

Symmetry Medical Inc.  
Form 10-K  
February 27, 2006

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2005

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number 333-116038

**SYMMETRY MEDICAL INC.**

(Exact name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**35-1996126**  
(I.R.S. Employer  
Identification No.)

**220 W. Market Street, Warsaw, Indiana**  
(Address of Principal Executive Offices)

**46580**  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (574) 268-2252

Securities Registered Pursuant to Section 12(b) of the Act:

**Title of Each Class**  
Common Stock, \$0.0001 par value

**Name of Exchange on Which Registered**  
New York Stock Exchange

Securities Registered Pursuant to Section 12(g) of the Act:

None  
(Title of Class)

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

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

## Edgar Filing: Symmetry Medical Inc. - Form 10-K

**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. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check One)

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The aggregate market value of voting stock of Symmetry Medical Inc. held by non-affiliates as of the Registrant as of July 2, 2005, based on the closing price of was \$23.68, as reported on the New York Stock Exchange: Approximately \$320,193,667.

The number of shares outstanding of the registrant's common stock as of February 17, 2006, was 34,709,074.

### DOCUMENTS INCORPORATED BY REFERENCE

Certain information is incorporated into Part III of this report by reference to the Registrant's 2006 Proxy Statement to be filed with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year covered by this Form 10-K.

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**Special Note Regarding Forward-Looking Statements**

Throughout this report, or in other reports or registration statements filed from time to time with the Securities and Exchange Commission under the Securities Exchange Act of 1934, or under the Securities Act of 1933, as well as in documents we incorporate by reference or in press releases or oral statements made by our officers or representatives, we may make statements that express our opinions, expectations, or projections regarding future events or future results, in contrast with statements that reflect historical facts. These predictive statements, which we generally precede or accompany by such typical conditional words such as anticipate, intend, believe, estimate, plan, seek, project or by the words may, will, or should, are intended to operate as forward looking statements of the kind permitted by the Private Securities Litigation Reform Act of 1995, incorporated in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. That legislation protects such predictive statements by creating a safe harbor from liability in the event that a particular prediction does not turn out as anticipated.

While we always intend to express our best judgment when we make statements about what we believe will occur in the future, and although we base these statements on assumptions that we believe to be reasonable when made, these forward-looking statements are not a guarantee of performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many uncertainties and other variable circumstances, many of which are outside of our control, that could cause our actual results and experience to differ materially from those we thought would occur.

We also refer you to and believe that you should carefully read the portion of this report described in Risk Factors to better understand the risks and uncertainties that are inherent in our business and in owning our securities.

Any forward looking statements which we make in this report or in any of the documents that are incorporated by reference herein speak only as of the date of such statement, and we undertake no ongoing obligation to update such statements. Comparisons of results between current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

**PART I**

**ITEM 1. BUSINESS**

**General**

Symmetry Medical Inc. (which we sometimes refer to, together with our consolidated subsidiaries, as the we , our or Symmetry ) is the world s largest independent provider of implants and related instruments and cases to orthopedic device manufacturers. We design, develop and produce these products for companies in other segments of the medical device market, including the dental, osteobiologic and endoscopy segments, and we also provide limited specialized products and services to non-healthcare markets, such as the aerospace market. Our Total Solutions® approach presents our customers with a broad range of products, as well as comprehensive design, engineering and project management services and state of the art production capabilities to help them bring their implant systems to market quickly and efficiently. We believe that our Total Solutions® approach gives us a competitive advantage, which should increase in the future.

During fiscal year 2005, we generated revenue of \$263.8 million, derived primarily from the sale of products and services to the orthopedic device market. Our Total Solutions® approach is supported by an experienced team of designers, development engineers, logistics specialists and by our global sales force that work with our customers to coordinate all of our products and services.

Our primary products and services include:

- implants, including forged, cast and machined products for the global orthopedic device market;
- instruments used in the placement and removal of orthopedic implants and in other surgical procedures;
- cases, including plastic, metal and hybrid cases used to organize, secure and transport medical devices for orthopedic and other surgical procedures; and
- other specialized products and services for non-healthcare markets, primarily the aerospace market.

**History**

Our business was established in 1976 as a supplier of instruments to orthopedic device manufacturers. Symmetry Medical Inc. was incorporated in Delaware on July 25, 1996. During the 1990 s we made several acquisitions, which expanded our customer base, enhanced our instrument product offerings and extended our product line to include cases designed for various medical devices and their related instruments. In October 2000, investment funds controlled by Olympus Partners (which we sometimes refer to as the Olympus Funds ) acquired control of Symmetry through a recapitalization. In this transaction, the Olympus Funds invested a total of \$40.5 million in cash to acquire securities representing approximately 94% of our then outstanding voting stock. In June 2003, we acquired Mettis (UK) Limited (which we sometimes refer to, together with our consolidated subsidiaries, as Mettis ), a leading manufacturer of forged, cast and machined implants for the global orthopedic device market. This acquisition significantly expanded our product offerings and increased our European presence, allowing us to develop and manufacture implants, instruments and cases for orthopedic device manufacturers on a global basis. In connection with the Mettis acquisition, the Olympus Funds collectively invested an additional \$63.0 million in equity and loaned Symmetry \$8.0 million through the purchase of senior subordinated notes and stock purchase warrants. In December, 2004, we completed an initial public offering of our common stock and entered into a new senior credit facility. In July 2005, we successfully completed a secondary offering which included 11.0 million shares. 0.5 million were sold as primary shares and 10.5 million shares were sold by certain selling shareholders.

### **Our Total Solutions® Approach**

We believe that we have created a distinctive competitive position in the orthopedic device market based upon our Total Solutions® approach. Our acquisition of Mettis in June 2003 expanded our products and services, enabling us to offer an integrated outsourcing solution. Our Total Solutions® approach presents our customers with a broad range of products, as well as comprehensive design, engineering and project management services and state of the art production capabilities to help them bring their implant systems to market quickly and efficiently. Our Total Solutions® offering is based on:

*Comprehensive services.* We can support our customers' new product offerings from product concept through market introduction and thereafter, by providing seamless design, engineering, prototyping and manufacturing services.

*Single source for complete systems.* We assist our customers in developing new implants, and we design and produce instruments for implant-specific surgical procedures. We also provide customized cases that provide a secure, clearly labeled and well organized arrangement of instruments and devices.

*Proprietary Symmetry instruments and cases.* Our established lines of proprietary products allow our customers to complete their proprietary implant systems and bring them to market sooner.

*Precision manufacturing expertise.* Our extensive expertise and know-how enable us to produce large volumes of specialized products to our customers' precise standards, which we believe makes us a supplier of choice to the largest orthopedic companies. Our core production competencies include net shaped forging, precision casting, thermo forming, precision sheet metal working and machining/finishing.

*Quality and regulatory compliance.* Our quality systems are based upon and in compliance with International Organization for Standardization, or ISO, requirements and, where applicable, United States Food and Drug Administration, or FDA, regulations. We believe our level of quality and regulatory compliance systems meet our customers' expectations.

*Global reach.* Our manufacturing capabilities in the United States and Europe allow us to offer single-source products and services to our multinational customers, and the geographic breadth of our experienced sales force effectively brings our Total Solutions® approach to customers globally.

We believe that our Total Solutions® approach offers a number of benefits to our customers, including:

*Shorter time to market.* Our design, engineering and prototyping skills, as well as our ability to transition seamlessly from product development to production of implants, instruments and cases, enable our customers to reduce time to market for their new products.

*Reduced total product acquisition costs.* Our comprehensive services, including design, engineering, prototyping, project management, production and inventory control, allow our customers to reduce their procurement costs and inventory levels, resulting in lower product acquisition costs.

*Increased focus on marketing and research and development efforts.* Our extensive production capabilities and comprehensive services offer a one-stop outsourcing solution and allow our customers to focus their resources on their design, development and marketing efforts.

*Rationalized and reliable supply chain.* Our scale, scope of products and services and Total Solutions® approach allow large orthopedic companies to reduce the number of their independent suppliers and streamline their operations.

*Enhanced product consistency on a global basis.* Our extensive production platform, Total Solutions® approach and international presence allow us to meet global demand for orthopedic devices, which is expected to increase.

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## **Business Strategy**

Our goal is to increase our share of the orthopedic device market and to leverage our strengths to expand in other medical device market segments. The key elements of our business strategy are to:

*Develop strategic relationships with our customers through access to key decision makers.* Our scale, scope of products and services and Total Solutions® approach position us as an important partner to our customers. This position gives us access to key decision makers, with whom we intend to continue to build strategic relationships.

*Capitalize on our Total Solutions® approach.* We believe that our Total Solutions® approach shortens product development cycles, reduces design and manufacturing costs and simplifies purchasing and logistics, and we intend to aggressively market these benefits to our customers.

*Increase sales to existing customers by cross selling products and services.* Our cases are currently sold in nearly every segment of the medical device market. We believe that our diverse customer base offers us a natural entry point to new orthopedic and non-orthopedic customers for our implants and instruments.

*Leverage manufacturing skills.* During fiscal years 2005 and 2004, we expanded most of our facilities and opened new facilities to add manufacturing capacity and design resources, and updated much of our manufacturing and development equipment. We intend to continue to leverage our investments in sophisticated equipment and manufacturing know-how to expand our existing customer relationships and to obtain new customers.

*Increase new product offerings.* Our Design and Development Centers provide expertise and coordination for our design, engineering and prototyping services. We intend to use the dedicated expertise of our Design and Development Centers to generate additional development projects with our customers and to expand our line of innovative and independently developed instruments and cases.

*Collaborate with emerging companies.* We believe that new and innovative medical device companies are creating a meaningful market presence and that our Total Solutions® approach positions us to help these companies, many of which may have limited resources.

## **Products and Services**

We design, develop and manufacture implants and related surgical instruments and cases for orthopedic device companies. We also design, develop and manufacture products for companies in other medical device markets, such as dental, osteobiologic and endoscopy, and we provide limited specialized products and services used in the aerospace and other non-healthcare markets. Our revenue from the sale of implants, instruments, cases and other products and services represented 39.2%, 32.9%, 21.0% and 6.9%, respectively, of our revenue in fiscal 2005, compared with 36.6%, 33.0%, 23.0% and 7.4%, respectively, of our revenue in fiscal 2004.

