

MERIT MEDICAL SYSTEMS INC

Form 10-K

March 10, 2010

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**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, 2009,

or

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

**MERIT MEDICAL SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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

**0-18592**  
(Commission File No.)

**87-0447695**  
(IRS Employer  
Identification No.)

**1600 West Merit Parkway**

**South Jordan, Utah 84095**

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(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(801) 253-1600**

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, No Par Value**

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

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  No

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 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 (§ 229.405 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  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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, an accelerated filer or 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

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

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The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30, 2009, which is the last day of the registrant's most recently completed second fiscal quarter (based upon the closing sale price of the registrant's common stock on the NASDAQ National Market System on June 30, 2009), was approximately \$425,936,800. Shares of common stock held by each officer and director of the registrant and by each person who may be deemed to be an affiliate have been excluded.

As of March 5, 2010, the registrant had 28,180,527 shares of the registrant's common stock outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the following document are incorporated by reference in Part III of this Report: the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders scheduled for May 26, 2010.

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**PART I**

*Unless otherwise indicated in this report, Merit, we, us, our, and similar terms refer to Merit Medical Systems, Inc. and our consolidated subsidiaries.*

**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical fact are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, intends, believes, estimates, potential, or continue, or thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including risks relating to the integration of the business, assets and operations we acquired in transactions we completed with Alveolus, Inc. ( Alveolus ) and Biosearch Medical Products, Inc., a wholly-owned subsidiary of Hydromer, Inc. ( Biosearch ), Hatch Medical, L.L.C. ( Hatch ) and Vysera BioMedical Limited ( Vysera ); challenges associated with our efforts to pursue new market opportunities, including opportunities in the gastroenterology and pulmonary markets; infringement of Merit's technology or the assertion that Merit's technology infringes the rights of other parties; product recalls and product liability claims; infringement of our technology or the assertion that our technology infringes the rights of other parties; product recalls and product liability claims; downturn of the national economy and its effect on our revenues, collections and supplier relations; termination of supplier relationships, or failure of suppliers to perform; inability to successfully manage growth through acquisitions; delays in obtaining regulatory approvals, or the failure to maintain such approvals; concentration of our revenues among a few products and procedures; development of new products and technologies that could render our products obsolete; market acceptance of new products; delayed introduction of products; price and product competition; availability of labor and materials; cost increases; fluctuations in and obsolescence of inventory; volatility of the market price of our common stock (the Common Stock ); foreign currency fluctuations; changes in key personnel; work stoppage or transportation risks; modification or limitation of governmental or private insurance reimbursement; changes in health care markets related to health care reform initiatives; failure to comply with environmental laws and regulations and other factors referenced in our press releases and reports filed with the Securities and Exchange Commission (the SEC ). All subsequent forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on our operating results are described under Item 1A. Risk Factors beginning on page 10.

**Item 1. Business.**

**GENERAL**

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Merit Medical Systems, Inc. designs, develops, manufactures and markets single-use medical products for interventional and diagnostic procedures. Our focus is divided into four markets: cardiology, radiology, gastroenterology and pulmonary. We are able to introduce new products and capture significant market share because of our expertise in product design, our proprietary technology and our skills in injection and insert molding. Our innovative products are designed to enable physicians and other healthcare professionals perform interventional and diagnostic procedures with enhanced patient care and efficiency.

Our broad offering of cardiology and radiology medical device products assists in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases. Our innovative products aid in conducting dialysis treatment for kidney failure, performing drainage procedures and clearing clots, as well as removing foreign objects from the vasculature, providing access into vasculature and recording hemo-dynamic pressure. These products, which are distributed through our direct sales force and through distributors, include inflation devices, snares, non-vascular stents, aspiration extraction catheters, angiographic catheters, dialysis catheters, micro catheters, sheath introducers and micro access products, standard and hydrophilic coated guide wires, transducers and pressure monitoring accessories, needles, safety products, therapeutic infusion catheters and accessories, drainage catheters, waste

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management systems, high pressure tubing and contrast management systems, pressure infusion bags, syringes, safety scalpels, coagulation probes, kits and procedure trays.

Our gastroenterology and pulmonary medical device products assist physicians, nurses and technicians in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. These products, which are distributed through our direct sales force as well as through distributors, include esophageal and tracheobronchial stents pre-loaded on a catheter-based delivery system, guide wires and sizing devices. Our esophageal stent helps occlude esophageal tracheal fistula. Our newest division, Merit Endotek, creates, develops, manufactures and distributes our new line of gastroenterology and pulmonary medical device products.

Our Original Equipment Manufacturers division ( OEM ) is engaged in efforts to expand the markets in which Merit products are distributed. We sell molded components, sub-assembled goods, and bulk non-sterile goods, which are combined with other components and/or goods from other companies and then sold under a Merit or non-Merit label. Our OEM division sells products in international and domestic markets.

During the first quarter of 2009, we entered into an asset purchase agreement and supply agreement with Biosearch, pursuant to which we purchased a bipolar coagulation probe and grafted biliary stents. During the first quarter of 2009, we also entered into an asset purchase agreement with Alveolus, pursuant to which, among other things, we purchased substantially all of Alveolus' assets. The assets acquired relate to Alveolus' non-vascular interventional stent business for esophageal, tracheobronchial and biliary stenting procedures.

During the second quarter of 2009, we entered into an asset purchase agreement with Hatch, pursuant to which we purchased assets associated with the EN Snare® foreign body retrieval system.

During the fourth quarter of 2009, we entered into an exclusive license, development and supply agreement with Vysera, pursuant to which Vysera granted to us an exclusive license to use, modify and sell certain valve technology and biomaterial coating technology for medical devices (the Vysera Technology) and other intellectual property associated with the Vysera Technology, and to develop and market improvements to the Vysera Technology.

Merit Medical Systems, Inc. was organized in July 1987 as a Utah corporation. We also conduct our operations through a number of domestic and foreign subsidiaries. Our principal offices are located at 1600 West Merit Parkway, South Jordan, Utah, 84095, and our telephone number is (801) 253-1600. See Item 2. Properties. We maintain an Internet website at [www.merit.com](http://www.merit.com).

**PRODUCTS**

We develop, manufacture and market innovative products that offer a high level of quality, value, and safety to our customers, as well as the patients they serve. In response to feedback from health care professionals, we have devoted our focus to four primary areas, cardiology, radiology, pulmonary and gastroenterology. We have expanded our product offerings into other parts of radiology, including interventional nephrology, CT and ultrasound labs. Our products are also used in other clinical areas such as pain management centers, vein clinics, endovascular surgery, and thoracic surgery, as well as in other areas of the health care industry.

The competitive advantages of our products are enhanced by the extensive experience of our management team in the health care industry; our experienced direct sales force and distributors; our ability to combine and customize devices, kits, and trays at the request of our customers; and our dedication to offering “stick to stitch” solutions in the markets we serve worldwide.

