research and development	18,421	6.2%	16,151	6.5%	10,357	5.2%
Amortization of intangible assets	3,889	1.3%	3,562	1.4%	3,946	2.0%
Stock-based expense	1,489	0.5%	2,068	0.8%	1,724	0.8%
Acquired in-process research and development costs			4,558	1.8%		
Arbitration settlement award					(4,200)	(2.1)%

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Total operating expenses	174,943	58.8%	153,951	61.8%	118,702	59.1%
Operating income	38,413	12.9%	27,166	10.9%	26,555	13.2%
Interest expense, net	1,064	0.4%	1,107	0.4%	938	0.5%
Other income, net	(74)	0.0%	(1,060)	(0.4)%	(1,277)	(0.6)%
Income before income taxes	37,423	12.6%	27,119	10.9%	26,894	13.4%
Provision for income taxes	13,401	4.5%	9,722	3.9%	1,834	0.9%
Net income	\$ 24,022	8.1%	\$ 17,397	7.0%	\$ 25,060	12.5%

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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:

	<b>Year Ended December 31, 2004</b>	<b>Year Ended December 31, 2003</b>	<b>2004 vs. 2003 %</b> <b>Change</b>	<b>Year Ended December 31, 2002</b>	<b>2003 vs. 2002 %</b> <b>Change</b>
Hip products	\$ 99,133	\$ 78,071	27.0%	\$ 56,945	37.1%
Knee products	87,408	78,338	11.6%	72,058	8.7%
Biologics products	62,070	50,056	24.0%	38,347	30.5%
Extremity products	36,433	31,876	14.3%	25,367	25.7%
Other	12,495	10,591	18.0%	8,156	29.9%
Total net sales	\$ 297,539	\$ 248,932	19.5%	\$ 200,873	23.9%

The following graphs illustrate our product line sales as a percentage of total net sales for the years ended December 31, 2004, 2003, and 2002:

**Comparison of the year ended December 31, 2004 to the year ended December 31, 2003**

**Net sales.** Net sales growth in 2004 was attributable to strong demand across all of our principal products lines, with significant contributions from hips and biologics which grew by 27% and 24%, respectively, and solid growth in our extremity and knee business which grew by 14% and 12%, respectively. Geographically, our domestic net sales totaled \$180.4 million in 2004 and \$152.9 million in 2003, representing approximately 61% of total net sales in both years and growth of 18%. Our international net sales totaled \$117.2 million in 2004, a 22% increase as compared to net sales of \$96.1 million in 2003. Our 2004 international net sales include a favorable currency impact of approximately \$8.1 million, principally resulting from the 2004 performance of the euro against the U.S. dollar. Our international growth was primarily driven by increased sales in our European and Asian markets, with expansion across all product lines.

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Our hip product sales totaled \$99.1 million in 2004, representing a 27% increase. Growth in our hip business in 2004 is attributable to continued success in domestic markets, where total hip procedures grew by 20%, driven by our CONSERVE® Total Implant with BFH Technology and our PROFEMUR® line of primary stems featuring our innovative neck modularity. Additionally, a favorable shift in our sales mix to premium priced hard bearing procedures, which includes our ceramic-on-ceramic and metal-on-metal products, contributed to our domestic growth. Our percentage of hard bearing surgeries grew from 57% of total domestic hip surgeries in 2003 to 66% in 2004. In our international markets, unit sales growth of our CONSERVE® Plus Resurfacing Implant and a favorable currency impact of \$4 million both impacted the year over year sales increase. We believe that our hip product portfolio, which focuses on innovative solutions including bone-conserving implants, advanced bearing surfaces and modular neck technology, will position us for continued success in 2005.

Sales of our biologics products in 2004 totaled \$62.1 million, representing an increase of 24%. The growth of our biologics business in 2004 is primarily attributable to the continued favorable performance, in domestic markets, of our GRAFTJACKET® tissue repair and containment membranes combined with the performance of our ADCON® Gel product in international markets. Domestically, total biologics procedures grew by 4%, as significant growth of our GRAFTJACKET® product line, combined with growth of our OSTEOSET® family of products and our MIIG® (Minimally Invasive Injectable Graft) family of products, was offset by declines in our DBM (demineralized bone matrix) containing ALLOMATRIX® family of products. During 2004, competitive pressures in the mature market for DBM containing products had a negative impact on the performance of our ALLOMATRIX® products. From an international perspective, unit sales growth of our ADCON® Gel product and a favorable currency impact of approximately \$400,000 contributed to our biologics growth in 2004. As we move into 2005, significant investment in high performance synthetic bone graft substitutes should enable us to take advantage of longer-term opportunities within the trauma and spine segments of the orthopaedic market.

Our extremity product sales increased to \$36.4 million in 2004, representing growth of 14% over 2003. Increased unit sales of our higher priced extremity products, such as our foot and ankle products and our EVOLVE® Modular Radial Head System, combined with pricing increases across our entire extremity product platform, were the most significant factors contributing to our year over year growth. For 2005, we anticipate that our extremity line of business will continue to benefit from our EVOLVE® Modular Radial Head System, as well as the 2004 launch of our MICRONAIL system and our mid-February 2005 launch of our CHARLOTTE Foot and Ankle System, a next-generation line of internally developed foot and ankle products.

Sales of our knee products totaled \$87.4 million in 2004, representing growth of 12%. Our domestic knee performance is attributable to a combination of increased unit sales and increased prices. Our international knee growth is attributable to a combination of increased unit sales and a favorable currency impact of approximately \$2.4 million. In the latter half of 2004, we introduced our minimally invasive surgical instrumentation for knee procedures to certain key customers. As we move into 2005, we anticipate further success in our knee product line as we are able to more fully penetrate the U.S. market with this instrumentation.

**Cost of sales.** Cost of sales as a percentage of net sales increased to 28.3% in 2004 from 27.2% in 2003. Approximately 0.8 percentage points of this increase is attributable to \$2.4 million of costs incurred during the fourth quarter of 2004 to write down certain foot and ankle implant inventory to its net realizable value as a result of the transition of this product line to our CHARLOTTE Foot and Ankle System. The remaining increase as a percentage of sales is primarily attributable to higher levels of charges incurred for excess and obsolete inventories. Our cost of sales and corresponding gross profit percentages can be expected to fluctuate in future periods depending upon changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses and levels of production volume.



***Selling, general and administrative.*** Our selling, general and administrative expenses as a percentage of net sales totaled 50.8% in 2004, a 0.5 percentage point decrease from 51.3% in 2003. This decrease is attributable to decreased royalty expenses as a percentage of net sales, decreased commission expense as a percentage of net sales due to shifts in our geographic sales mix to higher levels of international sales which generally incur a lower commission rate, and our ability to control other discretionary costs while continuing to significantly expand our business. These decreases were offset by approximately \$1.2 million of incremental costs related to corporate governance, approximately \$700,000 resulting from our limited market withdrawal of certain CONSERVE® hip

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components, approximately \$500,000 of accelerated depreciation expense related to surgical instrumentation for certain foot and ankle products that will be transitioned out of our product offerings during the first quarter of 2005, and additional legal costs related to the on-going transition of certain management and distribution personnel in Southern Europe.

We anticipate that our selling, general and administrative expenses as a percentage of net sales will continue to decrease in future periods as we manage the growth of our existing infrastructure while continuing to expand our business. During the first half of 2005, we expect our selling, general and administrative expenses to be impacted by additional costs associated with the transition of certain management and distribution personnel in Southern Europe and additional accelerated depreciation on surgical instrumentation. Additionally, selling, general and administrative expenses will increase in absolute dollars to the extent that any additional growth in net sales results in increases in sales commissions and royalty expense associated with those sales.

**Research and development.** Our investment in research and development activities represented approximately 6.2% of net sales in 2004, as compared to 6.5% in 2003. In absolute dollars, research and development expenditures increased to \$18.4 million in 2004 from \$16.2 million in 2003. This increase can be attributed to increased spending on product development and clinical evaluations for pre-market products and products already on the market. Our key product launches in 2004 included our OSTEOSSET® DBM Pellets, our ADVANCE® Double-High Knee design, our MICRONAIL intramedullary distal radius implant, our ODYSSEY Tissue Preserving Initiative for Hip and Knee procedures, and our PROFEMUR® Tapered Stem Total Hip System.

For 2005, we anticipate that our research and development expenditures as a percentage of net sales will be in the range of 6% to 7%. As our business continues to grow, we expect our research and development expenditures to increase in absolute dollars, and may increase as a percentage of net sales as we continue to increase our investment in product development initiatives and clinical studies.

**Amortization of intangible assets.** Our amortization expense during 2004 was consistent with 2003, totaling \$3.9 million in 2004 as compared to \$3.6 million in 2003. Based on the intangible assets held at December 31, 2004, we expect to amortize approximately \$4.0 million in 2005, \$3.5 million in 2006, \$2.9 million in 2007, \$2.7 million in 2008 and \$2.5 million in 2009.

**Stock-based expense.** We recognized \$1.5 million and \$2.1 million of stock-based expense during 2004 and 2003, respectively, primarily resulting from the amortization of our deferred compensation. In December 2004, the Financial Accounting Standards Board (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 expense will be recognized over the service period. We will adopt SFAS No. 123R effective July 1, 2005. We anticipate that we will record material amounts of incremental non-cash stock-based expense in future periods following the adoption of SFAS No. 123R. However, the exact amount cannot be determined until management's evaluation of SFAS No. 123R is complete and an appropriate valuation model has been selected and applied to determine the fair value of our stock options outstanding. The effect of expensing stock options on our historical results of operations using the Black-Scholes model is presented in the table in Note 2 to our consolidated financial statements in Item 8 of this report.

**In-process research and development cost.** Upon consummation of our acquisition of certain ADCON® Gel technology assets from Gliatech Inc. in March 2003, we immediately recognized as expense approximately \$4.6 million in costs representing the estimated fair value of acquired in-process research and development (IPRD) that had not yet reached technological feasibility and had no alternative future use (see Note 3 to our consolidated financial statements in Item 8 of this report).

We engaged an independent third party to conduct a valuation of the intangible assets acquired. The value was determined by estimating the costs to develop the acquired IPRD into commercially viable products, estimating the resulting net cash flows from this project, and discounting the net cash flows back to their present values. An additional discount was applied to take into account the uncertainty surrounding the successful development and commercialization of the acquired IPRD. The resulting net cash flows from the project were based on our

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management's best estimates of revenue, cost of sales, research and development costs, selling, general and administrative costs, and income taxes from the project. A summary of the estimates used to calculate the net cash flows for the project is as follows:

Project	Year net cash	Discount rate	Acquired IPRD
	in-flows expected to begin	including factor to account for uncertainty of success	
ADCON® Gel	2004	32.3%	\$ 4,558,000

ADCON® Gel products are designed to reduce adhesion formation following lumbar spine (ADCON®-L Gel) and peripheral tendon/nerve (ADCON®-T/N Gel) procedures, thus reducing or eliminating post-operative pain. 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 product had previously received regulatory clearance from the FDA in 1998. In 2000, the FDA determined that the provisions of its Application Integrity Policy (AIP) would be applied to Gliatech due to 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 Gliatech, which subsequently allowed us, as the new owner of the technology, to present the FDA with clinical data intended to support the return of ADCON®-L Gel to the U.S. market. Since the submission of our ADCON®-L Gel PMA application to the FDA in December 2003, we have been working to satisfy additional requirements necessary to obtain FDA approval to market ADCON®-L Gel in the U.S. We will be required to conduct a separate clinical study to enter the U.S. market with ADCON®-T/N Gel.

Our original estimate for receipt of net cash flows associated with this project was in 2004; however, we now anticipate that ADCON®-L Gel will be available for sale in the U.S. market no sooner than 2006. This delay in the estimated completion date has not had a significant impact on our results of operations or financial condition. We expect to pursue necessary clinical studies to allow FDA approval for additional applications outside of the spine, such as the peripheral tendon/nerve. We are unable to estimate at this time when such additional FDA approvals would occur.

We anticipate that portions of our existing cash will be used to continue to develop the acquired IPRD into commercially viable products. This development consists primarily of the completion of all clinical evaluation testing activities and regulatory approvals that are necessary to establish the safety and efficacy of the products and to market them in the U.S. Bringing the acquired IPRD to market also includes testing the products for compatibility and interoperability with commercially viable products. Due to the history of the ADCON® Gel products with the FDA, we are unable to estimate the extent of research and development activities that will be necessary to develop these products into commercially viable products.

We are continuously monitoring our research and development projects. We believe that the assumptions used in the valuation of acquired IPRD represent a reasonably reliable estimate of the future benefits attributable to the acquired IPRD. No assurance can be given that actual results will not deviate from those assumptions in future periods.

**Interest expense, net.** Our interest expense, net, consists primarily of interest on borrowings outstanding under our senior credit facility and certain of our factoring agreements and is partially offset by interest income of approximately \$815,000 and \$636,000 in 2004 and 2003, respectively, from our invested cash balances. Our net interest expense also

includes non-cash expense associated with the amortization of deferred financing costs resulting from the origination of our senior credit facility of approximately \$261,000 during both 2004 and 2003.

***Other income, net.*** Other income, net, primarily consists of gains and losses resulting from foreign currency fluctuations, offset in the second half of 2004 by the impact of gains and losses resulting from certain foreign currency forward contracts. These contracts are discussed further in Note 2 to our consolidated financial statements in Item 8 of this report. Primarily as a result of these forward contracts, our other income, net, decreased from \$1.1 million in 2003 to a nominal amount in 2004.