### ***Implants***

We design, develop and manufacture implants for use in specific implant systems developed by our customers. We make orthopedic implants used primarily in knee and hip implant systems. Our orthopedic implants are used in reconstructive surgeries to replace or repair hips, knees and other joints, such as shoulders, ankles and elbows, sometimes referred to as extremities that have deteriorated as a result of disease or injury. An orthopedic implant system is generally comprised of several implants designed to work in concert to replicate the structure and function of a healthy joint.

We also manufacture implant products for trauma, spine and other implant systems. Trauma implant systems are used primarily to reattach or stabilize damaged bone or tissue while the body heals. Spinal





implant systems are used by orthopedic surgeons and neurosurgeons in the treatment of degenerative diseases, deformities and injuries in various regions of the spine.

Our design, engineering and prototyping expertise is an integral part of our implant offering. Medical device companies, which typically focus their resources on developing new implant systems as well as sales and marketing, may rely on us and companies like us to design, develop and manufacture the implants that comprise their implant systems. Our manufacturing capabilities, including our net shaped forging capabilities, technologically advanced casting facility and machining expertise, allow us to produce consistent, tight tolerance implants in large volumes for our customers.

We produce gross shaped, near-net shaped and net shaped implants for medical device manufacturers. Gross shaped implants require a significant amount of machining and hand processing post-forging. Near-net shaped implants are distinguished by geometric features that are thinner; more detailed and have tighter tolerances. Net shaped and near-net shaped implants require far fewer machine and hand operations post-forging. Net shaped implants typically require machining only on vital areas, such as the taper segment of a hip where it is joined to the femoral head.

We have the machining expertise needed to provide finished implants to our customers. Some customers purchase finished implants from us while others purchase unfinished implants and machine them to final specifications.

Our primary implant products and their applications are:

*Knees.* The knee joint includes the surfaces of three distinct bones: the lower end of the femur, the upper end of the tibia or shin bone, and the patella (knee cap). Cartilage on any of these surfaces can be compromised by disease or injury, leading to pain and inflammation that may require knee reconstruction. Our knee implants include a femoral component, a patella, a tibial tray and an articulating surface (placed on the tibial tray) and are used in total knee reconstruction, partial knee reconstruction and revision procedures. We provide one or more, and in some cases all, of these implants for our customers' knee implant systems. We use proprietary manufacturing know-how and advanced computer aided simulation techniques to produce tight tolerance near-net shaped to net shaped tibial implants that require minimal if any machining.

*Hips.* The hip joint consists of a ball-and-socket joint that enables a wide range of motion. The hip joint is often replaced due to degeneration of the cartilage between the head of the femur (the ball) and the acetabulum or hollow portion of the pelvis (the socket). This loss of cartilage causes pain, stiffness and a reduction in hip mobility. We produce tight tolerance femoral heads, hip stems, acetabular cups and spiked acetabular cups used in bone conservation, total-hip reconstruction and revision replacement procedures. Our hip stems are forged with tight tolerance details.

*Extremities, Trauma and Spine.* Extremity reconstruction involves the use of an implant system to replace or reconstruct injured or diseased joints, such as the finger, toe, wrist, elbow, foot, ankle and shoulder. Our forging capabilities allow us to produce thin cross sections of material to very tight tolerances for these smaller joint procedures. Trauma implant procedures commonly involve the internal fixation of bone fragments using an assortment of plates, screws, rods, wires and pins. Our spinal implant products consist primarily of plates and screws. We manufacture trauma and spinal plate implants to exact details to fit bone contours.

#### *Instruments*

We make high-precision surgical instruments used in hip, knee and shoulder reconstruction procedures, as well as in spinal, trauma and other implant procedures. We design, develop and manufacture implant-specific and procedure-specific instruments. We rarely manufacture general surgical instruments, but will procure them as a service to our customers in order to provide our customers with complete instrument sets. We have several reamer systems used by many of our large customers. Symmetry



currently has over 500 standard products in our catalog, and we plan on adding over 1,000 new products in a new catalog this coming year.

We primarily make a wide range of knee cutting blocks (instruments that guide blades that cut bone), osteotome revision systems (instruments used to cut through bone), reamers (instruments used for shaping bone sockets or cavities) and retractors (instruments used to pull back tissue for clear sight during surgery). Some of our instrument handles are made with our patented plastic insertion machine, which is designed to withstand the intense heat produced during frequent sterilizations and is attached to the instrument. Our instruments are made to tight tolerances to ensure precise alignment and fitting of implants.

Each implant system typically has an associated instrument set that is used in the surgical procedure to insert that specific implant system. Instruments included in a set vary by implant system. For example, hip and knee implant procedure instrument sets often contain in excess of 100 instruments, whereas revision procedure sets may contain approximately 50 instruments. Usually, instrument sets are sterilized after each use and then reused.

The instruments we produce are typically used in either open, minimally invasive, or revision implant procedures and can generally be categorized as:

Implant-specific instruments, which are used solely for a specific brand of implant, such as high-precision knee cutting blocks, certain reamers and broaches; and

Procedure-specific instruments, which are designed for a particular type of procedure, such as a minimally invasive hip implant procedure, but can be used with the implant systems of multiple companies.

*Implant-Specific Instruments.* The size, shape and other features of each implant system are unique. Consequently, unique instruments must be used to ensure precise alignment and fitting during the surgical procedure to insert an implant system. Accordingly, when a medical device company develops a new implant system, it typically also develops instruments specifically designed to insert the implant system. Medical device companies typically provide complete, customized implant-specific instrument sets to end users (hospitals, outpatient centers and physicians) in order to facilitate use of the implant.

We seek to collaborate with our customers early in the development process to facilitate the concurrent design of the implant system and the instruments that will accompany the system. Our implant-specific instruments generally include customized reamers, cutting blocks, broaches, rasps, guides and other instruments designed to accommodate the unique size, shape and other features of our customers' implant systems. These instruments are used by the surgeon to cut and shape bone and cavities during the surgical procedure and to align and fit the implant system. We are recognized in the orthopedic community for constructing these instruments to extremely tight tolerances.

*Procedure-Specific Instruments.* We also manufacture independently developed instruments referred to as our Symmetry Products. We have developed these products through our years of experience serving the orthopedic market and our investments in research and development. Complete implant procedure instrument sets typically include certain instruments that are designed for a particular type of procedure but can be used with the implant systems of multiple companies. By purchasing our proven Symmetry Products, customers can leverage our extensive experience and expertise to complete their instrument sets more quickly and efficiently.

Our Symmetry Products include successful hip and knee revision systems. Instruments that make up revision systems, which are used to remove orthopedic implants, are typically designed for a specific type of procedure but can be used to remove various brands of implants. These self-contained systems include an assortment of osteotome blades that assist the surgeon in separating an implant from cement or bony in-growth where access is limited, while minimizing damage to the bone. Our established revision systems can also be readily modified for a customer by adding additional instruments. For example, we developed a hip

revision system in 1996 that we currently sell to six different customers, with the system being customized for each customer.

### *Cases*

We produce a wide range of plastic, metal and hybrid cases used in over 25 medical device markets, including orthopedic, arthroscopy, osteobiologic, endoscopy, cardiovascular, dental, ophthalmology, diagnostic imaging and ear, nose and throat surgical procedures. Cases are used to store, transport and arrange implant systems and other medical devices and related surgical instruments. Our cases are generally designed to allow for sterilization and re-use after an implant or other surgical procedure is performed. Our plastic cases are designed to withstand the intense heat produced during the sterilization process.

The majority of the cases we make are tailored for specific implant procedures so that the instruments, implants and other devices are arranged within the case to match the order of use in the procedure and are securely held in clearly labeled, custom-formed pockets. We seek to collaborate with our customers early in the development processes to facilitate the concurrent design of the case and related instruments.

We also produce standard cases which are primarily used in those non-orthopedic market segments where the security or presentation of the instruments and devices is less important. Over the past two years, we have made a significant investment to obtain 510(k) clearance for our PolyVac line of standard cases through the FDA pre-market notification process. We believe this allows our customers to reduce time to market and to reallocate financial and human resources that would otherwise be spent on compliance efforts, which provides us with a significant competitive advantage in selling our standard cases.

We have more than 25 patents related to our case designs and manufacturing processes. We believe that our complete line of plastic, metal and hybrid product offerings strategically positions us in the case market.

Highlights of our case product offerings include:

*Orthopedic Cases.* We produce custom metal, plastic and hybrid cases designed to store, transport and arrange surgical instruments and related implant systems for orthopedic device manufacturers. Proper identification of instruments, such as reamers which are generally included in a range of sizes in one to two millimeter increments, is critical in orthopedic implant procedures. Our graphics and thermo formed tray pockets provide a secure and organized arrangement to assist surgeons during procedures.

*Dental Cases.* We produce cases used in dental implant and general dental procedures. Dental implant cases are typically complex and include many levels of trays, while cases used in general dental procedures tend to be smaller and less complex.

*Other Cases.* We also manufacture and sell cases for arthroscopy, osteobiologic, endoscopy, cardiovascular, ophthalmology, diagnostic imaging and ear, nose and throat procedures.

### *Specialized Non-healthcare Products and Services*

We offer specialized non-healthcare products and services on a limited basis. One of our UK based facilities acquired as part of the Mettis acquisition produced a range of cutting tools, cutlery and surgical instruments in the 1950 s. This facility evolved to focus on net shaped forgings, which resulted in a business focusing on orthopedic instruments and aerospace products for jet engines in the late 1990 s. Thereafter, this facility began focusing our net shaped forging capabilities on orthopedic implants and shifting our non-healthcare operations toward product development support and specialized products. Our core design, engineering and manufacturing competencies give us the expertise to offer specialized non-healthcare

products and services. Our non-healthcare products primarily are net shaped aerofoils and non-rotating aircraft engine forgings produced for our aerospace customers.

### ***Product Development***

Our Design and Development Centers provide dedicated expertise and greater coordination for our design, engineering and prototyping services. The main Design and Development Center is located in Warsaw, Indiana, and brings together talented engineering and design personnel and provides them with state-of-the-art design software and prototyping equipment. Our Design and Development Centers serve to centralize and better institutionalize our design and engineering knowledge and creates a fertile environment for new product development. We can coordinate the product development projects for our customers as well as the efforts of our engineers and designers in order to ensure that we have the appropriate people and technology focused on particular product development initiatives. Symmetry also has Design & Development Centers in Memphis, TN, Manchester, NH, Lansing, MI and Cheltenham, UK. We intend to open our new, larger Warsaw Design & Development Center in April 2006.