### **Cardiology and Radiology Products**

Interventional cardiology is a branch of the medical specialty of cardiology that deals specifically with the catheter-based diagnosis and treatment of heart diseases. A large number of procedures can be performed by catheterization, and more commonly involve the insertion of a sheath into the femoral, radial, or brachial artery. Fluoroscopy (real-time moving X-ray images) and computed tomography or three-dimensional computer generated images are most often used to visualize the vessels and chambers of the heart during these diagnostic and interventional procedures. Percutaneous Coronary Interventions ( PCI ) are used to treat coronary atherosclerosis and the resulting narrowing of the arteries of the heart. Interventional Radiology is related to the minimally invasive treatment of disease in other peripheral vessels and organs of the body and Percutaneous Peripheral Intervention ( PPI ) is used to treat similar disease conditions outside the heart.



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**Inflation Devices.** During PCI and PPI procedures, balloons and/or stents are placed within the vasculature. The balloons must be carefully placed, inflated, and deflated within the vessel in order to achieve optimal results without injury to the patient. For almost two decades, we have offered an extensive, innovative line of inflation devices that accurately measure pressures during balloon and stent deployment. Products like our IntelliSystem® and Monarch® (state of the art digital inflation systems), as well as the Basix COMPAK inflation device, offer the clinician a wide range of features and prices, along with the quality and ergonomic superiority for which we are known.

**Hemostasis Valves.** We have developed a complete line of technically sophisticated, clinically acclaimed hemostasis valves and angioplasty accessories. Hemostasis valves connect to catheters and allow passage of additional guide wires, balloon catheters, and other devices into the vasculature while reducing the amount of blood loss during the procedures.

**Vascular Retrieval Devices.** An increase in vascular procedures influenced our acquisition of the EN Snare® endovascular system from Hatch in 2009. Primary target markets for our snare technology are cardiology, interventional radiology and vascular surgery. The EN Snare® is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. The EN Snare® is designed with three loops to increase the probability of foreign body capture and is offered in seven sizes to accommodate a broad range of vessels throughout the body.

**Vascular Access Products.** We offer a broad line of devices used to gain and maintain vascular access while protecting the clinician from accidental cuts and needle-sticks during the procedure. These effective and useful devices and kits include the Futura® Safety Scalpel and an improved line of angiography needles (Merit Advance®), as well as the SecureLoc Angiographic Needle. In addition, we offer an extensive line of sheath introducers (Prelude®) and mini access kits (MAK and S-MAK ), which are designed to allow the clinician smooth, less traumatic, and convenient access to the patient's vasculature. In 2009, we launched an innovative line extension to the Merit Advance® needle offering including several sizes of 21 gauge, echo-enhanced needles. We also added stand-alone Prelude® dilators to complement our sheath introducer line.

**Diagnostic Catheters, Guide Wires, and Torque Devices.** We offer diagnostic catheters and guide wires for use during both cardiology and radiology angiographic procedures. Merit's diagnostic catheter offering includes our new Impress® line of diagnostic radiology catheters as well as the Performa® and Softouch® brands for both cardiology and peripheral catheters. These catheters offer interventional radiologists and cardiologists superior performance during a variety of angiography procedures. Additionally, our diagnostic guide wires are used to traverse vascular anatomy and aid in placing catheters and other devices. Our precoated, high performance InQwire® guide wires are lubricious and are available in a wide range of configurations to meet clinicians' diagnostic needs. The Merit H2O® hydrophilic guide wire provides enhanced maneuverability through tortuous anatomy. We also offer a line of torque devices (guide wire steering tools) that can be used on both standard and hydrophilic guide wires in both large and small diameters and are often included as a component in our angioplasty packs.

**Angiography and Angioplasty Accessories.** Since the introduction of the CCS disposable coronary control syringe line in 1988, we have continued to develop innovative, problem-solving devices, accessories, kits and procedure trays for use during minimally invasive diagnosis and treatment of coronary artery and peripheral disease. In 2009, we complemented the syringe offering with several new product line extensions and enhancements, including sword-handled Medallions, a new 10ml VacLok® and clear-handled syringes. Additionally, we offer an extensive line of kits containing manifolds, syringes, tubing, and disposable pressure transducers (MeriTrans®) for measurement of pressures within the vessels and chambers of the heart. We also provide devices, kits, and procedure trays used to effectively and safely manage fluids, contrast media, and waste during angiography and interventional procedures. For example, in 2009, we introduced a new Miser II contrast management system to complement our comprehensive line of fluid management products used in angiography procedures.

**Safety and Waste Management Systems.** We offer a variety of safety-related products and kits. Our ShortStop® and ShortStop Advantage® temporary sharps holders address the potential safety issues associated with accidental needle sticks. Our extensive line of color-coded Medallion® specialty syringes and the PAL medication labeling system (which complies with the latest patient safety initiatives of the Joint Commission on Accreditation of Healthcare Organization ( JCAHO )) help minimize mix-ups in administering medication. We also offer waste management products to help avoid accidental exposure to contaminated fluids. These include our OSHA-compliant waste disposal basins, including the BackStop®, BackStop Plus , MiniStop , MiniStop+ and DugOut®. In 2009, we added the Grandstand® to the temporary sharps family of products. These products have been designed to complement other Merit devices and are included in many of our kits and procedure trays in order to make the clinical setting safer for both clinicians and the patients.

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**Drainage Catheters and Accessories.** We have a broad line of catheters for nephrostomy, abscess, and other drainage procedures. Our ReSolve® non-locking and locking drainage catheter line has been expanded every year since the product family was introduced in 2006. These catheters' unique, convenient locking mechanisms are appreciated by clinicians and patients who often comment on the enhanced comfort that the catheter provides them. We also offer a range of catheter fixation devices including the Revolution® catheter fixation device which was designed to be cost-effective, to save time, and to enhance patient comfort. We also provide a wide selection of accessories that complement our drainage catheters, including tubing sets and drainage bags. For non-vascular applications we offer mini access kits (MAK-NV®). This popular device was designed for easy visualization and quick access into the drainage area. For enhanced visibility, the device features an echo-enhanced needle and radiopaque marker tip on the introducer.

**Paracentesis and Pericardiocentesis Catheters.** Paracentesis is a procedure to remove fluid that has accumulated in the abdominal cavity (peritoneal fluid). Our One-Step™ centesis catheter and our Safety Paracentesis Procedure Tray are designed to provide clinicians with a safe, convenient, and cost-effective alternative for paracentesis procedures. In 2009, we expanded and improved the One-Step® product line to include a slip-version of the device that we believe will make our products more competitive in the paracentesis market. Pericardiocentesis is a procedure in which fluid is aspirated from the pericardium (the sac enveloping the heart). Our pericardiocentesis kit is designed as an organized, ready-to-use, convenient tray to assist the clinician in draining fluid quickly from the pericardial sac.

**Therapeutic Infusion Catheters.** We offer an extensive line of therapeutic thrombolytic infusion systems featuring the Fountain® Infusion Systems and the Mistique® Infusion Catheters. These technically advanced catheters are used to treat thrombus (blood clot) formation in the peripheral vessels of the body.

**Multipurpose Microcatheters.** In 2009, we introduced a multipurpose microcatheter for the controlled and selected infusion of diagnostic media or the delivery of interventional devices or therapeutic pharmaceuticals into selected blood vessels. These specialty catheters are used to deliver various embolic agents including alcohol, glue, metallic coils, poly-vinyl alcohol particles, encapsulated chemo-microsphere, and gel foam that can block blood vessels (e.g. for the purpose of stopping bleeding) to tissues or organs including uterine artery embolization for percutaneous treatment of uterine fibroids. These hydrophilic-coated microcatheters are used in both peripheral and coronary vasculature.

