WRIGHT MEDICAL GROUP INC
Form 10-K
February 22, 2010

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

(Mark One)

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

For the fiscal year ended December 31, 2009

OR

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

For the transition period from _____ to _____

Commission file number: 000-32883

WRIGHT MEDICAL GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4088127**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
5677 Airline Road, Arlington, Tennessee	**38002**
(Address of principal executive offices)	(Zip code)

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

Securities registered pursuant to Section 1 2(b) of the Act**:**

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	**NASDAQ Global Select Market**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

þ Yes o No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

o Yes þ No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

þ Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

o Yes o No

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

þ

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

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the voting and non-voting common equity held by nonaffiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter was $622,880,113.

As of February 17, 2010, there were 38,765,208 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, 2009, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on May 13, 2010.

WRIGHT MEDICAL GROUP, INC.
ANNUAL REPORT ON FORM 10-K
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Safe-Harbor Statement

This annual report contains forward-looking statements as defined under U.S. federal securities laws. These statements reflect management s current knowledge, assumptions, beliefs, estimates, and expectations and express management s current views of future performance, results, and trends and may be identified by their use of terms such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will, and oth Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Such risks and uncertainties include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A and elsewhere in this report and in our quarterly reports). Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date of this annual report, and we undertake no obligation to update such statements 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 (Wright), is a global orthopaedic medical device company specializing in the design, manufacture and marketing of devices and biologic products for extremity, hip, and knee repair and reconstruction. We are a leading provider of surgical solutions for the foot and ankle market. Reconstructive devices are used to replace or repair knee, hip and other joints and bones that have deteriorated or have been damaged 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 foot and ankle and upper extremity markets, as well as on the integration of our biologic products into reconstructive procedures and other orthopaedic applications.

For the year ended December 31, 2009, we had net sales of $488 million and net income of $12 million. As of December 31, 2009, we had total assets of $714 million. Detailed information on our net sales by product line and our net sales, operating income and long-lived assets by geographic region can be found in Note 16 to the consolidated financial statements contained in Financial Statements and Supplementary Data.

Orthopaedic Industry

It is estimated that the worldwide orthopaedic industry generated sales of approximately $28 billion in 2009. We believe this figure will grow by approximately 5-7% annually over the next three years. Five multinational companies currently dominate the orthopaedic industry, each with approximately $2 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 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 less contested, higher-growth sectors of the orthopaedic market.

In recent years, we focused our efforts into growing our position in the higher-growth extremities and biologics markets, which we estimate had combined sales of approximately $3.3 billion in 2009. We believe that this figure will grow by approximately 9-11% annually over the next three years.

Orthopaedic devices are commonly divided into several primary sectors corresponding to the major product categories within the orthopaedic field: reconstruction, trauma, arthroscopy, spine and biologics. We specialize in those products used by extremity focused surgeon specialists which include products from the reconstruction, trauma and arthroscopy markets, hip and knee reconstructive joint devices and biologic products.

Extremity Hardware. Extremity hardware includes implants and other devices to replace or reconstruct injured or diseased joints and bones of the foot, ankle, hand, wrist, elbow and shoulder. Extremities hardware is one of the fastest growing market segments within orthopaedics with annual growth rates of 9-11%. It is estimated that the extremity hardware market had sales of approximately $2.4 billion worldwide in 2009. Major trends in extremity hardware include procedure specific and anatomy specific devices, locking plates and an increase in total ankle arthroplasty procedures.

Foot and Ankle Hardware

Foot and ankle reconstruction includes implants and other devices to replace or reconstruct injured or diseased joints and bones in the foot and ankle. It is estimated that the foot and ankle extremity hardware market had sales of approximately $1 billion worldwide in 2009. A large segment of the foot and ankle hardware market is comprised of plating and screw systems for reconstructing and fusing joints or repairing bones after traumatic injury. Major trends in foot and ankle hardware include the use of external fixation devices in diabetic patients, total ankle arthroplasty and advanced tissue fixation devices. According to two recent customer and market surveys, we are deemed the market leader in foot and ankle surgical products, and hold 25% of the U.S. total ankle arthroplasty market in 2009.

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Upper Extremity Reconstruction

Upper extremity reconstruction involves implanting devices to replace or reconstruct, or fixate injured or diseased joints and bones in the hand, wrist, elbow and shoulder. It is estimated that the upper extremity hardware market had sales of approximately $1.5 billion worldwide for 2009, approximately 30% of which is in total shoulder replacement implants. Major trends in upper extremity hardware include minimally invasive fracture repair devices and next generation joint arthroplasty systems. We are the market leader in several segments of the upper extremity market including finger joints, radial head replacement, ulnar shortening system, and intramedullary wrist fracture repair devices.

Biologics Market. Biologic products use both biological tissue-based and synthetic materials to regenerate damaged or diseased bone and to repair damaged or diseased soft tissue. These products stimulate the body s natural regenerative capabilities to heal itself, minimizing or delaying the need for invasive implant surgery.

Our biologic products are primarily used in extremity related procedures as well as in trauma and tumor induced voids of the long bones, joint replacements, and spine procedures. Biologic products provide a lower morbidity 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: osteoconductive, osteoinductive and osteogenic. Each category refers to the way in which the materials affect bone growth. Osteoconductive materials serve as a scaffold that supports the formation of bone but do not trigger new bone growth, whereas osteoinductive materials induce bone growth. Finally, osteogenic materials combine the latter with a cell-based component. Our flagship, PRO-DENSE® injectable regenerative graft is an osteoconductive bone graft which provides the benefits of injectability, hardness to support bone and predictable bone regeneration. Products such as our GRAFTJACKET® regenerative tissue matrix enable the repair of soft tissue such as tendons (e.g., rotator cuff and Achilles), ligaments or chronic wounds (such as diabetic foot ulcers). The need for biomaterials that speed wound healing and reduce amputation rates is critical. Excluding viscosupplements, tissue processing services and bone morphogenic protein, it is estimated that the biologics market generated sales of approximately $1 billion worldwide in 2009.

Hip and Knee Reconstructive Joint Device Market

Most reconstructive joint devices are used to replace or repair joints that have deteriorated or have been damaged as a result of disease or injury. Despite the availability of non-surgical treatment alternatives such as oral medications, injections and joint fluid supplementation, 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.

Knee Reconstruction. The knee joint involves the surfaces of three distinct bones: the lower end of the femur or thigh bone, 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 2009, with estimated sales of approximately $6.5 billion worldwide.

One of the major trends in knee reconstruction includes the use of alternative surface materials to extend the implant life and increase conservation of the patient s bone to minimize surgical trauma and accelerate recovery. Our BIOFOAM material is a 70% porous material which provides a trabecular structure that acts as an interface for bone in-growth. The microstructure of our BIOFOAM material is designed to allow rigid fixation for faster biological attachment. This material made its debut on the ADVANCE® BIOFOAM tibial base, and will eventually be incorporated into a number of our products spanning from hip arthroplasty to foot and ankle reconstruction. Another example of our innovation in knee arthroplasty was the introduction of the PROPHECY pre-operative navigation system in 2009. The PROPHECY system allows surgeons to visualize what the implant will look like after the surgery is performed before the skin is dissected. This patent-pending process utilizes custom fit cutting instruments made for each specific patient, thus reducing time in the operating room.

Hip Reconstruction. The hip joint is a ball-and-socket joint that 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 or the ball and the acetabulum or hollow portion of the pelvis or the socket. This degeneration causes pain, stiffness and a reduction in hip mobility. It is estimated that the worldwide hip reconstruction market had sales of

approximately $4 billion in 2009.

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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. 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. One example of our commitment to the advancement of bearing technology is the development of our A-CLASS metal-on-metal articulation which provides a 90% reduction in initial (run-in) wear and 68% reduction in lifetime wear of the implant. In addition to advances in bearing surfaces, implants that preserve more natural bone have been developed in order to minimize surgical trauma and recovery time for patients. These implants, known as bone-conserving implants, leave more of the hip bones intact, which is beneficial given the likelihood of future revision replacement procedures as the average patient s lifetime increases. Bone-conserving procedures are intended to enable patients to delay their first total hip procedure and may significantly increase the time from the first procedure to the time when a revision replacement implant is required. One example of bone conserving implant technology is our CONSERVE® Plus total hip resurfacing system, which was recently approved by the United States Food and Drug Administration (FDA). Resurfacing of the femoral head allows surgeons to reconstruct the patients hip while leaving the femoral head and neck in place. Additionally, PATH® surgical technique is a tissue sparing hip replacement technique that offers patients quicker recovery due to a decrease of intraoperative soft tissue trauma. The decreased soft tissue trauma results in less pain and blood loss for the patient, as well as a lower risk of dislocation.

