Symmetry Medical Inc.
Form 10-K
March 08, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended January 1, 2011
Commission File Number 001-32374

SYMMETRY MEDICAL INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	35-1996126
(State of Incorporation)	(I.R.S. Employer Identification No.)

3724 North State Road 15
Warsaw, Indiana 46582
(Address of Principal Executive Offices) (Zip Code)
(574) 268-2252
(Registrant's Telephone Number, Including Area Code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Name of Each Exchange on Which Registered:
Common Stock, Par Value $0.001 Per Share	New York Stock Exchange

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (l) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of l934 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 x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (S232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o
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. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and" smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨

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

The aggregate market value of voting stock of Symmetry Medical Inc. held by non-affiliates of the Registrant as of July 3, 2010, based on the closing price was $10.39, as reported by the New York Stock Exchange: Approximately $373.5 million.

The number of shares outstanding of the registrant's common stock as of March 4, 2011 was 36,345,292.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information is incorporated into Part III of this report by reference to the Registrant's 2011 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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Cautionary Note Regarding Forward-Looking Statements

Throughout this Annual Report on Form 10-K, 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," "potential," or "expect," or by the words "may," "will," "could," or "should," and similar expressions or terminology are intended to operate as "forward-looking statements" of the kind permitted by the Private Securities Litigation Reform Act of 1995. 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.

Forward-looking statements convey our current expectations or forecast future events. 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 "Corporation," "we," "our" or "Symmetry") is a leading independent provider of implants and related instruments and cases to global orthopedic device manufacturers. We design, develop and produce these products for companies in other segments of the medical device market, including the arthroscopy, dental, laparoscopy, osteobiologic and endoscopy segments, and we also provide limited specialized products to non-healthcare markets, such as the aerospace market. Our Total Solutions® concept provides our customers with a collaborative process for developing complete implant systems, including the implant, the surgical instruments, and the related case. This 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 systems to market quickly and efficiently. We believe that our close customer relationships, broad product offering and leading quality and regulatory performance give us a competitive advantage.

During fiscal year 2010, we generated revenue of $360.8 million, derived primarily from the sale of products to the orthopedic device market and other medical markets. Our Total Solutions® approach is supported by an experienced team of designers, development engineers, logistics specialists and by our global sales force that works with our customers to coordinate all of our products.

Our primary products 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, endoscopy, dental and other surgical procedures; and
- other specialized products for 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. Over the past five years, we have made several acquisitions which expanded our customer base, enhanced our product offerings and extended our product lines.

In 2006, we acquired Riley Medical and Everest Metal. Riley Medical specializes in cases and trays for the orthopedic industry and the acquisition of Riley Medical included many patented products and expanded our product offering of medical cases and trays to the medical markets. Everest Metal specializes in finishing implants for the orthopedic industry.

During 2007, we acquired Clamonta Ltd., TNCO, Inc., Specialty Surgical Instrumentation, Inc. and UCA, LLC. Clamonta Ltd. machines products for the global aerospace industry. TNCO was a privately owned company with a 40-year history of designing and supplying instruments for arthroscopic, laparoscopic, sinus and other minimally invasive procedures. TNCO allows us to leverage our instrument manufacturing while also leveraging their customer base in non-orthopedic segments of the healthcare market. Specialty Surgical Instrumentation, Inc. and UCA, LLC (collectively "SSI") located in Nashville, Tennessee distributes surgical instruments and sterilization containers directly to hospitals. The addition of SSI allows us to offer a broad array of medical instruments and related products to our customer base. This includes over 13,000 individual items, many of which are held in inventory for quick delivery. For Symmetry, this was our first entry into the medical product distribution industry, which provides us direct access to hospitals.

In January of 2008, we acquired DePuy Orthopaedics, Inc.'s New Bedford, Massachusetts instrument manufacturing facility ("New Bedford") for approximately $45.2 million. This facility manufactures orthopedic instruments as well as general surgical instruments and small implants. In connection with the acquisition, we entered into a supply agreement which, starting January 25, 2008, requires DePuy to make minimum purchases totaling $106 million from New Bedford for a four year period, with specific amounts in each year. The agreement stipulates that these purchases are incremental to other products we previously produced on DePuy’s behalf. These minimum purchases have been met each year since acquisition.