**Products for Dialysis and Interventional Nephrology.** In 2007, we acquired the ProGuide® chronic dialysis catheter product line from Datascope Corporation, a New Jersey corporation (Datascope®). The ProGuide® is considered a workhorse catheter for chronic dialysis and provides a platform for additional Merit products in the dialysis and interventional nephrology market. For example, the new Prelude® Short Sheath provides vascular access to dialysis grafts, along with our extensive line of micro access devices such as the MAK® and S-MAK® line of mini access kits. We also offer a wide range of guide wires, diagnostic catheters, therapeutic infusion systems, and safety products that can be used during dialysis-related procedures. In 2009, we launched the OuTake® Catheter Extractor. This novel device is used to remove tunneled chronic dialysis catheters from dialysis patients. Also in 2009, we continued to add to our offering of unique products for the dialysis and interventional nephrology market with a curved introducer needle to aid clinicians who choose to place a tunneled dialysis catheter over a wire with a single stick. The Slip-Not® Suture Retention Device provides a unique and effective method for securing a purse-string suture that controls bleeding after an arteriovenous (AV®) fistula intervention. In addition, we offer the Impress® 30cm angiographic catheters which can be used by interventional nephrologists. Our dialysis and interventional nephrology products are designed to provide comprehensive coverage for completing AV fistula interventions.

**Obesity-Related Products.** Patient obesity presents an ever-growing challenge to clinicians and patients during vascular access, angiography, and interventional procedures. Our KanguruWeb® abdominal retraction device is designed to address this challenge. This device allows easier vessel access to clinicians while maintaining patient comfort and dignity during interventional cardiology and radiology procedures. In addition,

we offer longer angiography and anesthesia needles, as well as mini access kits for improved vascular access of obese patients.

**Gastroenterology and Pulmonary Products**

**Non-Vascular Stents.** Our core pulmonary products include the AERO® and AERO DV® Fully Covered Tracheobronchial Stent and offer our customers a patented, self-expanding metal stent used to improve patency of the airways both tracheal and bronchial and to offer palliation to patients suffering from the effects of cancer. Our gastroenterology products, the Alimaxx-ES® Fully Covered Esophageal Stent System and the Alimaxx-B® Biliary Stent System are used to palliate symptoms associated with malignant tumors affecting the esophagus and the biliary duct. Additionally, we sell a plastic biliary stent to restore patency and relieve symptoms associated with strictures and blockages within the biliary system. These stents are often used to stage treatment of malignant tumors such as pancreatic cancer and other serious conditions. We also sell ancillary products, namely, the AEROSIZER®

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tracheobronchial stent sizing device used in interventional pulmonary procedures and the MAXXWIRE®, which is a line of specialty guide wires which have pulmonary applications.

**Bi-polar probes.** Bi-polar probes are used by physicians as one means of controlling bleeding within a variety of non-vascular systems. These products are currently sold on an OEM basis to customers who further sell them to a large number of gastroenterologists and pulmonologists.

**Specialty Procedure Products**

In addition to the procedures and devices detailed above, interventional radiology (also referred to as the special procedures or specials lab) performs a variety of additional minimally invasive diagnostic and interventional procedures. We offer a variety of devices and accessories used during these procedures.

**Discography Products.** Discography is a technique used to determine whether a disc is the source of pain in patients with back or neck pain. During discography, contrast medium is injected into the disc and the patient's response to the injection is noted. Due to their quality and accuracy, our digital inflation devices (IntelliSystem® and Monarch®) are used in many pain management clinics.

**Pressure Sensors.** Our sensor division manufactures and sells microelectromechanical systems sensor components focusing on piezoresistive pressure sensors in various forms, including bare silicon die, die mounted on ceramic substrates, and custom assemblies for specific customers.

**MARKETING AND SALES**

**Target Market/Industry.** Our target markets include diagnostic and interventional cardiology, interventional radiology, gastroenterology, pulmonology, vascular surgery, interventional nephrology, cardiothoracic surgery, pain management, and thoracic surgery.

According to government statistics, cardiovascular disease continues to be a leading cause of death and a significant health problem in the United States. Treatment options range from dietary changes to surgery, depending on the nature of the specific disease or disorder. Endovascular techniques, including angioplasty, stenting, and endoluminal stent grafts, continue to represent important therapeutic options for the treatment of vascular disease. We derive a large percentage of our revenues from sales of products used during percutaneous (through the skin) diagnostic and interventional procedures such as angiography, angioplasty, and stent placement, and we intend to pursue additional sales growth by building on our existing market position in both catheter technology and accessory products.

In addition to products used in the treatment of coronary and peripheral vascular disease, we continue our efforts to develop and distribute other devices used in the major markets we serve. For example, we have developed and are distributing products used for percutaneous drainage. Prior to the widespread use of CT or ultrasound imaging, surgery was necessary to drain internal fluid from body cavities and organs. Now

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percutaneous drainage is frequently prescribed as the treatment of choice for many types of fluid collections. Our family of drainage catheters and associated devices are used by physicians in the interventional radiology, vascular surgery, and the cardiology catheter lab for the percutaneous drainage collection of simple serous fluid to viscous fluid (blood, or infected secretion) within the body.

We also service the growing interventional nephrology market. Dialysis, or cleaning of the blood, is necessary in conditions such as acute renal failure, chronic renal failure and end-stage renal disease, or ESRD. The kidneys remove excess water and chemical wastes from blood, permitting clean blood to return to the circulatory system. When the kidneys malfunction, waste substances are not properly excreted, creating an abnormal buildup of wastes in the bloodstream. Dialysis machines are used to treat this condition. Dialysis catheters, which connect the patient to the dialysis machine, are used at various stages in the treatment of dialysis patients. In the past few years, we have added catheters and other accessories to our dialysis-related product offering.

We believe our move into the areas of gastroenterology and pulmonology, as well as thoracic surgery, will open new opportunities to provide not only existing Merit products, such as inflation devices, syringes, centesis catheters, and procedure kits to those markets, but also to provide additional offerings built upon our non-vascular stent technology.

In general, our target markets are characterized by rapid change resulting from technological advances and scientific discoveries. We plan to continue to develop and launch innovative products to support clinical trends designed to address the demands of those markets.

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**Market Strategy.** Our marketing strategy is focused on identifying and introducing a regular flow of highly profitable differentiated products that meet customer needs. In order to stay abreast of customer needs, we seek suggestions from hospital personnel working with our products in cardiology and radiology applications, as well as gastroenterology, pulmonology, and thoracic surgery. Suggestions for new products and product improvements may come from engineers, sales people, physicians and technicians who perform the clinical procedures.

When we determine that a product suggestion demonstrates a sustainable competitive advantage, meets customer needs, fits strategically and technologically with our business, and has a good potential financial return, we generally assemble a project team comprised of individuals from our sales, marketing, engineering, manufacturing, legal, and quality assurance departments. This team works to identify the customer requirements, integrate the design, compile necessary documentation and testing, and prepare the product for market introduction. We believe that one of our marketing strengths is our capacity to rapidly conceive, design, develop, and introduce new products.