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 the pre-clinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, recordkeeping, advertising and promotion of our medical device products. Our tissue-based products are subject to FDA regulations, the National Organ Transplant Act (NOTA), and various state agency regulations. We are an accredited member of the American Association of Tissue Banks (AATB) and an FDA registered tissue establishment, which includes the packaging, processing, storage, labeling, and distribution of tissue products regulated as medical devices and the storage and distribution of tissue products regulated solely as human cell and tissue products. In addition, we maintain tissue bank licenses in Florida, Maryland, New York, California, and Oregon.

Generally, before we can market a new medical device, marketing clearance from the FDA must be obtained through either a premarket notification under Section 510(k) of the FDC Act or the 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 usually takes about 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, require a PMA application. PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of human clinical trials, bench tests and laboratory and animal studies. The PMA application must also contain a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission must include the proposed labeling and any training materials. The PMA application process can be expensive and generally takes significantly longer than the 510(k) process. Additionally, the FDA may never approve the PMA application. As part of the PMA application review process, the FDA generally will conduct an inspection of the manufacturer s facilities to ensure compliance with applicable quality system regulatory requirements, which include quality control testing, documentation control and other quality assurance procedures.

If human clinical trials of a medical device are required and the device presents a significant risk, the sponsor of the trial 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

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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 institutional investigational sites with the specific number of patients approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA. Submission of an IDE does not give assurance that the FDA will approve the IDE. If it is approved, there can be no assurance the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial must also comply with the FDA s IDE regulations, and informed consent must be obtained from each subject.

The FDA has statutory authority to regulate allograft-based products, processing and materials. The FDA and other international regulatory agencies have been working to establish more comprehensive regulatory frameworks for allograft-based tissue-containing products, which are principally derived from human cadaveric tissue. The framework developed by the FDA establishes risk-based criteria for determining whether a particular human tissue-based product will be classified as human tissue, a medical device or a biologic drug requiring premarket clearance or approval. All tissue-based products are subject to extensive FDA regulation, including establishment registration requirements, product listing requirements, good tissue practice requirements for manufacturing and screening requirements that ensure that diseases are not transmitted to tissue recipients. The FDA has also proposed extensive additional requirements that address sub-contracted tissue services, tracking to the recipient/patient and donor records review. If a tissue-based product is considered human tissue, the FDA requirements focus on preventing the introduction, transmission and spread of communicable diseases to recipients. Neither clinical data nor review of safety and efficacy are required before the tissue can be marketed. However, if the tissue is considered a medical device, or a biologic drug, then FDA clearance or approval is 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 our operations. 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. to assure compliance with applicable quality system regulations.

Most of our products are FDA cleared through the 510(k) premarket notification process. We have conducted clinical trials to support some 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. If the FDA believes that we are not in compliance with the FDC Act, it can institute proceedings to detain or seize products, issue a market withdrawal, enjoin future violations and/or 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.

Further, we are subject to various federal and state laws concerning healthcare fraud and abuse, including false claims laws, anti-kickback laws and physician self-referral laws. Violations of these laws can result in criminal and/or civil punishment, including fines, imprisonment and, in the U.S., exclusion from participation in government healthcare reimbursement programs. If a governmental authority were to determine that we do not comply with these laws and regulations, then we and our officers and employees could be subject to criminal and civil sanctions.

International

All of our products sold internationally are subject to certain foreign regulatory approvals. We must 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 foreign approvals to market our products may be longer or shorter than the time required in the U.S., and requirements for such approvals may differ from FDA requirements.

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

Products

We operate as one reportable segment, offering products in four primary market sectors: extremity reconstruction, biologics, knee reconstruction and hip reconstruction. Sales in each of these markets represent greater than 15% of our consolidated revenue. Detailed information on our net sales by product line can be found in Note 16 to the consolidated financial statements contained in Financial Statements and Supplementary Data.

Extremity Hardware

We offer extremity products for the foot and ankle and upper extremities in a number of markets worldwide. Some of our extremity implants have over 40 years of successful clinical history. We are a recognized leader in the U.S. and German markets for foot and ankle surgical products. Additionally, we hold leading positions in several segments of the upper extremity market such as radial head repair, finger joint replacements and intramedullary wrist fracture implants.

Foot and Ankle Hardware:

Our CHARLOTTE foot and ankle system is an extensive offering of fixation products for foot and ankle surgery, and includes products that feature advanced design elements for simplicity, versatility and high performance. Adding to the CHARLOTTE portfolio, in 2006, we introduced the first ever locking compressing plate designed for corrective foot surgeries. The CLAW® plate allows surgeons to modify the length of screws used and amount of compression to the fusion site, a strong advantage over traditional staples.

The DARCO® foot and ankle plating systems were designed to address the specific needs of reconstructive foot and ankle surgery. The DARCO® MFS and MRS plates were the first implants to incorporate fixed angle, locking screw technology into a comprehensive fixation set for foot surgery. Surgeons believe that surgical repairs are more stable with locking screw technology, thus allowing patients to return to activity faster.

Our INBONE total ankle system represents the third generation in ankle replacement implants, utilizing a patented intramedullary alignment mechanism for more accurate placement of the implant. The unique modular nature of the implant allows the surgeon to customize the fixation stems for the tibial and talar components in order to maximize stability of the implant. Accuracy of placement and implant stability have been shown to be key factors impacting longevity of the implant. The INBONE system represents key advances in these critical arenas.

Our SIDEKICK line of external fixators is designed to facilitate compression or distraction of bones in the foot from the outside in and in a minimally invasive manner. In many cases, surgeons will opt for the minimally invasive nature of external fixation versus more invasive plate and screw internal fixation. One growing application of our SIDEKICK is in the diabetic population for which small incisions are preferred due to wound healing issues present with these patients.

In late 2009, we announced the commercial release of the ORTHOLOC polyaxial trauma plating system. The ORTHOLOC system provides foot and ankle surgeons a comprehensive line of plates and screws to address most trauma injuries of the foot and ankle. The polyaxial locking feature allows the surgeon to customize the angle of screw placement through the plate to maximize implant to bone fit. Additionally, we announced the limited release of the VALOR TTC fusion nail. The VALOR nail provides surgeons with a solution for fusing the calcaneal, talar and tibial bones required in patients suffering from severe ankle arthritis. The combination of the INBONE™ total ankle replacement system and the VALOR fusion nail provide foot and ankle surgeons with what we believe to be the most compelling portfolio for treating patients with varying degrees of ankle arthritis.

Other products in our foot and ankle portfolio include our BIOARCH subtalar arthoereisis implant, our line of AM Surgical foot and ankle endoscopic tissue release products, and our line of Swanson toe joints.

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Upper Extremity Hardware:

Our EVOLVE® modular radial head replacement prosthesis addresses the need for modularity in the anatomically highly-variable joint of the elbow and is the market leading radial head prosthesis. The EVOLVE® modular radial head device provides 150 different combinations of heads and stems allowing the surgeon to choose implant heads and stems to accommodate the unpredictable anatomy of each patient. The smooth stem design allows for rotational motion at the implant and bone interface and for radiocapitellar articulation, potentially reducing capitellar wear. Our EVOLVE® radial head plating system is for surgeons who wish to repair rather than replace the damaged radial head. With prostheses and plating, we believe we have become the vendor of choice for repair of radial head fractures. Further strengthening our position in the radial head market, in 2007, we introduced our EVOLVE® proline system, which adds additional size offerings and in-situ locking of the implant, a favorable feature for surgeons treating patients with intact elbow ligaments.

Our line of Swanson finger joints are used in finger joint replacement for patients suffering from rheumatoid arthritis of the hand. With nearly 40 years of clinical success, Swanson digit implants are a foundation in our upper extremity business and are used by a loyal base of hand surgeons worldwide.