Our Total Solutions® Approach

We believe that we have created a distinct competitive position in the orthopedic device market based upon our Total Solutions® approach. 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 bring their implant systems to market quickly and efficiently.

Our Total Solutions® offering is based on:

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

- 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. Over the past several years, we developed high precision machining capabilities to better serve the spine implant market.

- Quality and Regulatory Compliance. Our quality systems are based upon and in compliance with International Organization for Standardization ("ISO") requirements and, where applicable, United States Food and Drug Administration ("FDA") regulations. We believe our level of quality and regulatory compliance systems meet or exceed our customers' expectations. We continue investing in this area to strengthen our leadership position.

- Global Reach. Our manufacturing capabilities in the United States, United Kingdom, France, Ireland and Malaysia allow us to offer single-source products to our multinational customers, and the geographic breadth of our experienced sales force effectively brings our Total Solutions® approach to customers around the globe.

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 offerings, 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 offerings provide 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 Total Solutions® approach allow large orthopedic companies to reduce their number of 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 continue to increase.

Over the past several years, we have further developed our Total Solutions® offering through strategic acquisitions which expanded our product offerings to include medical cases and trays to non-orthopedic medical markets, additional patented products, enhanced implant finishing capabilities and minimally invasive instrumentation.

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 Total Solutions® approach positions 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 Offerings. 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 recent years, we have continued to expand our 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. During the past several years, we developed high precision machining capabilities to better serve the spine implant market.

- Increase New Product Offerings. Our Design and Development Centers provide expertise and coordination for our design, engineering and prototyping offerings. 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, manage their product manufacturing and logistic services.

- Continued Global Expansion. Our global facilities allow us to serve the global medical marketplace. We believe that having local facilities near our global customers and closer to the end consumer allows us to better serve their needs. In December 2006, we opened a facility in Malaysia to better serve our customers in Asia. We are continuing to expand our Malaysian operations and increase its product offerings.

- Leverage Technology. Our expertise in metal processing and in particular high integrity net shape forging enables us to develop a role as a niche supplier in certain other markets, most notably the aerospace sector, where we supply engine aerofoil blades and other similar parts.

- Expand Our Sales Channels to Market. Our 2007 acquisition of SSI in Nashville, Tennessee has created an opportunity to sell a range of products that we procure and manufacture directly to hospitals.

Products

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 specialized products used in the aerospace market. We also market and sell highly specialized operating room products, such as instrumentation, fiber optic light sources and non-toxic enzymatic detergent, targeted directly to surgeons. Our revenue from the sale of instruments, implants, cases and other products represented 40.3%, 30.8%, 22.7% and 6.2%, respectively, of our revenue in fiscal 2010, compared with 45.6%, 29.5%, 18.7% and 6.2%, respectively, of our revenue in fiscal 2009.

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. We have in place a high precision machining cell to serve the spine market.

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. In addition, we have several orthopedic reamer systems used by many of our large customers. We typically do not manufacture general surgical instruments, but will procure them as an offering to our customers in order to provide our customers with complete instrument sets. We also market and sell highly specialized

operating room instrumentation targeted directly to specialty surgeons. We currently have over 1,500 Symmetry standard products in our catalog plus over 13,000 individual items sold directly to hospitals.

We produce a wide variety of products, primarily 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 bone 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. In recent years we have seen our Symmetry product sets grow in demand as our large OEM customers distribute the products and we maintain the device files.

Specialty Surgical Instrumentation. We distribute a wide array of instruments and related products directly to hospitals. These instruments comprise cutting, dissecting, grasping, cauterizing, ligating, coagulating, hot blade cutting, bi-polar and mono-polar instruments as well as reusable and disposable instruments. Most of these instruments are sold into operating room settings, including neurology, ophthalmology, rhinoplasty, reconstructive, cardiovascular, thoracic, vascular, laparoscopic, and gynecology.

Cases

We produce a wide range of plastic, metal and hybrid cases used in over 25 medical device markets, including orthopedic, spinal, 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.