**U. S. Sales.** Sales of our products in the United States accounted for 66%, 68% and 68% of our total sales for the years ended December 31, 2009, 2008 and 2007, respectively. Our direct sales force currently consists of an Executive Vice President of Marketing and Sales, a Vice President of U. S. Sales, ten regional sales managers and 85 direct sales representatives and clinical specialists located in major metropolitan areas throughout the United States. In addition, we have developed another sales force in the United States for Merit Endotek, consisting of a Vice President of Sales, two regional sales managers and 11 direct sales representatives. We consider training to be a critical factor in the success of our direct sales force. Our sales people are trained by our personnel at our facilities, by a senior sales person in their respective territories, at regular national and regional sales meetings, by consulting cardiologists, radiologists, endoscopists, and thoracic surgeons and by observation of procedures in laboratories and operating rooms throughout the U.S.

**International Sales.** Approximately 174 independent dealer organizations and packers distribute our products worldwide, including territories in Europe, Africa, the Middle East, Asia, South and Central America, and Canada. We have a Vice President for International Sales, based in South Jordan, Utah, who oversees Asia, South and Central America, Australia and Canada. We also have a Vice President of European Sales who oversees Europe, the Middle East and Africa. Approximately 30 direct sales representatives and country managers presently sell our products in Germany, France, the United Kingdom, Belgium, The Netherlands, Denmark, Sweden, Finland, Ireland and Austria. In 2009, our international sales grew approximately 19% over our total sales for the year ended December 31, 2008 and accounted for approximately 34% of total sales. Our new Merit Endotek division, has a small, but growing, presence in international markets. With the recent and planned additions to our product lines, we believe that our international sales will continue to increase.

We require our international dealers to inventory products and sell directly to customers within defined sales territories. Each of our products must be approved for sale under the laws of the country in which it is sold. International dealers are responsible for compliance with all applicable laws and regulations in their respective countries.

**OEM Sales.** We currently have a worldwide OEM division that sells molded components, sub-assembled goods, and bulk non-sterile goods which may be combined with other components and/or goods from other companies and then sold under a Merit or non-Merit label.

**CUSTOMERS**

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We provide products to hospitals and clinic-based cardiologists, radiologists, anesthesiologists, physiatrists (pain management physicians), neurologists, nephrologists, vascular surgeons, interventional gastroenterologists and pulmonologists, thoracic surgeons, technicians and nurses. Hospitals and acute care facilities in the United States purchase our products through our direct sales forces, distributors, OEM partners, custom packagers and packers who assemble and combine our products in custom kits and packs. Outside the United States, hospitals and acute care facilities purchase our products through our direct sales force, or in the absence of a sales force, through independent distributors or OEM partners.

In 2009, our U.S. domestic sales force completed approximately 43% of our sales directly to U.S. hospitals and approximately 13% of our sales through other channels such as U.S. custom packagers and distributors. Approximately 34% of our sales were made by our direct European sales force, international distributors, and our OEM sales force. Sales to our single largest customer, an OEM partner, accounted for approximately 6% of total sales during the year ended December 31, 2009. We generally manufacture products for other medical device companies through our OEM division. During the year ended December 31, 2009, OEM sales represented approximately 14% of our total sales. Our new Merit Endotek division, which was in existence for less than the full year, represented approximately 3% of total sales.



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**RESEARCH AND DEVELOPMENT**

In 2009, we continued to innovate in the treatment of cardiovascular disease by offering our customers a number of new products, improvements to existing products and line extensions. Additionally, we expanded our product offerings by entering the gastrointestinal and pulmonary markets through the acquisition of Alveolus. We subsequently retained key research and development personnel and have since added new sizes of non-vascular stents to the esophageal product line previously developed by Alveolus. Furthermore, we have initiated multiple projects to expand Merit Endotek's products scheduled for release in 2010 through 2012.

Our research and development expenses were approximately \$11.2 million, \$9.2 million, and \$8.7 million in 2009, 2008 and 2007, respectively. Our future growth continues to be fueled with multiple product ideas guided by our Chief Executive Officer, our Vice President of Engineering and our sales and marketing teams, as well as by collaboration with physicians with whom we have long-term relationships. We have research and development facilities in South Jordan, Utah; Angleton and Dallas, Texas; Howell, New Jersey; Galway, Ireland; and Venlo, The Netherlands.

**MANUFACTURING**

We manufacture many of our products utilizing our proprietary technology and our expertise in plastic injection and insert molding. We generally contract with third parties for the tooling of molds, but we design and own all of our molds. We utilize our experience in injection and insert molding technologies in the manufacture of most of the custom components used in our products.

We either assemble the electronic monitors and sensors used in our IntelliSystem® and Monarch® inflation devices from standard electronic components or we purchase them from third-party suppliers. Merit Sensor Systems, Inc., a wholly-owned subsidiary of Merit Medical Systems, Inc. ( Merit Sensor Systems ), develops and markets silicon sensors. It is presently supplying all of the sensors we utilize in our digital inflation devices.

Our products are manufactured at several factories, including facilities located in South Jordan and Murray, Utah; Galway, Ireland; Venlo, The Netherlands; Angleton, Texas; and Chester, Virginia. See Item 2. Properties. We also manufacture at a contract manufacturing facility in Mexico.

We have distribution centers located in South Jordan, Utah; Angleton, Texas; Chester, Virginia; and Maastricht, The Netherlands.

We believe that our variety of suppliers for raw materials and components necessary for the manufacture of our products, as well as our long-term relationships with such suppliers, promote stability in our manufacturing process. Historically, we have not been materially affected by interruptions with such suppliers. Furthermore, we seek to develop relationships with potential back-up suppliers for materials and components in the event of supply interruptions.

## COMPETITION

We compete in several global markets, including diagnostic and interventional cardiology, interventional radiology, vascular surgery, interventional nephrology, cardiothoracic surgery, interventional gastroenterology and pulmonology, anesthesiology and pain management. These markets encompass a large number of suppliers of varying sizes.

In the interventional cardiology and radiology markets, as well as the gastroenterology and pulmonary markets, we compete with large international, multi-divisional medical supply companies such as Cordis Corporation (Johnson & Johnson), Boston Scientific Corporation, Medtronic, C.R. Bard, Abbott, and Terumo. Medium-size companies we compete with include Cook, Arrow, AngioDynamics, Vascular Solutions, B. Braun, Olympus, Navilyst, Edwards Lifescience, and ICU Medical. Many of our competitors have substantially greater financial, technical, and marketing resources than we do.

The principal competitive factors in the markets in which our products are sold are quality, price, value, device feature, customer service, breadth of line, and customer relationships. We believe that our products have achieved market acceptance due to the quality of materials and workmanship of our products, innovative design, our willingness to customize to fit customer needs, and our prompt attention to customer requests. Our products are priced competitively, but generally not below prices for competing products. One of our primary competitive strengths is our relative stability in the marketplace; a comprehensive, broad line of ancillary products; and our history of introducing a variety of new products and product line extensions to the market on a regular basis.

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Based on available industry data, with respect to the number of procedures performed, we believe we are the leading provider of digital inflation technology in the world. In addition, we believe we are the world market leader for inflation devices, hemostasis devices and torque devices. We believe that we are one of two market leaders in the United States for control syringes, waste-disposal systems, tubing, and manifold kits.