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**Provision for income taxes.** We recorded tax provisions of \$13.4 million and \$9.7 million in 2004 and 2003, respectively. Our effective tax rate for both 2004 and 2003 was approximately 36%, which reflects the impact of certain tax saving initiatives, including research and development credits and changes in estimates related to the valuation allowances recorded against our deferred tax assets.

During 2004, the American Jobs Creation Act of 2004 (Jobs Creation Act) was signed into law. Beginning in 2005, the Jobs Creation Act includes relief for domestic manufacturers by providing a tax deduction up to 9% of the lesser of qualified production activities income or taxable income. In addition, the Jobs Creation Act also provides for a one-time tax deduction of 85% of certain foreign earnings that are repatriated. Based on our assessment of the repatriation deduction, we have determined to continue our current policy of permanently reinvesting all foreign earnings. With respect to the tax deduction provided for domestic manufacturers, we are in the process of evaluating the potential impact of this portion of the Jobs Creation Act to our business. The transition issues related to this deduction are complex and little interpretative guidance has been issued to date. Accordingly, management has not determined, what, if any, the impact of this tax deduction will have to on our effective tax rate in future periods. Excluding any favorable impact of the Jobs Creation Act, for 2005, we expect our effective tax rate to increase from 2004 to a range of 38% to 39%; however, the actual rate will depend on a number of factors, including the amount of pre-tax income by jurisdiction, any incremental tax saving initiatives that might be identified and implemented and the ultimate impact, if any, of the Jobs Creation Act.

## **Comparison of the year ended December 31, 2003 to the year ended December 31, 2002**

**Net sales.** Our net sales grew 24% in 2003, totaling \$248.9 million. This was attributable to the success of our biologics and extremity product lines, as well as significant growth in our hip product line. Geographically, our domestic net sales totaled \$152.9 million in 2003 and \$122.4 million in 2002, representing 61% of total net sales in both years and growth of 25%. Our international net sales totaled \$96.1 million in 2003, increasing by 22% over net sales of \$78.5 million in 2002. Our 2003 international net sales included a favorable currency impact of approximately \$11.9 million, principally resulting from the 2003 performance of the euro against the U.S. dollar, when compared to 2002. Our European and Japanese operations were the significant drivers of our sales growth in our international operations in 2003.

From a product line perspective, our net sales growth for 2003 was attributable to increases in sales across all of our principal product lines. For 2003, we experienced growth of 37%, 31%, 26% and 9%, in our hip, biologics, extremity, and knee product lines, respectively. Our most significant growth drivers in 2003 were our hip and biologics product lines. During 2003, our 37% hip sales growth was attributable primarily to demand for our higher-priced CONSERVE® Total Implant with BFH Technology, as well as our LINEAGE® Acetabular System and our PROFEMUR® stem products, both of which were positively influenced by the launch of our LINEAGE® ceramic-on-ceramic hip system in the first quarter 2003. Our biologics sales growth of 31% in 2003 was primarily the result of strong growth across all of our biologics product offerings.

**Cost of sales.** Our cost of sales as a percentage of net sales decreased slightly to 27.2% in 2003 from 27.7% in 2002. This decrease is primarily a result of our ability to manage certain of our fixed manufacturing costs while our business significantly expanded during 2003.

**Operating expenses.** Our total operating expenses increased, as a percentage of net sales, by 2.7 percentage points to 61.8% in 2003. Operating expenses include selling, general and administrative expenses, research and development expenses, amortization of intangibles, and stock-based expenses. Additionally, operating expenses included approximately \$4.6 million of acquired IPRD costs in 2003 and the favorable impact of our \$4.2 million arbitration settlement award in 2002. These two items were the primary drivers of the increase in operating expenses. These amounts were partially offset by favorable selling, general and administrative expenses, resulting from our ability to

control our discretionary spending while significantly growing our business, and reductions in amortization of intangible assets.

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**Provision for income taxes.** Our effective tax rate for 2003 was approximately 36% as compared to an effective tax rate of 7% for 2002. Our 2002 effective tax rate was favorably impacted by the reduction of the valuation allowance against our deferred tax assets, which resulted in an \$8.1 million non-cash benefit to our provision for income taxes. Excluding this benefit, our effective tax rate for 2002 would have been approximately 37%. The decrease in our effective tax rate in 2003, excluding this benefit, reflected the effect of certain tax savings initiatives that were implemented in 2003.

**Seasonal Nature of Business**

Our business is seasonal in nature. 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 during the summer months. 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.

**Liquidity and Capital Resources**

The following table sets forth, for the periods indicated, certain liquidity measures (in thousands):

	<b>As of December 31,</b>	
	<b>2004</b>	<b>2003</b>
Cash and cash equivalents	\$ 83,470	\$ 66,571
Working capital	189,466	147,255
Line of credit availability	59,708	57,742

Our cash and cash equivalents increased during 2004 by \$16.9 million, compared to an increase of \$15.2 million in 2003. Our 2004 increase in cash and cash equivalents is primarily attributable to the generation of \$37 million of cash from operating activities during 2004, partially offset by routine capital expenditures. Our 2003 increase in cash and cash equivalents and working capital is primarily attributable to the generation of \$40 million of cash from operating activities during 2003, partially offset by capital expenditures and the acquisition of ADCON<sup>®</sup> Gel technology assets.

**Operating Activities.** Operating cash flow in 2004 benefited from the profitability of our business and working capital management, which resulted primarily from improved collection of our outstanding receivables during 2004. The improvement in our collections was offset by increased investments in new product inventory during 2004 in order to prepare for anticipated product launches, as well as an increase of approximately \$3.9 million in cash tax payments. Operating cash flow in 2003 benefited from the profitability of our business, as well as improved inventory management. Cash generated from operating activities in 2002 totaled approximately \$22 million and included the favorable \$4.2 million arbitration settlement award, which was partially offset by significant investments in new product inventory

**Investing Activities.** Our capital expenditures totaled approximately \$18.3 million in 2004, \$18.1 million in 2003, and \$18.0 million in 2002. Our industry is capital intensive, particularly as it relates to surgical instrumentation. Historically, our capital expenditures have consisted of purchased manufacturing equipment, research and testing equipment, computer systems, office furniture and equipment, and surgical instruments. We expect to incur capital expenditures of approximately \$30 million in total for 2005 for routine capital expenditures. The increase in anticipated capital spending from 2004 is expected to be primarily attributable to increased investments in surgical instrumentation for new products. Furthermore, as mentioned under the heading, Properties, in Item 2 of this report,



we are evaluating our long-term facility needs in the U.S. in response to our anticipated growth. We cannot estimate the amount of capital spending, if any, that will be incurred in 2005 should we expand or construct new facilities.

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In 2003, in addition to our routine capital expenditures, we paid \$7.8 million to complete the purchase of IPRD, tangible assets, and intangible assets from Gliatech, which were primarily related to the ADCON<sup>®</sup> Gel technology. We are continuously evaluating opportunities to purchase technology and other forms of intellectual property and are, therefore, unable to predict the timing of future purchases.

**Financing Activities.** During 2004, we made \$4.5 million in scheduled payments related to borrowings under our senior credit facility and approximately \$1.8 million in payments related to our long-term capital leases. In the fourth quarter of 2003, our operating subsidiary in Italy began factoring portions of its accounts receivable balances under a new agreement, which is considered a financing transaction for financial reporting purposes. The cash proceeds received from this factoring agreement, net of the amount of factored receivables collected, are reflected as cash flow from financing activities in our consolidated statements of cash flows. In 2004, the net activity under this agreement was consistent as the amount of cash received approximated the receivables collected. We recorded an obligation of \$5.2 million and \$4.8 million for the amount of receivables factored under this agreement as of December 31, 2004 and 2003, respectively, which is included within Accrued expenses and other current liabilities in our consolidated balance sheet. The proceeds received under the agreement in 2004 and 2003 totaled approximately \$10.7 million and \$4.7 million, respectively. Additionally, we received cash proceeds of \$4.1 million from the exercise of stock options and warrants during 2004.

In 2005, our debt payments will increase to \$5 million based on the terms of our senior credit facility. Additionally, we will make continued payments under our long-term capital leases, including interest, of approximately \$1.6 million. We anticipate that our factoring program in Italy will continue; however, the level and extent of the amounts factored under the agreement and the ultimate amount of proceeds received under the program cannot be predicted. Therefore, we are unable to predict the ultimate amount of proceeds that will be received in 2005 related to this factoring agreement.

**Contractual Cash Obligations.** At December 31, 2004, we had contractual cash obligations and commercial commitments as follows (in thousands):

		Payments Due by Periods			
	Total	2005	2006-2007	2008 - 2009	After 2009
<i>Amounts reflected in balance sheet:</i>					
Notes payable	\$ 8,750	\$ 5,000	\$ 3,750	\$	\$
Capital lease obligations <sup>(1)</sup>	5,032	1,642	2,193	864	333
<i>Amounts not reflected in balance sheet:</i>					
Operating leases	16,150	6,532	7,152	1,004	1,462
Purchase obligations	11,872	6,609	5,263		
Royalty and consulting agreements	15,167	6,266	2,903	1,998	4,000
Total contractual cash obligations	\$ 56,971	\$ 26,049	\$ 21,261	\$ 3,866	\$ 5,795

<sup>(1)</sup> Payments include amounts representing interest

Our senior credit facility, which we entered into in August 2001, has a five-year term and consists of \$20 million in term loans, with an unpaid balance of approximately \$8.8 million at December 31, 2004, and a revolving loan facility of up to \$60 million. Borrowings under the senior credit facility are guaranteed by all of our subsidiaries and collateralized by all of the assets of Wright Medical Technology, Inc., our wholly-owned subsidiary. The credit

facility contains customary covenants including, among other things, restrictions on our ability to pay cash dividends, prepay debt, incur additional debt and sell assets. The credit facility also requires us to maintain certain financial covenants, including a specified consolidated leverage (or debt-to-equity) ratio and a specified consolidated fixed charge coverage ratio. In the event that we violate any covenants, we could be required to repay the remaining balance of the debt. Additionally, should we be required to repay the loan before its scheduled maturity, we would incur a charge to operating income for unamortized financing costs. At our option, borrowings under the credit facility bear interest either at a rate equal to a fixed base rate plus a spread of .75% to 1.25% or at a rate equal to an adjusted LIBOR plus a spread of 1.75% to 2.25%, depending on our consolidated leverage ratio, with a current annual rate of 3.625%.

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The amounts reflected in the table above for capital lease obligations represent future minimum lease payments under our capital lease agreements which are primarily for certain property and equipment. The present value of the minimum lease payments are recorded in our balance sheet at December 31, 2004. The minimum lease payments related to these leases are discussed further in Note 9 to our consolidated financial statements contained in Item 8 of this report.

The amounts reflected in the table above for operating leases represent future minimum lease payments under noncancellable operating leases primarily for certain equipment and office space. Portions of these payments are denominated in foreign currencies and were translated in the table above based on their respective U.S. dollar exchange rates at December 31, 2004. These future payments are subject to foreign currency exchange rate risk. In accordance with accounting principles generally accepted in the U.S., our operating leases are not recognized in our consolidated balance sheet; however, the minimum lease payments related to these agreements are disclosed in Note 15 to our consolidated financial statements contained in Item 8 of this report.

Our purchase obligations reflected in the table above consist of minimum purchase obligations related to certain supply agreements. The royalty and consulting agreements in the above table represent minimum payments to consultants that are contingent upon future services. Portions of these payments are denominated in foreign currencies and were translated in the table above based on their respective U.S. dollar exchange rates at December 31, 2004. These future payments are subject to foreign currency exchange rate risk. Our purchase obligations and royalty and consulting agreements are disclosed in Note 15 to our consolidated financial statements contained in Item 8 of this report.

In addition to the contractual cash obligations discussed above, all of our domestic sales and a portion of our international sales are subject to commissions based on net sales, and a substantial portion of our global sales are subject to other royalties earned based on product sales. Further, under our factoring agreement in Italy, our liability for cash proceeds received of \$5.2 million discussed under the heading, Financing Activities, may be subject to repayment upon 15 days notice. None of these amounts are included in the table above.

***Other Liquidity Information.*** We have funded our cash needs since 2000 through various equity and debt issuances and through cash flow from operations. 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.

Although it is difficult for us to predict our future liquidity requirements, we believe that our current cash balance of approximately \$83.5 million, our existing available credit line of approximately \$59.7 million, and our expected cash flow from our operating activities, which in 2004 totaled approximately \$37.4 million, will be sufficient for the foreseeable future to fund our working capital requirements and operations, permit anticipated capital expenditures in 2005 of approximately \$30 million, meet our contractual cash obligations in 2005, and fund any potential expansion of our current facilities or the construction of new facilities.

## **Critical Accounting Estimates**

All of our significant accounting policies and estimates are described in Note 2 to our consolidated financial statements contained in Item 8 of this report. However, certain of our more critical accounting estimates require the application of significant judgment by management in selecting the appropriate assumptions in determining the estimate. By their nature, these judgments are subject to an inherent degree of uncertainty. We develop these judgments based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers, and information available from other outside sources, as appropriate. Different, reasonable estimates could have been used in the current period. Additionally, changes in accounting

estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition or results of operations.