Our MICRONAIL® intramedullary wrist fracture repair system is a next-generation minimally invasive treatment for distal radius fractures that provides immediate fracture stabilization with minimal soft tissue disruption. The result is rapid recovery of hand and wrist functions. Also, as the product is implanted within the bone, it has no external profile on top of the bone, thereby removing the potential for tendon irritation or rupture, which is an appreciable problem with conventional plates designed to lie on top of the bone.

Our RAYHACK® system is comprised of a series of precision cutting guides and procedure-specific plates for ulnar shortening procedures and the surgical corrections to treat radial malunions and Keinbock s disease.

Biologics

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

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

GRAFTJACKET® ulcer repair matrix 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® ulcer repair matrix has the ability to reliably repair deep foot wounds, which have a much higher risk of leading to amputation. Unlike some other diabetic foot ulcer products, GRAFTJACKET® ulcer repair matrix generally requires only one application to treat the foot ulcer, thereby reducing the time and cost of treatment. We procure our GRAFTJACKET® product through an exclusive distribution agreement that expires December 31, 2013.

Our BIOTAPE XM Reinforcement Matrix was released for sale in the U.S. and many international markets in September 2008. The BIOTAPE XM matrix, an animal derived (xenograft) soft-tissue graft, expands our market-leading portfolio of soft-tissue reinforcement technologies and provides a less burdensome entrance into many of our international markets where human tissue regulations make providing human tissue products difficult or impossible.

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We sell PRO-DENSE® injectable graft in the U.S. and select international markets. PRO-DENSE® injectable graft is a composite graft of surgical grade calcium sulfate and calcium phosphate. In animal studies, this unique graft composite has demonstrated excellent bone regenerative characteristics, forming new bone that is over three times stronger than the natural surrounding bone at the 13-week time point. Beyond 13 weeks, the regenerated bone gradually remodels to natural bone strength. Subsequent clinical data series have demonstrated dense new bone regeneration at an accelerated rate. Ultimately, we believe that this may bode well for patients to return to their presurgery activity levels at a faster pace. PRO-STIM injectable inductive graft is built on the PRO-DENSE® material platform, but adds demineralized bone matrix (DBM) for osteoinductive potential. PRO-STIM graft has demonstrated accelerated healing compared to autograft in pre-clinical testing. Since the mechanism of action is different than PRO-DENSE® graft, PRO-STIM graft will allow us to expand the applicable procedures to more challenging bone defects for the material platform. Currently available on a limited basis to key centers, PRO-STIM graft is expected to be fully launched in the second half of 2010.

Our OSTEOSET® bone graft substitute is a synthetic bone graft substitute made of surgical grade calcium sulfate. OSTEOSET® 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, OSTEOSET® pellets are cleared for use in infected sites, an advantage over tissue-based material. The human body resorbs the OSTEOSET® material at a rate close to the rate that new bone grows. We offer surgeons the option of custom-molding their own beads in the operating room using the OSTEOSET® resorbable bead kit, which is available in mixable powder form. OSTEOSET® 2 DBM graft is a unique bone graft substitute incorporating demineralized bone matrix (DBM) into OSTEOSET® surgical-grade calcium sulfate pellets. These two bone graft materials, each with a long clinical history, provide an ideal combination of osteoinduction via osteoinductive DBM in OSTEOSET® DBM and osteoconduction for guided bone regeneration. Our surgical grade calcium sulfate is manufactured using proprietary processes that consistently produce a high quality product. Our OSTEOSET® T medicated pellets, which contain tobramycin, are currently one of the few resorbable bone void fillers available in international markets for the prevention and treatment of osteomyelitis, an acute or chronic infection of the bone.

ALLOMATRIX® injectable putty combines a high content of DBM with our proprietary surgical grade calcium sulfate carrier. The combination provides an injectable putty with the osteoinductive properties of DBM, as well as exceptional handling qualities. 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.

We have signed a supply agreement with RTI Biologics, Inc., to develop advanced implants for use in foot and ankle surgeries. Under this agreement, we offer our CANCELLO-PURE bone wedge line as well as the ALLOPURE™ allograft bone wedges, which offer surgeons off-the-shelf, sterile grafts with appropriate handling characteristics. The ease of use and time savings in the operating room have made this product line an attractive option to foot and ankle surgeons and expand our offering in this key surgical area of need.

Knee Reconstruction

Our knee reconstruction product portfolio strategically positions us in the areas of partial, total and revision knee reconstruction as well as 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 natural movement and stability, resulting in products that more closely resemble a healthy knee.

The ADVANCE® knee system is our primary knee product line. There are several innovative product offerings within the ADVANCE® knee system, but our flagship is the ADVANCE® medial-pivot knee. Launched eleven years ago, the ADVANCE® medial-pivot knee is the first mass marketed knee designed to replicate modern concepts of anatomic motion. It approximates the movement and stability of a healthy knee by incorporating a patented ball-in-socket feature on its medial side which allows both surgeons and patients to feel the stability. Studies have

shown the ADVANCE® medial-pivot knee more closely approximates natural knee motion.

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To offer better size-specificity for our patients, the ADVANCE® knee system features an expanded number of sizing options called ADVANCE STATURE® components. These components are designed to accommodate those male or female femora with a larger front to back dimension than side to side. This helps ensure that patients will receive the best implant fit possible.

We provide a broad array of surgical knee instrumentation to accommodate surgeon and patient preference. Our ODYSSEY® instrumentation is a modification of traditional total knee instrumentation for use in contemporary less-invasive approaches. Additionally, in 2009 we launched the PROPHECY pre-operative navigation system. The PROPHECY system enables surgeons to utilize basic CT or MRI scan technology to plan precise implant placement and alignment before they enter the operating room. Therefore, surgeons are able to envision the results of surgery before it actually occurs. In contrast to utilizing traditional instruments to align the knee during surgery, the PROPHECY program utilizes computer imaging to develop patient-specific guides that follow the unique curvature of the patient s bone anatomy. These guides allow the surgeon to complete implant placement with accuracy. By promoting accurate alignment, providing optimal sizing and guiding precision implant placement, our new PROPHECY pre-operative navigation system delivers reproducible surgical results for knee arthroplasty. Our goal is not only to improve accuracy and decrease patient anesthesia time, but to allow for greater function and long-term survival of the implants by placing them in a position for optimal mechanical function.

We anticipate launching the ZEN tension-based knee instruments in 2010; these instruments help the surgeon put the medial pivot knee design in natural balance by allowing the patients soft tissues to guide the implant placement. We also expect an increased utilization of our ADVANCE® BIOFOAM cancellous titanium tibial base, as our BIOFOAM tibial base features proprietary bone-like titanium with a roughened texture that bites into bone for cementless fixation of the implant. The combination of the PROPHECY system, our BIOFOAM material and medial pivot motion allows surgeons to potentially reduce their surgery time significantly while increasing accuracy and stability.

Our breakthrough REPIPHYSIS® technology is implanted in children and expands as they grow. 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 technology is in the field of pediatric oncology, where growing children can have their limbs lengthened without the need for additional surgeries.

Hip Reconstruction

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

The CONSERVE® family of products incorporates anatomically-replicating large diameter bearings, led recently by the A-CLASS® advanced metal technology. This proprietary metal-on-metal articulation has undergone extensive laboratory tests which suggest that over the life of the implant, this advanced surface technology will result in significantly less wear than traditional metal-on-metal hip implants. This new innovation is coupled with our BFH® technology, which is designed to reduce rates of post-operative hip dislocation. Most recently we received clearance from the FDA for the CONSERVE® Plus total resurfacing system. This innovative resurfacing design conserves a patient s natural anatomy and allows for a more kinematically correct joint reconstruction.

The PROFEMUR® patented modular neck systems allow surgeons to carefully adjust and implant positioning during surgery. If a surgeon requires a change in leg length, offset or version, the PROFEMUR® hip system conveniently allows these options, as all of these options can be changed after the hip stem is in place. Our principal PROFEMUR® stem offerings, which provide this innovative modularity, include our PROFEMUR® Z, PROFEMUR® Plasma Z, PROFEMUR® LX, PROFEMUR® Tapered, PROFEMUR® RAZ, PROFEMUR® TL, PROFEMUR® X^{m}, and the PROFEMUR® RENAISSANCE® stems. These stems represent the vast majority of popular stem philosophies in the current marketplace.