We anticipate the recent and planned additions to our product lines will enable us to compete even more effectively in both the U.S. and international markets. There is no assurance that we will be able to maintain our existing competitive advantages or compete successfully in the future.

We derive a substantial majority of our revenues from sales of products used in diagnostic angiography and interventional cardiology and radiology stent procedures. Medical professionals are starting to use new diagnostic methods and interventional procedures and devices, as well as drugs for the treatment and prevention of cardiovascular disease. These new methods, procedures and devices may render some of our products obsolete or limit the markets for our products. However, with the advent of vascular stents and other procedures, we have experienced continued growth in sales of our products.

#### **PATENTS, LICENSES, TRADEMARKS AND COPYRIGHTS**

We consider our proprietary technology to be important in the development and manufacture of our products. We seek to protect our technology through a combination of patents, trademarks, trade secrets, copyrights, confidentiality agreements and non-compete agreements. We generally seek patent protection of our technology in the United States and certain foreign countries where such protection appears to be advantageous.

As of December 31, 2009, we either owned or had licenses to use more than 100 U.S. patents. Additionally, we either owned or had exclusive rights to 66 pending U.S. patent applications. We owned 66 international patents, and either owned or had exclusive rights to 60 pending international patent applications. We also operate under licenses from other owners of certain patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks.

We believe that our patents and pending patent applications are materially important to our business, but we do not believe that our business is dependent upon securing such patents. We believe that no single patent, patent application, technology, trade secret, know-how, copyright, trademark, or license is material in relation to our business as a whole.

Certain U.S. patents related to the digital display in our inflation devices expired in 2009 and other patent rights are scheduled to expire thereafter. We expect that related patents will continue to be valuable, in part because of proprietary innovations made since the issuance of our first patent. In 1992, we were granted a license to use patented technology that we incorporated into our inflation devices. In return, we paid a 5.75% ongoing royalty to the licensor, not to exceed \$450,000 annually. Royalties paid for such license in each of 2008 and 2007 were \$450,000. The license agreement terminated in August 2008 and we did not pay royalties under that license during 2009.

We have also registered or applied for registration of several trade names or trademarks. See [Products](#) above. We have received 154 U.S. and foreign trademark registrations, and other U.S. and foreign trademark applications are currently pending. We have registered copyrights relating to certain software used in our electronic inflation devices.

**REGULATION**

We face comprehensive governmental regulation both within and outside the United States relating to the development, manufacture, sale and distribution of our products. A number of factors substantially increase the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. These include detailed inspection of and controls over research and laboratory procedures, clinical investigations, manufacturing, marketing, sampling, distribution, recordkeeping, storage and disposal practices and various post-market requirements. Governmental regulatory actions can result in the seizure or recall of products, suspension or revocation of the authority necessary for their production and sale, and civil or criminal sanctions.

Under the Federal Food, Drug and Cosmetic Act, (the Food, Drug and Cosmetic Act ) and through its own rules, the U.S. Food and Drug Administration ( FDA ) regulates the development, testing, packaging, labeling, and marketing of medical devices and manufacturing procedures relating to these devices. In general, the FDA requires that manufacturers adhere to certain standards designed to ensure the safety and effectiveness of medical devices. We employ a Chief Regulatory Officer and a Vice President of Quality Systems who are responsible to promote our compliance with applicable FDA regulations.

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The FDA's Quality Systems Regulations define the requirements for our manufacturing processes, require the maintenance of certain records, and provide for unscheduled inspections of our facilities. We must also comply with certain requirements of state, local, and foreign governments in the manufacture and marketing of our products.

New medical devices may also be subject to either the Section 510(k) Pre-Market Notification regulations or the Pre-Market Approval ( PMA ) regulations promulgated by the FDA and similar regulatory requirements in foreign countries. New products in either category require extensive documentation, careful engineering, and manufacturing controls to ensure quality. Products needing PMA approval require extensive pre-clinical and clinical testing and approval by the FDA prior to marketing. Products subject to Section 510(k) of the Food Drug and Cosmetic Act require FDA clearance prior to marketing. To date, our products have required only compliance with Section 510(k). Most of our products are subject to foreign regulatory approvals before they may be marketed abroad. We place the CE mark on devices sold in Europe. The CE mark represents that a product has met EU health, safety, and environmental requirements. We have received ISO 13485 certification for our facilities in Utah, Texas, Virginia and Ireland. We have also received ISO 9001:2008 certification for our Merit Sensor Systems facility in South Jordan, Utah.

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. Healthcare costs continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. Recently, in the United States, particular attention has been focused on medical device prices and profits, and on programs that encourage doctors to recommend, use or purchase particular medical devices. Payers have become more influential in the marketplace and increasingly are focused on medical device pricing and medical device utilization and the quality and costs of healthcare. Violations of these frauds and abuse-related laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States.

**EMPLOYEES**

As of December 31, 2009, we employed 1,875 people, including 1,402 in manufacturing; 218 in sales and marketing; 145 in engineering, research and development; and 110 in administration.

Many of our present employees are highly skilled. Our failure or success will depend, in part, upon our ability to retain such employees. We believe that an adequate supply of skilled employees is available. We have, from time-to-time, experienced rapid turnover among our entry-level assembly workers, as well as occasional shortages of such workers, resulting in increased labor costs and administrative expenses related to hiring and training replacement and new entry-level employees. Our key employees are bound by agreements or policies of confidentiality. None of our employees are represented by a union or other collective bargaining group. We believe that our relations with our employees are generally good.

**AVAILABLE INFORMATION**

We file annual, quarterly and current reports and other information with the SEC. These materials can be inspected and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Copies of these materials may also be obtained by mail at prescribed rates from the SEC's Public Reference Room at the above address. Information about the Public Reference Room can be obtained by calling the

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SEC at 1-800-SEC-0330. The SEC also 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 the SEC's Internet website is [www.sec.gov](http://www.sec.gov).

We make available, free of charge, on our Internet website, located at [www.merit.com](http://www.merit.com), our most recent Annual Report on Form 10-K, our most recent Quarterly Report on Form 10-Q, any Current Reports on Form 8-K filed since our most recent Annual Report on Form 10-K, and any amendments to such reports as soon as reasonably practicable following the electronic filing of such report with the SEC. In addition, we provide electronic or paper copies of such filings free of charge upon request.

### **FINANCIAL INFORMATION ABOUT FOREIGN AND DOMESTIC SALES**

For financial information relating to our foreign and domestic sales see Note 11 to our consolidated financial statements set forth in Item 8 of this report.

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**Item 1A. Risk Factors.**

Our business, operations, and financial condition are subject to certain risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, our actual results will vary, and may vary materially from those anticipated, estimated, projected or expected. Among the key factors that may have a direct bearing on our business, operations, or financial condition are the factors identified below:

**We may be unable to protect our proprietary technology or may infringe on the proprietary technology of others.**

We have obtained U.S. patents and filed additional U.S. and foreign patent applications; however, there can be no assurance that any patents we hold, or for which we have applied, will provide us with any significant competitive advantages, that third parties will not challenge our patents, or that patents owned by others will not have an adverse effect on our ability to conduct business. We could incur substantial costs in preventing patent infringement, in curbing the unauthorized use of our proprietary technology by others, or in defending against similar claims of others. Since we rely on trade secrets and proprietary know-how to maintain our competitive position, there can be no assurance that others may not independently develop similar or superior technologies.