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We believe that the following financial estimates are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recorded in the financial statements for all periods presented. Our management has discussed the development, selection, and disclosure of our most critical financial estimates with the audit committee of our Board of Directors and with our independent auditors. The judgments about those financial estimates are based on information available as of the date of the financial statements. Those financial estimates include:

***Revenue recognition.*** Our revenues are generated through two types of customers, hospitals and stocking distributors, with the majority of our revenue derived from sales to hospitals. Our products are sold through a network of independent sales representatives in the U.S. and by a combination of employee sales representatives, independent sales representatives, and stocking distributors outside the U.S. We record revenues from sales to hospitals when the hospital takes title to the product, which is when the product is surgically implanted in a patient and a purchase order is received from the hospital. We view the receipt of a purchase order as the evidence of customer acceptance of the product.

We record revenues from sales to our stocking distributors at the time the product is shipped to the distributor. Our stocking distributors, who sell the products to their customers, take title to the products and assume all risks of ownership. Our distributors are obligated to pay us within specified terms regardless of when, if ever, they sell the products. In general, our distributors do not have any rights of return or exchange; however, in limited situations we have repurchase agreements with certain stocking distributors. Those certain agreements require us to repurchase a specified percentage of the inventory purchased by the distributor within a specified period of time prior to the expiration of the contract. During those specified periods, we defer the applicable percentage of the sales. Approximately \$87,000 and \$247,000 of deferred revenue related to these types of agreements was recorded at December 31, 2004 and 2003, respectively.

We must make estimates of potential future product returns related to current period product revenue. To do so, we analyze our historical experience related to product returns when evaluating the adequacy of the allowance for sales returns. Judgment must be used and estimates made in connection with establishing the allowance for product returns in any accounting period. Our allowances for product returns of \$395,000 and \$412,000 are included as a reduction of accounts receivable at December 31, 2004 and 2003, respectively. Should actual future returns vary significantly from our historical averages, our operating results could be affected.

***Allowances for doubtful accounts.*** We experience some credit loss on our accounts receivable and accordingly we must make estimates related to the ultimate collection of our accounts receivable. Specifically, we analyze our accounts receivable, historical bad debt experience, customer concentrations, customer creditworthiness, and current economic trends when evaluating the adequacy of our allowance for doubtful accounts.

The majority of our receivables are from hospitals, many of which are government funded. Accordingly, our collection history with these customers has been favorable. Historically, we have experienced minimal bad debts from our hospital customers and more significant bad debts from certain international distributors, typically as a result of specific financial difficulty or geo-political factors. In 2003 and 2004, the increases in our accounts receivable balance have related almost exclusively to our hospital customers. As the historical bad debt experience with this class of customer is minimal, our allowance has not increased proportionately to the increase in our accounts receivable balance. We write off receivables when we determine that the receivable is uncollectible, typically upon customer bankruptcy or the customer's non-response to collection efforts.

We believe that the amount included in our allowance for doubtful accounts has been a historically accurate estimate of the amount of accounts receivable that are ultimately collected. While we believe that our allowance for doubtful accounts is adequate, the financial condition of our customers and the geo-political factors that impact reimbursement

under individual countries healthcare systems can change rapidly and as such, additional allowances may be required in future periods. Our accounts receivable balance was \$61.7 million and \$55.8 million, net of allowances for doubtful accounts of \$1.8 million and \$1.5 million, at December 31, 2004 and 2003, respectively.

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***Excess and obsolete inventories.*** We value our inventory at the lower of the actual cost to purchase and/or manufacture the inventory or its net realizable value. We regularly review inventory quantities on hand for excess and obsolete inventory and, when circumstances indicate, we incur charges to write down inventories to their net realizable value. Our review of inventory for excess and obsolete quantities is based primarily on our estimated forecast of product demand and production requirements for the next twenty-four months. A significant decrease in demand could result in an increase in the amount of excess inventory quantities on hand. Additionally, our industry is characterized by regular new product development that could result in an increase in the amount of obsolete inventory quantities on hand due to cannibalization of existing products. Also, our estimates of future product demand may prove to be inaccurate, in which case we may be required to incur charges for excess and obsolete inventory. In the future, if additional inventory write-downs are required, we would recognize additional cost of goods sold at the time of such determination. Regardless of changes in our estimates of future product demand, we do not increase the value of our inventory above its adjusted cost basis. Therefore, although we make every effort to ensure the accuracy of our forecasts of future product demand, significant unanticipated decreases in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results.

Charges incurred for excess and obsolete inventory were \$5.8 million, \$2.6 million and \$2.8 million for the years ended December 31, 2004, 2003 and 2002, respectively. In 2004, charges incurred for excess and obsolete inventory included \$2.4 million recorded to write down certain foot and ankle implant inventory to its net realizable value as a result of our transition to our CHARLOTTE Foot and Ankle System.

***Goodwill and long-lived assets.*** We have approximately \$8.8 million of goodwill recorded as a result of acquisition of businesses. Goodwill is tested for impairment annually, or more frequently if changes in circumstances or the occurrence of events suggest that impairment exists. We have two reporting units for purposes of evaluating goodwill for impairment, Wright Medical Technology, Inc. (WMT) and Wright Medical Europe (WME). WMT consists of our U.S., Canadian, and Japanese subsidiaries and is primarily consistent with our predecessor company prior its recapitalization. WME consists of our European subsidiaries and is primarily consistent with the former Cremascoli operations prior to its acquisition by us. The annual evaluation of goodwill impairment requires the use of estimates and assumptions to determine the fair value of our reporting units using projections of future cash flows. Our estimates of future sales growth rates and operating margin can significantly affect the outcome of the impairment test. We performed our annual impairment test during the fourth quarter of 2004 and determined that the fair value of our reporting units exceeded the carrying value of those units and, therefore, no impairment charge was necessary.

Our business is capital intensive, particularly as it relates to surgical instrumentation. We depreciate our property, plant and equipment and amortize our intangible assets based upon our estimate of the respective asset's useful life. Our estimate of the useful life of an asset requires us to make judgments about future events, such as product life cycles, new product development, product cannibalization and technological obsolescence, as well as other competitive factors beyond our control. We account for the impairment of long-lived assets in accordance SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Accordingly, we evaluate impairments of our property, plant and equipment based upon an analysis of estimated undiscounted future cash flows. If we determine that a change is required in the useful life of an asset, future depreciation/amortization is adjusted accordingly. Alternatively, should we determine that an asset has been impaired, an adjustment would be charged to income based on its fair market value, or discounted cash flows if the fair market value is not readily determinable, reducing income in that period. During 2004, based on our decision to transition to a new line of internally developed foot and ankle products in the first quarter of 2005, we reviewed for impairment our instrumentation related to foot and ankle products sold under a distribution agreement. The projected undiscounted cash flows for these instruments exceeded the carrying value of the instruments and accordingly, no impairment charge was necessary. However, based on our transition to a new product line in the first quarter of 2005, we revised the estimated useful life of these instruments and recorded accelerated depreciation during the fourth quarter of 2004 of approximately \$500,000. We expect to record additional accelerated depreciation of approximately \$500,000 in the first quarter of 2005.





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**Product liability claims.** Periodically, claims arise involving the use of our products. We make provisions for claims specifically identified for which we believe the likelihood of an unfavorable outcome is probable and an estimate of the amount of loss has been developed. We have recorded at least the minimum estimated liability related to those claims where a range of loss has been established. As additional information becomes available, we reassess the estimated liability related to our pending claims and make revisions as necessary. Future revisions in our estimates of the liability could materially impact our results of operation and financial position. We maintain insurance coverage that limits the severity of any single claim as well as total amounts incurred per policy year, and we believe our insurance coverage is adequate. We use the best information available to us in determining the level of accrued product liabilities and we believe our accruals are adequate. During 2004, we recorded \$500,000 in product liability reserves for probable losses following our announcement of a voluntary market withdrawal of a limited number of metal acetabular hip cups intended for use in our CONSERVE® hip systems. Management developed this estimate and believes that the amount recorded is appropriate based on assumptions with respect to estimated patient claims related to the market withdrawal and the acceptance of such claims by our insurer. The nature of a market withdrawal and the associated claims are such that the claims will occur over an extended period of time. Our estimate includes an assumption for unasserted claims based on management's industry experience with similar circumstances. While we believe that the amount recorded related to the market withdrawal is appropriate, it is possible that changes in assumptions related to potential claims or insurance coverage could have an adverse effect on our estimate.

For the years ended December 31, 2003 and 2002, operating expenses were not materially affected by our estimates of product liability claims. Our accrual for product liability claims was approximately \$1.0 million and \$750,000 at December 31, 2004 and 2003, respectively.

**Accounting for income taxes.** Our effective tax rate is based on income by tax jurisdiction, statutory rates and tax saving initiatives available to us in the various jurisdictions in which we operate. Significant judgment is required in determining our effective tax rate and evaluating our tax positions. This process includes assessing temporary differences resulting from differing recognition of items for income tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We establish valuation allowances when the amount of future taxable income is not likely to support the recovery of the deferred tax asset. To the extent that we establish a valuation allowance or increase the allowance in a period, we reflect the increase as expense within the tax provision in our statement of operations. In addition to establishing valuation allowances for deferred tax assets, we establish accruals for tax contingencies for certain tax jurisdictions, when, despite our belief that our tax return positions are fully supportable, we believe that certain positions may be challenged and that we may not prevail upon review. We adjust these accruals for tax contingencies in light of changing facts and circumstances, such as the progress of a tax audit. Our tax provision reflects the impact of establishing these accruals for tax contingencies and any subsequent adjustments.

We have recorded valuation allowances of \$5.9 million and \$16.0 million as of December 31, 2004 and 2003, respectively, due to uncertainties related to our ability to realize, before expiration, some of our deferred tax assets for both U.S. and foreign income tax purposes. These deferred tax assets primarily consist of the carry forward of certain net operating losses and general business tax credits. We established these valuation allowances based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to increase or decrease our valuation allowance, which could materially impact our financial position and results of operations.

We have recorded accruals for tax contingencies of \$13.0 million and \$7.8 million as of December 31, 2004 and 2003, respectively, for certain exposure items. We established these accruals for tax jurisdictions where we believe that certain positions may be challenged and the likelihood of a favorable outcome upon review is less than probable.

During 2004, we completed certain tax studies. These studies indicated that a revision to our original estimates of the limitations on the utilization of our net operating losses and tax credit carryforwards was required. Accordingly, the completion of the studies resulted in a reduction of approximately \$10.7 million in the valuation allowance for these deferred tax assets as the deferred tax assets were more likely than not to be realized in the future. Additionally, these studies indicated that approximately \$8.5 million of tax exposure existed as a result of the tax filing positions taken with respect to these net operating losses and tax credit carryforwards. Based on these findings, we reclassified

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approximately \$8.5 million of the valuation allowance to our accruals for tax contingencies. The remaining reduction in our valuation allowance was released through the income tax provision or was a result of currency fluctuations on the portion of our valuation allowances recorded in foreign currencies.

Additionally, in 2004, we favorably resolved certain tax contingencies associated with our December 1999 acquisition of Cremascoli. The favorable resolution of these matters resulted in a reduction of our previously recorded accrual for tax contingencies and goodwill of approximately \$3.0 million. Our accruals for tax contingencies are included within Other liabilities on our consolidated balance sheet. Additional discussion of our accounting for income taxes is included in Notes 6, 10 and 11 to our consolidated financial statements contained in Item 8 of this report.

## **Impact of Recently Issued Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123R, which requires the recognition of compensation expense for the fair value of share-based transactions. We further describe this pronouncement and its anticipated impact on our results of operations under the heading, Stock based expense within the Results of Operations section of MD&A.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 will no longer allow companies to capitalize inventory costs on their balance sheet when the production defect rate varies significantly from the expected rate. All abnormal freight, handling and material waste will be treated as period expenses. Additionally, SFAS No. 151 requires that a facility's fixed production overhead be charged to inventory based on a range of normal capacity. If the production level is abnormally low or high, unallocated overhead should be charged to current period expense. SFAS No. 151 is required to be adopted for annual periods beginning after June 15, 2005; accordingly, we will adopt SFAS No. 151 effective January 1, 2006. We are evaluating the impact of this standard on our results of operations and financial statements.

In December 2004, the FASB issued two FASB Staff Positions (FSP) in response to the Jobs Creation Act related to accounting and disclosures associated with the provisions of the Jobs Creation Act. We further describe the Jobs Creation Act and our evaluation of its impact within the Results of Operations section of MD&A. FSP 109-1 requires the deduction for qualified domestic production activities to be accounted for as a special deduction under SFAS No. 109, not as a tax-rate deduction. We will comply with the provisions of FSP 109-1 effective January 1, 2005, should this deduction become available to us. FSP 109-2 allows for additional time for companies to determine whether any foreign earnings will be repatriated under the Jobs Creation Act's one-time deduction for repatriated earnings. Companies that take the additional time are required to provide disclosures about the status of their evaluation. Based on management's assessment of the repatriation deduction, we have determined to continue our current policy of permanently reinvesting all foreign earnings. Therefore, the provisions of FSP 109-2 are not applicable to us.

## **Factors Affecting Future Operating Results**

In addition to the factors described above in MD&A and elsewhere in this report, our future financial results could vary from period to period due to a variety of causes, including the following factors:

***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:

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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.

***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)

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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 depend upon a limited number of sources of DBM and CBM, and any failure to obtain DBM and CBM from these sources in a timely manner will interfere with our ability to process and distribute allograft products. Two not-for-profit tissue banks supplied us with 100% of the DBM and CBM, a key component in the allograft products we currently produce, market and distribute, that we obtained in the U.S. in 2004. 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 our 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 these sources 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.