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Additionally, our hip revision products include the PROFEMUR® Z Revision and PROFEMUR® LX Revision stems which were launched in 2008 and continue to gain traction. A North American distribution agreement with Waldemar Link GmbH for the distribution of the LINK® MP revision stem has also proven to be an important addition to our hip product portfolio.

In 2008, we launched our DYNASTY® acetabular system, which offers surgeons the benefit of our BFH® technology both in metal-on-metal and metal-on-cross-linked polyethylene options, with the added benefit of screw fixation. Screw fixation is sometimes needed in the case of poor bone quality. Recently, we launched our patented BIOFOAM® technology in conjunction with the DYNASTY® system. The BIOFOAM® DYNASTY® acetabular shell allows physicians to address more complex acetabular cases along with simple revision surgeries.

Wright continues to invest in pioneering approaches to tissue sparing hip replacement. The PATH® surgical technique offers patients quicker recovery due to a decrease of intraoperative soft tissue trauma. The decreased soft tissue trauma results in less pain and blood loss for the patient, as well as a lower risk of dislocation.

Product Development

Our research and development staff focuses on developing new products in the extremity hardware, knee and hip 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. In addition, we have clinical and regulatory departments devoted to verifying the safety and efficacy of our products in close collaboration with the FDA and other international regulatory bodies. Our research and development expenses totaled $35.7 million, $33.3 million and $28.4 million in 2009, 2008 and 2007, respectively.

In the extremity hardware areas our research and development activities focus on providing a comprehensive portfolio of surgical solutions to extremity focused surgeons, including procedure and anatomy specific products.

In the hip and knee reconstruction areas, our research and development activities continue to explore and develop advanced bearing and fixation surfaces that improve the clinical performance of reconstructive devices, including ceramic-on-ceramic and low-wear, metal-on-metal surfaces. Further, we provide minimally invasive, tissue sparing techniques that allow patients to quickly return to work and resume their daily activities as well as decreasing the time and cost requirements of the surgical facility.

In the biologics area, we have a variety of research and development projects underway that are designed to further expand our product offerings and provide differentiation of our advanced materials in the marketplace. Such projects include developing new instrumentation, particularly for use with different biomaterials, to facilitate early intervention procedures for a broad array of clinical applications as well as the integration of new biologic products into foot and ankle procedures, soft tissue applications and other demanding orthopaedic uses.

In 2009, we launched several extremity and biologic products. Our new foot and ankle offerings included products such as:

- the CHARLOTTE LisFranc reconstruction system,
- G-FORCE foot and ankle tenodesis system,
- BIOFOAM® Evans foot and ankle wedge system,
- DART-FIRE compression screws,
- ORTHOLOC calcaneal fracture system,
- ORTHOLOC 2.0/2.4 forefoot plate system, and
- the VALOR hindfoot fusion nail.

In addition to the foot and ankle products, in our upper extremities line of products we also launched a second generation MICRONAIL® II distal radius implant.

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Our new biologic offerings include PRO-DENSE® CDK, the ALLOPURE wedge, and the BIOTAPE® XM tissue matrix.

In 2009, we launched the DYNASTY® BIOFOAM cancellous titanium acetabular cup system, which features proprietary bone-like titanium with a roughened texture for cementless fixation of the implant. We also added to our PROFEMUR® hip product line by adding the PROFEMUR® FC Primary stem. Additionally, we expanded our CONSERVE® family of products by offering the CONSERVE® press-fit, which offers an uncemented option of the CONSERVE® Plus femoral component. PROPHECY pre-operative navigational guides for total knee replacement surgery were introduced to provide surgeons with a low-cost, customized, minimally invasive alternative to traditional instrumentation and expensive computer-aided navigation systems.

Manufacturing, Facilities and Quality

We operate a state of the art manufacturing facility in Arlington, Tennessee. At this facility, we primarily produce orthopaedic implants and some related surgical instrumentation while utilizing lean manufacturing philosophies. The majority of our biologic products and surgical instrumentation are produced to our specifications by qualified subcontractors who serve medical device companies. Our present manufacturing facility is adequate for our projected needs in the upcoming years.

We maintain a comprehensive quality system that is certified to the European standards ISO 9001 and ISO 13485 and to the Canadian Medical Devices Assessment System (CMDCAS). We are accredited by the AATB and have registrations with the FDA as a medical device establishment and as a tissue establishment. These certifications and registrations require periodic audits and inspections by various regulatory entities to determine if we have systems in place to ensure our product is safe and effective for its intended use and that we are compliant with applicable regulatory requirements. The quality system exists so that management has the proper oversight, designs are evaluated and tested, production processes are established and maintained and monitoring activities are in place to ensure products are safe, effective and manufactured according to our specifications. Consequently, our quality system provides the way for us to ensure we design and build quality into our products while meeting global requirements. We are committed to meet or exceed customer needs as we improve patient outcomes.

Supply

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, stainless steel, various grades of high density polyethylenes and ceramics. We rely on one source to supply us with a certain grade of cobalt chrome alloy and 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. For certain biologic products, we depend on one supplier of DBM, cancellous bone matrix (CBM) and soft tissue graft for BIOTAPE® XM . We rely on one supplier for our GRAFTJACKET® family of soft tissue repair and graft containment products, and one supplier for our xenograft bone wedge product. We maintain adequate stock from these suppliers to meet market demand.

Sales and Marketing

Our sales and marketing efforts are focused primarily on orthopaedic and podiatric surgeons, who typically are the primary decision-makers in orthopaedic device purchases. We have established relationships with surgeons, who we believe are leaders in their chosen orthopaedic specialties. These surgeons help us design products to solve some of the most challenging problems facing orthopaedic surgeons today. They also help us train other surgeons in the safe and effective use of our products and help other surgeons perfect new surgical techniques.

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 products using our surgeon advisors in an instructional capacity. Additionally, approximately 16,000 practicing orthopaedic surgeons in the U.S. receive information on our latest products through our distribution network, our website and brochure mailings.

We sell our products in the U.S. through a sales force of approximately 400 people as of December 31, 2009. This sales force primarily consists of independent, commission-based sales representatives and distributors engaged

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principally in the business of supplying orthopaedic products to hospitals in their geographic areas. However, we also directly employ 25% of our sales force through a group of corporate sales representatives in select locations throughout the U.S. Our U.S. field sales force is supported by our Tennessee-based sales and marketing organization. In early 2007, we began an initiative to separate and focus our sales representatives in the U.S. as either large joints and upper extremities specialists or foot and ankle specialists, with biologics being sold by all reps. We now have over 100 focused foot and ankle sales representatives, and we intend to continue to increase this number in the upcoming years.

Our independent distributors, independent sales representatives and direct sales representatives are provided opportunities for product training throughout the year.

We believe our success in every market sector is dependent upon having a robust and compelling product offering, and equally as important, a dedicated, highly trained, focused sales organization to service the customer.

Our products are marketed internationally through a combination of direct sales offices (subsidiaries) in certain key international markets and distributors in other markets. We have subsidiaries in Italy, the United Kingdom, Belgium, Germany, France, the Netherlands, Japan, Canada and Australia that employ direct sales employees and in some cases use independent sales representatives to sell our products in their respective markets. Our products are sold in other countries in Europe, Asia, Africa and Latin America using stocking distribution partners. 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, 2009, through a combination of our direct sales offices and approximately 75 stocking distribution partners, we have approximately 700 international sales representatives that sell our products in approximately 60 countries.

Seasonal Nature of Business

We traditionally experience lower sales volumes in the third quarter than throughout the rest of the year as many of our products are used in elective procedures, which generally decline during the summer months, typically resulting in selling, general and administrative expenses and research and development expenses as a percentage of sales that are higher during this period than throughout the rest of the year. 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 (AAOS). 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 three-day event, we display our most recent and innovative products for these surgeons.

Competition

Competition in the orthopaedic device industry is intense and is characterized by extensive research efforts and rapid technological progress. Competitors include major companies in 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 and stronger name recognition than we do within the total joint reconstruction area. Our ability to compete is affected by our ability to:

- develop new products and innovative technologies;
- obtain regulatory clearance and reimbursement for our products;
- manufacture and sell our products cost-effectively;
- meet all relevant quality standards for our products and their markets;

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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 focused sales representatives; and
maintain and establish distribution relationships.

Intellectual Property

We currently own or have licenses to use more than 250 patents and pending patent applications throughout the world. We seek to aggressively protect technology, inventions and improvements that we consider important through the use of patents and trade secrets in the U.S. and significant foreign markets. We manufacture and market products both under patents and license agreements with other parties. These patents have a defined life and expire from time to time.