Many 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 the non-orthopedic market segments where the security or presentation of the instruments and devices is not customized for a specific surgery. Over the past several years, we have made a significant investment to obtain 510(k) clearance for our 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 40 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. We also offer medical containers which are used by hospitals to hold instruments when they are sterilized.

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.

    - Endoscopy Cases. We produce cases for endoscope sterilization for many types of sterilization methods.

- 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.

- Sterilization Containers. We produce lightweight and durable Ultra Container System which is designed for the sterilization of all surgical instruments. This product is primarily sold directly to hospitals.

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

Specialized Non-Healthcare Products

We offer specialized non-healthcare products on a limited basis. Our core design, engineering and manufacturing competencies give us the expertise to offer aerospace products. Our aerospace products primarily are net shaped aerofoils and non-rotating aircraft engine forgings produced for our aerospace customers. Additionally, our offering in the aerospace industry includes aerospace machining capabilities.

Product Development

Our Design and Development Centers provide dedicated expertise and greater coordination for our design, engineering and prototyping offerings. Our 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 create 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. 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 utilize 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 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, which we refer to as Symmetry products. We develop products by utilizing 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 1,500 Symmetry 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 large orthopedic device manufacturers, including Biomet Inc., DePuy Orthopaedics, Inc., a subsidiary of Johnson & Johnson, ("DePuy"), Medtronic Inc., Smith & Nephew Plc, Stryker Corp. and Zimmer Holdings, Inc. ("Zimmer"). We also have established relationships, primarily through our case product offerings, with leading medical device manufacturers and distributors in numerous other medical device market segments, including Cardinal Health, Inc., Karl Storz, Edward Lifesciences and St. Jude Medical Inc. With the addition of SSI in August 2007, we serve over 1,000 additional customers, some of which own multiple hospitals.

We sold to approximately 1,850 customers in fiscal 2010. Sales to our ten largest customers represented 71.3% and 73.1% of our revenue in fiscal 2010 and 2009, respectively. Our three largest customers accounted for 31.7%, 10.5% and 10.0% of our revenue in fiscal 2010 and were, in alphabetical order, DePuy, Stryker Corp and Zimmer. In 2009, our largest customer, DePuy, accounted for 39.1% of our revenue. No other customer, other than those stated above, accounted for more than 10% of our revenue in fiscal 2010 or fiscal 2009. We typically serve several product teams and facilities within each of our largest customers, which mitigates our reliance on any particular customer. Over the past five years, we have reduced our concentration in the orthopedic industry through various acquisitions, which increased our presence in non-orthopedic markets.

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 percent of revenue by selected geographic locations in our last three fiscal years, based on the location to which we shipped our products:

	Fiscal Year Ended					
	2010		2009		2008	
United States	74.2	%	73.3	%	71.5	%
Ireland	8.8	%	10.2	%	7.5	%
United Kingdom	7.7	%	8.0	%	13.0	%
Other foreign countries	9.3	%	8.5	%	8.0	%
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 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 serving our Original Equipment Manufacturer ("OEM") customers and more than 30 direct sales personnel selling directly to hospitals. In addition to our internal sales efforts, we also sell standard cases through distributors. Our sales personnel are trained in all of our products in order to cross-sell and identify opportunities outside their immediate area of focus. We typically serve several product teams and facilities within each OEM 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 an 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 and Materials

We have manufacturing facilities in the United States, United Kingdom, France, Ireland and Malaysia. We have made 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 thermoform 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. During the past several years, we developed machining capabilities to better serve the spine implant market.

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 endeavor to 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 plastic, 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 Radel® R 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, France, Malaysia and United Kingdom these regulations include the current good manufacturing practice regulations and other quality system regulations imposed by the FDA. Specific United States based facilities are registered with and audited by the FDA. Our line of standard cases received FDA 510(k) clearance, which can reduce our customers' burden in obtaining FDA approval. The European, Malaysia and specific United States based facilities are ISO registered and audited annually. Our facilities have obtained numerous industry-specific quality and regulatory assurance certifications.