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***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.

***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

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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. In recent years, our industry has experienced significant increases in product liability insurance premiums. 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, our ability to enforce non-compete arrangements related to key personnel who have left the business could have a material adverse effect on our business.

***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 7 direct sales offices and 89 stocking distribution partners, which combined employ approximately 400 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, 2004 and 2003, approximately 39% 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.

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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.

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 health 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.

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

Our ADCON<sup>®</sup> Gel products and our CONSERVE<sup>®</sup> Plus Resurfacing Implant are available outside the U.S. and are pending FDA clearance for the U.S. market. There can be no assurance that the sale of our ADCON<sup>®</sup> Gel or CONSERVE<sup>®</sup> 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.

***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.

***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 relied to date principally 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 \$8.1 million in 2004 and \$11.9 million in 2003. During the second half of 2004, we began 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.



***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:

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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;

changes in accounting policies, estimates, and treatments; and

general economic factors.

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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.

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**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

*Interest Rate Risk*

Our exposure to interest rate risk arises principally from the variable rates associated with our credit facility. On December 31, 2004, we had borrowings of \$8.8 million under our credit facility which are subject to a variable interest rate, with a current annual rate of 3.625%. The carrying value of these borrowings approximates fair value due to the variable rate. Based on this debt level, a 10% increase in the interest rate of all such borrowings would cause us to incur an increase in interest expense of approximately \$32,000 on an annual basis. We currently do not hedge our exposure to interest rate fluctuations, but may do so in the future.

*Foreign Currency Rate Fluctuations*

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. Approximately 33% of our total net sales were denominated in foreign currencies during the year ended December 31, 2004. We expect that foreign currencies will continue to represent a similarly significant percentage of our net sales in the future. Costs related to these sales are largely denominated in the same respective currencies, thereby limiting our transaction risk exposures. However, for sales not denominated in U.S. dollars, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases, if we price our products in the foreign currency, we will receive less in U.S. dollars than we did before the rate increase went into effect. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our prices not being competitive in a market where business is transacted in the local currency.

A substantial majority of our sales denominated in foreign currencies are derived from European Union countries and are denominated in the euro. Additionally, we have significant intercompany receivables from our foreign subsidiaries which are denominated in foreign currencies, principally the euro and the Japanese yen. Our principal exchange rate risk, therefore, exists between the U.S. dollar and the euro and the U.S. dollar and the yen. Fluctuations from the beginning to the end of any given reporting period result in the revaluation of our foreign currency-denominated intercompany receivables and payables, generating currency translation gains or losses that impact our non-operating income/expense levels in the respective period. As discussed in Note 2 to our consolidated financial statements in Item 8 of this report, during the second half of 2004, we entered into certain short-term derivative financial instruments in the form of foreign currency forward contracts. These forward contracts are designed to mitigate our exposure to currency fluctuations in our intercompany balances denominated in euros, Japanese yen and Canadian dollars. Any change in the fair value of these forward contracts as a result of a fluctuation in a currency exchange rate is expected to be offset by a change in the value of the intercompany balance. These contracts are effectively closed at the end of each reporting period.

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**Item 8. Financial Statements and Supplementary Data.**

**Wright Medical Group, Inc.  
Consolidated Financial Statements  
for the Years Ended December 31, 2004, 2003 and 2002  
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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Wright Medical Group, Inc.:

We have audited the accompanying consolidated balance sheets of Wright Medical Group, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in stockholders' equity and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Wright Medical Group, Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the internal control over financial reporting of Wright Medical Group, Inc. and subsidiaries as of December 31, 2004, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 21, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

(signed) KPMG LLP

Memphis, Tennessee

February 21, 2005

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Wright Medical Group, Inc.:

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that Wright Medical Group, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Wright Medical Group, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, Wright Medical Group, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Wright Medical Group, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in stockholders' equity and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated



February 21, 2005 expressed an unqualified opinion on those consolidated financial statements.

(signed) KPMG LLP

Memphis, Tennessee

February 21, 2005

**Table of Contents****Wright Medical Group, Inc.****Consolidated Balance Sheets  
(In thousands, except share data)**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Assets:</b>		
Current assets:		
Cash and cash equivalents	\$ 83,470	\$ 66,571
Accounts receivable, net	61,662	55,821
Inventories	76,269	64,204
Prepaid expenses	4,822	5,046
Deferred income taxes	24,082	15,591
Other current assets	4,717	3,291
Total current assets	255,022	210,524
Property, plant and equipment, net	70,207	66,915
Goodwill	8,845	11,248
Intangible assets, net	17,140	18,646
Deferred income taxes	8,873	13,398
Other assets	1,071	1,372
Total assets	\$ 361,158	\$ 322,103
<b>Liabilities and Stockholders' Equity:</b>		
Current liabilities:		
Accounts payable	\$ 13,969	\$ 14,227
Accrued expenses and other current liabilities	45,256	42,814
Current portion of long-term obligations	6,331	6,228
Total current liabilities	65,556	63,269
Long-term obligations	5,952	11,096
Deferred income taxes	26	1,203
Other liabilities	13,555	8,217
Total liabilities	85,089	83,785
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, voting, \$.01 par value, shares authorized - 100,000,000; shares issued and outstanding 33,850,202 in 2004, 33,040,747 in 2003	339	330
Additional paid-in capital	269,944	263,455
Deferred compensation	(188)	(1,452)
Accumulated other comprehensive income	21,642	15,675
Accumulated deficit	(15,668)	(39,690)

Total stockholders' equity	276,069	238,318
	\$ 361,158	\$ 322,103

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****Wright Medical Group, Inc.****Consolidated Statements of Operations**  
**(In thousands, except per share data)**

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net sales	\$ 297,539	\$ 248,932	\$ 200,873
Cost of sales	84,183	67,815	55,616
Gross profit	213,356	181,117	145,257
Operating expenses:			
Selling, general and administrative	151,144	127,612	106,875
Research and development	18,421	16,151	10,357
Amortization of intangible assets	3,889	3,562	3,946
Stock-based expense <sup>1</sup>	1,489	2,068	1,724
Acquired in-process research and development costs		4,558	
Arbitration settlement award			(4,200)
Total operating expenses	174,943	153,951	118,702
Operating income	38,413	27,166	26,555
Interest expense, net	1,064	1,107	938
Other income, net	(74)	(1,060)	(1,277)
Income before income taxes	37,423	27,119	26,894
Provision for income taxes	13,401	9,722	1,834
Net income	\$ 24,022	\$ 17,397	\$ 25,060
<b>Net income per share (Note 8):</b>			
Basic	\$ 0.72	\$ 0.53	\$ 0.79
Diluted	\$ 0.68	\$ 0.50	\$ 0.75
Weighted-average number of common shares outstanding basic	33,391	32,857	31,870
Weighted-average number of common shares outstanding diluted	35,317	34,561	33,550

<sup>1</sup> Amounts presented as stock-based expense consist of; cost of sales totaling \$68, \$107, and \$108 for the years ended December 31, 2004, 2003, and 2002 respectively; selling, general and administrative expenses of \$1,364, \$1,875, and \$1,506 for the years ended December 31, 2004, 2003, and 2002, respectively; and research and development expenses of \$57, \$86, and \$110 for the years ended December 31, 2004, 2003, and 2002, respectively.

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****Wright Medical Group, Inc.****Consolidated Statements of Cash Flows**  
**(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Operating activities:</b>			
Net income	\$ 24,022	\$ 17,397	\$ 25,060
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	17,278	13,948	13,553
Amortization of deferred financing costs	261	261	261
Amortization of intangible assets	3,889	3,562	3,946
Deferred income taxes	5,068	4,565	946
Stock-based expenses	1,489	2,068	1,724
In-process research and development costs		4,558	
Other	623	275	900
Changes in assets and liabilities, net of acquisitions:			
Accounts receivable	(3,811)	(11,359)	(4,653)
Inventories	(7,861)	(3,466)	(12,242)
Other current assets	(3,223)	(676)	(2,596)
Accounts payable	(849)	3,153	509
Accrued expenses and other liabilities	479	5,779	(5,458)
 Net cash provided by operating activities	 37,365	 40,065	 21,950
<b>Investing activities:</b>			
Capital expenditures	(18,316)	(18,116)	(17,974)
Purchase of tangible and intangible assets (Note 3)	(161)	(7,799)	(4,469)
Other	49	71	13
 Net cash used in investing activities	 (18,428)	 (25,844)	 (22,430)
<b>Financing activities:</b>			
Issuance of common stock	4,056	1,678	52,347
Financing under factoring agreements, net	(29)	4,680	
Payments of bank and other financing	(6,332)	(5,844)	(3,963)
 Net cash (used in) provided by financing activities	 (2,305)	 514	 48,384
 Effect of exchange rates on cash and cash equivalents	 267	 463	 699
 Net increase in cash and cash equivalents	 16,899	 15,198	 48,603

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Cash and cash equivalents, beginning of period	66,571	51,373	2,770
Cash and cash equivalents, end of period	\$ 83,470	\$ 66,571	\$ 51,373

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Wright Medical Group, Inc.**

**Consolidated Statement of Changes in Stockholders' Equity and Comprehensive Income**  
**For the Year Ended December 31, 2002**  
(In thousands, except share data)

	<b>Common Stock, Voting</b>		<b>Common Stock, Non-voting</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Deferred Compensation</b>	<b>Accumulated Other Comprehensive Income (Loss)</b>	<b>Total Stockholders' Equity</b>
	<b>Number of Shares</b>	<b>Amount</b>	<b>Number of Shares</b>	<b>Amount</b>					
Balance at December 31, 2001	23,257,532	\$ 233	5,288,595	\$ 53	\$ 207,197	\$ (82,147)	\$ (4,798)	\$ (3,238)	\$ 117,300
2002 Activity:									
Net income						25,060			25,060
Foreign currency translation								7,521	7,521
Total comprehensive income									32,581
Issuance of common stock, net of costs	4,166,247	41			52,306				52,347
Tax benefit of employee stock option exercises					1,047				1,047
Conversion of non-voting common stock to voting common stock	5,288,595	53	(5,288,595)	(53)					
Deferred stock-based compensation					90		(90)		
Stock-based compensation							1,724		1,724
Balance at December 31, 2002	32,712,374	\$ 327			\$ 260,640	\$ (57,087)	\$ (3,164)	\$ 4,283	\$ 204,999

The accompanying notes are an integral part of these consolidated financial statements.





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**Wright Medical Group, Inc.**  
**Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income**  
**For the Years Ended December 31, 2003 and 2004**  
(In thousands, except share data)

	<b>Common Stock, Voting</b>		<b>Additional</b>		<b>Accumulated</b>		<b>Accumulated Other Comprehensive</b>		<b>Total</b>
	<b>Number of Shares</b>	<b>Amount</b>	<b>Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Deferred Compensation</b>		<b>Income</b>		<b>Stockholders' Equity</b>
Balance at December 31, 2002	32,712,374	\$ 327	\$ 260,640	\$ (57,087)	\$ (3,164)	\$	4,283	\$	204,999
2003 Activity:									
Net income				17,397					17,397
Foreign currency translation							11,392		11,392
Total comprehensive income									28,789
Issuance of common stock, net of costs	328,373	3	1,675						1,678
Tax benefit of employee stock option exercises			784						784
Deferred stock-based compensation			593		(593)				
Stock-based compensation					2,068				2,068
Forfeiture of stock options			(237)		237				
Balance at December 31, 2003	33,040,747	\$ 330	\$ 263,455	\$ (39,690)	\$ (1,452)	\$	15,675	\$	238,318
2004 Activity:									
Net income				24,022					24,022
Foreign currency translation							5,967		5,967
Total comprehensive income									29,989
Issuance of common stock, net of costs	809,455	9	4,047						4,056
Tax benefit of employee stock option exercises			2,217						2,217

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**WRIGHT MEDICAL GROUP, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Description of Business:**

Wright Medical Group, Inc. (the Company), through Wright Medical Technology, Inc. and other operating subsidiaries, is a global medical device company specializing in the design, manufacture and marketing of reconstructive joint devices and biologics products. The Company's products are sold through a network of independent sales representatives in the U.S. and by a combination of employee sales representatives, independent sales representatives, and stocking distributors outside the U.S. The Company promotes its products in over 60 countries with principal markets of the U.S., Europe, and Japan. The Company is headquartered in suburban Memphis, Tennessee.

The Company was 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. (Warburg) acquired majority ownership of Wright Medical Technology, Inc. (the Predecessor Company) on December 7, 1999. This transaction, which represents a recapitalization of the Predecessor Company and the inception of the Company in its present form, was accounted for using the purchase method of accounting.

On December 22, 1999 the Company acquired all of the outstanding common stock of Cremascoli Ortho Holding, S.A. (Cremascoli), an orthopaedic medical device company headquartered in Toulon, France. The acquisition was accounted for using the purchase method of accounting and, accordingly, the results of operations of Cremascoli have been included in the Company's consolidated financial statements from the date of acquisition.

On July 18, 2001, the Company completed its initial public offering (the IPO), issuing 7,500,000 shares of common stock which generated net proceeds of \$84.8 million. On March 6, 2002, the Company and certain selling stockholders completed a secondary offering which generated net proceeds of \$49.5 million.