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 and/or cease production, marketing and distribution of those products. Litigation may also be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. We are currently involved in an intellectual property lawsuit with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation. See Legal Proceedings for an additional discussion of this lawsuit.

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

Third-Party Reimbursement

In the 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 coverage does not exist among all of these payors relative to payment of claims. Therefore, coverage can be quite different from payor to payor as well as from one region of the country to another. We believe that reimbursement is an important factor in the success of any medical device. Consequently, we seek coverage for all of our products.

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Reimbursement in the U.S. depends, in part, upon our ability to obtain FDA clearances and approvals to market our products. Coverage also depends on our ability to demonstrate the short-term and long-term clinical evidence and cost-effectiveness of our products. These supportive data are obtained from both our clinical experience and formal clinical trials. We pursue and 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 coverage programs, whether government funded or insured commercially, are developing increasingly sophisticated methods of controlling healthcare costs through yet to be defined healthcare reform measures, government-managed healthcare systems, coverage with evidence development processes, quality initiatives, pay-for-performance, Comparative Effectiveness Research and capitation programs, group purchasing, redesign of benefit offerings, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering care. All of these types of programs can potentially impact pricing structures and, subsequently, the coverage for all medical devices and associated services.

Employees

As of December 31, 2009, we employed approximately 1,320 people in the following areas: 500 in manufacturing, 490 in sales and marketing, 170 in administration and 160 in research and development. We believe that we have an excellent relationship with our employees.

Environmental

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

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

Available Information

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

Item 1A. Risk Factors.

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

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

The production and marketing of our products and our ongoing research and development, pre-clinical 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

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products will be approved. Our failure to comply with applicable regulatory requirements could result in these governmental authorities:

- imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- recalling or seizing our products; or
- withdrawing or denying approvals or clearances for our products.

Even if regulatory approval or clearance of a product is granted, this could result in limitations on the uses for which the product may be labeled and promoted. Further, for a marketed product, its manufacturer and manufacturing facilities are subject to periodic review and inspection. Subsequent discovery of problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market or other enforcement actions. Our products can only be marketed in accordance with their FDA approved labeling. If we were to promote the use of our products in an off-label manner, we would be subject to civil and criminal sanctions.

In April 2009, the FDA issued an order requiring the manufacturers of approximately 25 Class III devices to submit to the FDA a summary of any information known or otherwise available to them concerning the safety and efficacy of the products. Metal-on-metal hip products, including ours, are included in this product code. Class III devices generally require submission and approval of a premarket approval (PMA) application prior to marketing. The FDA has historically allowed the devices in this product code to be marketed without the requirement of a PMA application, as they were marketed before May 28, 1976, or are substantially equivalent to devices that were marketed before May 28, 1976 or approved under a premarket notification 510(k) since May 28, 1976, when the Medical Device Amendments of 1976 were enacted, and Congress included transition provisions designed to preserve availability of then-marketed Class III devices pending FDA approval of PMA applications. The FDA will determine, for each device in this order, whether the classification of the device should (a) remain as Class III and require submission of a PMA or a notice of completion of a Product Development Protocol, or (b) be reclassified as Class I or II. We cannot predict the outcome of the FDA s review of these products; however, if we are required to submit a PMA application for our metal-on-metal hip products, we may be unable to continue to market these products until the FDA approves the PMA application.

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

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

In order to market our devices in the member countries of the European Union, we are required to comply with the European 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 European Medical Devices Directive, all medical devices including active implants must qualify for CE marking.

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We are involved in government investigations, the results of which may adversely impact our business and results of operations, and lead to other government investigations or actions by other third parties.

In December 2007, we received a subpoena from the U.S. Attorney s Office for the District of New Jersey requesting documents for the period January 1998 through the present related to any consulting and professional service agreements with orthopaedic surgeons in connection with U.S. hip or knee joint replacement procedures or products. We have cooperated and intend to continue to fully cooperate with the U.S. Department of Justice (DOJ) in this investigation. In June 2008, our principal operating subsidiary, Wright Medical Technology, Inc., received letters from the SEC and the DOJ informing us that they are conducting an informal investigation regarding potential violations of the Foreign Corrupt Practices Act (FCPA) in the sale of medical devices in a number of foreign countries by companies in the medical device industry. We understand that several other medical device companies received similar letters. We have cooperated and intend to continue to fully cooperate with this informal investigation.

The results of these inquiries may not be known for some time. If we are found to have violated one or more applicable laws as a result of these investigations or we otherwise must resolve the matters, our business, financial condition and results of operations could be materially adversely affected and we may be required to significantly change some of our existing business practices. These pending investigations could lead to investigations by state authorities or other government agencies. Other companies facing similar investigations have been subject to shareholder derivative actions. In addition, these types of inquiries could increase our exposure to lawsuits by potential whistle blowers under the federal false claims acts. We intend to review and take appropriate actions with respect to any such investigations or proceedings; however, we cannot assure that the costs of investigating, defending, or resolving those investigations or proceedings would not have a material adverse effect on our results of operations, financial condition and cash flow.

Cooperating with these inquiries requires considerable time and significant expense. During 2009 and 2008, we incurred $7.8 million and $7.6 million of expenses, respectively, associated with these U.S. government inquiries, primarily related to legal fees. We anticipate that future expenses related to these inquires may continue to be significant. In addition, upon the conclusion of these inquiries, we may incur significant expenses associated with compliance and monitoring.

In 2007, as a result of a two-year government investigation regarding potential financial inducements paid to orthopaedic surgeons, five of our competitors entered into deferred prosecution or non-prosecution agreements with the DOJ, and four of those companies entered into settlement agreements with the U.S. Department of Health and Human Services, Office of the Inspector General. If we were to incur fines or enter into financial settlements, it is possible that they could have a material adverse effect to our results of operations, financial condition and cash flow.

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.

We obtain premarket clearance under Section 510(k) of the FDC Act for products we market in the U.S. We have modified some of our products and product labeling since obtaining 510(k) clearance, but we do not believe these modifications require us to submit new 510(k) notifications. However, if the FDA disagrees with us and requires us to submit a new 510(k) notification for modifications to our existing products, we may be the subject of enforcement actions by the FDA and be required to stop marketing the products while the FDA reviews the 510(k) modification. 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 clinical data to be submitted for 510(k) clearance more regularly or may 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.

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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, and ceramics. We rely on one source to supply us with a certain grade of cobalt chrome alloy and one supplier for the silicone elastomer used in some of 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.

Further, we rely on one supplier for our GRAFTJACKET® family of soft tissue repair and graft containment products. To remain an exclusive distributor of this material, we must achieve minimum two-year compound annual growth rates. If we fall below the required minimum growth rate, we have an option to preserve our exclusivity by making an additional cash payment for the royalty shortfall; however this payment would have an unfavorable impact on the product s cost of sales. In 2009, we did not meet the minimum, and we intend to pay approximately $650,000 to maintain exclusivity. No assurances can be made that we will maintain the required minimum growth rates in future years.

In addition, certain biologic products depend upon a single supplier as our source for DBM and CBM, and any failure to obtain DBM and CBM from this source in a timely manner will deplete levels of on-hand raw materials inventory and could interfere with our ability to process and distribute allograft products. During 2010, we are expecting a single not-for-profit tissue bank to meet all of our DBM and CBM order requirements, a key component in the allograft products we currently produce, market and distribute. In addition, we rely on a single supplier of soft tissue graft for BIOTAPE® XM.

We cannot be sure that our supply of DBM, CBM and soft tissue graft for BIOTAPE® XM will continue to be available at current levels or will be sufficient to meet our needs, or that future suppliers of DBM, CBM and soft tissue graft for BIOTAPE® XM will be free from FDA regulatory action impacting their sale of DBM, CBM and soft tissue graft for BIOTAPE® XM. As there is a small number of suppliers, if we cannot continue to obtain DBM, CBM and soft tissue graft for BIOTAPE® XM from our current sources in volumes sufficient to meet our needs, we may not be able to locate replacement sources of DBM, CBM and soft tissue graft for BIOTAPE® XM on commercially reasonable terms, if at all. This could have the effect of interrupting our business, which could adversely affect our sales.