Regulatory Compliance

We maintain an effective regulatory program to assure compliance to all applicable US and international regulatory standards and directives. Our regulatory program concentrates on assurance to minimize risks associated with regulatory requirements and standards that affects fit, form and function of our products to customers. Focus is on providing effective auditing practices and procedures to assure compliance to all applicable internal and external standard operating procedures and 510(k) process requirements.

Competition

Our OEM customers, to varying degrees, are capable of internally developing and producing most of the products we provide. While we believe that our comprehensive offerings 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 us. We compete on the basis of development capability, breadth of product offering, manufacturing quality, cost and on time delivery.

We also compete with independent suppliers of implants, instruments and cases to medical device companies. A majority of these suppliers are privately owned and produce some, but not all, of the products required in orthopedic implant systems. We compete with other independent suppliers primarily on the basis of development capability, breadth of product offering, manufacturing quality, costs and on time delivery. 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 88 total issued patents and have 55 patents pending related to our cases and instruments. These patents expire at various times beginning in 2011 and ending in 2026. We also have 37 issued trademarks and 5 pending trademarks. Our policy is to 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. 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 March 2, 2011 we had 2,797 employees. Our employees are not represented by any unions. We believe that we have a good relationship with our employees.

Government Regulation

Our business is subject to governmental regulation. We are subject to federal, state and local environmental laws and regulations governing the emission, discharge, use, storage and disposal of hazardous materials and the remediation of contamination associated with the release of these materials at our facilities and at off-site disposal locations. We are not aware of any material noncompliance with the environmental laws currently applicable to our business and we are not subject to any material claim for liability with respect to contamination at any company facility or any off-site location. We cannot assure you that we will not be subject to such environmental liabilities in the future as a result of historic or current operations.

As a component manufacturer, our medical products are subject to regulation by the FDA. The FDA and related state and foreign governmental agencies regulate many of our customers' products as medical devices. In many cases, the FDA must approve those products prior to commercialization. We believe that our existing medical manufacturing plants comply with current Good Manufacturing Practices as applicable.

We have "master files" on record with the FDA. Master files may be used to provide confidential detailed information about facilities, processes or articles used in the manufacturing, processing, packaging and storing of one or more

medical device components. These submissions may be used by device manufacturers to support the premarket notification process required by Section 510(k) of the federal Food Drug & Cosmetic Act. This notification process is necessary to obtain clearance from the FDA to market a device for human use in the United States.

We are also subject to various other environmental, transportation and labor laws as well as various other directives and regulations both in the U.S. and abroad. We believe that compliance with these laws will not have a material impact on our capital expenditures, earnings or competitive position. Given the scope and nature of these laws; however, there can be no assurance that they will not have a material impact on our results of operations.

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 as of March 2, 2011.

Name	Age	Position
Executive Officers:		
Thomas J. Sullivan	47	President and Chief Executive Officer
Brian S. Moore	64	President of Business Development
Fred L. Hite	43	Senior Vice President and Chief Financial Officer
D. Darin Martin	59	Senior Vice President, Quality Assurance/Regulatory Affairs and Compliance Officer
David C. Milne	43	Senior Vice President of Human Resources, General Counsel and Corporate Secretary
Ronda L. Harris	40	Chief Accounting Officer
Michael W. Curtis	56	Senior Vice President and Chief Operating Officer, USA
Christopher W. Huntington	38	Senior Vice President and Chief Operating Officer, Asia

Thomas J. Sullivan has served as President and Chief Executive Officer and has been a member of the Board of Directors since January 17, 2011. From 2007 to 2011, Mr. Sullivan served as the President of the Supply Chain & Business Process division of Johnson & Johnson Health Care Systems, Inc. Prior to this position, Mr. Sullivan served in several other senior leadership roles for Johnson & Johnson, including President of DePuy Orthopaedics, Inc. from 2005 to 2007, and President of Johnson & Johnson Medical Products Canada from 2002 to 2005. Mr. Sullivan began his career in operations at Johnson & Johnson in 1990. Prior to Johnson & Johnson, Mr. Sullivan spent five years at Verizon. Mr. Sullivan holds a Bachelor of Science in Applied Mathematics and Computer Science from the University of Pittsburgh and an MBA in Strategic Management and Information Technology from The Wharton School of the University of Pennsylvania.