**2. Summary of Significant Accounting Policies:**

*Principles of Consolidation.* The accompanying consolidated financial statements include the accounts of the Company and its wholly owned domestic and international subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States (U.S.) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. The most significant areas requiring the use of management estimates relate to revenue recognition, the determination of allowances for doubtful accounts, excess and obsolete inventories, accounting for goodwill and long-lived assets, product liability claims and accounting for income taxes.

*Cash and Cash Equivalents.* Cash and cash equivalents include all cash balances and short-term investments with original maturities of three months or less.

*Inventories.* The Company's inventories are valued at the lower of cost or market on a first-in, first-out (FIFO) basis. Inventory costs include material, labor costs and manufacturing overhead. The Company regularly reviews inventory quantities on hand for excess and obsolete inventory and, when circumstances indicate, the Company incurs charges

to write down inventories to their net realizable value. The Company's review of inventory for excess and obsolete quantities is based primarily on its estimated forecast of product demand and production requirements for the next twenty-four months. Charges incurred for excess and obsolete inventory were \$5.8 million, \$2.6 million and \$2.8 million for the years ended December 31, 2004, 2003 and 2002, respectively. In 2004, charges incurred for excess and obsolete inventory included \$2.4 million recorded to write down certain foot and ankle implant inventory to its net realizable value, as a result of the Company's transition to the CHARLOTTE Foot and Ankle System.

**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Product Liability Claims.* The Company makes provisions for claims specifically identified for which it believes the likelihood of an unfavorable outcome is probable and an estimate of the amount of loss has been developed. The Company has recorded at least the minimum estimated liability related to those claims where a range of loss has been established. The Company's accrual for product liability claims was approximately \$1.0 million and \$750,000 at December 31, 2004 and 2003, respectively.

*Property, Plant and Equipment.* The Company's property, plant and equipment is stated at cost. Depreciation, which includes amortization of assets under capital lease, is provided on a straight-line basis over the estimated useful lives based on the following categories:

Land improvements	15 to 25 years
Buildings	10 to 45 years
Machinery and equipment	3 to 20 years
Furniture, fixtures and office equipment	1 to 14 years
Instruments	5 to 6 years

Expenditures for major renewals and betterments that extend the useful life of the assets are capitalized. Maintenance and repair costs are charged to expense as incurred. Upon sale or retirement, the asset cost and related accumulated depreciation are eliminated from the respective accounts and any resulting gain or loss is included in income.

*Intangible Assets and Goodwill.* Goodwill is recognized for the excess of the purchase price over the fair value of assets of businesses acquired. Goodwill is required to be tested for impairment at least annually. Unless circumstances otherwise dictate, we perform our annual impairment test in the fourth quarter. Accordingly, during the fourth quarter of 2004, the Company evaluated goodwill for impairment and determined that the fair values of its reporting units exceeded their carrying values, indicating that goodwill was not impaired. The Company has two reporting units for purposes of evaluating goodwill for impairment, Wright Medical Technology, Inc. ( WMT ) and Wright Medical Europe ( WME ). WMT consists of the Company's U.S., Canadian, and Japanese subsidiaries, and is primarily consistent with the Predecessor Company prior its recapitalization. WME consists of the Company's European subsidiaries and is primarily consistent with the former Cremascoli operations prior to its acquisition by the Company.

The Company's intangible assets with estimable useful lives are amortized over their respective estimated useful lives to their estimated residual values, and are reviewed for impairment in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. The Company amortizes intangible assets on a straight line basis over their estimated useful lives. The weighted average amortization periods for completed technology, distribution channels, trademarks and licenses are 8 years, 10 years, 9 years, and 5 years, respectively. The weighted average amortization period of the Company's intangible assets on a combined basis is 9 years.

*Valuation of Long-Lived Assets.* Management periodically evaluates carrying values of long-lived assets, including property, plant and equipment and intangible assets, when events and circumstances indicate that these assets may have been impaired. The Company accounts for the impairment of long-lived assets in accordance SFAS No. 144,

*Accounting for the Impairment or Disposal of Long-Lived Assets.* Accordingly, the Company evaluates impairment of its property, plant and equipment based upon an analysis of estimated undiscounted future cash flows. If it is determined that a change is required in the useful life of an asset, future depreciation/amortization is adjusted

accordingly. Alternatively, should the Company determine that an asset is impaired, an adjustment would be charged to income based on its fair market value, or discounted cash flows if the fair market value is not readily determinable, reducing income in that period.

*Allowances for Doubtful Accounts.* The Company experiences some credit loss on its accounts receivable and accordingly it must make estimates related to the ultimate collection of its accounts receivable. Specifically,

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**WRIGHT MEDICAL GROUP, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

management analyzes the Company's accounts receivable, historical bad debt experience, customer concentrations, customer credit-worthiness, and current economic trends, when evaluating the adequacy of its allowance for doubtful accounts.

The majority of the Company's receivables are from hospitals, many of which are government funded. Accordingly, the Company's collection history with this class of customer has been favorable. Historically, the Company has experienced minimal bad debts from its hospital customers and more significant bad debts from certain international distributors, typically as a result of specific financial difficulty or geo-political factors. In 2003 and 2004, the increases in the Company's accounts receivable balance have related almost exclusively to its hospital customers. As the historical bad debt experience with this class of customer is minimal, the allowance has not increased proportionately to the increase in the accounts receivable balance. The Company writes off receivables when it determines that the receivables are uncollectible, typically upon customer bankruptcy or the customer's non-response to collection efforts. The Company's allowance for doubtful accounts totaled \$1.8 million and \$1.5 million at December 31, 2004 and 2003, respectively.

*Concentrations of Supply of Raw Material.* The Company relies on a limited number of suppliers for the components used in the Company's products. The Company's 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. The Company relies on one supplier for the silicone elastomer used in the Company's extremity products. The Company is aware of only two suppliers of silicone elastomer to the medical device industry for permanent implant usage. Further, the Company relies on one supplier of ceramics for use in the Company's hip products. In addition, for the Company's biologics products, it depends on a limited number of sources of demineralized bone matrix ( DBM ) and cancellous bone matrix ( CBM ). Two not-for-profit tissue banks supplied the Company with all of the DBM and CBM that it used in 2004 in its allograft products. Further, the Company relies on one supplier for its GRAFTJACKET® family of soft tissue repair and graft containment products, as well as one supplier for its ADCON® Gel products.

*Income Taxes.* Income taxes are accounted for pursuant to the provisions of SFAS No. 109, "Accounting for Income Taxes" ( SFAS No. 109 ). The Company's effective tax rate is based on income by tax jurisdiction, statutory rates and tax saving initiatives available to it in the various jurisdictions in which it operates. Significant judgment is required in determining the Company's effective tax rate and evaluating its tax positions. This process includes assessing temporary differences resulting from differing recognition of items for income tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within the Company's consolidated balance sheet.

*Revenue Recognition.* The Company's revenues are generated through two types of customers, hospitals and stocking distributors, with the majority of the Company's revenue derived from sales to hospitals. The Company's products are sold through a network of independent sales representatives in the U.S. and by a combination of employee sales representatives, independent sales representatives, and stocking distributors outside the U.S. Revenues from sales to hospitals are recorded when the hospital takes title to the product, which is when the product is surgically implanted in a patient and a purchase order is received from the hospital. The Company views the receipt of a purchase order as the evidence of customer acceptance of the product.

The Company records revenues from sales to its stocking distributors outside the U.S. at the time the product is shipped to the distributor. Stocking distributors, who sell the products to their customers, take title to the products and

assume all risks of ownership. The Company's distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. In general, the distributors do not have any rights of return or exchange; however, in limited situations the Company has repurchase agreements with certain stocking distributors. Those certain agreements require the Company to repurchase a specified percentage of the inventory purchased by the distributor within a specified period of time prior to the expiration of the contract. During those specified periods, the Company defers the applicable percentage of the sales. Approximately \$87,000 and \$247,000 of deferred revenue related to these types of agreements was recorded at December 31, 2004 and 2003, respectively.



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**WRIGHT MEDICAL GROUP, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company must make estimates of potential future product returns related to current period product revenue. The Company develops these estimates by analyzing historical experience related to product returns. Judgment must be used and estimates made in connection with establishing the allowance for sales returns in any accounting period. An allowance for sales returns of \$395,000 and \$412,000 is included as a reduction of accounts receivable at December 31, 2004 and 2003, respectively.

*Shipping and Handling Costs.* The Company incurs shipping and handling costs associated with the shipment of goods to customers, independent distributors and its subsidiaries. All shipping and handling amounts billed to customers are included in net sales. All shipping and handling costs associated with the shipment of goods to customers are included in cost of sales. All other shipping and handling costs are included in selling, general and administrative expenses.

*Research and Development Costs.* Research and development costs are charged to expense as incurred.

*Foreign Currency Translation.* The financial statements of the Company's international subsidiaries are translated into U.S. dollars using the exchange rate at the balance sheet date for assets and liabilities and the weighted average exchange rate for the applicable period for revenues, expenses, gains and losses. Translation adjustments are recorded as a separate component of comprehensive income. Gains and losses resulting from transactions denominated in a currency other than the local functional currency are included in other income.

*Comprehensive Income.* Comprehensive income is defined as the change in equity during a period related to transactions and other events and circumstances from non-owner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. The difference between the Company's net income and its comprehensive income is wholly attributable to foreign currency translation.

*Stock-Based Compensation.* At December 31, 2004, the Company has two stock-based employee compensation plans, which are described in Note 13. The Company accounts for those plans under the intrinsic value method in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. Accordingly, compensation cost related to stock option grants to employees has been recognized only to the extent that the fair market value of the stock exceeds the exercise price of the stock option at the date of the grant. Nonemployee stock-based compensation is accounted for in accordance with SFAS No. 123.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation (in thousands, except per share amounts):

Table of Contents**WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net income, as reported	\$ 24,022	\$ 17,397	\$ 25,060
Add: Stock-based employee compensation cost recognized under intrinsic value method, net of tax effects	681	920	998
Less: Stock-based employee compensation expense determined under fair value based method, net of tax effects	(8,626)	(4,334)	(2,918)
Pro forma net income	\$ 16,077	\$ 13,983	\$ 23,140
Net income per share:			
Basic, as reported	\$ 0.72	\$ 0.53	\$ 0.79
Basic, pro forma	\$ 0.48	\$ 0.43	\$ 0.73
Diluted, as reported	\$ 0.68	\$ 0.50	\$ 0.75
Diluted, pro forma	\$ 0.47	\$ 0.41	\$ 0.69

In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123 (Revised 2004), *Share Based Payment*, ( SFAS No. 123R ), effective for interim or annual reporting periods beginning after June 15, 2005. SFAS No. 123R 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 binomial lattice model. The Company has begun the process to evaluate and select an appropriate model for the valuation of its stock options. Until this evaluation is complete, the exact amount of the impact of SFAS No. 123R cannot be determined. The effect of expensing the fair value of the Company's stock options using the Black-Scholes model is presented in the table above.

*Fair Value of Financial Instruments.* The carrying value of cash and cash equivalents, accounts receivable, accounts payable and notes payable approximates the fair value of these financial instruments at December 31, 2004 and 2003 due to their short maturities or variable rates.

*Derivative Instruments and Hedging Activities .* The Company accounts for derivative instruments and hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended by SFAS No. 138. Accordingly, all of the Company's derivative instruments are recorded on the balance sheet as either an asset or liability and measured at fair value. The changes in the derivative's fair value are recognized currently in earnings unless specific hedge accounting criteria are met.

During the second half of 2004, the Company began a derivative program using 30-day foreign currency forward contracts to mitigate the risk of currency fluctuations on its 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. Accordingly, the changes in the fair value and the settlement of the contracts are recognized in the period

incurred in the accompanying consolidated statement of operations.

For the year ended December 31, 2004, the Company recorded approximately \$790,000 in losses on foreign currency contracts, which are included in Other income, net in the Company's consolidated statement of operations. These losses offset translation gains recorded on the Company's intercompany receivable and payable balances. At December 31, 2004 and 2003, the Company did not have any outstanding foreign currency contracts.

**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Supplemental Cash Flow Information.* Cash paid for interest expense and income taxes was as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Interest	\$ 717	\$ 994	\$ 883
Income taxes	\$ 8,289	\$ 4,411	\$ 359

During 2004, the Company favorably resolved certain income tax contingencies associated with the Company's acquisition of Cremascoli, resulting in a decrease in goodwill of approximately \$3.0 million. See Note 6 for further discussion of this matter. Additionally, the Company entered into capital leases of approximately \$1.1 million and \$628,000 during 2004 and 2003, respectively.

*Reclassifications.* Certain prior year amounts have been reclassified to conform to the 2004 presentation.

*Recent Pronouncements.* In November 2004, the FASB issued SFAS No. 151, *Inventory Costs: An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 will no longer allow companies to capitalize inventory costs on their balance sheet when the production defect rate varies significantly from the expected rate. All abnormal freight, handling and material waste will be treated as period expenses. Additionally, SFAS No. 151 requires that a facility's fixed production overhead be charged to inventory based on a range of normal capacity. If the production level is abnormally low or high, unallocated overhead should be charged to current period expense. SFAS No. 151 is required to be adopted for annual periods beginning after June 15, 2005. Accordingly, the Company will adopt the provisions of SFAS No. 151 effective January 1, 2006. Management is evaluating the impact of this standard on its results of operations and financial statements.

In December 2004, the FASB issued two FASB Staff Positions (FSP) in response to the American Jobs Creation Act of 2004 (the Jobs Creation Act) related to accounting and disclosures associated with certain provisions of the Jobs Creation Act. (The Jobs Creation Act and management's evaluation of its impact is further described within the Results of Operations section of Item 7 of this report.) FSP 109-1 requires the deduction for qualified domestic production activities to be accounted for as a special deduction under SFAS No. 109, not as a tax-rate deduction. The Company will comply with the provisions of FSP 109-1 effective January 1, 2005, should this deduction become available to the Company. FSP 109-2 allows for additional time for companies to determine whether any foreign earnings will be repatriated under the Jobs Creation Act's one-time deduction for repatriated earnings. Companies that take the additional time are required to provide disclosures about the status of their evaluation. Based on management's assessment of the repatriation deduction, the Company has determined to continue its current policy of permanently reinvesting all foreign earnings and therefore, the provisions of FSP 109-2 are not applicable to the Company.

**3. Acquisition of Assets:**

On March 5, 2003, the Company completed an acquisition of certain assets from Gliatech Inc. related to its ADCON® Gel technology for \$8.4 million in cash. Additionally, the Company entered into a royalty agreement that requires the Company to pay a royalty on future product sales. The Company paid \$840,000 of the purchase price as a deposit in the fourth quarter of 2002, and \$3.4 million in the first quarter of 2003. The remaining \$4.2 million was paid in the second quarter of 2003 upon final receipt of all assets. The following table summarizes the allocation of the purchase price (in thousands):



**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Inventories	\$ 1,312
Property, plant and equipment	160
Acquired in-process research and development	4,558
Intangible assets:	
Completed Technology	1,575
Trademarks	554
Other	286
	\$ 8,445

In connection with the acquisition of these assets, the Company engaged an independent third party to conduct a valuation of the intangible assets acquired. The value assigned to acquired in-process research and development ( IPRD ) was \$4.6 million of the purchase price. Accordingly, this amount was expensed in the first quarter of 2003. The value assigned to IPRD was determined by estimating the costs to develop the IPRD into commercially viable products, estimating the resulting cash flows from such projects, and discounting the net cash flows using a 32% risk adjusted discount rate. This discount rate reflected uncertainties surrounding the successful development of the IPRD.

**4. Inventories:**

Inventories consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Raw materials	\$ 3,373	\$ 2,816
Work-in-process	14,306	9,827
Finished goods	58,590	51,561
	\$ 76,269	\$ 64,204

**5. Property, Plant and Equipment:**

Property, plant and equipment consists of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Land and land improvements	\$ 1,944	\$ 1,567
Buildings	8,773	7,249
Machinery and equipment	31,849	26,922
Furniture, fixtures and office equipment	25,444	20,887
Construction in progress	2,284	5,654

Surgical instruments	56,963	45,664
	127,257	107,943
Less: Accumulated depreciation	(57,050)	(41,028)
	\$ 70,207	\$ 66,915

Table of Contents**WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of property, plant and equipment recorded under capital leases consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Land and land improvements	\$ 269	\$ 249
Buildings	3,247	3,116
Machinery and equipment	8,103	6,826
Furniture, fixtures and office equipment	2,135	1,873
	13,754	12,064
Less: Accumulated depreciation	(5,940)	(4,117)
	\$ 7,814	\$ 7,947

Depreciation expense approximated \$17.3 million, \$13.9 million, and \$13.6 million for the years ended December 31, 2004, 2003, and 2002, respectively, and included amortization of assets under capital leases.

**6. Goodwill and Intangible Assets:**

Changes in the carrying amount of goodwill occurring during the year ended December 31, 2004 are as follows (in thousands):

Goodwill, at December 31, 2003	\$ 11,248
Less: Resolution of pre-acquisition foreign income tax contingencies	(2,978)
Foreign currency translation	575
Goodwill, at December 31, 2004	\$ 8,845

During 2004, the Company favorably resolved certain foreign income tax contingencies associated with its December 1999 acquisition of Cremascoli. These amounts were established as an accrued liability in the purchase accounting associated with the acquisition of Cremascoli. Due to the favorable resolution of these matters, the Company reduced the previously recorded goodwill and associated accrued liabilities, which were recorded in Other liabilities in the Company's consolidated balance sheet.

The components of the Company's identifiable intangible assets are as follows (in thousands):

<b>December 31, 2004</b>		<b>December 31, 2003</b>	
<b>Cost</b>	<b>Accumulated Amortization</b>	<b>Cost</b>	<b>Accumulated Amortization</b>



Distribution channels	\$ 20,797	\$ 10,399	\$ 19,296	\$ 7,708
Completed technology	5,348	1,733	5,288	1,025
Licenses	2,683	1,538	2,593	983
Trademarks	657	152	657	75
Other	3,303	1,826	1,752	1,149
	32,788	\$ 15,648	29,586	\$ 10,940
Less: Accumulated amortization	(15,648)		(10,940)	
Intangible assets, net	\$ 17,140		\$ 18,646	

Based on the intangible assets held at December 31, 2004, we expect to amortize approximately \$4.0 million in 2005, \$3.5 million in 2006, \$2.9 million in 2007, \$2.7 million in 2008 and \$2.5 million in 2009.

Table of Contents**WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Accrued Expenses and Other Current Liabilities:**

Accrued expenses and other current liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Employee benefits	\$ 11,813	\$ 11,480
Advances from factoring arrangement	5,242	4,780
Royalties	4,664	5,658
Taxes other than income	4,120	3,281
Commissions	3,818	3,423
Professional fees	3,129	2,333
Purchased technology	1,500	1,500
Legal	1,153	1,343
Other	9,817	9,016
	<b>\$ 45,256</b>	<b>\$ 42,814</b>

**8. Earnings Per Share:**

SFAS No. 128, *Earnings Per Share*, requires the presentation of basic and diluted earnings per share. Basic earnings per share is calculated based on the weighted-average shares of common stock outstanding during the period. Diluted earnings per share is calculated to include any dilutive effect of the Company's common stock equivalents, which consist of stock options and warrants. The dilutive effect of such instruments is calculated using the treasury-stock method.

The weighted-average number of common shares outstanding for basic and diluted earnings per share purposes is as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Weighted-average number of common shares outstanding    basic	33,391	32,857	31,870
Common stock equivalents	1,926	1,704	1,680
Weighted-average number of common shares outstanding    diluted	35,317	34,561	33,550

For the years ended December 31, 2004, 2003 and 2002, options to purchase approximately 1.7 million, 671,000 and 447,000, respectively, shares of the Company's common stock were excluded from the calculation of diluted earnings per share because the effect was antidilutive. These stock options were antidilutive because the exercise price of the options was greater than the average market price of common stock for the respective period.

**9. Long-Term Obligations:**

Long-term obligations consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Notes payable	\$ 8,750	\$ 13,250
Capital lease obligations	3,533	4,074
	12,283	17,324
Less: current portion	(6,331)	(6,228)
	\$ 5,952	\$ 11,096

**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In August 2001, the Company entered into a five-year senior credit facility with a syndicate of commercial banks. This senior credit facility consists of \$20 million in term loans and a revolving loan facility of up to \$60 million. The Company had borrowings outstanding under the term loans of \$8.8 million and \$13.3 million at December 31, 2004 and 2003, respectively.

Borrowings under the senior credit facility are guaranteed by all of the Company's subsidiaries and collateralized by all of the assets of Wright Medical Technology, Inc., the Company's wholly-owned subsidiary. The credit facility contains customary covenants including, among other things, restrictions on the ability to pay cash dividends, prepay debt, incur additional debt and sell assets. The credit facility also requires the Company to maintain certain financial covenants, including a specified consolidated leverage (or debt-to-equity) ratio and a specified consolidated fixed charge coverage ratio. In the event that the Company violates any covenants, it could be required to repay the remaining balance of the debt. Additionally, should the Company be required to repay the loan before its scheduled maturity, a charge to operating income for unamortized financing costs would be incurred. At the Company's option, borrowings under the credit facility bear interest either at a rate equal to a fixed base rate plus a spread of .75% to 1.25% or at a rate equal to an adjusted LIBOR plus a spread of 1.75% to 2.25%, depending on the consolidated leverage ratio, with a current annual rate of 3.625%.

At December 31, 2004, the Company had availability under committed credit facilities, after considering outstanding letters of credit, totaling \$59.7 million.

Aggregate annual maturities of the Company's long-term obligations at December 31, 2004, excluding capital lease obligations, are as follows (in thousands):

2005	\$ 5,000
2006	3,750
	\$ 8,750

As discussed in Note 5, the Company has acquired certain property and equipment pursuant to capital leases. These leases have various maturity dates ranging from one to six years with interest rates ranging from 2.81% to 10.14%. At December 31, 2004, future minimum lease payments under capital lease obligations, together with the present value of the net minimum lease payments, are as follows (in thousands):

2005	\$ 1,642
2006	1,403
2007	790
2008	496
2009	368
Thereafter	333
Total minimum payments	5,032
Less amount representing interest	(1,499)

Present value of minimum lease payments	3,533
Current portion	(1,331)
Long-term portion	\$ 2,202

**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Income Taxes:**

The components of the Company's income before income taxes are as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Domestic	\$ 40,437	\$ 25,675	\$ 30,678
Foreign	(3,014)	1,444	(3,784)
Income before income taxes	\$ 37,423	\$ 27,119	\$ 26,894

The components of the Company's provision for income taxes are as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Current provision:			
Domestic:			
Federal	\$ 12,815	\$ 3,080	\$
State	811	203	
Foreign	4,401	1,404	819
Deferred provision (benefit):			
Domestic:			
Federal	(197)	4,313	1,331
State	803	1,098	1,841
Foreign	(5,232)	(376)	(2,157)
Total provision for income taxes	\$ 13,401	\$ 9,722	\$ 1,834

A reconciliation of the statutory federal income tax rate to the Company's effective income tax rate is as follows:

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Income tax provision at statutory rate	35.0%	35.0%	35.0%
State tax provision	4.8%	4.4%	4.6%
Change in valuation allowance	(3.1%)	4.5%	(30.2%)
Meals and entertainment limitation	1.0%	1.2%	1.0%
Research and development credit	(2.6%)	(9.9%)	(1.4%)
Other, net	0.7%	0.7%	(2.2%)
Total	35.8%	35.9%	6.8%

The significant components of the Company's deferred tax assets and liabilities as of December 31, 2004 and 2003 are as follows (in thousands):

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**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Deferred tax assets:		
Operating loss carryforwards	\$ 12,832	\$ 18,367
General business credit carryforward	2,309	4,393
Alternative minimum tax credits	621	3,080
Reserves and allowances	19,399	14,219
Amortization	5,660	4,235
Other	11,718	10,180
Valuation allowance	(5,897)	(16,039)
Total deferred tax assets	46,642	38,435
Deferred tax liabilities:		
Depreciation	4,523	4,446
Acquired intangible assets	3,767	4,369
Other	5,570	2,015
Total deferred tax liabilities	13,860	10,830
Net deferred tax assets	\$ 32,782	\$ 27,605

Provisions for federal income taxes are not made on the undistributed earnings of foreign subsidiaries where the subsidiaries do not have the capability to remit earnings in the foreseeable future and when earnings are considered permanently invested. Deferred taxes are not provided for temporary differences related to earnings of non-U.S. subsidiaries that are intended to be permanently reinvested. At December 31, 2004, the Company did not have undistributed earnings of foreign subsidiaries, as total earnings from these subsidiaries have been offset by losses.

At December 31, 2004, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately \$16.7 million, which expire in 2017 and 2018. Additionally, the Company had general business credit carryforwards of approximately \$2.3 million, which expire beginning in 2007 and extending through 2016, and alternative minimum tax credits of approximately \$600,000, which do not expire. At December 31, 2004, the Company had foreign net operating loss carryforwards of approximately \$20.2 million, of which \$2.6 million expire beginning in 2004 and extending through 2010.

Certain of the Company's U.S. and foreign net operating losses and general business credit carryforwards are subject to various limitations. The Company maintains valuation allowances for these net operating losses and tax credit carryforwards that will expire unused due to these limitations.

During 2004, the Company completed certain tax studies. These studies indicated that a revision to the Company's original estimates of the limitations on the utilization of its net operating losses and tax credit carryforwards was required. Accordingly, the completion of the studies resulted in a reduction of approximately \$10.7 million in the valuation allowance for these deferred tax assets as the deferred tax assets were more likely than not to be realized in



the future. Additionally, these studies indicated that approximately \$8.5 million of tax exposure exists as a result of the tax filing positions taken with respect to these net operating losses and tax credit carryforwards. Based on these findings, the Company reclassified approximately \$8.5 million of the valuation allowance to its accruals for tax contingencies. The remaining reduction in the Company's valuation allowance was released through the income tax provision or was a result of currency fluctuations on the portion of its valuation allowances recorded in foreign currencies.

# 11. Other Long-Term Liabilities:

Other long-term liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Accruals for tax contingencies	\$ 12,951	\$ 7,788
Other	604	429
	<b>\$ 13,555</b>	<b>\$ 8,217</b>

The Company establishes accruals for tax contingencies, when, despite its belief that tax return positions are fully supportable, certain of these positions may be challenged and the Company may not prevail upon review. During 2004, as discussed in Note 10, approximately \$8.5 million of the Company's valuation allowance for deferred tax assets was reclassified to accruals for tax contingencies. Additionally, as discussed in Note 6, the Company favorably resolved certain foreign tax contingencies associated with its December 1999 acquisition of Cremascoli.

Table of Contents**WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The favorable resolution of these matters resulted in a reduction of the Company's previously recorded accrual for tax contingencies and goodwill of approximately \$3.0 million.

**12. Capital Stock:**

*Common Stock.* The Company is authorized to issue up to 100,000,000 shares of voting common stock. The Company has 66,149,798 shares of voting common stock available for future issuance at December 31, 2004.

*Warrants.* In connection with the December 1999 recapitalization, the Company issued warrants to stockholders and certain employees to purchase an aggregate of 727,276 shares of the Company's common stock at an exercise price of \$4.35 per share. No warrants remain outstanding at December 31, 2004. The warrants were exercisable at any time after issuance and, unless exercised, expired five years from the date of issuance. During the years ended December 31, 2004, 2003 and 2002, warrants for 353,209, 6,691 and 349,194 shares were exercised, respectively.

**13. Stock Option Plans:**

At December 31, 2004, the Company has two stock-based incentive plans, which are described below. As permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, the Company applies APB Opinion No. 25 and related interpretations in accounting for its employee stock option plan. Accordingly, compensation cost related to stock option grants to employees has been recognized only to the extent that the fair market value of the stock exceeds the exercise price of the stock option at the date of the grant.

Equity Incentive Plan

On December 7, 1999, the Company adopted the 1999 Equity Incentive Plan (the Plan), which was subsequently amended and restated on July 6, 2001, May 13, 2003 and May 13, 2004. The Plan authorizes the Company to grant options to purchase up to 8,267,051 shares of common stock. Under the Plan, options to purchase common stock generally are exercisable in increments of 25% annually in each of the first through fourth anniversaries of the date of grant. Options to purchase Series A Preferred Stock that were outstanding at the time the Company completed its IPO in July 2001 became options to purchase the Company's common stock. Those options were immediately exercisable upon their issuance. All the options issued under the plan expire after ten years.

The weighted-average fair value of the Company's options granted in 2004, 2003 and 2002 was \$17.39 per share, \$12.96 per share and \$11.78 per share, respectively. The fair value of these options is estimated on the date of grant using the Black-Scholes methodology required by SFAS No. 123 for publicly traded companies. In applying the Black-Scholes methodology to the option grants, the Company used the following assumptions:

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Risk-free interest rate	4.0% - 4.8%	3.6% - 4.3%	4.0% - 5.0%
Expected option life	7 years	7 years	6 - 7 years
Expected price volatility	50.1%	54.3%	54.3%

The assumed forfeiture rate was not material to the calculation. The Company does not assume a dividend yield as it has never declared or paid cash dividends on its common stock.

**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

A summary of the Company's stock option activity is as follows (shares in thousands):

		<b>Common Stock</b>
		<b>Weighted</b>
		<b>Avg.</b>
	<b>Shares</b>	<b>Exercise Price</b>
Outstanding at December 31, 2001	3,127	\$ 5.09
Granted	630	18.09
Exercised	(374)	4.01
Forfeited or expired	(95)	9.30
Outstanding at December 31, 2002	3,288	\$ 7.58
Granted	1,333	21.80
Exercised	(309)	4.67
Forfeited or expired	(78)	7.25
Outstanding at December 31, 2003	4,234	\$ 12.28
Granted	2,458	30.61
Exercised	(505)	7.53
Forfeited or expired	(359)	24.34
Outstanding at December 31, 2004	5,828	\$ 19.68

As of December 31, 2004, there were 1,014,744 options available for future issuance.

In 2004, 2003, and 2002, the Company granted certain independent distributors a total of 19,900, 16,750 and 15,850 common stock options, respectively, under the Plan. The distributors were given options to purchase common stock, exercisable in 25% increments on the first through fourth anniversaries of the date of grant, at a weighted-average exercise price of \$32.56, \$16.31 and \$17.21 per share in 2004, 2003, and 2002, respectively. The options expire after ten years.

In connection with the distributor stock grants discussed above and the issuance of certain stock options to employees and distributors, the Company incurred stock-based compensation representing the fair value of the stock and stock options granted to distributors, and for employee stock options to the extent the fair value of the Company's stock exceeded the exercise price of the stock option at the date of the grant. The Company recognizes this stock-based compensation over the respective vesting period, as appropriate. For the years ended December 31, 2004, 2003 and 2002, stock-based expense of \$1.5 million, \$2.1 million, and \$1.7 million, respectively, was recorded in the accompanying statement of operations related to these stock options and stock grants.

A summary of the Company's stock options outstanding and exercisable at December 31, 2004, is as follows (shares in thousands):

Range of Exercise Prices		Options Outstanding Weighted-Average			Options Exercisable		
		Number Outstanding	Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price	
\$0.00	\$8.50	1,872	5.5	\$ 5.12	1,746	\$ 4.95	
\$8.51	\$16.00	80	7.6	15.26	31	15.31	
\$16.01	\$24.00	1,125	8.0	18.26	340	18.09	
\$24.01	\$32.00	2,003	9.2	28.39	151	27.03	
\$32.01	\$35.87	748	9.5	35.36			
		5,828	7.8	\$ 19.68	2,268	\$ 8.53	

**Table of Contents****WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Employee Stock Purchase Plan**

On May 30, 2002, the Company and its shareholders approved and adopted the 2002 Employee Stock Purchase Plan (the ESPP). The ESPP authorizes the Company to issue up to 200,000 shares of common stock to its employees who work at least 20 hours per week. Under the ESPP, there are two six-month plan periods during each calendar year, one beginning January 1 and ending on June 30, and the other beginning July 1 and ending on December 31. Under the terms of the ESPP, employees can choose each plan period to have up to 5% of their annual base earnings, limited to \$5,000, withheld to purchase the Company's common stock. The purchase price of the stock is 85 percent of the lower of its beginning-of-period or end-of-period market price. Under the ESPP, the Company sold to employees 8,792, 12,777, and 5,682 shares in 2004, 2003, and 2002, respectively. The weighted-average fair value of those purchase rights granted in 2004, 2003, and 2002 was \$9.04 per share, \$5.27 per share, and \$5.69 per share, respectively. As of December 31, 2004, there were 172,749 shares available for future issuance. In applying the Black-Scholes methodology to the purchase rights granted, the Company used the following assumptions:

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Risk-free interest rate	1.9% - 2.8%	1.1% - 1.8%	4.9%
Expected option life	6 months	6 months	6 months
Expected price volatility	50.1%	54.3%	54.3%

The assumed forfeiture rate was not material to the calculation. The Company does not assume a dividend yield as it has never declared or paid cash dividends on its common stock.

**14. Employee Benefit Plans:**

The Company sponsors a defined contribution plan under Section 401(k) of the Internal Revenue Code, which covers U.S. employees who are 21 years of age and over. Under this plan, the Company matches voluntary employee contributions at a rate of 100% for the first 2% of an employee's annual compensation and at a rate of 50% for the next 2% of an employee's annual compensation. Employees vest in the Company's contributions after three years of service with the Company. The Company's expense related to the plan was \$831,000, \$716,000, and \$677,000 in 2004, 2003, and 2002, respectively.

**15. Commitments and Contingencies:**

*Operating Leases.* The Company leases certain equipment and office space under non-cancelable operating leases. Rental expense under operating leases approximated \$6.2 million, \$5.0 million and \$3.9 million for the years ended December 31, 2004, 2003, and 2002, respectively. Future minimum payments, by year and in the aggregate, under non-cancelable operating leases with initial or remaining lease terms of one year or more, are as follows at December 31, 2004 (in thousands):

2005	\$ 6,532
2006	4,626
2007	2,526

2008	556
2009	448
Thereafter	1,462
	\$ 16,150

Table of Contents**WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Royalty and Consulting Agreements.* The Company has entered into various royalty and other consulting agreements with third party consultants. The Company incurred royalty and consulting expenses of \$6.2 million, \$5.0 million and \$4.5 million during the years ended December 31, 2004, 2003, and 2002, respectively, under minimum contractual obligations that were contingent upon services. The amounts in the table below represent minimum payments to consultants that are contingent upon future services. These fees are accrued when it is deemed probable that the performance thresholds are met. Payments under these agreements for which the Company has not recorded a liability, are as follows at December 31, 2004 (in thousands):

2005	\$ 6,266
2006	1,668
2007	1,235
2008	1,041
2009	957
Thereafter	4,000
	\$ 15,167

Portions of the Company's payments for operating leases and royalty agreements are denominated in foreign currencies and were translated in the tables above based on their respective U.S. dollar exchange rates at December 31, 2004. These future payments are subject to foreign currency exchange rate risk.

*Purchase Obligations.* The Company has entered into certain supply agreements for its products, which include minimum purchase obligations. During the years ended December 31, 2004, 2003, and 2002, the Company paid approximately \$6.4 million, \$6.8 million, and \$2.3 million, respectively, under those supply agreements. The amounts in the table below represent the Company's purchase obligations in future years under those supply agreements:

2005	\$ 6,609
2006	5,263
	\$ 11,872

Portions of these payments are denominated in foreign currencies and were translated based on their respective U.S. dollar exchange rates at December 31, 2004. These future payments are subject to foreign currency exchange rate risk.

*Legal Proceedings.* On June 30, 1993, prior to the December 1999 recapitalization and inception of the Company in its present form, the Predecessor Company acquired substantially all the assets of the large joint orthopaedic implant business from Dow Corning Corporation (DCC). DCC retains liability for matters arising from certain conduct of DCC prior to June 30, 1993. As such, DCC has agreed to indemnify the Predecessor Company against all liability for all products manufactured prior to the acquisition except for products provided under the Predecessor Company's 1993 agreement with DCC pursuant to which the Predecessor Company purchased certain small joint orthopaedic implants for worldwide distribution.



The Predecessor Company was notified in May 1995 that DCC, which filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code, would no longer defend the Predecessor Company in such matters until it received further direction from the bankruptcy court. Based on the most recent plan of reorganization submitted to the court, it appears that the Predecessor Company would be considered an unsecured creditor and, under the terms of the plan, would receive 24% of any such claim as a cash payment with the remainder to be paid by a senior note due within ten years. There are several appeals regarding the confirmed plan of reorganization pending before the U.S. District Court in Detroit, Michigan, which have delayed implementation of the plan.

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**WRIGHT MEDICAL GROUP, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

There can be no assurance that DCC will indemnify the Predecessor Company or the Company on any claims in the future. Although neither the Predecessor Company nor the Company maintains insurance for claims arising on products sold by DCC, the Company does not believe the outcome of any of these matters will have a material adverse effect on the Company's financial position or results of operations.

In 2000, Howmedica Osteonics Corp. ( Howmedica ) filed a lawsuit against the Company alleging patent infringement. The lawsuit seeks an order of infringement, injunctive relief, unspecified damages and various other costs and relief. The claims in this case could impact a substantial portion of our knee product line. The Company believes, however, that it has strong defenses against the claims and that the claims are, in part, covered by the Company's patent infringement insurance. In 2004, a Markman hearing was held regarding interpretation of the patent claims that have been asserted by Howmedica in this lawsuit. The court has taken the issue of claim interpretation under advisement and both parties await the decision of the court on this issue. Management is 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, 2004. However, management does not believe that the outcome of this lawsuit will have a material adverse effect on the Company's financial position or results of operations.

In July 2002, the Company entered into a license agreement to resolve an intellectual property dispute that, among other things, provided for a payment of up to \$1.25 million if a particular patent re-issued by February 10, 2004, and certain other conditions, as defined in the license agreement, were satisfied. While the patent in question re-issued prior to February 10, 2004, based on its assessment, the Company has concluded that the other required conditions were not satisfied upon re-issuance and the consequential payment of any amount is not probable. Accordingly, no provision has been made for this contingency as of December 31, 2004.

In July 2002, pursuant to a purchase and royalty agreement with CERAbio LLC ( CERAbio ), the Company 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 due once 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. The Company, believing that the contractual obligations for payment had not been met, disputed whether the second payment and royalties had been earned. In 2003, CERAbio and Phillips Plastics Corporation filed a lawsuit against the Company in United States District Court for the Western District of Wisconsin for payment of the remaining \$1.5 million of the purchase price and the royalties earned to date. In November 2003, the trial court ruled in favor of CERAbio and ordered the Company 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, the Company appealed the trial court's judgment to the United States Court of Appeals for the Seventh Circuit, briefs and oral arguments were submitted, and the appeal is pending. The Company does not believe that the outcome of this lawsuit will have a material adverse effect on its financial position or results of operations.

In September 2004, the Company announced a voluntary market withdrawal of a limited number of metal acetabular hip cups that are intended for use in the Company's CONSERVE hip systems. In connection with this market withdrawal, the Company recorded \$500,000 in product liability reserves for probable losses related to the market withdrawal. Management developed this estimate and believes that the amount recorded is appropriate based on assumptions with respect to estimated patient claims related to the market withdrawal and the acceptance of such claims by our insurer. The nature of a market withdrawal and the associated claims are such that the claims will occur

over an extended period of time. The Company's loss estimate includes an assumption for unasserted claims based on management's industry experience with similar circumstances. While the Company believes that the amount recorded related to the market withdrawal is appropriate, it is possible that changes in assumptions related to potential claims or insurance coverage could have an adverse effect on the Company's estimate.

The Company is currently involved in separate disputes, in Italy, with a former agent and two former employees. No lawsuits have been filed by a party in any of these matters. Management believes that it has meritorious defenses

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should any claim arise and that the payment of any amount is not probable and cannot be estimated at this time. Accordingly, no provisions have been made for these matters as of December 31, 2004.

In addition to those noted above, the Company is subject to various other legal proceedings, product liability claims and other matters which arise in the ordinary course of business. In the opinion of management, the amount of liability, if any, with respect to these matters will not materially affect the results of operations or financial position of the Company.

**16. Segment Data:**

The Company has one reportable segment, orthopaedic products, which includes the design, manufacture and marketing of reconstructive joint devices and biologics products. The Company's geographic business units consist of operations in the United States, Europe and Other (which principally represents Canada and Japan). Identifiable assets are those assets used exclusively in the operations of each business unit. Revenues attributed to each geographic unit are based on the location in which the sale originated.

Net sales of orthopaedic products by category and information by geographic area are as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net sales by product line:			
Hips products	\$ 99,133	\$ 78,071	\$ 56,945
Knee products	87,408	78,338	72,058
Biologics products	62,070	50,056	38,347
Extremity products	36,433	31,876	25,367
Other	12,495	10,591	8,156
Total	\$ 297,539	\$ 248,932	\$ 200,873
Net sales by geographic business unit:			
United States	\$ 200,500	\$ 168,138	\$ 138,853
Europe	74,292	61,075	47,011
Other	22,747	19,719	15,009
Total	\$ 297,539	\$ 248,932	\$ 200,873
Operating income by geographic business unit:			
United States	\$ 33,102	\$ 19,472	\$ 24,136
Europe	(433)	3,912	1,844
Other	5,744	3,782	575
Total	\$ 38,413	\$ 27,166	\$ 26,555

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Long-lived assets:		
United States	\$ 45,905	\$ 44,863
Europe	18,012	18,688
Other	6,290	3,364
Total	\$ 70,207	\$ 66,915

Sales to United States-based customers, aggregated \$180.4 million, \$152.9 million, and \$122.4 million, for the years ended December 31, 2004, 2003, and 2002, respectively. These sales, along with United States export sales, are

Table of Contents**WRIGHT MEDICAL GROUP, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

included in United States sales in the above table. No single foreign country accounted for more than 10% of the Company's total net sales during 2004, 2003 or 2002; however, Italy and France together represented approximately 16% of the Company's total net sales in each of 2004, 2003 and 2002.

**17. Quarterly Results of Operations (unaudited):**

The following table presents a summary of the Company's unaudited quarterly operating results for each of the four quarters in 2004 and 2003, respectively (in thousands). This information was derived from unaudited interim financial statements that, in the opinion of management, have been prepared on a basis consistent with the financial statements contained elsewhere in this filing and include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with our audited financial statements and related notes. The operating results for any quarter are not necessarily indicative of results for any future period.

	<b>2004</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Net sales	\$ 74,917	\$ 75,616	\$ 69,299	\$ 77,707
Cost of sales	20,386	21,383	19,998	22,416
Gross profit	54,531	54,233	49,301	55,291
Operating expenses:				
Selling, general and administrative	37,134	37,714	36,611	39,685
Research and development	4,982	4,524	4,302	4,613
Amortization of intangible assets	942	928	975	1,044
Stock-based expense	424	465	271	329
Total operating expenses	43,482	43,631	42,159	45,671
Operating income	\$ 11,049	\$ 10,602	\$ 7,142	\$ 9,620
	<b>2003</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Net sales	\$ 58,622	\$ 62,152	\$ 59,268	\$ 68,890
Cost of sales	15,540	17,386	15,453	19,436
Gross profit	43,082	44,766	43,815	49,454
Operating expenses:				
Selling, general and administrative	30,305	31,963	32,292	33,052
Research and development	3,535	3,908	4,397	4,311
Amortization of intangible assets	804	923	900	935

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Stock-based expense	409	420	482	757
Acquired in-process research and development costs	4,558			
Total operating expenses	39,611	37,214	38,071	39,055
Operating income	\$ 3,471	\$ 7,552	\$ 5,744	\$ 10,399

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**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not applicable.

**Item 9A. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures*

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. Our disclosure controls and procedures are designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2004. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2004, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

*Management's Annual Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2004. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which is included herein.

**Item 9B. Other Information.**

Not applicable.



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**PART III**

**Item 10. Directors and Executive Officers of the Registrant.**

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2004, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 12, 2005.

**Item 11. Executive Compensation.**

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2004, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 12, 2005.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2004, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 12, 2005.

**Item 13. Certain Relationships and Related Transactions.**

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2004, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 12, 2005.

**Item 14. Principal Accountant Fees and Services.**

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2004, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 12, 2005.

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**PART IV**

**Item 15. Exhibits and Financial Statement Schedules.**

**Financial Statements**

See Index to Consolidated Financial Statements in Item 8 of this report.

**Financial Statement Schedules**

See Schedule II - Valuation and Qualifying Accounts on page S-2 of this report.

**Index to Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
2.1	Amended and Restated Agreement and Plan of Merger, dated as of December 7, 1999, among Wright Medical Technology, Inc., Warburg Pincus Equity Partners, LP, Wright Acquisition Corp., Inc. and Wright Medical Group, Inc. <sup>(1)</sup>
2.2	ADCON Asset Purchase and Intellectual Property Assignment Agreement dated as of December 23, 2002, between Wright Medical Technology, Inc. and Gliatech Inc., as amended by First Amendment to Asset Purchase and Intellectual Property Assignment Agreement dated as of December 31, 2002, between Wright Medical Technology, Inc. and Gliatech Inc. <sup>(2)</sup>
3.1	Fourth Amended and Restated Certificate of Incorporation of Wright Medical Group, Inc., <sup>(1)</sup> as amended by Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Wright Medical Group, Inc. <sup>(3)</sup>
3.2	Amended and Restated By-laws of Wright Medical Group, Inc. <sup>(4)</sup>
4.1	Registration Rights Agreement, dated December 7, 1999, among the investors listed on Schedule I thereto and Wright Medical Group, Inc. <sup>(1)</sup>
4.2	Investor Rights Agreement, dated December 22, 1999, among the investors listed on Schedule I thereto, Warburg, Pincus Equity Partners, L.P., and Wright Medical Group, Inc. <sup>(1)</sup>
4.3	Stockholders Agreement, dated December 7, 1999, among the stockholders, the investors listed on Schedule I thereto and Wright Medical Group, Inc., as amended by Amendment No. 1 to the Stockholders Agreement, dated August 7, 2000. <sup>(1)</sup>
4.4	Form of Common Stock certificate. <sup>(1)</sup>
4.5	Form of Warrant. <sup>(1)</sup>
10.1	Credit Agreement, dated as of August 1, 2001, among Wright Medical Group, Inc., Wright Medical Technology, Inc., the Lenders named therein, The Chase Manhattan Bank (now named JPMorgan Chase Bank), as Administrative Agent, Collateral Agent and Issuing Bank, Credit Suisse First Boston, as Co-Syndication Agent, and U.S. Bank National Association, as Co-Syndication Agent, <sup>(5)</sup> as amended

by Amendment No. 1 to Credit Agreement dated as of July 31, 2002, among the parties thereto, <sup>(6)</sup>  
Amendment No. 2 to Credit Agreement dated as of May 23, 2003, among the parties thereto, <sup>(6)</sup> and  
Amendment No. 3 to Credit Agreement dated as of September 11, 2003, among the parties thereto, <sup>(7)</sup>  
and Amendment No. 4 to Credit Agreement dated as of December 3, 2004, among the parties thereto.<sup>(8)</sup>

- 10.2 Third Amended and Restated 1999 Equity Incentive Plan (the 1999 Plan <sup>(9)</sup>).<sup>(10)</sup>
- 10.3 Form of Incentive Stock Option Agreement, as amended by form of Amendment No. 1 to Incentive Stock Option Agreement, pursuant to the 1999 Plan. <sup>(1)</sup> <sup>(10)</sup>

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<b>Exhibit No.</b>	<b>Description</b>
10.4	Form of Non-Qualified Stock Option Agreement pursuant to the 1999 Plan. <sup>(1)</sup> (10)
10.5	Form of Non-Employee Director Stock Option Agreement pursuant to the 1999 Plan. <sup>(1)</sup> (10)
10.6	Form of Executive Stock Option Agreement pursuant to the 1999 Plan. <sup>(3)</sup> (10)
10.7	Form of Sales Representative Award Agreement pursuant to the 1999 Plan. <sup>(1)</sup> (10)
10.8	Wright Medical Group, Inc. Executive Performance Incentive Plan. <sup>(10)</sup> (11)
10.9	Form of Indemnification Agreement between Wright Medical Group, Inc. and its directors and executive officers. <sup>(1)</sup> (10)
10.10	Employment Agreement dated as of July 1, 2004, between Wright Medical Technology, Inc. and Laurence Y. Fairey. <sup>(10)</sup> (12)
10.11	Employment Agreement dated as of July 1, 2004, between Wright Medical Technology, Inc. and F. Barry Bays. <sup>(10)</sup> (12)
10.12	Employment Agreement dated as of December 11, 2003, between Wright Medical Technology, Inc. and John K. Bakewell. <sup>(10)</sup> (13)
10.13	Employment Agreement dated as of January 1, 2004, between Wright Medical Technology, Inc. and R. Glen Coleman. <sup>(10)</sup> (12)
10.14	Employment Agreement dated as of April 1, 2004, between Wright Medical Technology, Inc. and Jeffrey G. Roberts. <sup>(10)</sup>
10.15	Employment Agreement dated as of February 8, 2005, between Wright Medical Technology, Inc. and Brian T. Ennis. <sup>(10)</sup> (11)
10.16	Severance and Release Agreement dated as of August 31, 2004, between Wright Medical Technology, Inc. and Jack E. Parr. <sup>(10)</sup> (14)
10.17	Severance and Release Agreement dated as of October 31, 2004, between Wright Medical Technology, Inc. and Robert W. Churinetz. <sup>(10)</sup> (15)
21	Subsidiaries of Wright Medical Group, Inc. <sup>(13)</sup>
23	Consent of KPMG LLP.
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934.

- 32      Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) Under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code.
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- (1)      Incorporated by reference to the Company's Registration Statement on Form S-1(Registration No. 333-59732), as amended.
- (2)      Incorporated by reference to the Company's annual report on Form 10-K for the year ended December 31, 2002.
- (3)      Incorporated by reference to the Company's Registration Statement on Form S-8 filed May 14, 2004.
- (4)      Incorporated by reference to the Company's current report on Form 8-K filed March 31, 2004.
- (5)      Incorporated by reference to the Company's current report on Form 8-K filed August 3, 2001.

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- (6) Incorporated by reference to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2003.
- (7) Incorporated by reference to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2003.
- (8) Incorporated by reference to the Company's current report on Form 8-K filed December 7, 2004.
- (9) Incorporated by reference to the Company's definitive proxy statement filed April 7, 2004.
- (10) Management contract or compensatory plan or arrangement required to be filed as an exhibit to this report pursuant to Item 15(c) of Form 10-K.
- (11) Incorporated by reference to the Company's current report on Form 8-K filed February 10, 2005.
- (12) Incorporated by reference to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2004.
- (13) Incorporated by reference to the Company's annual report on Form 10-K for the year ended December 31, 2003.
- (14) Incorporated by reference to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2004.
- (15) Incorporated by reference to the Company's current report on Form 8-K filed November 18, 2004.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

March 1, 2005

Wright Medical Group, Inc.

By: /s/ Laurence Y. Fairey

Laurence Y. Fairey  
*President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Laurence Y. Fairey</u> Laurence Y. Fairey	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2005
<u>/s/ John K. Bakewell</u> John K. Bakewell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2005
<u>/s/ F. Barry Bays</u> F. Barry Bays	Executive Chairman of the Board	March 1, 2005
<u>/s/ Richard B. Emmitt</u> Richard B. Emmitt	Director	March 1, 2005
<u>/s/ David D. Stevens</u> David D. Stevens	Director	March 1, 2005
<u>/s/ James E. Thomas</u> James E. Thomas	Director	March 1, 2005
<u>/s/ Thomas E. Timbie</u> Thomas E. Timbie	Director	March 1, 2005

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/s/ James T. Treace

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Director

March 1, 2005

James T. Treace

/s/ Elizabeth H. Weatherman

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Director

March 1, 2005

Elizabeth H. Weatherman



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Wright Medical Group, Inc.:

Under date of February 21, 2005, we reported on the consolidated balance sheets of Wright Medical Group, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in stockholders' equity and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements, and our report thereon, are included in the annual report on Form 10-K for the year 2004. In connection with our audits of the aforementioned consolidated financial statements, we also audited the related consolidated financial statement schedule listed in Item 15 in the annual report on Form 10-K. The financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statement schedule based on our audit.

In our opinion, the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

(signed) KPMG LLP

Memphis, Tennessee

February 21, 2005

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**Wright Medical Group, Inc.**  
**Schedule II-Valuation and Qualifying Accounts**  
**(In thousands)**

	Balance at Beginning of Period	Charged to Cost and Expenses	Deductions and Other	Balance at End of Period
Allowance for doubtful accounts:				
For the period ended:				
December 31, 2004	\$ 1,489	\$ 268	\$ (63)	\$ 1,820
December 31, 2003	\$ 1,509	\$ 87	\$ 107	\$ 1,489
December 31, 2002	\$ 1,893	\$ 515	\$ 899	\$ 1,509
Sales returns and allowance:				
For the period ended:				
December 31, 2004	\$ 412	\$ (17)	\$	\$ 395
December 31, 2003	\$ 987	\$ (101)	\$ 474	\$ 412
December 31, 2002	\$ 643	\$ 344	\$	\$ 987

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