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 market clearance is not obtained for enhancements to the CONSERVE® Plus implant in the U.S., growth of our hip product line could be impacted.

In November 2009, we received approval from the FDA to market our original CONSERVE® Plus total hip resurfacing system, which enables us to initiate efforts to introduce additional enhancements to the system which are currently available outside the U.S. We intend to incorporate these future product options into the system s femoral and component offerings via a PMA Supplement. There can be no assurance that these enhancements will be cleared by the FDA in a timely manner if at all, which could have a significant impact on the future growth of our hip product line.

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, European Union and Health Canada have been working to establish more comprehensive regulatory frameworks for allograft-based, tissue-containing products, which are principally derived from cadaveric tissue. The framework developed by the FDA establishes risk-based criteria for determining whether a particular human tissue-based product will be

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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 establishment registration requirements, product listing requirements, good tissue practice requirements for manufacturing and screening requirements that ensure that diseases are not transmitted to tissue recipients. The FDA has also proposed extensive additional requirements that address sub-contracted tissue services, traceability to the recipient/patient and donor records review. If a tissue-based product is considered human tissue, the FDA requirements focus on preventing the introduction, transmission and spread of communicable diseases to recipients. Clinical data or review of safety and efficacy are not required before the tissue can be marketed. However, if it is considered a medical device or biologic drug, then FDA clearance or approval is required.

Additionally, our biologics business involves the procurement and transplantation of allograft tissue, which is subject to federal regulation under the National Organ Transplant Act (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.

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.

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 eight direct sales offices and approximately 75 stocking distribution partners, which combined employ approximately 700 sales representatives who sell in approximately 60 countries. Most of these countries are, to some degree, subject to political, social and economic instability. For the years ended December 31, 2009, 2008 and 2007, 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 biologic products;
- new export license requirements, particularly related to our biologic 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 biologic products;

work stoppages or strikes in the healthcare industry, such as those that have affected our operations in France, Canada, Korea and Finland in the past;

a shortage of nurses in some of our target markets; and

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exposure to different legal and political standards due to our conducting business in approximately 60 countries. As a U.S. based company doing business in foreign jurisdictions, not only are we subject to the laws of other jurisdictions, we are also subject to U.S. laws governing our activities in foreign countries, such as the FCPA, as well as various import-export laws, regulations, and embargoes. If our business activities were determined to violate these laws, regulations or rules, we could suffer serious consequences.

Any material decrease in our foreign sales may negatively impact our profitability. Our international sales are predominately generated in Europe. In Europe, healthcare 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.

The collectability of our accounts receivable may be affected by general economic conditions.

Our liquidity is dependent on, among other things, the collection of our accounts receivable. Collections of our receivables may be affected by general economic conditions. Although current economic conditions have not had a material adverse effect on our ability to collect such receivables, we can make no assurances regarding future economic conditions or their effect on our ability to collect our receivables, particularly from our international stocking distributors.

As of December 31, 2009, our accounts receivable balance totaled $101.7 million, and one customer, our stocking distributor in Turkey, accounted for approximately 10% of accounts receivable. As of December 31, 2009 and 2008, the balance due from this customer was $10.7 million, or 10.5% of our accounts receivable balance, and $10.6 million or 10.4% of our accounts receivable balance, respectively, a significant portion of which was past due. As of December 31, 2009, we have recorded a $5.6 million provision for potential losses related to this trade receivable.

Recent turmoil in the credit markets and the financial services industry may negatively impact our business.

Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. and foreign governments. While the ultimate outcome of these events cannot be predicted, they may have an adverse effect on our customers ability to borrow money from their existing lenders or to obtain credit from other sources to purchase our products. In addition, the recent economic crisis could also adversely impact our suppliers ability to provide us with materials and components, either of which may negatively impact our business.

Efforts to enhance our corporate compliance program require the cooperation of many individuals and may divert substantial financial and human resources from our other business activities.

We are committed to enhancing our corporate compliance program. This will require additional financial and human resources. Successful implementation of our enhanced corporate compliance program will require the full and sustained cooperation of our employees, distributors, and sales agents as well as the healthcare professionals with whom they interact. These efforts will not only require increased expenses, but will also require time and attention from management and key employees preventing them from devoting as much time as they might otherwise spend on other business matters.

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. With respect to the acquisitions completed or other future acquisitions, we may also experience:

difficulties in integrating any acquired companies, personnel and products into our existing business;

delays in realizing the benefits of the acquired company or products;

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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, any future acquisitions could materially impair our operating results by causing us to incur debt or requiring us to amortize acquired assets.

Recent restructuring efforts could adversely affect our operations and financial results.

In June 2007, we announced plans to close our manufacturing, distribution and administrative facility located in Toulon, France. The facility s closure affected approximately 130 Toulon-based employees. The majority of our restructuring activities were complete by the end of 2007, with Toulon s production being transferred to our existing manufacturing facility in Arlington, Tennessee and its distribution activities being transferred to our European headquarters in Amsterdam, the Netherlands.

In October 2009, we announced our plans to close our distribution and finance support office in Creteil, France, to migrate all relevant French distribution and support functions into our European organization based out of our European headquarters in Amsterdam. The majority of our restructuring activities were complete by the end of 2009, with Creteil s distribution and support functions being transferred to our European headquarters in Amsterdam, the Netherlands.

With respect to the restructuring activities in process, we may experience:

higher costs of restructuring than we anticipated;

difficulties in completing all restructuring activities within the budgeted time; or

diversion of our management s time and attention from other business concerns.

In connection with the closure of our Toulon, France facility, 103 of our former employees have filed claims to challenge the economic justification for their dismissal. To date, we have received judgments for 86 of those claims, the substantial majority of which were unfavorable to us. All of these judgments have been appealed, or are expected to be appealed, by both parties. Management has estimated the probable liability upon the ultimate resolution of these 103 claims to be $4.6 million, and has therefore recorded this amount as a liability within Accrued expenses and other current liabilities in our consolidated balance sheet as of December 31, 2009.

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 completely 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.

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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. In 2009, we received a favorable ruling from the district court ruling that Howmedica s asserted patent is invalid. However, Howmedica has the right to appeal the decision to the United States Court of Appeals for the Federal Circuit. The judge has determined to also rule on our defense regarding patent unenforceability before Howmedica will be allowed to appeal. 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, pay ongoing royalties, redesign our products, or prevent us from manufacturing, using or selling our products. In addition to being costly, protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

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

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

One of our insurers has reserved the right to recover from us up to approximately $10.5 million paid by the insurer for the settlements of 33 product liability lawsuits in West Virginia during 2009. We believe that an ultimate unfavorable resolution of this matter is not probable; therefore, no provision has been made for any claim by our insurer as of the date of this report.

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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Our inability to maintain adequate working relationships with healthcare professionals could have a negative impact on the Company s future operating results.

We maintain close working relationships with respected physicians and medical personnel in hospitals and universities who assist in product research and development. We continue to place emphasis on the development of proprietary products and product improvements to complement and expand our existing product lines. If we are unable to maintain these relationships, our ability to develop and market new and improved products could decrease, and future operating results could be unfavorably affected.

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 allograft products 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., healthcare providers who purchase our products generally rely on third-party payors, principally federally-funded 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 healthcare programs and private health insurers reimbursing patients medical expenses. Surgeons, hospitals and other healthcare 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 healthcare 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. Healthcare 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. Additionally, there is some likelihood of reform of the U.S. healthcare system, and changes in reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for our products may cause our revenues to decline.

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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 healthcare 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.

Our business could be significantly and adversely impacted if certain types of healthcare reform programs are adopted and other legislative proposals are enacted into law.

Recently, President Obama and Congress have proposed significant reforms to the U.S. healthcare system. The Obama administration s fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes.

On November 7, 2009, the U.S. House of Representatives passed its healthcare reform bill, the Affordable Health Choices Act, H.R. 3962. Among other initiatives, this bill authorizes the creation of a national public plan that would negotiate rates with providers and would be offered through a new national health insurance exchange market, and imposes a 2.5% deductible excise tax on domestic sales of certain medical devices following December 31, 2012, which is estimated to contribute approximately $20 billion to healthcare reform over a period of 10 years.