We seek to collaborate with our customers' product development teams and to assist in the design, engineering and prototyping of new medical device systems from the beginning of the development process. Our sales staff is technically trained and works closely with our customers' staff. As new product concepts are formulated, our sales people bring in our design and engineering personnel and leverage the resources of our Design and Development Centers to provide dedicated design teams with exceptional knowledge and experience. As a project evolves, we can rapidly create prototypes of the proposed product, instrument, case or implant. Working closely with our customers through the conceptual, planning and prototyping stages positions allows us to quickly scale up for manufacturing of the product.

In addition to supporting our customers' product development efforts, our Design and Development Centers are continuously developing our own product lines, referred to as Symmetry Products. We develop products by leveraging years of experience and knowledge, investing in research and development and continually seeking to expand our knowledge of the marketplace by consulting surgeons and other end users of our products. We currently offer over 500 internally developed products, including instruments for minimally invasive surgical implant procedures and hip and knee revision systems.

### **Environmental Issues**

Our discussion of environmental issues is presented under the caption "Environmental" in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in this Form 10-K.

### **Capital Investment**

Information concerning our capital expenditures is presented under the caption "Capital Expenditures" in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in this Form 10-K.

### **Customers**

We supply our products primarily to manufacturers in the medical device market. Our customers include all of the large orthopedic device manufacturers, including Biomet Inc., DePuy Inc. (a subsidiary of Johnson & Johnson), Medtronic Sofamor Danek, Smith & Nephew plc, Stryker Corporation, and Zimmer Holdings, Inc. We also have established relationships, primarily through our cases product offerings, with leading medical device manufacturers in numerous other medical device market segments, including Cardinal Health, Inc., 3i and St. Jude Medical Inc. We sold to approximately 750 customers, including over 100 new customers, in fiscal 2005. We may experience a seasonal impact of the orthopedic industry on revenue in the third quarter because many of our products are used in elective procedures that tend to

decline to some degree during the summer months. Sales to our ten largest customers represented 78.8% and 78.7% of our revenue in 2005 and fiscal 2004, respectively. Our two largest customers accounted for 33.2%, and 13.6% of our revenue in fiscal 2005 and our three largest customers accounted for 25.4%, 14.6% and 13.6% of our revenue in fiscal 2004. Our three largest customers in alphabetical order in fiscal 2004 were DePuy, Smith & Nephew and Zimmer and our two largest customers in alphabetical order for fiscal 2005 were DePuy and Zimmer. No other customer accounted for more than 10% of our revenue in fiscal 2005 or fiscal 2004. We typically serve several product teams and facilities within each of our largest customers, which mitigates our reliance on any particular customer.

We sell our products to customers domestically and in a number of regions outside the United States. In addition, our customers often distribute globally products purchased from us in the United States. Set forth below is a summary of revenue by selected geographic locations in our last three fiscal years, based on the location to which we shipped our products:

**Percent of Revenue by Geographic Location**

	Fiscal Year Ended		
	2005	2004	2003
United States	65.1 %	66.6 %	73.2 %
United Kingdom	12.5 %	13.3 %	16.1 %
Ireland	12.3 %	10.3 %	7.2 %
Other foreign countries	10.1 %	9.8 %	3.5 %
Total net revenues	100.0 %	100.0 %	100.0 %

**Sales and Marketing**

Our sales and marketing efforts emphasize our design and engineering expertise, internally developed Symmetry Products, manufacturing capabilities, international distribution network and our ability to provide customers with a comprehensive product offering. We are increasingly presenting our products and services to customers in a Total Solutions® concept which offers the customer a collaborator for developing complete implant, instrument and case solutions.

We have over 70 sales and marketing personnel worldwide. In addition to our internal sales efforts, we also sell standard cases through distributors. Our sales personnel are trained in all of our products and services in order to cross-sell and identify opportunities outside their immediate area of focus. We typically serve several product teams and facilities within each customer which diminishes our reliance on any one purchasing decision. Our customer base for cases extends into nearly every segment of the medical device market. We believe there is a significant opportunity to leverage our existing relationships among this customer base to achieve greater penetration of our customized instrument and implant products. We intend to increase our marketing of implants, instruments and our Total Solutions® concept to these customers.

Our sales personnel are technically trained and are based in close proximity to or located at our largest customers' sites. This physical proximity allows sales personnel to engage quickly with the marketing, design, engineering and purchasing staffs of these orthopedic device manufacturers. Our sales people are empowered to bring in design and engineering product development teams to facilitate a customer's efforts. Our goal is to collaborate with customers early in the development cycle and to continue through production, packaging, delivery and logistics.

**Manufacturing**

We have manufacturing facilities in the United States, the United Kingdom and France. We have made significant investments in recent years to modernize our production facilities, improve our

production processes and develop superior technical skills that complement our manufacturing capabilities. These investments have allowed us to continue to improve the quality of our products, increase our manufacturing capacity and improve our efficiency. Our manufacturing processes include:

*Forging.* Our forging process uses presses to force heated metal between two dies (called tooling) that contain a precut profile of the desired implant. The forging process enhances the strength of an implant, which is important for hip stems and other implants that must withstand significant stress. Many customers prefer forging because it provides greater mechanical properties. We forge gross shaped, near-net shaped and net shaped implants. Our know-how enables us to produce precision net shaped forgings in large volumes.

*Casting.* In the casting process, metal is heated until it is liquid and then poured into an implant mold. Casting can be used to produce implants with intricate shapes. We have developed a technologically advanced, highly automated, casting facility in Sheffield, United Kingdom.

*Plastic and Metal Forming.* Our know-how and technology facilitates our extensive plastic and metal forming capabilities. We use thermo form processes to draw uniform plastic cases and specialized equipment to form metal. Our laser controlled metal working machines allow us to punch and shape metal in intricate and complex detail.

*Machining / Finishing.* Machining is used extensively to enhance our forged, cast and formed products. We use computer numerically controlled, multi-axis and wire electric discharge equipment to cut, bend, punch, polish and otherwise shape or detail metal or plastic. Our finishing processes include polishing, laser etch marking, graphics and other customer specific processes.

The majority of products that we produce are customized to the unique specifications of our customers. Our ability to maintain flexible operations is an important factor in maintaining high levels of productivity. We primarily use just-in-time manufacturing and flexible manufacturing cells in our production processes. Just-in-time manufacturing is a production technique that minimizes work-in-process inventory and manufacturing cycles. Manufacturing cells are clusters of individual manufacturing operations and work stations grouped in a circular configuration, with the operators placed centrally within the configuration. Cell manufacturing provides flexibility by allowing efficient changes to the number of operations each operator performs, which enhances our ability to maintain product volumes that are consistent with our customers requirements and reduce our level of inventory.

We use raw materials, including titanium, cobalt chrome, stainless steel and nickel alloys, and various other components in the manufacture of our products. Although we generally believe these materials are readily available from multiple sources, from time to time we rely on a limited number of suppliers and in some cases on a single source vendor. For example, we obtain patented plastic, which is designed to withstand intense heat produced during frequent sterilizations, from a single supplier for use in our instrument handles and plastic cases.

#### **Quality Assurance**

We maintain a comprehensive quality assurance and quality control program, which includes the control and documentation of all material specifications, operating procedures, equipment maintenance and quality control methods. Our quality systems are based upon FDA requirements and the ISO standards for medical device manufacturers. We believe that all of our facilities are currently in substantial compliance with regulations applicable to them. For example, in the United States and United Kingdom these regulations include the current good manufacturing practice regulations and other quality system regulations imposed by the FDA. Our Sheffield, United Kingdom facility and our United States based facilities are registered with and audited by the FDA. Our line of PolyVac standard case received FDA 510(k) clearance, which can reduce our customers burden in obtaining FDA approval. Our facilities have obtained numerous industry-specific quality and regulatory assurance certifications.



## Competition

Our customers, to varying degrees, are capable of internally developing and producing the products we provide. While we believe that our comprehensive services and core production competencies allow medical device companies to reduce costs and shorten time to market, one or more of our customers may seek to expand their development and manufacturing operations which may reduce their reliance on independent suppliers such as ours.

We also compete with independent suppliers of implants, instruments and cases to medical device companies. The majority of these suppliers is privately owned and produces some, but not all, of the products required in orthopedic implant systems. We believe that we are the only independent supplier to offer a complete implant, instrument and case solution to orthopedic device manufacturers. We compete with other independent suppliers primarily on the basis of development capability, breadth of product offering, manufacturing quality, cost and service. We believe that we are the largest independent supplier of implants, instruments and cases to orthopedic device manufacturers. However, other independent suppliers may consolidate and some of our current and future competitors, either alone or in conjunction with their respective parent corporate groups, may have financial resources and research and development, sales and marketing, and manufacturing capabilities and brand recognition that are greater than ours.

## Intellectual Property

We believe our patents are valuable; however, our knowledge, experience, proprietary and trade secret information, manufacturing processes, product design and development staff and sales staff have been equally or more important in maintaining our competitive position. We seek to protect our non-patented know-how, trade secrets, processes and other proprietary confidential information principally through confidentiality, non-compete and invention assignment agreements.

We currently own 42 U.S. and 14 foreign patents related to our cases and instruments. These patents expire at various times beginning in 2006 and ending in 2020. We also have 26 U.S. and 6 foreign patent applications at various stages of approval. Our policy is to aggressively protect technology, inventions and improvements that we consider important through the use of patents, trademarks, copyrights and trade secrets in the United States and significant foreign markets.

While we do not believe that any of our products infringe any valid claims of patents or other proprietary rights held by third parties, we cannot provide complete assurance that we do not infringe any patents or other proprietary rights held by third parties. If our products were found to infringe any proprietary right of a third party, we could be required to pay significant damages or license fees to the third party or cease production, marketing and distribution of those products. Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets or other proprietary information we own and to determine the validity and scope of our proprietary rights.

We cannot provide complete assurance that our existing or future patents, if any, will afford adequate protection, that any existing patent applications will result in issued patents, that our patents will not be circumvented, invalidated, or held unenforceable, that our proprietary information will not become known to, or be independently developed by, our competitors, or that the validity or enforceability of any patents or other intellectual property owned by or licensed to us will be upheld if challenged by others in litigation. Due to these and other risks, we do not rely solely on our patents and other intellectual property to maintain our competitive position. Although intellectual property is important to our business operations and in the aggregate constitutes a valuable asset, we do not believe that any single patent, trade secret, trademark or copyright, or group of patents, trade secrets, trademarks or copyrights is critical to the success of our business.

## Employees

As of January 28, 2006, we had 1,862 employees. Our employees are not represented by any unions. From time to time in the past, however, some of our employees have attempted to unionize at two of our facilities. We believe that we have a good relationship with our employees.

## Executive Officers of the Registrant

Set forth below are the name, age, position and a brief account of the business experience of each of the Corporation's executive officers, and key employees, as of December 31, 2005.

Name	Age	Position
<i>Executive Officers:</i>		
Brian Moore	59	President and Chief Executive Officer
Fred Hite	38	Senior Vice President and Chief Financial Officer
Andrew Miclot	50	Senior Vice President, Marketing, Sales, Business Development and Investor Relations Officer
D. Darin Martin	54	Senior Vice President, Quality Assurance/Regulatory Affairs and Compliance Officer
Richard J. Senior	42	Senior Vice President and General Manager, Europe

**BRIAN MOORE**, has served as the Corporation's President and Chief Executive Officer and a director of the Corporation since the Corporation's acquisition of Mettis in June 2003. From April 1999 to June 2003, Mr. Moore served as the Chief Executive Officer of Mettis Group Limited, the parent company of Mettis. From April 1994 to March 1999, Mr. Moore held various positions with EIS Group plc, including Chairman of the Aircraft and Precision Engineering Division, and from 1987 to 1999, Mr. Moore served as Chief Executive Officer of AB Precision (Poole) Limited. Prior thereto, Mr. Moore served in various management positions at Vanderhoff plc, Land Rover Vehicles, Bass Brewing and Prudential Insurance, and as the Financial Director for a subsidiary of GEC Ltd. (UK). Mr. Moore has qualified as a Graduate Mechanical Engineer by the Institution of Mechanical Engineers (the qualifying body for mechanical engineers in the United Kingdom) and as an Accountant with the U.K. Chartered Institute of Management Accountants.

**FRED HITE** has served as the Corporation's Chief Financial Officer since March 2004. From 1997 to 2004, Mr. Hite served in various capacities at General Electric Industrial Systems, including Finance Manager of General Electric Motors and Controls from 2001 to 2004, Manufacturing Finance Manager from 2000 to 2001, and Finance Manager of Engineering Services from 1997 to 2000. From 1995 to 1997, Mr. Hite served as Sourcing Finance Manager and Commercial Finance Analyst at General Electric Industrial Control Systems. From 1990 to 1995, Mr. Hite served in various finance positions at General Electric Appliances. Mr. Hite received a B.S. in Finance at Indiana University.

**ANDREW MICLOT** has served as the Corporation's Senior Vice President of Sales, Marketing and Business Development since June 2003 and as the Corporation's Vice President of Marketing, Sales & Business Development since 1994. From 1992 to 1994, Mr. Miclot served as the Director of the Medical Products Group of DePuy Inc. From 1987 to 1992, Mr. Miclot served as Marketing Manager for Zimmer, Inc. and from 1986 to 1987, Mr. Miclot served as Director of Marketing for Ulti-Med, Inc. Mr. Miclot received a B.A. and M.A. in Speech and Hearing Sciences and Audiology from Indiana University and a M.B.A. from Lake Forest Graduate School of Management.

**D. DARIN MARTIN** has served as the Corporation's Senior Vice President of Quality Assurance and Regulatory Affairs since June 2003. From 1994 to 2003, Mr. Martin served as the Corporation's Vice President of Quality Assurance and Regulatory Affairs. Mr. Martin joined the Corporation in 1990 as Director of Quality Assurance. From 1984 to 1990, Mr. Martin served as Quality Assurance Supervisor for



Owens-Illinois Inc.'s Kimble HealthCare Division. Mr. Martin has been a member in various medical device industry associations, including a 20 year membership with the American Society of Quality, Biomedical Devices-NE Indiana Division. Mr. Martin received a B.S. in Business Management from Ball State University, a S.P.C. Instructor Certification from Baldwin-Wallace College and a M.B.A. from Kennedy-Western University.

**RICHARD J. SENIOR** has served as Senior Vice President and General Manager of the Corporation's European Operations since the Corporation's acquisition of Mettis in June 2003. He previously served in various capacities at Mettis in the Thornton Precision Components operating unit, including Managing Director from 1999 to 2003, Director and General Manager from 1997 to 1998, Operations Director from 1995 to 1996, Production Manager during 1995, CMR Operations Manager from 1993 to 1994 and Orthopaedic Sales Manager (UK) from 1990 to 1995. Mr. Senior attended Myers Grove Comprehensive School in the United Kingdom.

#### **Family Relationships**

There are no family relationships between any of the executive officers or directors of the Corporation.

#### **Available Information**

*Symmetry Medical 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 or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through our website [www.symmetrymedical.com](http://www.symmetrymedical.com) (from the Investors link on the home page, and SEC Filings within the Investors box located in the text) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). If you wish to receive a hard copy of any exhibit to our reports filed with or furnished to the SEC, such exhibit may be obtained, upon payment of reasonable expenses, by writing to: Fred Hite, Senior Vice President, Chief Financial Officer and Secretary, Symmetry Medical Inc., 220 W. Market Street, Warsaw, IN 46580. You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Information relating to corporate governance at Symmetry, including our Principles of Corporate Governance, Code of Conduct (including our Code of Ethics for Senior Financial Officers), Code of Business Conduct and Ethics for Board Members and information concerning our executive officers, directors and Board committees (including committee charters), and transactions in Symmetry securities by directors and officers, is available on or through our website at [www.symmetrymedical.com](http://www.symmetrymedical.com) under the Corporate Governance and Investor Relations captions.

We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

#### **ITEM 1A. RISK FACTORS**

Our profitability is subject to risks described under this section on Risk Factors described below. Although the following are not necessarily the only ones facing our company, our business, financial condition or results of operations they could be materially adversely affected by many of the following risks.

## Risks Related to Our Business

***We depend heavily on sales to our significant customers, and our business could be adversely affected if any of them reduced or terminated purchases from us.***

A limited number of large orthopedic device manufacturers, all of whom are our customers, control the predominate share of the orthopedic device market. We depend heavily on revenue from these large companies. Revenue from our ten largest customers represented approximately 78.8% of our revenue in fiscal year 2005 and 78.7% of our revenue in fiscal year 2004. Our two largest customers accounted for approximately 33.2% and 13.6% of our revenue in the fiscal year 2005 and our three largest customers accounted for 25.4%, 14.6% and 13.6% of our revenue in fiscal 2004.

We expect that we will continue to depend on a limited number of large customers for a significant portion of our revenue. In addition, our customer base could become more concentrated if, among other things, there is further consolidation among orthopedic device manufacturers. If a significant customer reduces or delays orders from us, terminates its relationship with us or fails to pay its obligations to us, our revenues could decrease significantly.

***If we are unable to continue to improve our current products and develop new products, we may experience a decrease in demand for our products or our products could become obsolete, and our business would be adversely affected.***

We sell our products to customers in markets that are characterized by technological change, product innovation and evolving industry standards. We are continually engaged in product development and improvement programs, both in collaboration with our customers and independently. Our customers may engage in additional in-house development and manufacturing, and we may be unable to compete effectively with our independent competitors, unless we can continue to develop and assist our customers in developing innovative products. Our competitors' product development capabilities could become more effective than ours, and their new products may get to market before our products, may be more effective or less expensive than our products or render our products obsolete. If one or more of these events were to occur, our business, financial condition and results of operation could be adversely affected.

***We face competition from our customers' in-house capabilities, established independent suppliers and potential new market entrants, and if we lose customers it could have an adverse effect on our revenue and operating results.***

Our customers have varying degrees of development and manufacturing capabilities, and one or more of them may seek to expand their in-house capabilities in the future, including adding capacity in existing sites or expanding into low labor cost areas such as Asia. Many of our customers are larger and have greater financial and other resources than we do and can commit significant resources to product development and manufacturing. Most of our independent competitors are smaller companies, many of which have close customer relationships and either a low cost structure or highly specialized design or production capabilities. Our independent competitors may consolidate and some of our current and future competitors, either alone or in conjunction with their respective parent corporate groups, may have financial resources and research and development, sales and marketing and manufacturing capabilities or brand recognition that are greater than ours. In addition, the innovative nature of our markets may attract new entrants to the field. Our products may not be able to compete successfully with the products of other companies, which could result in the loss of customers and, as a result, decreased revenue and operating results.

***If product liability lawsuits are brought against us or our customers our business may be harmed.***

The manufacture and sale of our healthcare and other products, including our aerospace products, expose us to potential product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design or manufacturing flaws in, our products, or use of our products with components or systems not manufactured by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or otherwise require us to pay significant damages, which could adversely affect our earnings and financial condition.

We carry product liability insurance but it is limited in scope and amount and may not be adequate to protect us against product liability claims. We may be unable to maintain this insurance at reasonable costs and on reasonable terms, if at all.

***Our operating results are subject to significant potential fluctuation and you should not rely on historical results as an indication of our future results.***

Our operating results have fluctuated in the past and may vary significantly from quarter to quarter or year to year in the future due to a combination of factors, many of which are beyond our control. These factors include:

- the timing of significant orders and shipments, including the effects of changes in inventory management practices by our customers;
- the number, timing and significance of new products and product introductions and enhancements by us, our customers and our competitors;
- changes in pricing policies by us and our competitors;
- changes in medical treatment or regulatory practices;
- restrictions and delays caused by regulatory review of our customers' products;
- recalls of our customers' products;
- availability and cost of raw materials; and
- general economic factors.

Our quarterly revenue 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 our future performance. We cannot assure you that our revenue will increase or be sustained in future periods or that we will be profitable in any future period. Any shortfalls in revenue or earnings from levels expected by securities or industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period.

***If we do not retain key individuals and retain and attract skilled manufacturing workers, we may not be able to operate successfully, and we may not be able to meet our strategic objectives.***

Our success depends in part upon the retention of key managerial, sales and technical personnel, particularly skilled manufacturing workers. We compete for such personnel with other companies and other organizations, many of which are larger and have greater name recognition and financial and other resources than we do. 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. The 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.

We compete with numerous precision manufacturing companies to attract and retain qualified and highly skilled manufacturing employees. Our Warsaw, Indiana facilities, in particular, faces significant competition, including from certain of our customers and other companies located in or near Warsaw that are larger and have greater financial and other resources than we do, for skilled production employees. If

we are not able to retain and attract skilled manufacturing employees, we may be unable to support our anticipated growth, which could adversely affect our profitability.

***A significant shift in technologies or methods used in the treatment of damaged or diseased bone and tissue could make our products obsolete or less attractive.***

The development of new technologies could reduce demand for our products. For example, pharmaceutical advances could result in non-surgical treatments gaining more widespread acceptance as a viable alternative to orthopedic implants. The emergence of successful new biological tissue-based or synthetic materials to regenerate damaged or diseased bone and to repair damaged tissue could increasingly minimize or delay the need for implant surgery and provide other biological alternatives to orthopedic implants. New surgical procedures could diminish demand for our instruments. A significant shift in technologies or methods used in the treatment of damaged or diseased bone and tissue could adversely affect demand for our products.

***We depend on third party suppliers, and in some cases a single third party supplier, for key components and raw materials used in our manufacturing processes and the loss of these sources could harm our business.***

We use titanium, cobalt chrome, stainless steel and nickel alloys, and various other raw materials in our products. Although we generally believe these materials are readily available from multiple sources, from time to time we rely on a limited number of suppliers and in some cases on a single source vendor. For example, we obtain patented Radel R plastic, which is designed to withstand intense heat produced during frequent sterilizations, for use in our instrument handles and plastic cases from a single supplier. Any supply interruption in a limited or sole-sourced component or raw material could materially harm our ability to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms if at all. This could interrupt our business or reduce the quality of our products.

***If we are unable to manage changes in our business and our anticipated growth, our business could be harmed.***

Our acquisition of Mettis on June 11, 2003 significantly increased the size and scope of our operations. Our business has continued to grow at a fast pace since the acquisition, and we believe we will continue to grow at a significant rate. Rapid growth of our business may place a strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. Any failure by us to expand and train our work force or increase production capacity or otherwise manage our growth effectively could have an adverse effect on our ability to achieve our business strategy. Our growth may be impaired if we are unable to meet the demands of our customers, which could result in our customers turning to alternative suppliers.

***Our current or future levels of indebtedness may limit our ability to operate our business, finance acquisitions and pursue new business strategies.***

As of December 31, 2005, our total indebtedness, including short-term debt, long-term debt and capital lease obligations, was \$39.3 million. As of December 31, 2005, we had an additional \$40.0 million of borrowings available under our revolving credit facility. Although covenants under our senior credit facility limit our ability to incur additional indebtedness, in the future we may incur additional debt to finance acquisitions, business opportunities, capital expenditures or other capital requirements.

Our indebtedness could:

make us more vulnerable to unfavorable economic conditions;

make it more difficult to obtain additional financing in the future for working capital, capital expenditures or other general corporate purposes;

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require us to dedicate or reserve a large portion of our cash flow from operations for making payments on our indebtedness, which would prevent us from using it for other purposes;

make us susceptible to fluctuations in market interest rates that affect the cost of our borrowings to the extent that our variable rate debt is not covered by interest rate derivative agreements; and

make it more difficult to pursue strategic acquisitions, alliances and collaborations.

Our ability to service our indebtedness will depend on our future performance, which will be affected by prevailing economic conditions and financial, business, regulatory and other factors. Some of these factors are beyond our control. We believe that, based upon current levels of operations, we will be able to meet our debt service obligations when due. Significant assumptions underlie this belief, including, among others, that we will continue to be successful in implementing our business strategy and that there will be no material adverse developments in our business, liquidity or capital requirements. If we cannot generate sufficient cash flow from operations to service our indebtedness and to meet our other obligations and commitments, we may be required to refinance our debt or to dispose of assets to obtain funds for such purpose. We cannot assure you that refinancing or asset dispositions could be effected on a timely basis or on satisfactory terms, if at all, or would be permitted by the terms of our debt instruments. To the extent we incur additional indebtedness or other obligations in the future, the risks associated with our indebtedness described above, including our possible inability to service our debt, would increase.

***Our senior credit facility contains restrictions that limit our ability to pay dividends, incur additional debt, make acquisitions and make other investments.***

Our senior credit facility contains covenants that restrict our ability to make distributions to stockholders or other payments unless we satisfy certain financial tests and comply with various financial ratios. If we do not satisfy these tests or comply with these ratios, our creditors could declare a default under our debt instruments, and our indebtedness could be declared immediately due and payable. Our ability to comply with the provisions of our senior credit facility may be affected by changes in economic or business conditions beyond our control.

Our senior credit facility also contains covenants that limit our ability to incur indebtedness, acquire other businesses and make capital expenditures, and impose various other restrictions. These covenants could affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities as they arise. We may be unable to comply with the forgoing financial ratios or covenants and, if we fail to do so, we may be unable to obtain waivers from our lenders.

***Our future capital needs are uncertain and we may need to raise additional funds in the future.***

Our future capital needs are uncertain and we may need to raise additional funds in the future through debt or equity offerings. Our future capital requirements will depend on many factors, including:

revenue generated by sales of our products;

expenses incurred in manufacturing and selling our products;

costs of developing new products or technologies;

costs associated with capital expenditures;

costs associated with our expansion;

costs associated with regulatory compliance, including maintaining compliance with the quality system regulations imposed by the FDA; and

the number and timing of acquisitions and other strategic transactions.





As a result of these factors, we may need to raise additional funds, and these funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, execute our business strategy, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements.

***We may not realize all of the sales expected from new product development programs.***

We incur substantial expenses in developing and testing new products and related devices. The realization of additional revenue from new product development efforts is inherently subject to a number of important risks and uncertainties, including, directly or indirectly, end-user acceptance of the product, reimbursement approval of third-party payors such as Medicaid, Medicare and private insurers and, in some cases, FDA or comparable foreign regulatory approval of the product. In addition, our customers typically have no contractual requirement to purchase from us the products that we develop for their medical devices, and they could seek to have another supplier or in-house facilities manufacture products that we have developed for their medical devices. We also incur costs and make capital expenditures for new product development and production based upon certain estimates of production volumes for our existing and anticipated products. If the actual demand for our products is less than planned, our revenue and net income may decline.

***Our earnings could decline if we write off goodwill or intangible assets created as a result of our various acquisitions.***

As a result of acquisitions we have accumulated a substantial amount of goodwill, amounting to \$124.5 million as of December 31, 2005, or approximately 36.8% of our total assets as of such date. Goodwill and certain intangible assets are not amortized but rather are tested for impairment by us annually or more frequently if an event occurs or circumstances develop that would likely result in impairment. Examples of such events or circumstances include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition. We completed annual impairment tests as of October 2005 and 2004 and concluded at those dates that no impairment of goodwill or intangible assets existed. During 2002, in connection with the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*, we recognized impairment of approximately \$1.1 million, which is reflected as a cumulative effect of accounting change in our statement of operations. In the future, we could recognize impairment of our goodwill or other intangible assets, and that impairment could result in a charge to our results of operation and have an adverse effect on our financial condition.

***If we are unable to protect our intellectual property and property rights, or are subject to intellectual property claims by third parties, our business could be harmed.***

We rely on a combination of patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish and protect our proprietary rights to our technologies and products. We cannot guarantee that the steps we have taken or will take to protect our intellectual property rights will be adequate or that they will deter infringement, misappropriation or violation of our intellectual property. Litigation may be necessary to enforce our intellectual property rights and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expenses and may not adequately protect our intellectual property rights. In addition, the laws of some of the countries in which our products are or may be sold may not protect our products and intellectual property to the same extent as U.S. laws, or at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries. If our trade secrets become known, we may lose our competitive advantages.

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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 customers. We cannot assure you, however, that:

these agreements will not be breached;

we will have adequate remedies for any breach; or

trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or independently developed by our competitors.

We hold licenses with 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.

In addition, third parties may claim that we are infringing, misappropriating or violating their intellectual property rights. We could be found to infringe those intellectual property rights, which could affect our ability to manufacture any affected product. In addition, any protracted litigation to defend or prosecute our intellectual property rights could drain our financial resources, divert the time and effort of our management and cause customers to delay or limit their purchases of the affected product until resolution of the litigation.

Any litigation or claims against us, whether or not successful, could result in substantial costs and could harm our reputation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

cease selling or using any of our products that incorporate the challenged intellectual property, which could adversely affect our revenue;

obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and

redesign or, in the case of trademark claims, rename our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

***Efforts to acquire other companies or product lines may divert our managerial resources away from our business operations, and if we complete an acquisition, we may incur or assume additional liabilities or experience integration problems.***

We may seek to acquire businesses or product lines for various reasons, including to provide new product manufacturing and service capabilities, add new customers, increase penetration with existing customers or expand into new geographic markets. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These efforts could divert the attention of our management and key personnel from our business operations. If we complete acquisitions, we may also experience:

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

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

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

limited or no direct prior experience in new markets or countries we may enter;

higher costs of integration than we anticipated;

difficulties in retaining key employees of the acquired business who are necessary to manage these businesses;

difficulties in maintaining uniform standards, controls, procedures and policies throughout our acquired companies; or

adverse customer reaction to the business combination.

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

***We are subject to risks associated with our foreign operations.***

We have significant international operations, specifically in the United Kingdom and France. Certain risks are inherent in international operations, including:

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

foreign customers who may have longer payment cycles than customers in the United States;

tax rates in certain foreign countries that may exceed those in the United States and foreign earnings that may be subject to withholding requirements or the imposition of tariffs, exchange controls or other restrictions including transfer pricing restrictions when products produced in one country are sold to an affiliated entity in another country;

general economic and political conditions in countries where we operate or where end users of orthopedic devices reside may have an adverse effect on our operations;

difficulties associated with managing a large organization spread throughout various countries;

difficulties in enforcing intellectual property rights; and

required compliance with a variety of foreign laws and regulations.

As we continue to expand our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other risks. We cannot assure you that these and other factors will not have a material adverse effect on our international operations or our business as a whole.

***Currency exchange rate fluctuations could have an adverse effect on our revenue and financial results.***

We generate a significant portion of our revenue and incur a significant portion of our expenses in currencies other than U.S. dollars. Currency exchange rates are subject to fluctuation due to, among other things, changes in local, regional or global economic conditions, the imposition of currency exchange restrictions and unexpected changes in regulatory or taxation environments. To the extent that we are unable to match revenue received in foreign currencies with costs incurred in the same currency, exchange rate fluctuations in any such currency could have an adverse effect on our financial results. During fiscal year 2003 and 2004, we benefited from foreign exchange rates, in particular because of the weakening U.S. dollar versus both the pound sterling and the euro, the primary currencies to which we are exposed. The U.S. dollar has recently strengthened against these currencies and caused an unfavorable impact to operations in fiscal 2005. We cannot assure you that exchange rates will not impact us favorably or unfavorably in the future. In addition, as of December 31, 2005, we did not hold or issue foreign exchange options or forward contracts to mitigate this risk; however, we may enter into such agreements in the future. Any change in the exchange rates of currencies of jurisdictions into which we sell products or incur expenses could result in a decrease in our revenue or operating income.

***We may be adversely affected as a result of the long lead times required for sales of certain new products.***

We often compete for business at the beginning of the development of new medical devices or upon customer redesign of existing medical devices. Our customers generally must obtain clearance or approval from the FDA before commercially distributing their products. Unless exempt, a new medical device must be approved for commercial distribution in the United States by the FDA through the 510(k) pre-market Notification Process or, in some cases, through the more burdensome pre-market approval, or PMA, process. It generally takes three to six months from the date of submission to the FDA to obtain



510(k) clearance and one to three years from the date of submission to the FDA to obtain approval through the PMA process, but in each case may take significantly longer. This results in long lead times for some of our customers' new products, which may make it difficult in the short term for us to obtain sales of new products to replace any unexpected decline in sales of existing products.

***We may be adversely impacted by work stoppages and other labor matters.***

Currently, none of our employees are unionized. However, from time to time some of our employees have attempted to unionize at two of our facilities. In addition, some of our orthopedic device customers have unionized work forces. While we have not experienced any adverse effects from work stoppages or low-downs at our customers' facilities, work stoppages or slow-downs experienced by us, our suppliers or our customers or their suppliers could result in slow-downs or closures of facilities where our products are made or used. We cannot assure you that we will not encounter strikes, further unionization efforts or other types of conflicts with labor unions or our employees, which could have an adverse effect on our financial results.

***If a natural or man-made disaster strikes one or more of our manufacturing facilities, we may be unable to manufacture certain products for a substantial amount of time and our revenue could decline.***

We have thirteen manufacturing facilities, which are located in the United States, the United Kingdom and France. These facilities and the manufacturing equipment and personnel know-how that we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. In the event that one of our facilities was affected by a disaster, we would be forced to attempt to shift production to our other manufacturing facilities or rely on third-party manufacturers, and our other facilities or a third-party manufacturer may not have the capability to effectively supply the affected products. Although we have insurance for damage to our property and the interruption of our business, this insurance may not be sufficient in scope or amount to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

#### **Risks Related to Our Industry**

***Orthopedic device manufacturers have significant leverage over their independent suppliers and consolidation could increase their leverage, which could result in the loss of customers or force us to reduce our prices.***

We compete with many distributors and manufacturers to develop and supply implants, surgical instruments and cases to a limited number of large orthopedic device manufacturers. As a result, orthopedic device manufacturers have historically had significant leverage over their independent suppliers. For example, independent suppliers like us are subject to continuing pressure from the major orthopedic device manufacturers to reduce the cost of products and services while maintaining quality levels. In recent years, the medical device industry has experienced substantial consolidation. If the medical device industry, and the orthopedic device industry in particular, continues to consolidate, competition to provide products and services to orthopedic device manufacturers may become more intense. Orthopedic device manufacturers may seek to use their market power to negotiate price or other concessions for our products. If we are forced to reduce prices or if we lose customers because of competition, our revenue and results of operations would suffer.

***Our business is indirectly subject to healthcare industry cost containment measures and other industry trends affecting pricing that could result in reduced sales of or prices for our products.***

Acceptance of our customers' products by hospitals, outpatient centers and physicians depend on, among other things, reimbursement approval of third-party payors such as Medicaid, Medicare and private insurers. The continuing efforts of government, insurance companies and other payors of healthcare costs to contain or reduce those costs could lead to lower reimbursement rates or non-reimbursement for medical devices that use our products. If that were to occur, medical device manufacturers might insist that

we lower prices on products related to the affected medical device or they might significantly reduce or eliminate their purchases from us of these related products, which could affect our profitability.

We are aware of several legal developments that could negatively impact prices of orthopedic devices. At least one major hospital chain is seeking permission from the U.S. Office of the Inspector General to implement gain-sharing initiatives which could, if approved, negatively impact the prices of orthopedic devices because it would enable hospitals to consolidate vendors and share cost savings with doctors. We are also aware of governmental investigations of some of the largest orthopedic device companies reportedly focusing on consulting and service agreements between these companies and orthopedic surgeons. If one of these investigations results in a judgment against one of our large customers our results of operations could be negatively impacted.

***We and our customers are subject to substantial government regulation that is subject to change and could force us to make modifications to how we develop, manufacture and price our products.***

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Some of our manufacturing processes are required to comply with quality systems regulations, including current good manufacturing practice requirements that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. Further, some of our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA or other agencies. Failure to comply with applicable medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspensions of production, refusal of the FDA or other regulatory agencies to grant future pre-market clearances or approvals, withdrawals or suspensions of current clearances or approvals and criminal prosecution.

In addition, orthopedic implants and other medical devices produced by our customers are subject to intensive regulation and potential pre-approval requirements by the FDA and similar international agencies that govern a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales and distribution. Compliance with these regulations may be time consuming, burdensome and expensive for our customers and, indirectly, for us to the extent that our customers' compliance depends on our operations. These regulations could negatively affect our customers' abilities to sell their products, which in turn would adversely affect our ability to sell our products. This may result in higher than anticipated costs or lower than anticipated revenue.

The regulations that we and our customers are subject to are complex, change frequently and have tended to become more stringent over time. Federal and state legislatures have periodically considered programs to reform or amend the U.S. healthcare system at both the federal and state levels. In addition, these regulations may contain proposals to increase governmental involvement in healthcare, lower reimbursement rates or otherwise change the environment in which healthcare industry participants operate. Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we sell our products in foreign countries, we may be subject to rigorous regulation in the future. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenue.

***If our customers fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals to commercially distribute our future products our ability to sell our products could suffer.***

Some of our medical devices are subject to rigorous regulatory pre-approval by the FDA and other federal, state and foreign governmental authorities. Our customers are typically responsible for obtaining the applicable regulatory approval for the commercial distribution of our products. The process of obtaining this approval, particularly from the FDA, can be costly and time consuming, and there can be no assurance that our customers will obtain the required approvals on a timely basis, if at all. The FDA, for example, assigns medical devices to one of three classes which determines, among other things, the type and degree of FDA approval required to commercially distribute the device in the United States. We

produce Class I, II and III devices. Class I devices are deemed to present little risk to patients and are generally exempt from FDA approval requirements. Class II devices can generally be commercially distributed only after the device has received 510(k) clearance. The FDA will clear marketing of a medical device through the 510(k) process if certain design, testing and validation requirements are met and it is demonstrated that the device is substantially equivalent to a device that was legally marketed prior to May 28, 1976, or to another commercially available device subsequently cleared through the 510(k) Pre-Market Notification process. This process generally takes three to six months, but may take substantially longer. Before a Class III device can be commercially distributed in the United States, a pre-market approval, or PMA, must be obtained from the FDA. The PMA process can be expensive and uncertain, requires detailed and comprehensive scientific and other data and generally takes between one and three years, but may take significantly longer. The commercial distribution of any products we develop that require regulatory clearance may be delayed. In addition, because we cannot assure you that any new products or any product enhancements we develop for commercial distribution in the United States will be exempt from the FDA market clearance requirements or subject to the shorter 510(k) clearance process, the regulatory approval process for our products or product enhancements may take significantly longer than anticipated by us or our customers.

***We may be adversely affected by the impact of environmental and safety regulations.***

We are subject to foreign, federal, state, local and foreign laws and regulations governing the protection of the environment and occupational health and safety, including laws regulating air emissions, wastewater discharges, and the management and disposal of hazardous materials and wastes; and the health and safety of our employees. We are also required to obtain permits from governmental authorities for certain operations. If we violate or fail to comply with these laws, regulations or permits, we could incur fines, penalties or other sanctions, which could have a material adverse effect on us. Environmental laws tend to become more stringent over time, and we could incur material expenses in the future relating to compliance with future environmental laws. In addition, we could be held responsible for costs and damages arising from any contamination at our past or present facilities or at third-party waste disposal sites. Such costs could be material. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur material liability as a result of any contamination or injury.

**Risks Relating to Our Common Stock**

***Our common stock may be volatile and could decline substantially.***

There has been significant volatility in the market price and trading volume of securities of companies operating in the medical device industry, including our company, which has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

actual or anticipated fluctuations in our operating results;

our announcements or our competitors' announcements regarding new products, significant contracts, acquisitions or strategic investments;

loss of any of our key management or technical personnel;

conditions affecting orthopedic device manufacturers or the medical device industry generally;

product liability lawsuits against us or our customers;

clinical trial results with respect to our customers' medical devices;

changes in our growth rates or our competitors' growth rates;

developments regarding our patents or proprietary rights, or those of our competitors;



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FDA and international actions with respect to the government regulation of medical devices and third-party reimbursement practices;

public concern as to the safety of our products;

changes in health care policy in the United States and internationally;

conditions in the financial markets in general or changes in general economic conditions;

our inability to raise additional capital;

changes in stock market analyst recommendations regarding our common stock, other comparable companies or the medical device industry generally, or lack of analyst coverage of our common stock;

sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of common stock; and

changes in accounting principles.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and the company's resources.

***A large percentage of our voting stock is controlled by one principal stockholder whose interests may conflict with those of our other stockholders.***

As of December 31, 2005 the Olympus Funds beneficially own 24.9% of our common stock. As a result of this ownership, the Olympus Funds have a substantial influence on our affairs and their voting power will constitute a large percentage of any quorum of our stockholders voting on any matter requiring the approval of our stockholders. Such matters include the election of directors, the adoption of amendments to our certificate of incorporation and by-laws and approval of mergers or sales of substantially all our assets. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company or discouraging others from making tender offers for our shares, which could prevent stockholders from receiving a premium for their shares. In addition, as of December 31, 2005, three of our seven directors, including the chairman of our board, are representatives of the Olympus Funds. The Olympus Funds may cause corporate actions to be taken even if the interests of the Olympus Funds conflict with the interests of our other stockholders.

***We are no longer a controlled company within the meaning of the New York Stock Exchange Rules, and as a result will no longer qualify for exemptions from certain corporate governance requirements.***

We are listed on the New York Stock Exchange and are therefore subject to the NYSE's corporate governance rules. We are no longer a controlled company within the meaning of Section 303A of the NYSE's Listed Company Manual. Furthermore, by July 19, 2006, all of our committees must be comprised solely of independent directors and a majority of the directors on our board must be independent. Currently our board consists of seven directors, three of whom are independent. During the phase-in period granted to us by the NYSE, our stockholders will not have the same protections afforded to stockholders of companies that are subject to all NYSE corporate governance rules. If, by July 19, 2006 we do not comply with NYSE requirements, we may be subject to enforcement actions by the NYSE. In addition, this change in our board and committee membership may result in a change in corporate strategy and operating philosophies, and may result in deviations from our current growth strategy, and the board's limited history of working together may inhibit its ability to function at current levels of efficiency.

*A significant portion of our total outstanding shares may be sold into the market in the near future. If there are substantial sales of our common stock or the perception that these sales could occur, the price of our common stock could decline.*

Our current stockholders hold a substantial number of shares of our common stock that they are able to sell in the public market in the near future. A significant portion of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares could significantly reduce the market price of our common stock. As of December 31, 2005, Olympus Funds held approximately 8.6 million shares of our common stock, including shares issuable upon the exercise of warrants, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Effective February 21, 2006, Olympus Funds distributed approximately 3.6 million net shares to investors in their fund. After this distribution, Olympus funds held approximately 5.0 million shares of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

*Our certificate of incorporation, our by-laws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.*

Provisions of the Delaware General Corporation Law, our certificate of incorporation and our by-laws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- providing for a classified board of directors with staggered terms;

- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and by-laws;

- eliminating the ability of stockholders to call special meetings of stockholders;

- prohibiting stockholder action by written consent;

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

- limiting the ability of stockholders to amend, alter or repeal the by-laws; and

- authorizing of the board of directors to issue, without stockholder approval, shares of preferred stock with such terms as the board of directors may determine and shares of our common stock.

We are also protected by Section 203 of the Delaware General Corporation Law, which prevents us from engaging in a business combination with a person who becomes a 15.0% or greater stockholder for a period of three years from the date such person acquired such status unless certain board or stockholder approvals were obtained.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our corporate office is located in Warsaw, Indiana. We have operations facilities, including warehouse, administrative and manufacturing facilities, located at twelve locations throughout the world. We believe that these facilities are adequate for our current and foreseeable purposes and that additional space will be available if needed.

The lease on our approximately 122,000 square foot Manchester, New Hampshire facility is a capital lease that runs through October 1, 2016. The initial annual base rent under the lease, as amended, was \$0.6 million, payable in equal monthly installments. On October 31, 2001, and every five years thereafter, including extensions, the annual base rent will change based on the percentage increase, if any, in the Consumer Price Index for the Northeast U.S. region. The current annual base rent under the lease is \$0.7 million. We have an option to extend the lease for an additional five-year period and have a right of first opportunity to purchase the leased property.

The table below provides selected information regarding our facilities.

Location	Use	Approximate Square Footage(1)	Own/ Lease
Warsaw, Indiana	Instrument design and manufacturing	63,000	Own
Warsaw, Indiana	Design and Development Center; instrument design and manufacturing	17,000	Lease
Memphis, Tennessee	Design and Development Center	6,400	Lease
Warsaw, Indiana	Corporate headquarters	10,000	Own
Claypool, Indiana	Instrument design and manufacturing	22,500	Own
Cheltenham, United Kingdom	Instrument design and manufacturing	9,000	Lease
Cheltenham, United Kingdom	Instrument design and manufacturing	25,000	Lease
Manchester, New Hampshire	Plastic and metal case design and manufacturing	122,000	Lease
Villeneuve d Ascq, France	Case design and assembly	10,800	Lease
Lansing, Michigan	Implant design, forging and machining	65,000	Own
Lansing Michigan	Implant Finishing and Design and Development Center	15,000	Lease
Sheffield, United Kingdom	Implant and specialized non-healthcare product design, forging, casting and machining	134,600	Own
Sheffield, United Kingdom	Implant machining	43,400	Own
Avilla, Indiana	Instrument and implant design and manufacturing	41,000	Lease

(1) We own approximately 21 acres of land in Warsaw, Indiana, and approximately 9 acres in Lansing, Michigan. In fiscal 2005, we purchased approximately 3 acres of land adjacent to our Sheffield, United Kingdom facility. These sites are available for future expansion.

(2) We are currently building a new Design & Development Center in Warsaw, Indiana on a portion of the 21 acres available. Completion is expected by April 2006 at an estimated cost of \$2.5 million and will be approximately 30,000 square feet.

(3) We are constructing a new building for future expansion at our Villeneuve d Ascq, France location. The new facility will be 25,000 square feet and will be a leased facility. Estimated completion is March 2006.

**ITEM 3. LEGAL PROCEEDINGS**

None

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None

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**PART II**

**Item 5. MARKET FOR THE REGISTRANT'S COMMON STOCK, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock trades on the New York Stock Exchange (the NYSE) under the trading symbol SMA. As of February 17, 2006, there were approximately 42 registered holders of record of our common stock. The transfer agent and registrar for our common stock is Computershare Trust Company, N.A., P.O. Box 43023, Providence, RI 02940-3023, telephone (877) 282-1168.

We have not in the two most recent fiscal years, and do not expect for the foreseeable future, to pay dividends on our common stock. Instead, we anticipate that our earnings in the foreseeable future will be used in the operation and growth of our business. The payment of dividends by us to holders of our common stock is restricted by our senior credit facility. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

We currently do not have a share repurchase plan or program.

See Part III, Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, for information regarding common stock authorized for issuance under equity compensation plans.

Our common stock has been listed on the New York Stock Exchange since our initial public offering on December 9, 2004. The following table sets forth, for the period indicated, the highest and lowest closing sale price for our common stock by quarter for 2005, as reported by the New York Stock Exchange:

	<b>2005</b>	
	<b>High</b>	<b>Low</b>
Fourth Quarter	\$ 23.65	\$ 17.18
Third Quarter	\$ 25.75	\$ 22.42
Second Quarter	\$ 24.31	\$ 17.15
First Quarter	\$ 22.26	\$ 18.00
	<b>2004</b>	
	<b>High</b>	<b>Low</b>
Fourth Quarter (Commencing December 9, 2004)	\$ 21.05	\$ 15.00

The closing sale price for our common stock on February 22, 2006 was \$22.02.

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**Item 6. SELECTED FINANCIAL DATA**

The following table sets forth our selected financial data for the year indicated and should be read in conjunction with the disclosures to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements of this Form 10-K.

	<b>Fiscal Year Ended</b>				
	<b>2005</b>	<b>2004</b>	<b>2003(1)</b>	<b>2002</b>	<b>2001</b>
<i>(dollars in thousands, except share and per share data)</i>					
<b>Consolidated Statements of Operations Data:</b>					
Revenue	\$ 263,766	\$ 205,391	\$ 122,029	\$ 65,395	\$ 66,495
Cost of Revenue	185,227	145,081	86,124	47,859	48,205
Gross Profit	78,539	60,310	35,905	17,536	18,290
Selling, general, and administrative expenses	27,570	22,569	17,115	9,440	10,494
Operating Income	50,969	37,741	18,790	8,096	7,796
Interest expense, net	2,954	13,757	10,172	4,968	5,070
Loss on debt extinguishment		8,956	(5) 1,436	(2)	
Interest rate swap valuation(3)	(98 )	(1,451 )	(1,358 )	979	847
Other (income) expense	1,872	(740 )	(374 )	(42 )	290
Income before income taxes and cumulative effect of accounting change	46,241	17,219	8,914	2,191	1,589
Income tax expense	14,441	5,524	3,009	841	1,400
Net income (loss) before cumulative effect of accounting change	31,800	11,695	5,905	1,350	189
Cumulative effect of accounting change(4)				(1,146 )	(293 )
Net income (loss)	31,800	11,695	5,905	204	(104 )
Preferred stock dividends		(8,977 )	(7,028 )	(4,410 )	(3,185 )
Net income (loss) applicable to common shareholders	\$ 31,800	\$ 2,718	\$ (1,123 )	\$ (4,206 )	\$ (3,289 )
Basic per share:					
Net income (loss) applicable to common shareholders before cumulative effect of accounting change	\$ 0.94	\$ 0.16	\$ (0.10 )	\$ (0.44 )	\$ (0.44 )
Cumulative effect of accounting change, net of tax				(0.17 )	(0.04 )
Net income (loss)	\$ 0.94	\$ 0.16	\$ (0.10 )	\$ (0.61 )	\$ (0.48 )
Diluted per share:					
Net income (loss) applicable to common shareholders before cumulative effect of accounting change	\$ 0.92	\$ 0.15	\$ (0.10 )	\$ (0.44 )	\$ (0.44 )
Cumulative effect of accounting change, net of tax				(0.17 )	(0.04 )
Net income (loss)	\$ 0.92	\$ 0.15	\$ (0.10 )	\$ (0.61 )	\$ (0.48 )
Weighted average common shares and equivalent shares outstanding:					
Basic	33,841	16,905	11,798	6,906	6,855
Diluted	34,670	17,767	11,798	6,906	6,855
<b>Consolidated Statements of Operations Data:</b>					
Cash and cash equivalents	\$ 12,471	\$ 4,849	\$ 2,348	\$ 781	\$ 835
Working capital	63,777	50,854	36,064	9,587	10,533
Total Assets	337,645	306,868	267,217	63,554	59,714
Long-term debt and capital lease obligations, less current portion	34,782	43,209	129,696	47,234	48,641
Redeemable preferred stock				3,530	
Total shareholders' equity (deficit)	253,255	216,145	100,390	(1,121 )	(1,629 )
<b>Other Financial Data:</b>					
Depreciation and amortization	\$ 13,674	\$ 11,198	\$ 6,662	\$ 2,744	\$ 4,151

(1) Includes the results of Mettis since its acquisition on June 11, 2003.

(2) In fiscal 2003, we refinanced substantially all of our existing indebtedness as part of the financing of the acquisition of Mettis, resulting in a loss on debt extinguishment of \$1,436.

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(3) We entered into interest rate swap agreements to offset against changes in interest rates on our variable rate long-term debt. In accordance with SFAS No. 133, as amended, *Accounting For Derivative Instruments and Hedging Activities*, these agreements do not qualify for hedge accounting and accordingly, changes in the fair market value of such agreements are recorded each period in earnings.

(4) For fiscal 2001, reflects the cumulative effect of change in accounting principles resulting in the adoption of SFAS No. 133. For fiscal 2002, reflects a write-off of goodwill in connection with the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*. Upon completion of the adoption of SFAS No. 142, we determined that the fair market value of the goodwill was lower than book value for one reporting unit, which resulted in an impairment charge.

(5) In fiscal 2004, we refinanced substantially all of our existing indebtedness as part of the proceeds from our December 9, 2004 initial public offering, resulting in a loss on debt extinguishment of \$8,956. This charge includes \$5.1 million of unamortized discount recorded upon the issuance of the subordinated notes and \$3.9 million of deferred debt issuance costs as a result of the Mettis acquisition on June 11, 2003.

**Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION**

**Overview**

We are the world's largest independent provider of implants and related instruments and cases to orthopedic device manufacturers. We also design, develop and produce these products for companies in other segments of the medical device market, including dental, osteobiologic and endoscopy sectors, and provides limited specialized products and services to non-healthcare markets.

The global medical device market was estimated to be approximately \$220 billion in 2004, according to our most recent research reports available. The orthopedic device segment of the medical device market was estimated to be approximately \$19 billion in 2004, and is expected to grow approximately 12% annually to greater than \$30 billion by 2008. Orthopedic devices principally consist of reconstructive implants used to replace or repair knees, hips, shoulders and other joints, as well as other orthopedic devices to repair bone fractures and the spine. There were approximately 1.7 million reconstructive orthopedic implant procedures performed globally in 2004, an increase of approximately 10% over the previous year. We expect continued growth in the orthopedic device market to be driven by a number of trends including:

- growing elderly population;
- aging, affluent and active baby boomers ;
- improving technologies that expand the market, including minimally invasive surgery;
- successful clinical outcomes increasing patient confidence;
- increasing patient awareness through orthopedic device companies' direct marketing programs;
- increasing volume of procedures to replace older implants (or revision procedures); and
- developing international markets.

We acquired Mettis on June 11, 2003 for aggregate consideration of approximately \$164 million. Mettis is a leading manufacturer of forged, cast and machined implants for global orthopedic device manufacturers. This acquisition added implants to our product offerings and increased our European presence. We offer a comprehensive line of implants, surgical instruments and cases for orthopedic device manufacturers on a global basis. In fiscal 2005, we had revenue of \$263.8 million, operating income of \$51.0 million and net income applicable to common shareholders of \$31.8 million.

Our acquisition of Mettis enabled us to offer our customers Total Solutions® for complete implant systems implants, instruments and cases. While our revenue to date has been derived primarily from the sale of implants, instruments and cases separately, or instruments and cases together, our ability to provide Total Solutions® for complete implant systems has already proven to be attractive to our customers and we expect this capability will provide us with growth opportunities. In addition, we expect that our Total Solutions® capability will increase the relative percentage of value added products that we supply to our customers.

During fiscal 2005, we sold our products and services to approximately 750 customers, including over 100 new customers. Our two largest customers accounted for approximately 33.2% and 13.6% of our revenue in fiscal 2005 and our three largest customers accounted for 25.4%, 14.6% and 13.6% of our revenue in fiscal 2004. Our ten largest customers collectively accounted for approximately 78.8% and 78.7% of our revenue in fiscal 2005 and fiscal 2004, respectively. Within each of our largest customers, we typically serve several product teams and facilities, which diminishes our reliance on any single purchasing decision. Approximately 65.1%, 12.5%, 12.3% and 10.1% of our revenue in fiscal 2005 and approximately





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66.6%, 13.3%, 10.3% and 9.8% of our revenue in fiscal 2004 was from sales to the United States, United Kingdom, Ireland and other foreign countries, respectively.

We believe that we have well-established relationships with our major customers and these relationships to a significant extent involve the sale of products that we have developed or modified specifically for our customers' particular product lines. In connection with the launch of a new implant system, our customers typically provide a customized implant-specific instrument set in cases to end users (hospitals, outpatient centers and physicians) for use with the new implant system. As a result, our sales of instruments and cases in any particular period are significantly impacted by the amount of new product launch activity by our customers.

Our revenue from the sale of implants, instruments, cases and other products and services represented 39.2%, 32.9%, 21.0%, and 6.9% respectively, of our revenue in fiscal 2005, compared with 36.6%, 33.0%, 23.0% and 7.4% respectively, of our revenue in fiscal 2004.

Our management reviews and analyzes several trends and key performance indicators in order to manage our business. To assist us in evaluating our capacity, we monitor long-term trends in the orthopedic industry, which currently include the growing elderly population, general aging of the population, affluent and active baby boomers, improving technologies that expand the market, including minimally invasive surgeries, and other factors. Further, we consider the information obtained from discussions with our customers on the upcoming demand for our products, including new product launches. We use this information to determine an appropriate level of capital expenditures to meet the anticipated demand for our products. To this end, we recently added approximately 100,000 square feet of capacity through facility expansions and openings. In addition, we plan on moving our existing Villeneuve d'Ascq, France case facility to a newly-constructed, larger facility in Villeneuve d'Ascq, France and opening a new Design and Development Center in Warsaw, Indiana in the first quarter of 2006.

On an ongoing basis, our management considers several variables associated with the ongoing operations of the business, including scheduled production, utilization of machinery and equipment, monitoring purchasing activity and inventory levels and associated costs, headcount, overhead costs, and selling and general and administrative expenses.

Our revenues are affected by changes in the number and size of orders and the timing of delivery dates. Our revenues have fluctuated in the past and may vary in the future due to the effects of changes in inventory management practices and new product introductions by our customers.

**Results of Operations**

The table below sets forth certain operating data expressed as a percentage of revenue for the periods indicated. Fiscal 2003 operating data in the table below includes the results of Mettis since its acquisition on June 11, 2003. Our historical results are not necessarily indicative of the operating results that may be expected in the future.

	Fiscal Year Ended		
	2005	2004	2003
<b>Statement of Operations Data:</b>			
Revenue	100.0 %	100.0 %	100.0 %
Cost of Revenue	70.2 %	70.6 %	70.6 %
Gross Profit	29.8 %	29.4 %	29.4 %
Selling, general, and administrative expenses	10.5 %	11.0 %	14.0 %
Operating Income	19.3 %	18.4 %	15.4 %
Other (income) expense:			
Interest expense	1.1 %	6.7 %	8.3 %
Loss on debt extinguishment		4.4 %	1.2 %
Interest rate swap valuation	(0.0 )%	(0.7 )%	(1.1 )%
Other	0.7 %	(0.4 )%	(0.3 )%
Income before income taxes	17.5 %	8.4 %	7.3 %
Income tax expense	5.5 %	2.7 %	2.5 %
Net income	12.1 %	5.7 %	4.8 %

***Fiscal Year 2005 Compared to Fiscal Year 2004***

*Revenue.* Revenue for fiscal 2005 increased \$58.4 million, or 28.4%, to \$263.8 million from \$205.4 million in fiscal 2004. Revenue for each of our principal product categories in these periods was as follows:

Product Category	Fiscal Year Ended	
	2005	2004
	(in millions)	
Implants	\$ 103.5	\$ 75.1
Instruments	86.7	67.7
Cases	55.5	47.3
Other	18.1	15.3
Total	\$ 263.8	\$ 205.4

The \$58.4 million increase in revenue resulted from increased implant, instrument, case, and non-healthcare/other sales of \$28.4 million, \$19.0 million, \$8.2 million, and \$2.8 million, respectively, as a result of increased demand from customers due primarily to continued industry growth and their launches of new systems. We estimate that global orthopedic device procedures grew at approximately 7% to 9% in 2005 and expect similar industry procedure growth in the near future. In addition to industry growth, our Total Solutions® model, new product offerings and increased implant finishing operations contributed to the increase in revenue.

*Gross Profit.* Gross profit for fiscal 2005 increased \$18.2 million, or 30.2%, to \$78.5 million from \$60.3 million in fiscal 2004. This increase in gross profit resulted from a slightly higher gross margin rate on significantly higher revenues. As a percentage of revenue, gross margin was 29.8% for the fiscal 2005 compared to 29.4% in fiscal 2004. This slight increase in gross margin was primarily driven by controlled fixed costs, which generated volume leverage.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses in fiscal 2005 increased \$5.0 million, or 22.2%, to \$27.6 million from \$22.6 million in fiscal 2004. However, as a



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percentage of revenue, selling, general and administrative expenses declined to 10.5% of revenue in fiscal 2005 from 11.0% in fiscal 2004 despite increases related to Sarbanes-Oxley compliance and income tax consulting services. This 0.5% decrease as a percentage of revenue was driven by the 28.4% increase in revenue, which outpaced the rise in expenses of 22.2%. We expect an approximate \$0.5 million reduction in total Sarbanes-Oxley compliance expenses in fiscal 2006 compared to fiscal 2005 as the initial implementation is now complete; however, we expect an increase related to stock-based compensation expense, which includes the impact of implementing FASB Statement No. 123(R).

*Other (Income) Expense.* Interest expense for fiscal 2005 decreased \$10.8 million, or 78.5%, to \$3.0 million from \$13.8 million in fiscal 2004. This decrease primarily reflects the decrease in senior and subordinated debt that resulted from the proceeds of our initial public offering of our common stock in the fourth quarter of fiscal 2004. The \$9.0 million loss on debt extinguishment incurred in the fourth quarter of fiscal 2004 was also due to the debt reduction as part of this initial public offering. Approximately \$0.9 million of Other expense for fiscal 2005 was due to costs paid in connection with the secondary public offering completed in the third quarter of 2005.

*Provision for Income Taxes.* Our effective tax rate was 31.2% in fiscal 2005 as compared to 32.1% in fiscal 2004. The decrease in rate was mainly due to research and development credits and the new qualified production activities deduction. Reconciliation to the Federal statutory rate of 35% is more fully described in Note 7 to our consolidated financial statements that appear elsewhere in this Form 10-K. We would expect the rate to rise in 2006 because \$1.3 million of the research and development credits taken in 2005 relate to amendments of prior year returns.

### *Fiscal Year 2004 Compared to Fiscal Year 2003*

*Revenue.* Revenue increased \$83.4 million, or 68.3%, to \$205.4 million in fiscal 2004 from \$122.0 million in fiscal 2003. Revenue for each of our principal product categories in these periods was as follows:

Product Category	Fiscal Year Ended	
	2004	2003
	(in millions)	
Implants	\$ 75.1	\$ 33.3
Instruments	67.7	45.6
Cases	47.3	36.1
Other	15.3	7.0