Brian S. Moore has served as President of Business Development since January 17, 2011 and has been a member of the Board of Directors since the Company’s acquisition of Mettis in June 2003. From June 2003 to January 2011, Mr. Moore served as our President and Chief Executive Officer. 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 Accounts.

Fred L. Hite has served as Senior Vice President and Chief Financial Officer since March 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.

D. Darin Martin has served as the Corporation's Senior Vice President of Quality Assurance, Regulatory Affairs, and Chief Compliance Officer 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.

David C. Milne joined Symmetry in 2009 as Senior Vice President of Human Resources, General Counsel and Corporate Secretary. From 2000 through 2009 Mr. Milne was employed by The Steak `n Shake Company (NYSE: SNS), where he most recently served as Vice President, General Counsel and Corporate Secretary. After graduating cum laude from the Indiana University School of Law, Mr. Milne practiced with Bose, McKinney & Evans and Scopelitis, Garvin, Light, Hanson & Feary where he concentrated on representing employers in labor and employment law matters. Mr. Milne received his undergraduate degree from Wabash College and his MA English Literature from Indiana University, Bloomington.

Ronda L. Harris joined Symmetry on July 14, 2008 with extensive experience in financial management, planning and implementation of effective financial reporting and financial control processes. Prior to joining Symmetry, Ms. Harris served as Assistant Controller of General Electric's Consumer and Industrial Business. Ms. Harris began her career at PricewaterhouseCoopers. She received a Bachelor of Science degree from Indiana University and became a Certified Public Accountant in 1997.

Michael W. Curtis has served as the Corporation's Senior Vice President and Chief Operating Officer, USA since January 1, 2008. Mr. Curtis joined Symmetry in November 2002 and served in several leadership roles with incremental responsibility. Prior to joining Symmetry, Mr. Curtis served as Vice President of Operations for Lightchip, Inc. from May 2000 to 2002, and from 1998 to 2000, he served as Vice President/General Manager of Communications Products at Thomas & Betts Corporation. From 1994 to 1997, Mr. Curtis was employed at Amphenol Aerospace — Amphenol Corporation, initially as a Business Unit Manager and subsequently as Director of Filter Products. From 1976 through 1994, Mr. Curtis served in various capacities at Hamilton Standard Division of United Technologies Corporation, the last of which was Product Line Manager. Mr. Curtis received his B.S., M.B.A. and M.S. in Engineering Management from Western New England College.

Christopher W. Huntington joined Symmetry in August 2006 through Symmetry's acquisition of Everest Metal Orthopedics Inc. Initially serving as Vice President of Business Development, Mr. Huntington has progressed through the organization and now serves as Senior Vice President and Chief Operating Officer, Asia. Prior to joining Symmetry, Mr. Huntington founded Everest Metal Orthopedics Inc., an Implant manufacturer with locations in Cork Ireland and Suffern, New York. Mr. Huntington received his BA from St. Lawrence University and his Law Degree from Depaul University College of Law.

For information regarding our directors, and additional information regarding our executive officers, see our 2011 Proxy Statement which will be filed with the Securities Exchange Commission no later than 120 days after the end of our fiscal year.

Family Relationships

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

Available Information

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 free of charge through our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). Our internet address is www.symmetrymedical.com (access the filings by using the "Investor Relations" link on the home page, and "SEC Filings" within the "Investor Relations" box located in the text). You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., 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. The SEC

maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

Information relating to our corporate governance, including our Corporate Governance Guidelines, Code of Business Conduct and Ethics and information concerning our executive officers, directors and Board committees (including committee charters), and transactions in Symmetry Medical Inc. securities by directors and officers, is available on or through our website at www.symmetrymedical.com under "Investor Relations" then "Corporate Governance."

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 predominant share of the orthopedic device market. We depend heavily on revenue from these large companies. Revenue from our ten largest customers represented approximately 71.3% of our revenue in fiscal year 2010 and 73.1% of our revenue in fiscal year 2009. Our largest customer accounted for approximately 31.7% of our revenue in the fiscal year 2010 and 39.1% in fiscal 2009.

We expect that we will continue to depend on a limited number of large customers for a significant portion of our revenue. Our sales may be impacted by significant changes in our customers' market share, cyclicality, unpredictability of their new product launch activity and possible changes in their supply chain management.

Many healthcare companies are consolidating to create new companies with greater market power. As the healthcare industry continues to consolidate, our customers may delay demand as they integrate operations and products. A consolidation of our customers may also impact demand for our products as the consolidated company implements their supply chain management philosophy. Consolidation of our competitors may also increase pressure as they combine product and services offerings. Consolidation of our customers or competitors may increase pricing pressure or reduce our revenue, either of which would impact our operating results.

- 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 if the product advances we make are not sufficient for their needs, they may instead rely on internal capabilities. In addition, our independent competitors may produce products that are more appealing to our customers and thereby impair our ability to compete effectively with them. Our competitors' product development capabilities could also 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. Increased regulatory pressures and longer approval processes may also impair our ability to develop and assist our customers in developing innovative products, or to do so on a commercially effective timeline. 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. Many 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 continue to 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. The product liability insurance that we carry 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.

- Any claims beyond our insurance coverage may result in substantial costs and a reduction in its available capital resources.

The Company maintains property insurance policies covering physical damage to its equipment, facilities, buildings and inventory; employer's liability insurance generally covering death or work injury of employees; product liability insurance covering product liability claims arising from the use, consumption or operation of its products; general liability insurance covering certain incidents to third parties that occur on or in the premises of the Company; business interruption insurance, and directors and officers liability insurance, among others. The Company does not maintain key man life insurance on any of its senior management or key personnel. The Company's insurance coverage, however, may not be sufficient to cover all claims.

- Our direct sales efforts may be impaired by consolidation of customers or an inability to compete with regard to pricing or products.

The Company's direct sales success relies upon its ability to provide products to customers on competitive price, delivery and quantity terms. Some of our customers utilize a single or small group of suppliers, and some producers utilize a small or limited group of distributors. If consolidation in the hospital industry continues we may lose customers that are absorbed into larger hospital companies that work with a limited number of competitive suppliers, of whom we are not a member. In addition, our competitors may provide products similar to ours on a more price competitive basis, or we may find that we are unable to secure necessary products on a price or quantity basis required by our customers. Further, we may be unable to secure distribution rights for products required by our customers, causing them to consolidate their purchasing with competitors who are able to provide such products. Finally, some of the producers for whom we provide distribution services might decide to sell directly to customers, bypassing our distribution services. If any of these events should occur, it could impair our direct sales business and cause a decline in revenue and profit.

- Our operating results are subject to significant potential fluctuation and historical results should not be relied on 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;
- delays caused by the regulatory approval process for our new products;
- restrictions and delays caused by regulatory review of our customers' products;
- our ability to meet customer demand for certain products or types of product;
- 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 may not necessarily be 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 Northeast Indiana facilities, in particular, face significant and increasing competition, including from certain of our customers and other companies, including orthopedic related start-up companies located in or near Warsaw, Indiana. Some of these competitors are larger and have greater financial and other resources than we do. 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 or shift 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 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 or implants. New sterilization methods could also limit the demand for our sterilization cases. Any of these or other shifts 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 plastic, 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. Further, some of our raw materials are produced in areas of the world that are subject to political and other disruptions that could impair supply. 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. Further, our efforts to cover such materials could be costly and impair our ability to meet our contractual obligations for certain products on a profitable basis. 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, cause us to become involved in litigation with suppliers or customers, impair our profitability and/or reduce the quality of our products.

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

As of January 1, 2011, our total indebtedness, including short-term debt, long-term debt and capital lease obligations was $95.3 million and we had $113.0 million of our $200.0 million revolving credit facility remaining available. Additionally, we have the ability, subject to lender approval, to increase the capacity of the revolving credit facility by $100.0 million. Our revolving credit facility, maturing in November 2015, contains covenants limiting 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;
- 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 difficul