We operate in an increasingly competitive medical technology marketplace. There has also been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Our activities may require us to defend against claims and actions alleging infringement of the intellectual rights of others. If a court rules against us in any patent litigation, any of several negative outcomes could occur: we could be subject to significant liabilities, we could be forced to seek licenses from third parties, or we could be prevented from marketing certain products. Any of these outcomes could have a material adverse effect on our financial condition and operating results.

Our ability to remain competitive is dependent, in part, upon our ability to prevent other companies from using our proprietary technology incorporated into our products. We seek to protect our technology through a combination of patents, trademarks, and trade secrets, as well as licenses, proprietary know-how and confidentiality agreements. We may be unable, however, to prevent others from using our proprietary information, or continue to use such information our self, for numerous reasons, including the following, any of which could have a material adverse effect on our business, operations, or financial condition:

- Our issued patents may not be sufficiently broad to prevent others from copying our proprietary technologies
  
- Our issued patents may be challenged by third parties and deemed to be overbroad or unenforceable
  
- Our products may infringe on the patents or other intellectual property rights of other parties, requiring us to alter or discontinue our manufacture or sale of such products

- Costs associated with seeking enforcement of our patents against infringement, or defending our self against allegations of infringement, may be significant
- Our pending patent applications may not be granted for various reasons, including over breadth or conflict with an existing patent
- Other persons may independently develop, or have developed, similar or superior technologies

**Economic and industry conditions constantly change, and negative economic conditions in the United States and other countries could materially and adversely affect our business and results of operations.**

Our business and our results of operation are affected by many changing economic and other conditions beyond our control. Actual or potential changes in international, national, regional and local economic, business and financial conditions, including recession and inflation, may negatively affect consumer preferences, perceptions, spending patterns or demographic trends, any of which could adversely affect our business and results of operations. We may also experience higher bad-debt rates and slower receivable collection rates in our dealings with our customers. In addition, recent disruptions in the credit markets have resulted in greater volatility, less liquidity, widening of credit spreads, and decreased availability of financing. As a result of these factors, there can be no assurance that financing will be available to us on acceptable terms, if at all. An inability to obtain necessary additional financing on acceptable terms may have an adverse impact on us and on our ability to grow our business.



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**Termination or interruption of relationships with our suppliers, or failure of such suppliers to perform, could disrupt our business.**

We rely on raw materials, component parts, finished products, and services supplied by outside third parties in connection with our business. For example, substantially all of our products are sterilized by only a few different entities. In addition, some of our products are manufactured or assembled by third parties. If a supplier of significant raw materials, component parts, finished goods, or services were to terminate its relationship with us, or otherwise cease supplying raw materials, component parts, finished goods, or services consistent with past practice, our ability to meet our obligations to our end customers may be disrupted. A disruption with respect to numerous products, or with respect to a few significant products, could have a material adverse effect on our business, operations or financial condition.

**Our products may be subject to recall or product liability claims.**

Our products are used in connection with invasive procedures and in other medical contexts in which it is important that those products function with precision and accuracy. If our products do not function as designed, or are designed improperly, we may choose to or be forced by regulatory agencies to withdraw such products from the market. In addition, if medical personnel or their patients suffer injury as a result of any failure of our products to function as designed, or an inappropriate design, we could be subject to lawsuits seeking significant compensatory and punitive damages. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business, operations or financial condition.

We generally offer a limited warranty for product returns which are due to defects in quality and workmanship. We attempt to estimate our potential liability for future product returns and establish reserves on our financial statements in amounts that we believe will be sufficient to address our warranty obligations; however, our actual liability for product returns may significantly exceed the amount of our reserves. If we underestimate our potential liability for future product returns, or if unanticipated events result in returns that exceed our historical experience, our financial condition and operating results could be materially and adversely affected.

**We may be unable to successfully manage growth, particularly if accomplished through acquisitions.**

Successful implementation of our business strategy will require that we effectively manage any associated growth. To manage growth effectively, our management will need to continue to implement changes in certain aspects of our business, to improve our information systems and operations to respond to increased demand, to attract and retain qualified personnel, and to develop, train, and manage an increasing number of management-level and other employees. Growth could place an increasing strain on our management, financial, product design, marketing, distribution and other resources, and we could experience operating difficulties. Any failure to manage growth effectively could have a material adverse effect on our business, operations or financial condition.

To the extent that we grow through acquisition, we will face the additional challenges of integrating our current operations, culture, information management systems and other characteristics with that of the acquired entity. We may incur significant expenses in connection with negotiating and consummating one or more transactions, and we may inherit certain liabilities in connection with each acquisition. In addition, we may not realize competitive advantages, synergies or other benefits anticipated in connection with any such acquisition. If we do not adequately identify targets for, or manage issues related to, our future acquisitions, such acquisitions may have a negative adverse effect on our business and financial results.

**A significant adverse change in, or failure to comply with, governing regulations could adversely affect our business.**

Substantially all of our products are devices, as defined in the Federal Food, Drug and Cosmetic Act, and the manufacture, distribution, record keeping, labeling and advertisement of our products are subject to regulation by the FDA in the United States and its equivalent regulatory agencies in various foreign countries in which our products are manufactured, distributed, labeled, offered or sold. Further, we are subject to regular review and periodic inspections at our current facilities with respect to the FDA's Quality System Regulations and similar requirements of foreign countries. In addition, we are subject to certain export control restrictions governed by the U.S. Department of the Treasury and may be governed by other regulatory agencies in various foreign countries to which our products are exported. Although we believe we are currently in material compliance with these requirements, any failure on our part to comply with all applicable current and future regulations could adversely affect our business, operations, or financial condition.

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**A significant portion of our revenues are derived from a few products, procedures and/or customers.**

A significant portion of our revenues are attributable to sales of our inflation devices. During the year ended December 31, 2009, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for approximately 24% of our total revenues. Sales of our inflation devices to a single OEM customer, representing our largest customer, were approximately 6% of our total inflation device sales for the year ended December 31, 2009. Any material decline in market demand, or change in OEM supplier preference, for our inflation devices could have an adverse effect on our business, operations or financial condition.

In addition, the products that have accounted for a majority of our historical revenues are designed for use in connection with a few related medical procedures, including angioplasty, stent placement procedures, and spinal procedures. If subsequent developments in medical technology or drug therapy make such procedures obsolete, or alter the methodology of such procedures so as to eliminate the usefulness of our products, we may experience a material decrease in demand for our products and experience deteriorating financial performance.

**We may be unable to compete in our markets, particularly if there is a significant change in relevant practices or technology.**

The market for each of our products is highly competitive. We face competition from many companies which are larger, better established, have greater financial, technical and other resources and possess a greater market presence than we do. Such resources and market presence may enable our competition to more effectively market competing products or to market competing products at reduced prices in order to gain market share.

In addition, our ability to compete successfully is dependent, in part, upon our response to changes in technology and upon our efforts to develop and market new products which achieve significant market acceptance. Competing companies with substantially greater resources than us are actively engaged in research and development of new methods, treatments, drugs, and procedures to treat or prevent cardiovascular disease that could limit the market for our products and eventually make some of our products obsolete. A reduction in the demand for a significant number of our products, or a few key products, could have a material adverse effect on our business, operations or financial condition.

**The market price of our Common Stock has been, and may continue to be, volatile.**

The market price of our Common Stock has been, and may continue to be, volatile for various reasons, including the following, which could have a material adverse effect on our business, operations or financial condition:

- Our announcement of new products or technical innovations, or similar announcements by our competitors
- Development of new procedures that use, or do not use, our technology

- Quarter-to-quarter variances in our financial results
- Claims involving potential infringement of patents and other intellectual property rights
- Analysts and other projections or recommendations regarding our Common Stock specifically or medical technology stocks generally
- Any restatement of our financial statements or any investigation of us by the SEC, the FDA or another regulatory authority
- A decline, or rise, of stock prices in the capital markets generally

**Fluctuations in Euro and GBP exchange rates may negatively impact our financial results.**

Our material market risk relates primarily to fluctuations in the rate of exchange between the Euro and Great Britain Pound ( GBP ) relative to the value of the U.S. Dollar. Those fluctuations could have a negative impact on our margins and financial results. For example, during 2009, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$2.6 million and an increase of 0.10% in our gross profit.

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For the year ended December 31, 2009, approximately \$26.3 million, or 10%, of our sales, were denominated in foreign currencies. If the rate of exchange between the Euro and the GBP declines, against the U.S. Dollar, we may not be able to increase the prices we charge our European customers for products whose prices are denominated in Euros and GBP. Furthermore, we may be unable or elect not to enter into hedging transactions which could mitigate the effect of declining exchange rates. As a result, if the rate of exchange between Euros and GBP declines, against the U.S. Dollar, our financial results may be negatively impacted.

**Operations at our manufacturing facilities may be negatively impacted by certain factors, including severe weather conditions and the impact of natural disasters.**

Our operations could be affected by many factors beyond our control, including severe weather conditions and the impact of natural disasters, including hurricanes and tornados. These conditions could cause substantial damage to our facilities, interrupt our production and disrupt our ability to deliver products to our customers.

Our operations in Angleton, Texas have been suspended due to hurricanes in recent years. In September 2008 we shut down our operations in Angleton in anticipation of Hurricane Ike and production was restored shortly thereafter. While we incurred minimal damage to our facility, we experienced greater financial damage as a result of the production disruption. Although our insurance covered some of the losses associated with the event, future natural disasters could increase the cost of insurance. We cannot be certain that any losses from business interruption or property damages, along with the increases in insurance costs, will not have a material adverse effect on our results of operations or financial condition.

**We are dependent upon key personnel.**

Our success is dependent on key management personnel, including Fred P. Lampropoulos, our Chairman of the Board, President and Chief Executive Officer. Mr. Lampropoulos is not subject to any agreement prohibiting his departure, and we do not maintain key man life insurance on his life. The loss of Mr. Lampropoulos, or of certain other key management personnel, could have a materially adverse effect our business and operations. Our success also depends on, among other factors, the successful recruitment and retention of key operating, manufacturing, sales and other personnel.

**We are subject to work stoppage, transportation and related risks.**

We manufacture products at various locations in the United States and foreign countries and sell our products worldwide. We depend on third-party transportation companies to deliver supplies necessary to manufacture our products from vendors to our various facilities and to move our products to customers, operating divisions, and other subsidiaries located worldwide. Our manufacturing operations, and the operations of the transportation companies on which we depend, may be adversely affected by natural disasters or significant human events, such as a war, terrorist attack, riot, strike, slowdown or similar event. Any disruption in our manufacturing or transportation could materially adversely affect our ability to meet customer demands or our operations.

**Limits on reimbursement imposed by governmental and other programs may adversely affect our business.**

The cost of a significant portion of medical care is funded by governmental, social security or other insurance programs. Limits on reimbursement imposed by such programs may adversely affect the ability of hospitals and others to purchase our products. In addition, limitations on reimbursement for procedures which utilize our products could adversely affect sales.

**Our failure to comply with applicable environmental laws and regulations could affect our business and results of operations.**

Merit Sensor Systems, Inc. manufactures and assembles certain products that require the use of hazardous materials that are subject to various federal, state and local laws and regulations governing the protection of the environment. While the cost of compliance with such laws and regulations has not had a material adverse effect on our results of operations historically, compliance with future regulations may require additional capital investments in pollution control equipment or changes in the way Merit Sensor Systems makes its products. Additionally, because Merit Sensor Systems uses hazardous and other regulated materials in its manufacturing processes, we are subject to certain risks of liabilities and claims resulting from any accidental releases. While we believe the precautions and infrastructure Merit Sensor Systems has put in place are sufficient, any accidental release may have an adverse affect on our business and results of operations.

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**If certain proposed healthcare reform legislative proposals are enacted into law, our business, financial condition, results of operations and cash flows could be adversely affected.**

In October 2009, both the U.S. Senate and House of Representatives released draft healthcare reform legislation that includes provisions that would impose a fee or excise tax on certain medical devices. The proposals, as currently drafted, may apply to certain of our medical device products. Many details of the proposals remain uncertain, and any healthcare reform legislation must still be enacted by both Houses of Congress and signed by the President. If either of these medical device proposals is enacted into law, our results of operations could be adversely affected.

**If our employees or agents violate the U.S. Foreign Corrupt Practices Act or anti-bribery laws in other jurisdictions, we may incur fines or penalties, or experiences other adverse consequences.**

We are subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery laws in non-U.S. jurisdictions which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents. If our employees or agents violate the provisions of the FCPA or other anti-bribery laws, we may incur fines or penalties, we may be unable to market our products in other countries or we may experience other adverse consequences which could have a material adverse effect on our operating results or financial condition.

**We may be subject to laws targeting fraud and abuse in the healthcare industry, the violation of which could adversely affect our business or financial results.**

Our operations are subject to various state and federal laws targeting fraud and abuse in the healthcare industry, including federal anti-kickback laws, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. Violations of these fraud and abuse-related laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States, any of which could adversely affect our business or financial results.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

We own approximately 40 acres of real property in the city of South Jordan, Utah, surrounding an additional ten acres of leased real property on which our principal office and manufacturing facility is located which totals approximately 200,000 square feet. We sold the ten-acre site to an unrelated developer in order to facilitate construction of the facility and entered into a 25-year lease agreement (beginning in 1995) to finance the facility. Monthly lease payments attributable to the ten-acre parcel are approximately \$156,000. We also hold an option to purchase the facility, exercisable at market value after 25 years. At the end of 2004, we completed construction of an approximately 47,000 square-foot manufacturing facility in South Jordan, Utah. This facility is used for research, development and pilot production clean rooms and for production of sensors. We completed an approximately 140,000 square-foot manufacturing facility located in South Jordan, Utah in September 2005 which is used for injection and insert molding production, as an automated finished goods warehouse, and as the locale for management information systems and accounting employees. During 2009, we acquired an additional three and one-half acres of property west of our South Jordan facility. We believe the acquisition of this additional property will potentially enable us to expand our operations in the future as property surrounding our existing facilities is limited due to increased development.

We own a building of approximately 65,000 square feet, with approximately three acres of land, in Galway, County Galway, Republic of Ireland, which serves as our principal office and manufacturing facility for our European operations. The facility houses a research and development team, which developed our diagnostic guide wire, and is working to develop other new products. We also manufacture other products at the Galway facility.



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We lease a manufacturing facility of approximately 63,000 square feet located in Murray, Utah. The Murray facility is used for production of several of our products. We lease the facility on a month-to-month basis. The aggregate lease payments on our Murray facility are approximately \$37,000 per month.

We own approximately 19 acres of land and an approximately 75,000 square-foot building in Angleton, Texas. We use the facility for the production of catheter-related products.

We own approximately 12 acres of land and an approximately 100,000 square-foot building in Chester, Virginia. We use the facility for production of custom procedure trays used in the medical industry.

In December 2009, we leased a warehouse of approximately 33,500 square feet located in Chester, Virginia. We intend to use this facility as a warehouse for finished goods produced in our existing Chester, Virginia facility. The lease is scheduled to expire in April 30, 2015. The current monthly lease payment is approximately \$10,000.

In July 2009, we leased an office, warehouse and production facility of approximately 40,000 square feet located in West Jordan, Utah. We completed approximately \$1.1 million in renovations to the building largely related to additional clean rooms completed over the last several months of 2009 and through January of 2010, which will provide approximately 14,000 square feet of clean rooms. We intend to use the facility to produce products transferred from our other manufacturing sites in the U.S. and believe the facility will also provide capacity for new product releases and additional products we may obtain through prospective acquisitions. The current lease is scheduled to expire in July 2012 and has three, 18-month renewal options. The current monthly lease payment is approximately \$16,000.

We relocated our MCTec operations to a leased manufacturing facility of approximately 10,000 square feet located in Venlo, The Netherlands. We use the facility for the coating of wires and tubing for medical devices. The lease is scheduled to expire in January 2011. The current monthly lease payment is approximately \$8,000.

In May 2008, we completed construction of a new European headquarters in Beek, The Netherlands. The new 31,000 square-foot facility is designed to provide for anticipated growth in our European operations.

We believe that our existing and proposed facilities will generally be adequate for our present and future anticipated levels of operations.

**Item 3.           Legal Proceedings.**

In the course of conducting our business operations, we are, from time to time, involved in litigation and other disputes. Our management does not currently anticipate that any pending litigation or dispute against us will have a materially adverse effect on our business, operations or

financial condition.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****MARKET PRICE FOR THE COMMON STOCK**

Our Common Stock is traded on the NASDAQ Global Select Market under the symbol MMSI. The following table sets forth high and low sale prices for the Common Stock for the periods indicated.

<b>For the year ended December 31, 2009</b>		<b>High</b>		<b>Low</b>
First Quarter	\$	18.00	\$	9.57
Second Quarter	\$	16.99	\$	11.68
Third Quarter	\$	19.54	\$	15.71
Fourth Quarter	\$	19.90	\$	15.65

<b>For the year ended December 31, 2008</b>		<b>High</b>		<b>Low</b>
First Quarter	\$	17.41	\$	13.71
Second Quarter	\$	16.97	\$	14.00
Third Quarter	\$	21.36	\$	14.18
Fourth Quarter	\$	19.99	\$	12.35

**OUTSTANDING SHARES AND NUMBER OF SHAREHOLDERS**

As of March 5, 2010, the number of shares of Common Stock outstanding was 28,180,527, held by approximately 161 shareholders of record, not including shareholders whose shares are held in securities position listings.

**DIVIDENDS**

We have never declared or paid cash dividends on the Common Stock. We presently intend to retain any future earnings for use in our business and, therefore, do not anticipate paying any dividends on the Common Stock in the foreseeable future. In addition, our revolving line of credit contains covenants prohibiting the declaration and distribution of a cash dividend at any time prior to the termination of such line of credit.

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**PERFORMANCE GRAPH**

The following graph compares the performance of the Common Stock with the performance of the NASDAQ Stock Market (U.S. Companies) and NASDAQ Stocks (SIC 3840-3849 U.S. Companies - Surgical, Medical and Dental Instruments and Supplies) for a five-year period by measuring the changes in Common Stock prices from December 31, 2004 to December 31, 2009.

Comparison of 5 Year Cumulative Total Return

Among Merit Medical Systems, Inc., NASDAQ Stock Market (U.S.)

and NASDAQ Stocks (SIC 3840-3849)

	12/2004	12/2005	12/2006	12/2007	12/2008	12/2009
Merit Medical System Inc.	\$ 100	\$ 79	\$ 104	\$ 91	\$ 117	\$ 126
NASDAQ Stock Market (U.S. Companies)	100	102	112	122	59	84
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	110	116	147	79	116

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was \$100 on December 31, 2004 and that all dividends were reinvested. Past performance is not necessarily an indicator of future results.

NOTE: Performance graph data is complete through last fiscal year.

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NOTE: Performance graph with peer group uses peer group only performance (excludes only Merit).

NOTE: Peer group indices use beginning of period market capitalization weighting.

NOTE: Data and graph are calculated from CRSP Total Return Index for the NASDAQ Stock Market (US Companies), Center for Research in Security Prices (CRSP), Booth School of Business, The University of Chicago.

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**SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS**

The following table contains information regarding our equity compensation plans as of December 31, 2009 (in thousands):

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation Plans approved by security holders	3,631(1),(3)	\$ 12.76	2,191(2),(3)

(1) Consists of 3,630,891 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(2) Consists of 337,074 shares available to be issued under the Merit Medical Systems, Inc. Qualified and Non-Qualified Employee Stock Purchase Plan and 1,854,300 shares available to be issued under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(3) See Note 10 to our consolidated financial statements set forth in Item 8 of this report for additional information regarding these plans.

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	Years Ended December 31,				
	2009	2008	2007	2006	2005
<b>OPERATING DATA:</b>					
Net Sales	\$ 257,462	\$ 227,143	\$ 207,768	\$ 190,674	\$ 166,585
Cost of Sales	148,660	133,872	127,977	117,596	97,493
Gross Profit	108,802	93,271	79,791	73,078	69,092
Operating Expenses:					
Selling, general and administrative	64,787	53,127	48,133	45,486	38,579
Research and development	11,168	9,160	8,688	8,582	6,992
Total operating expenses	75,955	62,287	56,821	54,068	45,571
Income From Operations	32,847	30,984	22,970	19,010	23,521
Other Income (Expense):					
Interest income	178	781	393	250	491
Interest expense	(28)	(17)	(3)	(12)	(18)
Other income (expense)	97	97	39	(64)	(94)
Other income net	247	861	429	174	379
Income before income taxes	33,094	31,845	23,399	19,184	23,900
Income Tax Expense	10,564	11,118	7,811	6,883	8,122
Net Income	\$ 22,530	\$ 20,727	\$ 15,588	\$ 12,301	\$ 15,778
Earnings Per Common Share:					
Diluted	\$ 0.79	\$ 0.73	\$ 0.55	\$ 0.44	\$ 0.57
Average Common Shares:					
Diluted	28,606				