On December 24, 2009, the U.S. Senate passed its own version of a healthcare reform bill, the Patient Protection and Affordable Health Care Act, H.R. 3590. The Senate bill contains no provision for a national public plan but does authorize the creation of at least two multi-state plans to be offered on a new national health insurance exchange market and also authorizes approximately $6 billion to fund a Consumer Operated and Oriented Plan to support the creation of non-profit, member-run health insurance companies that would be offered through the exchange. The Senate bill also includes a $2 billion annual non-deductible excise tax on medical device manufacturers and importers, which applies to any domestic sales of certain medical devices after December 31, 2009, rising to a $3 billion annual excise tax after 2017.

It remains unclear how or when the differences between the two bills will be resolved, or if a final bill ultimately will be enacted. Various healthcare reform proposals have also emerged at the state level. We cannot predict with certainty which healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes, significantly increase our cost of doing business, and adversely affect our business and results of operations, possibly materially. In addition, if the excise tax contained in the proposed legislation from either the House or Senate bills is enacted into law, and we are unable to increase the selling prices of our products to mitigate its impact, our effective tax rate and results of operations would be materially and adversely affected.

There is an increasing trend for more criminal prosecutions and compliance enforcement activities for noncompliance with the Health Insurance Portability and Accountability Act (HIPAA) as well as for data breaches involving protected health information (PHI). In the ordinary course of our business, we may receive PHI. If we are unable to comply with HIPAA or experience a data breach involving PHI, we could be subject to criminal and civil sanctions.

Several states have enacted or are considering enacting legislation that limit the types of interactions we can have with Health Care Professionals (HCPs). These state laws may inhibit our ability to train HCPs on the safe and effective use of our products as well as make it more difficult to work with HCPs on developing new products. This could have a negative impact on our business.

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

For us to sell our products, surgeons must prescribe 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

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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.

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 sales distributors in the past, which adversely affected short-term financial results while we transitioned to new independent sales 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.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors and officers liability insurance, property insurance and workers compensation insurance. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted. Likewise, if the availability of any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers.

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

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

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

We rely on a single manufacturing facility in Arlington, Tennessee. The Arlington facility 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 facility may be affected by natural or man-made disasters. In the event our facility is affected by a disaster, we would be forced to rely on third-party manufacturers. Although we believe we have adequate disaster recovery plans in place and we possess adequate insurance for damage to our property and the disruption of our business from casualties, such plans and insurance may not cover such disasters and 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.

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Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings. Because 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. Approximately 28% of our total net sales were denominated in foreign currencies during the years ended December 31, 2009, 2008 and 2007, and we expect that foreign currencies will continue to represent a similarly significant percentage of our net sales in the future. Our international net sales were unfavorably impacted by the impact of foreign currency fluctuations of approximately $3.0 million in 2009, compared to the favorable impact of $7.9 million and $6.1 million in 2008 and 2007, respectively. Operating costs related to these sales are largely denominated in the same respective currencies, thereby partially limiting our transaction risk exposure. However, cost of sales related to these sales are primarily denominated in U.S. dollars; therefore, as the U.S. dollar strengthens, the gross margin associated with our sales denominated in foreign currencies experience declines.

We currently employ a derivative program using 30-day foreign currency forward contracts to mitigate the risk of currency fluctuations on our intercompany receivable and payable balances that are denominated in foreign currencies. These forward contracts are expected to offset the transactional gains and losses on the related intercompany balances. These forward contracts are not designated as hedging instruments under Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Section 815, *Derivatives and Hedging Activities.* Accordingly, the changes in the fair value and the settlement of the contracts are recognized in the period incurred. We have not historically entered into hedging activities to mitigate the risk of foreign currency fluctuations in our statement of operations.

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;
- prevailing interest rates on our excess cash investments;
- fluctuations in foreign currency rates;
- the timing of significant orders and shipments;

availability of raw materials;

work stoppages or strikes in the healthcare industry;

changes in FDA and foreign governmental regulatory policies, requirements and enforcement practices;

changes in accounting policies, estimates and treatments;

restructuring charges, costs associated with our U.S. governmental inquiries and other charges;

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variations in cost of sales due to the amount and timing of excess and obsolete inventory charges, commodity prices and manufacturing variances;

income tax fluctuations; and

general economic factors.

We believe our quarterly sales and operating results may vary significantly in the future and 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.

Conversion of our convertible senior notes into common stock could result in dilution to our stockholders.

Our convertible senior notes due 2014, with a face amount of $200 million, are convertible at the option of the holder, subject to certain conditions, into shares of our common stock at an initial conversion rate of 30.6279 shares per $1,000 principal amount of the notes, which represents a conversion price of approximately $32.65 per share, subject to adjustment, at any time before close of business on the business day preceding December 1, 2014, the maturity date of the notes. Beginning December 6, 2011, we may redeem the notes for cash, in whole or in part, at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus any accrued and unpaid interest, if the closing sales price of our common stock has exceeded 140% of the conversion price for at least 20 trading days in any 30-day trading period. In addition, if we experience a fundamental change event, as defined in the note agreement, we may be required to purchase for cash all or a portion of the notes, at a price equal to 100% of the principal amount of the notes plus any unpaid and accrued interest. Additionally, if upon a fundamental change event a holder elects to convert its notes, we may, under certain circumstances, increase the conversion rate for the notes surrendered. All of the above rights are subject to certain limitations imposed by our credit facility. Any issuance of shares as a result of the conversion of the notes would result in dilution to our stockholders.

We may be prohibited from paying the convertible senior notes when they are due or be unable to raise the funds necessary to repay the notes when due or finance a fundamental change purchase.

At maturity, the entire outstanding principal amount, which is currently $200 million, of our convertible senior notes due 2014 will become due and payable. In addition, upon the occurrence of a fundamental change event, holders of notes may require us to purchase their notes. A fundamental change event includes (1) a change in ownership, (2) a consummation of a recapitalization, reclassification, or change of common stock, share exchange or a consolidation or merger, (3) the first day the majority of our board of directors does not consist of continuing directors, (4) stockholder approval of any plan or proposal for liquidation of Wright, or (5) when our common stock ceases to be listed on the national securities exchange in the United States, except as a result of a merger, tender offer or exchange offer for our common stock. Additionally, the principal amount of our convertible notes will become due upon an uncured or unwaived default in our senior credit facility. However, we may not have sufficient funds to repay the notes at maturity or to make the required purchase of the notes.

In addition, our ability to pay the notes at maturity or to purchase the notes upon a fundamental change event may be limited by the terms of other agreements relating to our debt outstanding at the time, including our revolving credit facility, which limits our ability to purchase the notes for cash in certain circumstances. Our revolving credit facility prohibits us from making any cash payments for the purchase of the notes upon the occurrence of a fundamental change event, and hence we may not be able to purchase the notes for cash upon the occurrence of a fundamental change event unless the revolving credit facility is amended to eliminate these restrictions or is no longer outstanding at the time of such required payment. Any of our future debt agreements may contain similar restrictions. Our failure to purchase tendered notes at a time when the purchase is required by the indenture would constitute a default under the indenture, which in turn would constitute an event of default under our revolving credit facility or under the other future agreements governing our indebtedness at such time. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness or purchase the notes.

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Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters and U.S. operations consist of a manufacturing facility, a warehouse, and an administration building with research and development facilities located on more than 50 acres in Arlington, Tennessee. We lease the manufacturing facility from the Industrial Development Board of the Town of Arlington (IDB) under a lease agreement that 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 also own a small facility in Arlington used for pre-production engineering and general production. We lease the warehouse from the IDB under a lease agreement that has no predetermined expiration date. We may exercise an option to purchase the warehouse from the IDB at a nominal price at any time during the lease term. We lease a portion of the administration building from the IDB under a lease agreement that expires on July 8, 2011. We may exercise an option to purchase the leased portion of the administration building from the IDB at a price of $101,000, which we have prepaid, at any time during the lease term. We own another portion of the administrative building that was built in 2004.

During 2009, we purchased a building to address our future warehousing and customer service space requirements. This property was subsequently placed into a lease agreement with the Arlington IDB. The lease agreement expires in 2020, and we can purchase the property at any time for $1,000. This building is being renovated to meet our requirements and will be occupied in 2010.

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

Item 3. Legal Proceedings.

From time to time, we are subject to lawsuits and claims that 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.

In 2000, Howmedica Osteonics Corp. (Howmedica), a subsidiary of Stryker Corporation, filed a lawsuit against us in the United States District Court for the District of New Jersey (District Court) alleging that we infringed Howmedica s U.S. Patent No. 5,824,100 related to our ADVANCE® knee product line. The lawsuit seeks an order of infringement, injunctive relief, unspecified damages and various other costs and relief and could impact a substantial portion of our knee product line. We believe, however, that we have strong defenses against Howmedica s claims and are vigorously defending this lawsuit. In November 2005, the District Court issued a Markman ruling on claim construction. Howmedica conceded to the District Court that, if the claim construction as issued was applied to our knee product line, our products do not infringe their patent. Howmedica appealed the Markman ruling. In September 2008, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) overturned the District Court s Markman ruling on claim construction. The case was remanded to the District Court for further proceedings on alleged infringement and on our affirmative defenses, which include patent invalidity and unenforceability. In 2009, we received a favorable ruling from the District Court ruling that Howmedica s asserted patent is invalid. However, Howmedica has the right to appeal the decision to the Federal Circuit. The judge has determined to also rule on our defense regarding patent unenforceability before Howmedica will be allowed to appeal. No provision has been made for this contingency as of December 31, 2009. These claims are covered in part by our patent infringement insurance. Management does not believe that the outcome of this lawsuit will have a material adverse effect on our consolidated financial position or results of operations.

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In late 2004 and early 2005, approximately 120 plaintiffs sued Dr. John King in the Circuit Court of Putnam County, West Virginia. Plaintiffs alleged that Dr. King was professionally negligent when he performed surgery on the plaintiffs at Putnam General Hospital in Putnam County, West Virginia between November 2002 and June 2003. In 33 of the lawsuits, plaintiffs alleged that Dr. King inappropriately used a biologic product sold by us. In these lawsuits, plaintiffs named us as a defendant and alleged that our products had not been properly cleared by the United States Food and Drug Administration, that we failed to warn that our products were not safe for their intended use, and that we knew that Dr. King was not properly trained or was performing the surgeries inappropriately. Plaintiffs also alleged that we and two other co-defendants entered into a joint venture with Dr. King and/or his physician assistant, David McNair, such that we could be held liable for his/their conduct. Plaintiffs further asserted claims based on strict liability, express and implied breach of warranty, civil conspiracy, and negligence. They sought damages related to alleged lost income, medical expenses, future medical and life care expenses, damages relating to pain and suffering, and punitive and other damages. During 2009, we settled these 33 lawsuits pending against us, all of which were funded by our insurance carriers.

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

None.

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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 Global Select Market under the symbol WMGI. The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported on the Nasdaq Global Select Market.

	High	Low
Fiscal Year 2008		
First Quarter	$29.98	$21.06
Second Quarter	$31.49	$23.53
Third Quarter	$33.26	$28.00
Fourth Quarter	$30.71	$15.18
Fiscal Year 2009		
First Quarter	$22.35	$11.17
Second Quarter	$16.97	$12.03
Third Quarter	$18.38	$13.37
Fourth Quarter	$19.40	$15.32

Holders

As of February 2, 2010, there were 689 stockholders of record and an estimated 11,404 beneficial owners of our common stock.

Dividend Policy

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

Equity Compensation Plan Information

The table below sets forth information regarding the number of securities to be issued upon the exercise of the outstanding stock options granted under our equity compensation plans and the shares of common stock remaining available for future issuance under our equity compensation plans as of December 31, 2009 (in thousands):

Plan Category	Number of securities to be issued upon exercise of outstanding options (in thousands)	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (in thousands)
Equity compensation plans approved by security holders	3,965	$ 23.79	1,122

Equity compensation plans not approved by security holders				
Total	3,965	$	23.79	1,122

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Comparison of Total Stockholder Returns

The graph below compares the cumulative total stockholder returns for the period from December 31, 2004 to December 31, 2009, for our common stock, an index composed of U.S. companies whose stock is listed on the Nasdaq Global Select Market (the Nasdaq U.S. Companies Index), and an index consisting of Nasdaq-listed companies in the surgical, medical, and dental instruments and supplies industry (the Nasdaq Medical Equipment Companies Index). The graph assumes that $100.00 was invested on December 31, 2004, in our common stock, the Nasdaq U.S. Companies Index, and the Nasdaq Medical Equipment Companies Index, and that all dividends were reinvested. Total returns for the two Nasdaq indices are weighted based on the market capitalization of the companies included therein. Historic stock price performance is not indicative of future stock price performance. We do not make or endorse any prediction as to future stock price performance.

Cumulative Total Stockholder Returns
Based on Reinvestment of $100.00 Beginning on December 31, 2004

	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009
Wright Medical Group, Inc.	$100.00	$ 71.58	$ 81.67	$102.33	$71.68	$ 66.46
Nasdaq U.S. Companies Index	100.00	102.13	112.18	121.67	58.64	79.70
Nasdaq Medical Equipment Companies Index	100.00	109.81	115.73	147.16	79.25	108.49

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Item 6. Selected Financial Data.

The following tables set forth certain of our selected consolidated financial data as of the dates and for the years indicated. The selected consolidated financial data was derived from our consolidated financial statements audited by KPMG LLP. The audited consolidated financial statements as of December 31, 2009, 2008, and 2007, and for the years then ended, are included elsewhere in this annual report. The audited consolidated financial statements as of December 31, 2006 and 2005, and for the years then ended, are not included in this filing. Historical results are not necessarily indicative of the results to be expected for any future period. These tables are presented in thousands, except per share data.

	Year Ended December 31,				
	2009	**2008**	**2007**	**2006**	**2005**
Statement of Operations:					
Net sales	$ 487,508	$ 465,547	$ 386,850	$ 338,938	$ 319,137
Cost of sales [1]	148,715	134,377	108,407	97,234	91,752
Cost of sales restructuring [2]			2,139		
Gross profit	338,793	331,170	276,304	241,704	227,385
Operating expenses:					
Selling, general and administrative [1]	270,456	261,396	225,929	192,573	167,365
Research and development [1]	35,691	33,292	28,405	25,551	22,289
Amortization of intangible assets	5,151	4,874	3,782	4,149	4,250
Restructuring charges [2]	3,544	6,705	16,734		
Acquired in-process research and development costs [3]		2,490			
Total operating expenses	314,842	308,757	274,850	222,273	193,904
Operating income	23,951	22,413	1,454	19,431	33,481
Interest expense (income), net	5,466	2,181	(1,252)	(1,127)	(176)
Other expense(income), net [4]	2,873	(1,338)	375	(1,643)	237
Income before income taxes	15,612	21,570	2,331	22,201	33,420
Provision for income taxes [7]	3,481	18,373	1,370	7,790	12,355
Net income	$ 12,131	$ 3,197	$ 961	$ 14,411	$ 21,065
Net income per share:					
Basic	$ 0.32	$ 0.09	$ 0.03	$ 0.42	$ 0.62
Diluted	$ 0.32	$ 0.09	$ 0.03	$ 0.41	$ 0.60
Weighted-average number of common shares outstanding basic	37,366	36,933	35,812	34,434	33,959
Weighted-average number of common shares outstanding diluted	37,443	37,401	36,483	35,439	35,199

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	As of December 31,				
	2009	2008	2007	2006	2005
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 84,409	$ 87,865	$229,026	$ 57,939	$ 51,277
Marketable securities	86,819	57,614	15,535	30,325	25,000
Working capital	421,647	401,406	417,817	220,306	196,126
Total assets	714,284	692,130	669,985	409,402	371,810
Long-term liabilities	204,919	205,253	207,820	14,162	15,547
Stockholders equity	440,408	411,628	388,781	335,824	292,008

	Year Ended December 31,				
	2009	2008	2007	2006	2005
Other Data:					
Cash flow provided by (used in) operating activities	$ 71,751	$ (3,610)	$ 24,424	$ 29,975	$ 5,291
Cash flow used in investing activities	(74,956)	(148,942)	(63,841)	(28,349)	(31,583)
Cash flow provided by (used in) financing activities	532	12,406	209,897	4,646	(5,379)
Depreciation	32,717	26,462	23,522	21,361	17,895
Stock-based compensation expense [(5)]	13,191	13,501	16,532	13,840	467
Capital expenditures[(6)]	37,190	61,936	35,042	29,643	30,356

(1) These line items include the following amounts of non-cash, stock-based compensation expense for the periods indicated: