

MERIT MEDICAL SYSTEMS INC
Form 10-K
March 15, 2011
[Table of Contents](#)

**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, 2010,

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

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

South Jordan, Utah 84095

(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
(Do not check if a smaller reporting company)

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

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30, 2010, 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, 2010), was approximately \$424,399,251. 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 10, 2011, the registrant had 28,496,078 shares of 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 27, 2011.

Table of Contents

TABLE OF CONTENTS

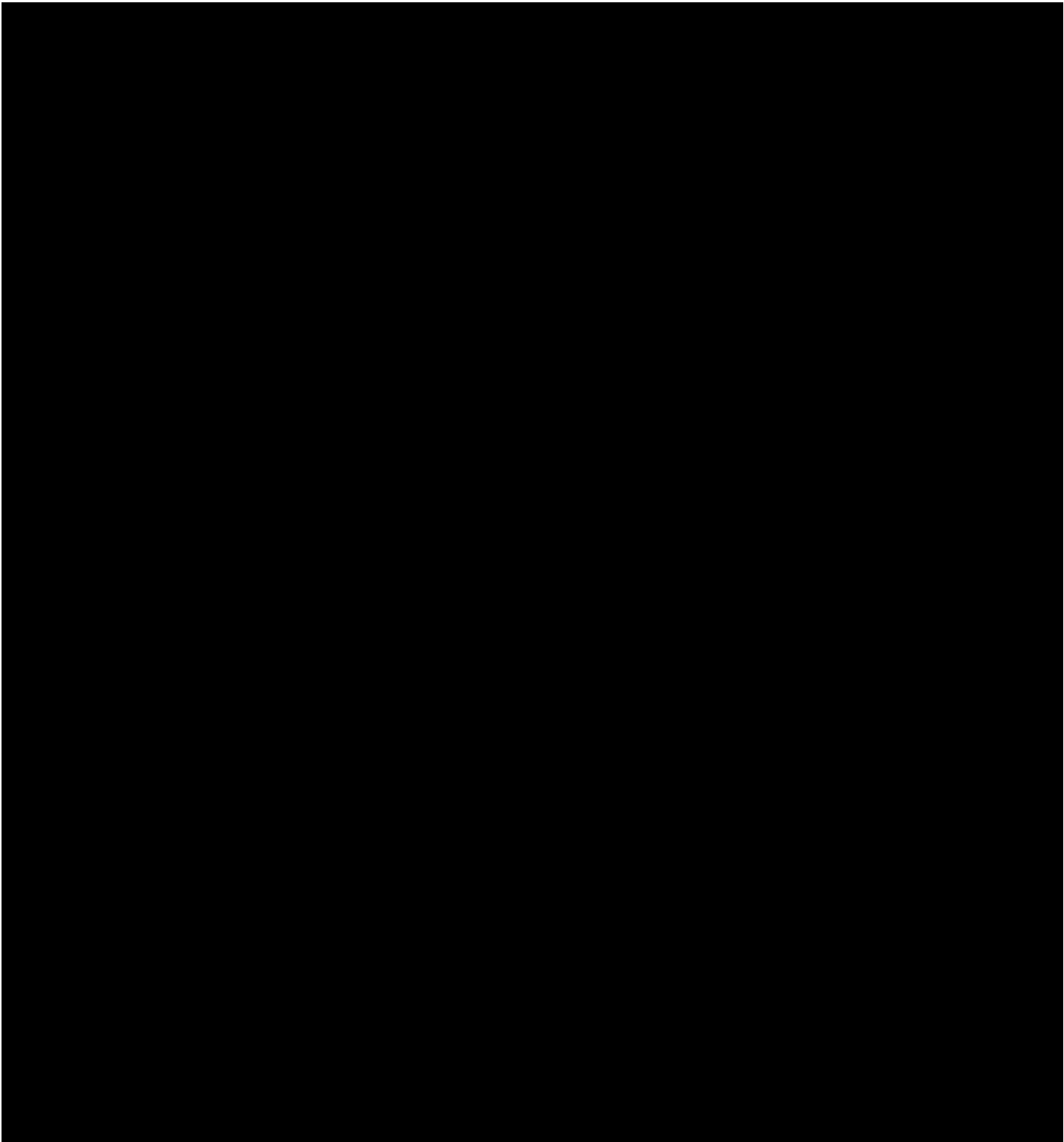


Table of Contents

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 will differ, and could differ materially, from those projected or assumed in the forward-looking statements. Our 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 product recalls or product liability claims; the consequences of debt obligations, including the effect of any breach of our credit documents or other agreements; infringement of our technology or the assertion that our technology infringes the rights of other parties; compliance (or the failure to comply) with federal, state, local or international laws or regulations; our research, development, product testing and regulatory compliance efforts, including challenges associated with our efforts to pursue new market opportunities; increasing regulation of the medical device industry in general and, as a result of our expanded operations, a larger segment of our operations; prospective reforms or other changes of the regulations administered by the U.S. Food and Drug Administration (the FDA); fluctuations in the price of components we use in our operations; changes in the national economy and the effect of those changes on our revenues, collections and supplier relations; termination of supplier relationships, or the failure of suppliers to perform; our failure to successfully manage growth, particularly growth resulting from acquisitions; currency exchange rate fluctuations; concentration of our revenues among a few products and procedures; development of new products and technologies that could render our products obsolete; volatility of the market price of our common stock (the Common Stock); weather fluctuations; changes in, or the loss of, our key personnel; work stoppage or transportation risks; failure to comply with environmental laws and regulations; changes in health care markets related to health care reform initiatives; and other factors referenced in our press releases and in our 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 14.

Item 1. Business.

GENERAL

Merit Medical Systems, Inc. is a worldwide designer, developer, manufacturer and marketer of medical devices used in a vast array of interventional and diagnostic procedures. Our mission is to provide innovative high quality products to physicians and health care professionals to enhance patient care and enable them to perform procedures safely and effectively.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Our operations are divided in the following markets: diagnostic and interventional cardiology, interventional radiology, gastroenterology, pulmonology and vascular surgery. We believe we have been 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.

On September 10, 2010, we completed our acquisition of BioSphere Medical, Inc. (BioSphere) in an all-cash merger transaction valued at approximately \$96 million, inclusive of all common equity and Series A Preferred preferences. BioSphere develops and markets embolotherapeutic products for the treatment of uterine fibroids, hypervascularized tumors and arteriovenous malformations. We believe our acquisition of BioSphere gives us a platform technology applicable to multiple therapeutic areas with significant market potential, while leveraging existing interventional radiology call points. Embolotherapy is the minimally invasive, image-guided therapeutic introduction of

Table of Contents

various biocompatible substances into a patient's circulatory system to occlude a blood vessel, either to arrest or prevent hemorrhaging, or to devitalize or destroy the structure by occluding its blood supply.

Our broad offering of cardiology and radiology medical devices is used by physicians to diagnose and treat coronary artery disease, peripheral vascular disease and other non-vascular diseases. Merit Endotek, one of our operating divisions, develops, manufactures and distributes our gastroenterology, pulmonology and thoracic surgery products to assist clinicians in the treatment of esophageal, tracheobronchial and biliary strictures. These products, which are distributed through our direct sales force, as well as through distributors, include fully-covered esophageal and tracheobronchial stents and bare metal biliary stents that are pre-loaded on catheter-based delivery systems, guide wires, bipolar coagulation probes, inflation devices and sizing devices.

Merit 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.

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, pulmonology and gastroenterology. We have expanded our product offerings for radiology segment, including interventional nephrology, computed tomography (or CT) ultrasound labs and, as a result of our BioSphere acquisition, embolization products. Our products are also used in other clinical areas such as pain management centers, 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 healthcare 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 involve the insertion of a sheath into the femoral, radial, or brachial artery. Fluoroscopy (real-time moving X-ray images) and CT 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.

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 more than 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® inflation systems (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 broad line of technically-sophisticated, clinically-acclaimed hemostasis valves, Merit Angioplasty Packs (MAP Kits) 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. Our hemostasis brands include: Honor®, AccessPLUS, Access-9, DoublePlay, MBA and MBAPlus and the Passage®.

Vascular Retrieval Devices. An increase in vascular procedures influenced our acquisition of the EN Snare® endovascular system from Hatch Medical L.L.C. (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

Table of Contents

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.

Embolic Microspheres. With the acquisition of BioSphere we now offer embolic microspheres and microsphere delivery systems. Microspheres are precisely calibrated, spherical, hydrophilic, micro-porous beads made with acrylic co-polymer cross-linked with gelatin. Microcatheters and small (mini) guide wires are also available as delivery systems for the embolic particles. These products include:

- *Embosphere® Microspheres*, which are marketed for symptomatic uterine fibroids, hypervascularized tumors and arteriovenous malformations in the United States, the European Union, the People's Republic of China and several other markets outside the United States;

- *EmboGold® Microspheres*, which are marketed for hypervascularized tumors and arteriovenous malformations in the United States, the European Union and several other markets outside the United States;

- *HepaSphere® Microspheres*, which are marketed in the European Union, Brazil and Russia for primary and metastatic liver cancer, and in the European Union and Russia for drug delivery in the treatment of primary and metastatic liver cancer; and

- *QuadraSphere® Microspheres*, which are marketed for the treatment of hypervascularized tumors and arteriovenous malformations in the United States.

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.

Diagnostic Catheters, Guide Wires, and Torque Devices. We offer diagnostic catheters and guide wires for use during both cardiology and radiology angiographic procedures. Our 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. In 2010, we launched the Merit Laureate® hydrophilic-coated guide wire to complement the Merit H2O® hydrophilic guide wire line. These wires provide 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.

Radial Artery Compression Devices. In recent years, radial artery catheterization has become increasingly popular as an alternative to femoral artery access when performing diagnostic and interventional cardiology procedures. We have developed and now offer two independent, highly-differentiated radial compression systems, including the Finale® and the RadStat®.

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. We now offer a broad range of specialty syringes including color-coded Medallion® syringes, and the proprietary, loss-of-resistance VacLok® syringe. The most recent line extensions to the syringe product family are frosted and sword-handled Medallion® syringes. Additionally, we offer an extensive line of kits containing fluid management products like syringes, manifolds, stopcocks, tubing, and disposable pressure transducers (MeriTrans®) for measurement of pressures within the vessels and chambers of the heart. In 2010, we introduced the Tram and Tram-P integrated transducers that combine a low torque manifold with the transducer. We also provide devices, kits, and procedure trays used to effectively and safely manage fluids, contrast media, and waste during angiography and interventional procedures. The Miser II contrast management system complements 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

Table of Contents

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®. 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.

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) 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. Our One-Step product line includes a valved version of the device that we believe makes our products more competitive in the thoracentesis 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, including native dialysis fistula and synthetic grafts.

Multipurpose Microcatheters. With our acquisition of BioSphere, we expanded our multipurpose microcatheter offering to include the Embocath Plus 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 microspheres, alcohol, metallic coils, poly-vinyl alcohol particles, 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.

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. The OuTake® Catheter Extractor is used to remove tunneled chronic dialysis catheters from dialysis patients. A curved introducer needle aids 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.

Table of Contents

Gastroenterology and Pulmonology Products

Non-Vascular Stents. We also sell airway products, principally our AERO® and AERO DV® Fully Covered Tracheobronchial Stent, for use in thoracic surgery. These products offer our customers patented, self-expanding metal stents used to improve patency of patient 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® tracheobronchial stent sizing device used in interventional pulmonology procedures and the MAXXWIRE®, which is a line of specialty guide wires which have pulmonology applications.

Bipolar Coagulation Probes. Bipolar probes are used by physicians as one means of controlling bleeding within a variety of non-vascular systems. Our Brighton Bipolar Probe is now sold directly by our Endotek division and our original bipolar probe is sold on an OEM basis to customers who market them to a large number of gastroenterologists.

Specialty Procedure Products

In addition to the procedures and devices detailed above, interventional radiology and other special procedure labs perform 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 (MEMS) 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.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

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 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.

As part of our embolic microsphere sales and marketing efforts, we attend major medical conventions throughout the world pertaining to our targeted markets and invest in market development (including physician training), practice building, referral network education and patient outreach. We work closely with major interventional radiology centers in the areas of training, therapy awareness programs, clinical studies and ongoing research. Our initiatives include a program called Community Health Talks, or CHTs, an educational outreach to women likely to have symptomatic fibroids. These programs were executed in partnership with multiple hospitals, with close collaboration

Table of Contents

between physicians in interventional radiology and gynecology. The goal of the CHT initiative is to educate women about fibroids and all their available treatment options, even though they may not seek immediate consult for Uterine Fibroid Embolization (UFE).

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.

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. and International Sales. Sales of our products in the United States accounted for 68%, 66% and 68% of our total sales for the years ended December 31, 2010, 2009 and 2008, 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. To support our U.S. direct sales team we have developed a national account department that includes a Vice President of National Accounts, field-based Health System Account Directors and contract administrators. In addition, our Merit Endotek division maintains a separate worldwide sales force consisting of a President, Vice President of Sales, Director of Marketing, two regional sales managers and 14 direct sales representatives.

Approximately 175 independent dealer organizations and packers distribute our products worldwide, including territories in Europe, Africa, the Middle East, Asia, South and Central America, Australia and Canada. We have a Vice President of International Sales, based in South Jordan, Utah, who directs our international sales efforts in Asia, South and Central America, Australia and Canada. We have a Vice President of

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Distribution Sales, based in Maastricht, The Netherlands, who directs distributor sales in Europe, the Middle East, and Africa. We also have a Vice President of European Sales who oversees direct sales in Europe. Approximately 32 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 2010, our international sales grew approximately 10% over our 2009 international sales, and accounted for approximately 32% of our 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.

We consider training to be a critical factor in the success of our direct sales force. Our sales representatives are trained by our personnel at our facilities, by a senior sales person in their respective territories, at regular national and

Table of Contents

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.

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 third-party label.

CUSTOMERS

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 2010, our U.S. sales force made approximately 46% of our sales directly to U.S. hospitals (includes 3% for our Endotek division) and approximately 12% of our sales through other channels such as U.S. custom packers and distributors. We also sell products to other medical device companies through our U.S. OEM sales force, which accounted for approximately 10% of our 2010 sales. Approximately 32% of our 2010 sales were made to international markets by our direct European sales force, international distributors, and our OEM sales force (includes 3% for OEM international). Sales to our single largest customer accounted for approximately four percent of total sales during the year ended December 31, 2010.

RESEARCH AND DEVELOPMENT

In 2010, 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 pulmonology markets through the acquisition of Alveolus, Inc. (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 introduced the new Brighton Bipolar Probe and initiated multiple projects to expand Merit Endotek's products scheduled for release in 2011 through 2012.

Our research and development expenses were approximately \$15.3 million, \$11.2 million, and \$9.2 million in 2010, 2009 and 2008, respectively. Our future growth continues to be fueled with multiple product ideas guided by our Chief Executive Officer, our Vice President of Research and Development 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; Paris, France 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 our molds, but we design and own most 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 have received ISO 13485:2003 certification for our facilities in Utah, Texas, Virginia, Massachusetts, Ireland and France. We have also received ISO 9001:2000 certification for our Merit Sensor Systems facility in South Jordan, Utah.

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., our wholly-owned subsidiary (Merit Sensor Systems), develops and markets silicon sensors. Merit Sensor Systems presently supplies all of the sensors we utilize in our digital inflation devices.

We currently produce and package all of our microspheres. Manufacturing of our microsphere products includes the synthesis and processing of raw materials and third-party manufactured compounds.

Table of Contents

Our products are manufactured at several factories, including facilities located in South Jordan, West Jordan and Murray, Utah; Galway, Ireland; Venlo, The Netherlands; Paris, France; 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; Beijing, China; 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 processes. 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 pulmonology 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, Teleflex, Cook and Terumo. Medium-size companies we compete with include AngioDynamics, Vascular Solutions, B. Braun, Olympus, Navilyst, Edwards Lifescience, and ICU Medical.

The primary competitive embolotherapy product has been non-spherical polyvinyl alcohol (or PVA) particles, a product introduced into the market more than 20 years ago. Currently, the primary products with which our microspheres compete are spherical PVA, sold by Boston Scientific Corporation, Biocompatibles and Terumo Corporation; Embozene sold by CeloNova Biosciences, Inc.; gel foam, sold by Pfizer Inc.; and non-spherical (particle) PVA, sold by Boston Scientific and Cook Incorporated. Our principal competitors in UFE are Biocompatibles, Boston Scientific, Cook, Cordis Corporation, a Johnson & Johnson company, Pfizer and Terumo, as well as companies selling or developing non-embolotherapy solutions for UFE.

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 our products have achieved market acceptance due to the quality of materials and workmanship of our products, their innovative design, our willingness to customize our products 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.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

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 one of the world market leaders for inflation devices, hemostasis devices and torque devices. We believe 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.

Within the field of uterine artery embolization, we believe we are the market share leader and one of only three companies in the United States to have embolic products specifically indicated for use in UFE. Based on both research and clinical studies conducted on our product for UFE, we believe we offer physicians a high degree of consistent and predictable product performance, ease of use, targeted delivery, and durable vessel occlusion, and therefore satisfactory short- and long-term clinical outcomes validated by peer-reviewed publications, when compared to our competitors.

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.

Table of Contents

PATENTS, LICENSES, TRADEMARKS AND COPYRIGHTS

We have a number of U.S. and foreign-issued patents and pending patent applications, including patents and rights to patent applications acquired through strategic transactions, which relate to various aspects of our products and technology. The duration of our patents is determined by the laws of the country of issuance and for the U.S. is typically 20 years from the date of filing of the patent. As of December 31, 2010, we owned more than 200 U.S. and international patents and patent applications. We also operate under licenses from other owners of certain patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks.

Merit and the Merit logo are trademarks in the U.S. and other countries. In addition to Merit and the Merit logo, we have used, registered, or applied other specific trademarks and service marks to help distinguish our products, technologies, and services from those of our competitors in the U.S. and foreign countries. See Products above. The duration of our trademark registrations varies from country to country, and in the U.S. we generally are able to maintain our trademark rights and renew any trademark registrations for as long as the trademarks are in use. We have received over 100 U.S. and foreign trademark registrations, and other U.S. and foreign trademark applications are currently pending.

Some of our products and product documentation are protected under U.S. and international copyright laws related to the protection of intellectual property and proprietary information. We have registered copyrights relating to certain software used in our electronic inflation devices.

REGULATION

FDA Regulation. The United States Food and Drug Administration, (FDA), and other federal, state and local authorities regulate our products and product-related activities. Pursuant to the U.S. Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated under that act, the FDA regulates the design, development, clinical trials, testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. We believe that our products and procedures are in material compliance with all applicable FDA regulations, but the regulations regarding the manufacture and sale of our products are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition and results of operations. In addition, if the FDA believes that we are not in compliance with the FDCA, it can institute proceedings to detain or seize products, issue a market withdrawal, enjoin future violations and/or seek civil and criminal penalties against us and our officers and employees. If we fail to comply with these regulatory requirements, our business, financial condition and results of operations could be harmed.

FDA Approval. Unless subject to a specific exemption issued by the FDA, before a new medical device that we develop can be introduced to the market, we must obtain market clearance through a 510(k) premarket notification or approval through a pre-market approval (PMA) application.

The FDA's 510(k) approval procedure is less rigorous than the PMA procedure, but is available only to sponsors that can establish that their device is substantially equivalent to a legally-marketed predicate device that was either on the market prior to the enactment of the Medical Devices Amendments of 1976 or has been cleared through the 510(k) procedure. It usually takes between three months and one year from the date a 510(k) application is submitted, but it may take longer, particularly if a clinical trial is required. The FDA may find that 510(k) approval is not appropriate or that substantial equivalence has not been shown and, as a result, require additional clinical or non-clinical testing or a PMA

application.

PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the subject device, typically including the results of human clinical trials, bench tests, and laboratory and animal studies. The PMA application must also contain a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission must include the proposed labeling and any training materials. As part of the PMA application review, the FDA will inspect the manufacturer's facilities for compliance with its Quality System Regulations (QSR). If the FDA approves the PMA, it may place restrictions on the device, such as requiring additional patient follow-up for an indefinite period of time. If the FDA's evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a "not approvable" letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years. The PMA application process can be expensive and generally takes several years to complete. After the PMA is approved, if significant changes are made to a device, its manufacturing or labeling, a PMA supplement containing additional information must be filed for prior FDA approval.

Table of Contents

If human clinical trials of a medical device are required for FDA approval and the device presents a significant risk, the sponsor of the trial must file with the FDA an investigational device exemption (IDE) application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and/or laboratory testing. If the IDE application is approved by the FDA and one or more institutional review boards (IRBs), human clinical trials may begin at a specific number of institutional investigational sites with the specific number of patients approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA. Submission of an IDE application does not give assurance that the FDA will issue the IDE. If the IDE application is approved, there can be no assurance the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan in such a way that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial must also comply with the FDA's IDE regulations, and informed consent must be obtained from each subject.

The FDA clearance and approval processes for medical devices are expensive, uncertain and lengthy. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals for any product on a timely basis or at all. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

In October 2009, BioSphere submitted to the FDA an IDE seeking to commence a clinical trial to compare the effectiveness of QuadraSphere® Microspheres combined with the chemotherapeutic agent doxorubicin to conventional transarterial chemoembolization, or cTACE, with doxorubicin in patients with primary liver cancer. On November 29, 2010, the FDA approved a phase 3 clinical trial protocol to treat primary liver cancer with QuadraSphere® Microspheres for delivery of doxorubicin. Subsequent to our acquisition of BioSphere, the FDA approved our application to perform a Phase 3 clinical trial protocol to treat primary liver cancer with QuadraSphere® Microspheres (hqTACE) for delivery of doxorubicin. Liver cancer is the third leading cause of cancer deaths worldwide. The sharp rise in hepatitis C infections, alcohol consumption and obesity are reported as key contributing factors to increased incidence of liver cirrhosis and liver cancer. Currently, surgical treatment of liver cancer (liver transplantation or tumor resection) is available for only approximately 25% of liver cancer cases. Surgical removal is not currently possible for more than two-thirds of primary liver cancer patients and 90% of patients with secondary liver cancer. According to the U.S. National Cancer Institute (NCI), no standard treatment currently exists for liver cancer when tumors cannot be surgically removed and liver transplantation is not a viable option. However, both the NCI and the Society of Interventional Radiologists (SIR) report that transarterial chemoembolization (TACE) has shown promising results in the treatment of liver cancer. We believe if we are successful with this clinical trial and are able to obtain all FDA approvals required to market our QuadraSphere® Microspheres in the United States, we will be the only market participant in this area with a product approved from the FDA. Unfavorable or inconsistent data from this trial may adversely affect our ability to obtain approval for this new indication.

Changes in Cleared or Approved Devices. We must obtain new FDA 510(k) clearance or premarket approval when there is a major change or modification in the intended use or indications for use of a legally marketed device or a change or modification of the device, including product enhancements and product line extensions of a legally marketed device, as required by FDA regulations. In some cases, supporting clinical data may be required. The FDA may determine that a new or modified device is not substantially equivalent to a predicate device or may require that additional information, including clinical data, be submitted before a determination is made, either of which could significantly delay the introduction of new or modified device products.

Current Good Manufacturing Practice / Quality System Regulation and Reporting. The FDCA requires us to comply with the QSR and good manufacturing practice requirements pertaining to all aspects of our product design and manufacturing processes, including requirements for packaging, labeling and record keeping, complaint handling, corrective and preventive actions and internal auditing. The FDA enforces these requirements through periodic inspections of medical device manufacturers. In addition, the Medical Device Reporting (MDR) regulation requires us to inform the FDA whenever information reasonably suggests that one of our devices may have caused or contributed to a death or serious injury, or when one of our devices has malfunctioned, if the device would be likely to cause or contribute to a death or a serious injury in

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

the event the malfunction were to recur. We believe that we, and the third parties who manufacture our delivery systems, are in compliance with all material QSRs and medical device reporting regulations.

Labeling and Advertising. Labeling and promotional activities are also subject to scrutiny by the FDA. Labeling includes not only the label on a device, but also includes any descriptive or informational literature that accompanies or is used to promote the device. Among other things, labeling violates the law if it is false or misleading

Table of Contents

in any respect or it fails to contain adequate directions for use. Moreover, product claims that are outside the labeling either approved or cleared by the FDA violate the FDCA. Allegations of off-label promotion can result in enforcement action by both federal and state agencies, including the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, as well as liability under the False Claims Act, discussed further below.

Federal Trade Commission. Our product promotion is also subject to regulation by the Federal Trade Commission (the FTC), which has primary oversight of the advertising of unrestricted devices. The Federal Trade Commission Act prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce, as well as unfair or deceptive practices such as the dissemination of any false advertisement pertaining to medical devices.

Import Requirements. To import a device, the importer must file an entry notice and bond with the United States Bureau of Customs and Border Protection (CBP). All devices are subject to FDA examination before release from CBP. Any article that appears to be in violation of the FDCA may be refused admission and a notice of detention and hearing may be issued. If the FDA ultimately refuses admission, CBP may issue a notice for redelivery and assess liquidated damages for up to three times the value of the lot.

Export Requirements. Products for export from Europe and from the United States are subject to foreign countries' import requirements and the exporting requirements of the FDA or European regulating bodies, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate for Foreign Government. To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with Quality Systems Regulation regulations at the time of the last FDA inspection.

Fines and Penalties for Noncompliance. Failure to comply with applicable FDA regulatory requirements could result in, among other things, withdrawal of market clearance or approval, injunctions, voluntary or mandatory patient/physician notifications, recalls, warning letters, product seizures, civil penalties, fines and criminal prosecutions. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, rescission of contracts and such other relief as may be deemed necessary.

Foreign Regulations. Medical device laws and regulations are also in effect in many countries outside of the United States. These laws and regulations vary significantly from country to country and range from comprehensive device approval requirements for some or all of our medical device products to more basic requests for product data or certification. The number and scope of these requirements are increasing.

In particular, marketing of medical devices in the European Union is subject to compliance with European Medical Device Directives and requires that the appropriate Regulatory agency has issued CE mark certification with respect to each device to be marketed. CE mark certification is the European symbol of adherence to quality assurance standards and compliance with applicable European Medical Device Directives. The European Medical Device Directives contain requirements for quality systems and other essential requirements with which all manufacturers must comply. Failure to materially comply with applicable foreign medical device laws and regulations would likely have a

material adverse effect on our business. In addition, foreign regulations regarding the manufacture and sale of medical devices are subject to future changes.

Environmental Regulations. We are subject to various federal, state, local and foreign laws and regulations relating to the protection of the environment, as well as health and safety. In the course of our business, we are involved in the handling, storage and disposal of limited amounts of certain chemicals. The laws and regulations applicable to our operations include provisions that regulate the discharge of materials into the environment. Usually these environmental laws and regulations impose strict liability, rendering a person liable without regard to negligence or fault on the part of such person. Such environmental laws and regulations may expose us to liability for the conduct of, or conditions caused by, others, or for acts that were in compliance with all applicable laws at the time the acts were performed. To date, we have not been required to expend material amounts in connection with our efforts to comply with environmental requirements and currently do not believe that compliance with such requirements will have a material adverse effect upon our capital expenditures, results of operations or competitive position in the future. Failure to comply with applicable environmental and related laws could have a material adverse effect on our business. In addition, because the

Table of Contents

requirements imposed by such laws and regulations are frequently changed, we are unable to predict the cost of compliance with such requirements in the future, or the effect of such laws on our capital expenditures, results of operations or competitive position.

Anti-Kickback Statutes. The Medicare and Medicaid Patient Protection Act of 1987, as amended, which is more commonly known as the federal health-care Anti-Kickback Statute, prohibits persons from, among other things, knowingly and willfully offering or paying remuneration, directly or indirectly, to a person to induce the purchase, order, lease, or recommendation of a good or service for which payment may be made in whole or part under a federal health-care program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intended requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal health-care programs, the statute has been violated. The law contains several statutory exceptions, including payments to bona fide employees, certain discounts and certain payments to group purchasing organizations. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal health-care programs. Exclusion of a manufacturer would preclude any federal health-care program from paying for its products. In addition, kickback arrangements can provide the basis for an action under the Federal False Claims Act, which is discussed in more detail below.

The Anti-Kickback Statute is broad and potentially prohibits many arrangements and practices that are lawful in businesses outside of the health-care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of Health and Human Services, or OIG, issued a series of regulations, known as the safe harbors, beginning in July 1991. These safe harbors set forth provisions that, if all the applicable requirements are met, will ensure that health-care providers and other parties will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Arrangements that implicate the Anti-Kickback Statute, and that do not fall within a safe harbor, are analyzed by the OIG on a case-by-case basis.

Government officials have focused recent enforcement efforts on, among other things, the sales and marketing activities of pharmaceutical, medical device, and other health-care companies, and recently have brought cases against individuals or entities with personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. Settlements of these cases by health-care companies have involved significant fines and/or penalties and in some instances criminal pleas.

In addition to the Federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial health insurance companies.

False Claims Laws. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Manufacturers can be held liable under false claims laws, even if they do not submit claims to the government, if they are found to have caused submission of false claims. The Federal Civil False Claims Act also includes whistle blower provisions that allow private citizens to bring suit against an entity or individual on behalf of the United States and to recover a portion of any monetary recovery. Many of the recent highly publicized settlements in the health-care industry relating to sales and marketing practices have been cases brought under the False Claims Act. The majority of states also have statutes or regulations similar to the federal false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Reimbursement. Our products are used in medical procedures generally covered by government or private health plans. In general, a third-party payer only covers a medical device or procedure when the plan administrator is satisfied that the product or procedure improves health outcomes, including quality of life or functional ability, in a safe and cost-effective manner. Even if a device has received clearance or approval for marketing by the FDA, there is no certainty that third-party payers will reimburse patients for the cost of the device and related procedures. Even if coverage is available, third-party payers may place restrictions on the circumstances in which they provide coverage or may offer reimbursement that is not sufficient to cover the cost of our products. If hospitals and physicians cannot

Table of Contents

obtain adequate reimbursement for our products or the procedures in which they are used, our business, financial condition, results of operations, and cash flows could suffer a material adverse impact.

Privacy and Security. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health Act (the HITECH Act), and the rules promulgated thereunder, require certain entities, referred to as covered entities, to comply with established standards, including standards regarding the privacy and security of protected health information, or PHI. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates, as such term is defined by HIPAA, which, among other things, obligate the business associates to safeguard the covered entity's PHI against improper use and disclosure. In addition, a business associate may face significant statutory and contractual liability if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. In the course of our business operations, we have entered into several business associate agreements with certain of our customers that are covered entities. Pursuant to the terms of these business associate agreements, we have agreed, among other things, not to use or further disclose the covered entity's PHI except as permitted or required by the agreements or as required by law, to use reasonable administrative, physical, and technical safeguards to prevent prohibited disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. Accordingly, we incur compliance-related costs in meeting HIPAA-related obligations under business associates agreements to which we are a party. Moreover, if we fail to meet our contractual obligations under such agreements, we may incur significant liability.

The HITECH Act, enacted in 2009, substantially enhances several of HIPAA's requirements and protections. Among other provisions, the HITECH Act extended certain provisions of the HIPAA Security Rule directly to business associates of covered entities, established a national data breach notification law, and placed additional restrictions on the use and disclosure of PHI.

In addition, HIPAA's criminal provisions potentially could be applied to a non-covered entity that aided and abetted the violation of, or conspired to violate, HIPAA, although we are unable at this time to determine conclusively whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. Also, many state laws regulate the use and disclosure of health information, and are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA. Finally, in the event we change our business model and become a HIPAA-covered entity, we would be directly subject to HIPAA, its rules and its civil and criminal penalties.

Affordable Care Act. In March 2010, Congress enacted legislation known as the Affordable Care Act, which will substantially change the way that health care is financed by both governmental and private insurers and significantly affect the medical device industry. This new law contains a number of provisions, including provisions governing enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government health care programs and will result in the development of new programs. A number of provisions contained in the Affordable Care Act may adversely affect our net revenue for our marketed products and any future products. The new law, among other things, subjects most medical devices to a 2.3% excise tax, beginning January 1, 2013, which may have a material effect on our results of operations and financial condition.

In addition to imposing the excise tax described above, the Affordable Care Act also includes substantial new provisions affecting the medical device industry. For example, the Affordable Care Act includes new reporting and disclosure requirements for device manufacturers with regard to payments or other transfers of value made to health care providers. Those requirements are scheduled to become effective March 2013 for calendar year 2012. Reports submitted under these new requirements will be placed on a public database. If we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties. In addition, developing the necessary systems to comply with the new reporting requirement could be financially burdensome.

EMPLOYEES

As of December 31, 2010, we employed 2,178 people, including 1,584 in manufacturing; 279 in sales and marketing; 178 in engineering, research and development; and 137 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 of replacement and new entry-level employees. Our key employees are bound by agreements or policies of confidentiality. None of our

Table of Contents

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 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.

We make available, free of charge, on our Internet website, located at 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 12 to our consolidated financial statements set forth in Item 8 of this report.

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:

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 recall such products from the market. Such a recall could result in significant costs and could divert management's attention from our business.

In addition, if medical personnel or their patients suffer injury in connection with the use of our products, whether as a result of a failure of our products to function as designed, an inappropriate design or for any other reason, we could be subject to lawsuits seeking significant compensatory and punitive damages. We have previously faced claims by patients claiming injuries from our products. To date, these claims have not resulted in a material negative impact on our business; however, patients or customers may bring claims in a number of circumstances, including if our products were misused, if our product's manufacture or design was flawed, if our products produced unsatisfactory results, or if the instructions for use and other disclosure of product-related risks for our products were found to be inadequate. The outcome of this type of personal injury litigation is difficult to assess or quantify. We maintain product liability insurance but there is no assurance that this coverage will be sufficient to satisfy any claim made against us. Moreover, any product liability claim brought against us, with or without merit, could result in significant costs, could increase our product liability insurance rates, or could prevent us from securing coverage in the future. As a result, 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.

Table of Contents

The agreements and instruments governing our debt contain restrictions and limitations that could significantly affect our ability to operate our business, as well as significantly affect our liquidity.

We have entered into an unsecured Credit Agreement, dated September 10, 2010 (the "Credit Agreement"), with the lenders who are or may become party thereto (collectively, the "Lenders") and Wells Fargo Bank, National Association ("Wells Fargo"), as administrative agent for the Lenders. The Credit Agreement contains a number of significant covenants that could adversely affect our ability to operate our business, our liquidity, and our results of operations. These covenants restrict, among other things, our and our subsidiaries' ability to incur additional debt; repurchase; repurchase or redeem equity interests and debt; issue equity; make certain investments or acquisitions; pay dividends or make other distributions; dispose of assets or merge; enter into related party transactions; and grant liens and pledge assets.

The breach of any covenants in the Credit Agreement, not otherwise waived or amended, could result in a default under the applicable debt obligations and could trigger acceleration of those obligations. Any default under the Credit Agreement could adversely affect our ability to service our debt and to fund our planned capital expenditures and ongoing operations.

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 or 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 may be unable to continue to use such information for our own purposes, 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

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

- 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 activities 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 or entities may independently develop, or have developed, similar or superior technologies.

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-

Table of Contents

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 will be required to expend significant resources for research, development, testing and regulatory approval or clearance of our products under development and these products may not be developed successfully or approved for commercial use.

We are developing and commercializing products for medical applications using embolotherapy techniques. Most of our products under development will require significant additional research, development, engineering and preclinical and/or clinical testing, as well as regulatory approval or clearance and a commitment of significant additional resources prior to their commercialization. It is possible that they may not: be developed successfully; be proven safe and effective in clinical trials; offer therapeutic or other improvements over current treatments and products; meet applicable regulatory standards or receive regulatory approvals or clearances; be capable of production in commercial quantities at acceptable costs and in compliance with regulatory requirements; or be successfully marketed or covered by private or public insurers.

We are conducting a clinical trial and seeking approval from the FDA to claim the use of the QuadraSphere® Microspheres for the treatment of a specific disease or condition, such as hepatocellular cancer or hepatic metastasis in the United States. European Union regulations do not require such an application for this class of medical devices. In order for us to obtain FDA approval or clearance to promote the use of QuadraSphere® Microspheres for the embolization of hepatocellular carcinoma and hepatic metastasis, we will need to complete a clinical trial and submit positive clinical data to the FDA. As we continue our clinical trial and if the results are not sufficient to obtain FDA approval, then we will not be able to promote our QuadraSphere® Microspheres for liver cancer indications in the U.S. Although we have not received approval or clearance from the FDA to market our QuadraSphere® Microspheres for primary or metastatic liver cancer in the United States, we believe that some physicians are using QuadraSphere® Microspheres in procedures which are not indicated on our labels (referred to as off-label use), including the treatment of primary and metastatic liver cancer. If the FDA or any other federal or state enforcement agency were to conclude that we have improperly promoted our products for unapproved indications, the FDA or such other agency could allege that our promotional activities misbrand or adulterate our products or violate other legal requirements, which could result in investigations, prosecutions, or other civil or criminal actions.

The medical device industry is experiencing greater scrutiny and regulation by governmental authorities.

Our medical devices and business activities are subject to rigorous regulation by the FDA and other federal, state and international governmental authorities. These authorities and members of Congress have been increasing their scrutiny over the medical device industry. In recent years, the U.S. Congress, Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and the Department of Defense have issued subpoenas and other requests for information to medical device manufacturers, primarily related to financial arrangements with health care providers, regulatory compliance and product promotional practices. The Physician Payment Sunshine Act, enacted as part of the Affordable Care Act, requires device manufacturers to report payments or other transfers of value made to health care providers, effective March 2013 for calendar year 2012. In addition, certain states have recently passed or are considering legislation restricting our interactions with health care providers and/or requiring disclosure of many payments to them. Recent Supreme Court decisions have clarified that the FDA's authority over medical devices preempts state tort laws, but some members of Congress have indicated an interest in introducing tort reform legislation. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by government authorities may increase compliance costs, exposure to litigation, and other adverse effects to our operations.

Potential reforms to the FDA's 510(k) process could adversely affect our business, operations, or financial condition.

In August 2010, the FDA issued its preliminary recommendations on reform of the 510(k) premarket notification process for medical devices. The FDA's preliminary recommendations included, among other things, granting to the FDA authority to rescind 510(k) clearance, revising existing guidance to clarify what types of modifications to existing 510(k)-cleared devices warrant submission of a new 510(k) application, exploring the possibility of potentially requiring manufacturers to provide periodic updates to the FDA's Center for Devices and Radiological Health (CDRH) listing modifications without submitting a new 510(k) application, adopting a framework for 510(k) submissions that requires formal validation of claims with supporting evidence and developing guidance

Table of Contents

requiring that the complete device description and intended use information be submitted and described in detail in a single section of a 510(k) application. On January 19, 2011, the FDA announced its Plan of Action for implementing these recommendations. The Plan of Action includes 25 action items for 2011, including streamlining the review process for innovative, lower risk products (the de novo process); improving training for CDRH staff and industry; increasing reliance on external experts; and addressing and improving CDRH processes. If implemented, these recommendations could have the effect of making it more difficult and expensive for us, and other companies, to obtain 510(k) clearance and potentially jeopardizing the regulatory status of certain 510(k)-cleared devices.

We are 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.

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 FDCA, and the manufacture, distribution, record keeping, labeling and advertisement of substantially all 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 compliance with the FDCA, 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.

Increases in the price of commodity components, particularly petroleum-based products, or loss of supply could have an adverse effect on our business.

Many of our products have components that are manufactured using resins, plastics and other petroleum-based materials. Our ability to operate profitably is dependent, in large part, on the availability and pricing of these materials. The availability of these products is affected by a variety of factors beyond our control, including political uncertainty in the Middle East, and there is no assurance that crude oil supplies will not be interrupted in the future. Any such interruption could have an adverse effect on our ability to produce, or on the cost to produce, our products. Also, crude oil prices generally fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel-related transportation costs, competition, import duties, tariffs, currency exchange rates and political uncertainty in the Middle East. Our suppliers may pass some of their cost increases on to us, and if such increased costs are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs generally increase based on the effect of higher crude oil prices, and these increased transportation costs may be passed on to us. Our ability to recover such increased costs may depend upon our ability to raise prices on our products. Due to the highly competitive nature of the healthcare industry and the cost-containment efforts of our customers and third party payors, we may be unable to pass along cost increases through higher prices.

If we are unable to fully recover these costs through price increases or offset these increases through cost reductions, we could experience lower margins and profitability and our business, results of operations, financial condition and cash flows could be materially and adversely affected.

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 or results of operations. We may also

Table of Contents

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.

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.

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 acquisitions, we will face the additional challenges of integrating the operations, culture, information management systems and other characteristics of the acquired entity with our own. We have incurred, and may incur, significant expenses in connection with negotiating and consummating one or more transactions, and we may inherit significant liabilities in connection with prospective acquisitions. 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 an adverse effect on our business and financial results.

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 2010, the exchange rate between all applicable foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$936,000.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

For the year ended December 31, 2010, approximately \$32.9 million, or 11%, 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.

We depend on generating sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations.

We are dependent on our cash on hand and free cash flow to fund our debt obligations, capital expenditures and ongoing operations. Our ability to service our debt and to fund our planned capital expenditures and ongoing operations will depend on our ability to continue to generate cash flow. If we are unable to generate sufficient cash flow or we are unable to access additional liquidity sources, we may not be able to service or repay our debt, operate our business, respond to competitive challenges, or fund our other liquidity and capital needs.

Table of Contents

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, 2010, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for approximately 21% of our total revenues. Sales of our inflation devices to a single OEM customer, representing our largest customer, were approximately 18% of our total inflation device sales for the year ended December 31, 2010. 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 markets in which our products compete are 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 at times been, and may in the future be, volatile for various reasons, including those discussed in these risks factors, which could have a material adverse effect on our business, operations or financial condition. Other events that could cause volatility in our stock, include without limitation, quarter-to-quarter variances in our financial results; 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; or a decline, or rise, of stock prices in the capital markets generally.

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 proceeds 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 damage, along with potential 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

Table of Contents

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 and 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 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 to prevent accidental releases of a material nature, any accidental release may have an adverse affect on our business and results of operations.

Recently healthcare reform legislation may have a material adverse effect on our business, financial condition, results of operations and cash flows.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. Certain provisions of the legislation will not be effective for a number of years. There are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impact of the legislation will be. The legislation imposes on medical device manufacturers a 2.3 percent excise tax on U.S. sales of certain medical devices beginning in 2013. This tax burden may have a material, negative impact on our results of operations and our cash flows. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future

legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our world headquarters is located in South Jordan, Utah, with our principal office for European operations located in Galway, Republic of Ireland. We also receive support for European operations from a second European facility located in Beek, The Netherlands. In addition, we lease office space in Washington D.C.; Jackson Township, New Jersey; and Tokyo, Japan. Our principal manufacturing facilities are located in South Jordan, Utah; West Jordan, Utah; Murray, Utah; Angleton, Texas; Chester, Virginia; Galway, Republic of Ireland; Paris, France; and Venlo, The Netherlands. Research and development is principally conducted at facilities located in South Jordan, Utah; Paris,

Table of Contents

France; and Galway, Republic of Ireland. The following is an approximate summary of our facilities as of December 31, 2010 (in square feet):

	Owned	Leased	Total
U.S.	358,525	346,012	704,537
International	96,000	38,147	134,147
	454,525	384,159	838,684

In February 2010, we acquired 0.79 acres of property located on the southwest corner of our South Jordan facility. The new property will allow construction of an additional employee entrance and provide a necessary land buffer between our new production, warehouse and administration offices and a group of office condominiums.

In March 2010, we leased an office of approximately 2,100 square feet located in the financial district of Beijing, China and a warehouse of approximately 6,900 square feet located in the southeast quadrant of Beijing, China.

In September 2010, we acquired BioSphere. BioSphere is a party to the lease of an administrative office located in Rockland, Massachusetts and a production and administrative building located in Paris, France.

In August 2010, we acquired approximately five acres of real property located in the Parkmore East Business Park in Galway, Ireland. The purpose for this acquisition is to build a new production facility. In November 2010, we commenced construction of a 74,680 square foot production, warehouse, and research and development building located on the parcel in the Parkmore East Business Park in Galway, Ireland.

In late 2010, we commenced construction of a production, warehouse and administration office building, which will total approximately 245,000 square feet, at our world headquarters in South Jordan, Utah. In 2010, we also commenced construction of a parking structure at our world headquarters.

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 or 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.

Item 4. [Removed and Reserved.]

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.

For the year ended December 31, 2010		High		Low
First Quarter	\$	19.85	\$	13.78
Second Quarter	\$	17.03	\$	14.28
Third Quarter	\$	17.75	\$	15.48
Fourth Quarter	\$	16.60	\$	14.64

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

As of March 10, 2011, the number of shares of Common Stock outstanding was 28,496,078 held by approximately 154 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 Credit Agreement contains covenants prohibiting the declaration and distribution of a cash dividend at any time prior to the termination of such Credit Agreement.

Table of Contents

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, 2005 to December 31, 2010.

Comparison of 5 Year Cumulative Total Return

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

and NASDAQ Stocks (SIC 3840-3849)

	12/2005	12/2006	12/2007	12/2008	12/2009	12/2010
Merit Medical Systems, Inc.	\$ 100	\$ 130	\$ 114	\$ 148	\$ 158	\$ 130
NASDAQ Stock Market (U.S. Companies)	100	110	119	57	83	125
NASDAQ Stocks (SIC 3840-3849 U.S. Companies)	100	103	135	74	101	107

The stock performance graph assumes for comparison that the value of the Common Stock and of each index was \$100 on December 31, 2005 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.

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: Index Data: Calculated (or Derived) based from CRSP NASDAQ Stock Market (US Companies) and CRSP NASDAQ Medical Equipment, Center for Research in Security Prices (CRSP®), Graduate School of Business, The University of Chicago. Copyright 2011. Used with permission. All rights reserved.

Table of Contents

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information regarding our equity compensation plans as of December 31, 2010 (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	3,511(1),(3)	\$13.20	2,085(2),(3)

(1) Consists of 3,510,786 shares of Common Stock subject to the options granted under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(2) Consists of 311,829 shares available to be issued under the Merit Medical Systems, Inc. Qualified and Non-Qualified Employee Stock Purchase Plan and 1,772,800 shares available to be issued under the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan.

(3) See Note 11 to our consolidated financial statements set forth in Item 8 of this report for additional information regarding these plans.

Table of Contents**Item 6. Selected Financial Data (in thousands).**

	Years Ended December 31,				
	2010	2009	2008	2007	2006
OPERATING DATA:					
Net Sales	\$ 296,755	\$ 257,462	\$ 227,143	\$ 207,768	\$ 190,674
Cost of Sales	168,257	148,660	133,872	127,977	117,596
Gross Profit	128,498	108,802	93,271	79,791	73,078
Operating Expenses:					
Selling, general and administrative	87,615	64,787	53,127	48,133	45,486
Research and development	15,335	11,168	9,160	8,688	8,582
Goodwill impairment charge	8,344				
Total operating expenses	111,294	75,955	62,287	56,821	54,068
Income From Operations	17,204	32,847	30,984	22,970	19,010
Other Income (Expense):					
Interest income	34	178	781	393	250
Interest expense	(596)	(28)	(17)	(3)	(12)
Other income (expense)	146	97	97	39	(64)
Other income (expense) net	(416)	247	861	429	174
Income Before Income Taxes	16,788	33,094	31,845	23,399	19,184
Income Tax Expense	4,328	10,564	11,118	7,811	6,883
Net Income	\$ 12,460	\$ 22,530	\$ 20,727	\$ 15,588	\$ 12,301
Earnings Per Common Share:					
Diluted	\$ 0.43	\$ 0.79	\$ 0.73	\$ 0.55	\$ 0.44
Average Common Shares:					
Diluted	28,781	28,606	28,550	28,204	28,245
BALANCE SHEET DATA:					
Working capital	\$ 72,125	\$ 57,706	\$ 84,283	\$ 60,194	\$ 54,972
Total assets	369,480	271,513	231,776	200,420	182,668
Line of credit	0	7,000	0	0	0
Long-term debt	81,538	0	0	0	0
Stockholders' equity	\$ 235,615	\$ 218,809	\$ 194,305	\$ 164,368	\$ 151,212

During the quarter ended September 30, 2010, we determined that our goodwill related to our endoscopy reporting unit was impaired and we recorded an impairment charge of approximately \$8.3 million, which was offset by approximately \$3.2 million of deferred tax asset. We determined that, based on estimated future cash flows for this reporting unit, discounted back to their present value using a discount rate that reflects the risk profiles of the underlying activities, the carry value amount of this reporting unit was less than its estimated fair value. Some of the factors that influenced our estimated cash flows were slower sales growth in the products acquired from our Alveolus acquisition in March of 2009, uncertainty regarding acceptance of new products and continued operating losses for our endoscopy business segment.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

During the quarter ended December 31, 2006, we determined it was not likely that we would pursue the product associated with the intellectual property and assets acquired from Sub-Q, Inc. (Sub-Q) due to other priorities and opportunities. Therefore, we recorded an impairment charge of approximately \$929,000 during the quarter, which is included in selling, general and administrative expenses, primarily relating to intellectual property assets acquired from Sub-Q in March 2005.

Table of Contents

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operation should be read in conjunction with the Consolidated Financial Statements and related Notes thereto, which are included in this Annual Report on Form 10-K.

OVERVIEW

We design, develop, manufacture and market single-use medical products for interventional and diagnostic procedures. We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases and includes the embolotherapeutic products we acquired through our acquisition of BioSphere. Our endoscopy segment consists of gastroenterology and pulmonology medical devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

On September 10, 2010, we completed our acquisition of BioSphere in an all-cash merger transaction valued at approximately \$96 million, inclusive of all common equity and Series A preferred shares. BioSphere develops and markets embolotherapeutic products for the treatment of uterine fibroids, hypervascularized tumors and arteriovenous malformations. We believe our acquisition of BioSphere gives us a platform technology applicable to multiple therapeutic areas with significant market potential while leveraging existing interventional radiology call points. Two immediate applications for the embolotherapy are uterine fibroids and primary liver cancer.

On November 29, 2010, the FDA approved our application to perform a phase 3 clinical trial protocol to treat primary liver cancer with QuadraSphere® Microspheres (hqTACE) for delivery of doxorubicin. We anticipate over the next three to four years that we will spend approximately \$10 million to support this clinical trial. We believe if we are successful with this clinical trial, we will be the only market participant in this area with a product approved from the FDA which will allow us to take advantage of a highly profitable market.

In September 2010, we began our first direct shipments to Chinese sub-distributors from our distribution warehouse in China. With our own direct sales force in China contacting sub-distributors we have eliminated one of the distribution levels in China, which we believe will allow us to increase our sales, gross margins and net income from our product sales in China. In addition, we are making significant investments in obtaining additional regulatory licenses from the Chinese State Food and Drug Administration in an effort to expand our product offerings in China.

We have made substantial investments over the last few years in the acquisition of new products with higher gross margins. Additionally, during this same timeframe we have made significant investments in our direct sales forces in the U.S., Europe and China. In order to successfully implement our business strategy, we will need to manage our operating expenses as a percentage of sales to achieve earnings growth in future periods.

RESULTS OF OPERATIONS

The following table sets forth certain operational data as a percentage of sales for the periods indicated:

	2010	2009	2008
Net sales	100.0%	100.0%	100.0%
Gross profit	43.3	42.3	41.1
Selling, general and administrative expenses	29.5	25.2	23.4
Research and development expenses	5.2	4.3	4.0
Goodwill impairment charge	2.8		
Income from operations	5.8	12.8	13.6
Income before income taxes	5.7	12.9	14.0
Net income	4.2	8.8	9.1

Table of Contents

Listed below are the sales by business segment for the years ended December 31, 2010, 2009, and 2008 (in thousands):

	% Change	2010	% Change	2009	% Change	2008
Cardiovascular						
Stand-alone devices	16%	\$ 88,586	12%	\$ 76,075	9%	\$ 68,005
Custom kits and procedure trays	11%	82,799	12%	74,541	11%	66,584
Inflation devices	2%	62,495	(1)%	61,058	3%	61,656
Catheters	18%	44,824	23%	38,126	20%	30,898
Embolization devices		9,003				
Total	15%	287,707	10%	249,800	9%	227,143
Endoscopy						
Endoscopy devices	18%	9,048		7,662		
Total	15%	\$ 296,755	13%	\$ 257,462	9%	\$ 227,143

Our endoscopy sales for 2010 of approximately \$9.0 million, when compared to 2009 sales of approximately \$7.7 million (sales for 2009 includes only nine and one-half months), were down on an annualized basis, primarily due to the elimination of sales of certain stent procedures and sales force turnover.

Our cardiovascular sales for 2010 of approximately \$287.7 million, compared to 2009 cardiovascular sales of \$249.8 million, were up \$37.9 million or approximately 15%. This improvement was largely the result of an increase in sales of \$22.2 million, or 9.5% of sales, related to our base business (which excludes EN Snare® and embolization devices sales); our acquisition of embolization devices from BioSphere of \$9.0 million, or 3.6% of sales; and \$6.7 million, or 2.7% of sales, related to the EN Snare® products we acquired from Hatch in June of 2009. Our growth in the cardiovascular business segment was favorably affected by increased sales of our base business growth of custom kits and procedure trays of approximately \$8.3 million, or 3.3% of base business sales, catheters (particularly our Prelude® sheath product line, micro access catheter product line and new microcatheter product line) of approximately \$6.7 million, or 2.7% of base business sales, and our stand-alone devices (particularly our hemostasis valves and stopcocks) of approximately \$5.8 million, or 2.3% of base business sales (excludes \$6.7 million in EN Snare® sales). Our sales increased during 2010, 2009, and 2008 notwithstanding the fact that the markets for many of our products experienced slight pricing declines as our customers tried to reduce their costs. Substantially all of the increase in our revenues was attributable to increased unit sales. Sales by our European direct sales force are subject to foreign currency exchange rate fluctuations between the natural currency of a foreign country and the U.S. Dollar. Foreign currency exchange rate fluctuations decreased sales by 0.3% in 2010 compared to 2009; decreased sales by 1.0% in 2009 compared to 2008; and increased sales by 0.6% in 2008 compared to 2007. New products are another source of revenue growth. In 2010, 2009 and 2008, our sales of new products represented 10%, 6% and 2% of sales, respectively. Included in those sales are revenues from recent acquisitions of 3%, 3% and 1% for 2010, 2009 and 2008, respectively. The third main source of revenue increases came from market share gains in our existing product lines.

International sales in 2010 were approximately \$95.2 million, or 32% of total sales; international sales in 2009 were approximately \$86.4 million, or 34% of total sales; international sales in 2008 were approximately \$72.5 million, or 32% of total sales. The increase in 2010 was primarily related to increased sales in China, Japan, Germany and the UK. The previous increases in 2009 and 2008 primarily resulted from greater acceptance of our products in international markets, continued growth in our European direct sales, and to a lesser degree, increased sales related to improvement in the exchange rate between the Euro and the U.S. Dollar, as discussed above. Our total direct sales in France, Germany, the U.K., Belgium, The Netherlands, Denmark, Sweden, Austria, Finland and Ireland were \$29.7 million, \$26.3 million and \$27.1 million in 2010, 2009 and 2008, respectively.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Our gross profit as a percentage of sales was 43.3%, 42.3% and 41.1% in 2010, 2009 and 2008, respectively. The improvement in gross profit in 2010 was primarily the result of the addition of higher-margin EN Snare® and embolization devices (including \$1.7 million in costs related to mark-up on finished goods) acquired from Hatch and BioSphere. The improved gross profits in 2009 can be attributed primarily to lower average fixed overhead unit costs through increased productivity as fixed costs are shared over an increased number of units and a reduction in material costs. The increase in gross profits in 2008 resulted primarily from lower average fixed overhead unit costs resulting from increased production (unit costs decreased as fixed costs were shared over an increased number of units), lower unit costs for products manufactured in Mexico, customer price increases and production automation. These improvements also helped offset raw material and production labor cost increases that occurred during 2008.

Our selling, general and administrative expenses increased \$22.8 million, or 35%, in 2010 compared to 2009; \$11.7 million, or 22%, in 2009 over 2008; and \$5.0 million, or 10%, in 2008 over 2007. The increase in selling, general

Table of Contents

and administrative expenses in 2010 was largely the result of our acquisition of BioSphere in September 2010 and subsequent integration expenses (additional sales representatives, marketing support and advertising costs). In connection with the BioSphere acquisition, we had \$2.8 million in one-time severance costs and \$2.5 million in acquisition costs included in selling, general and administrative expenses. The increased selling, general and administrative expenses in 2009 were primarily due to the increased expense associated with our acquisition and operation of the business and assets acquired from Alveolus of \$5.7 million and the hiring of additional domestic and international sales representatives. Selling, general and administrative expenses as a percentage of sales increased slightly in 2008 when compared to the prior year. This increase was primarily the result of higher commissions commensurate with higher sales, management and sales bonuses for meeting quarterly and annually objectives, increased travel-related expenses and increased national account administration fees. Selling, general and administrative expenses for 2008 were also affected by approximately \$415,000 of damages (net of insurance reimbursement of \$179,000) sustained by our Angleton, Texas facility during Hurricane Ike in September 2008.

Research and development expenses increased 37% to \$15.3 million in 2010, compared to \$11.2 million in 2009. The increase in research and development expenses in 2010 was primarily the result of product development initiatives for the endoscopy business segment and embolization devices acquired from BioSphere, as well as related regulatory support. Research and development increased 22% to \$11.2 million in 2009, compared to \$9.2 million in 2008. The increase in research and development expenses in 2009 related, in large part, to research and development project expenses for the Alveolus business we acquired of \$1.1 million and to growth in our traditional organic research and development projects, some of which are nearing completion. Research and development increased 5% to \$9.2 million in 2008, compared to \$8.7 million in 2007. The increase in research and development expenses in 2008 related primarily to research and development head count additions and indirect costs to support an increase in the number of new products we launched. Our research and development expenses as a percentage of sales were 5.2% for 2010, 4.3% for 2009 and 4.0% for 2008. We have a full pipeline of new products and we believe that we have an effective level of capabilities and expertise to continue the flow of new internally-developed products into the future with higher average gross margins.

Our operating profits by business segment for the years ended December 31, 2010, 2009 and 2008 were as follows (in thousands):

	2010	2009	2008
Operating Income (Loss)			
Cardiovascular	\$ 30,176	\$ 35,836	\$ 30,984
Endoscopy	(12,972)	(2,989)	
Total operating income	\$ 17,204	\$ 32,847	\$ 30,984

Our endoscopy net operating loss from operations for 2010 was approximately \$13.0 million, compared to an operating loss of \$3.0 million for 2009. The increase in loss from operations for 2010 was primarily affected by a goodwill impairment charge of approximately \$8.3 million and approximately \$2.0 million in additional research and development expenses over 2009. The increase in research and development expense in the endoscopy segment during 2010 was principally the result of our investment in new product development to help move this business segment to profitability. We anticipate that we will launch four to five new endoscopy products during 2011.

Our cardiovascular operating income remained relatively unchanged for 2010 at approximately \$25.4 million, compared to net operating income of \$25.5 million for 2009.

Our effective income tax rates for 2010, 2009 and 2008 were 26%, 32% and 35%, respectively. The decrease in the effective income tax rate for 2010 over 2009 was largely due to the fact that our Irish operations, which are taxed at a lower income tax rate than our U.S. and other foreign operations, made up a greater portion of our 2010 consolidated income compared to 2009. The decrease in the tax rate was also due to

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

permanent tax benefits (such as certain tax credits) being applied to a lower pre-tax book income in 2010. The decrease in the effective income tax rate for 2009 over 2008 was primarily related to the profitability of our Irish operations, which are taxed at a lower income tax rate than our U.S. and other foreign operations; research and development tax credits generated from our Irish operations; and investment gains sustained in our deferred compensation that are not deductible for tax purposes. The increase in the effective income tax rate for 2008 and 2007 was primarily the result of investment losses sustained in our deferred compensation plan that are not deductible for tax purposes.

Our other income (expense) for 2010, 2009 and 2008 was approximately (\$416,000), \$247,000 and \$861,000, respectively. The increase in other expenses for 2010 over 2009 was principally the result of interest expense of

Table of Contents

approximately \$451,000 on our long-term debt incurred in connection with the acquisition of BioSphere. The decrease in other income for 2009 over 2008 was primarily the result of a decrease in interest income attributable to lower average cash balances, when compared to 2008. The increase in other income for 2008 and 2007 was primarily the result of an increase in interest income attributable to higher average cash balances and higher interest rates.

Our net income for 2010, 2009 and 2008 was approximately \$12.5 million, \$22.5 million and \$20.7 million, respectively. Net income for 2010 was unfavorably affected by the goodwill impairment of approximately \$8.3 million, or approximately \$5.2 million net of tax, related to our endoscopy reporting unit. In addition, 2010 net income was negatively affected by BioSphere acquisition costs of approximately \$2.5 million, or approximately \$1.5 million net of tax, BioSphere severance costs of approximately \$2.8 million, or approximately \$1.7 million net of tax and BioSphere's increase in the cost of goods sold related to mark-up on finished goods of approximately \$1.7 million, or approximately \$1.1 million net of tax. Net income for 2009 was favorably affected by increased sales volumes, higher gross margins and a lower effective income tax rate, all of which offset higher selling, general and administrative expenses and research and development expenses, primarily associated with our acquisition of the Alveolus assets in the first quarter of 2010. Net income for 2008 was positively affected by increased sales volumes and higher gross margins and partially offset by higher effective income tax rates.

LIQUIDITY AND CAPITAL RESOURCES**Capital Commitments and Contractual Obligations**

The following table summarizes our capital commitments and contractual obligations as of December 31, 2010, including operating lease payments and office lease payments, as well as the future periods in which such payments are currently anticipated to become due:

Contractual Obligations	Total	Payment due by period (in thousands)			
		Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	\$ 22,483	\$ 3,385	\$ 5,142	\$ 4,417	\$ 9,539
Royalty obligations	648	85	170	78	315
Total contractual cash	\$ 23,171	\$ 3,470	\$ 5,312	\$ 4,495	\$ 9,854

We have approximately \$3.5 million of unrecognized tax positions that have been recognized as liabilities that have not been included in the contractual obligations table due to uncertainty as to when such amounts may be settled.

Additional information regarding our capital commitments and contractual obligations, including royalty payments, is contained in notes 7, 9 and 13 of the notes to our consolidated financial statements, set forth in Item 8 below.

Cash Flows

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Our cash flow from operations was \$34.8 million in 2010, an increase of \$3.5 million over 2009. This increase in cash flow from operations in 2010, when compared to 2009, came primarily from an increase in non-cash amortization of intangibles from our acquisitions of Hatch and BioSphere. Our working capital for 2010, 2009 and 2008, was \$72.1 million, \$57.7 million and \$84.3 million, respectively. The increase in working capital in 2010 from 2009 was primarily the result of the acquisition of BioSphere's current assets (primarily inventory and receivables). The decrease in working capital in 2009 from 2008 was primarily the result of a decrease in cash of \$40.1 million related to our acquisition of the Alveolus assets and the EN Snare® product line. The increase in working capital for 2008 over 2007 was primarily the result of an increase in cash generated from our net income and cash generated from the issuance of shares of Common Stock related to employee stock option exercises.

During the year ended December 31, 2010, our inventory balances increased \$13.4 million, from \$47.2 million at December 31, 2009 to \$60.6 million at December 31, 2010. The increase in inventory was primarily related to our acquisition of the Biosphere's inventory of approximately \$5.7 million, higher inventory levels of approximately \$4.3 million attributable to a 9.2% increase in our base business, approximately \$2.0 million related to new product launches and approximately \$900,000 related to our new Chinese distribution warehouse and in-transit inventory used to support our direct sales efforts in China.

During the year ended December 31, 2009, our inventory balances increased by approximately \$8.8 million, from \$38.4 million at December 31, 2008 to \$47.2 million at December 31, 2009. The increase resulted from a combination of factors, including the following principal elements: a \$3.2 million increase in raw materials, work in

Table of Contents

process and finished goods inventory attributable to the products we acquired from Hydromer, Inc. (Biosearch), Hatch and Alveolus; a change in our in-transit finished goods and raw materials inventory shipping practices (from air freight to ocean freight) between our manufacturing facility in Ireland and our distribution facility in The Netherlands, which increased our in-transit finished goods and raw materials inventory levels by four weeks or approximately \$1.8 million; higher inventory levels of approximately \$3.8 million attributable to a 10% increase in our cardiovascular operating segment; and our management's decision to increase inventory levels for many of our products in order to improve product delivery time frames.

During the year ended December 31, 2008, our inventory balances increased by approximately \$4.3 million, from \$34.1 million at December 31, 2007 to \$38.4 million at December 31, 2008. This increase resulted primarily from higher inventory levels of approximately \$3.1 million attributable to a 9% increase in sales.

On September 10, 2010 we entered into the Credit Agreement with the Lenders and Wells Fargo, as administrative agent for the Lenders. As of December 31, 2010, Wells Fargo is the only bank involved in the Credit Agreement. Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of \$125 million. Wells Fargo has also agreed to make swingline loans from time to time through the maturity date of September 10, 2015 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate credit commitment. Our interest rate as of December 31, 2010 was a fixed rate of 2.73% on \$55.0 million, a fixed rate at 1.52% on \$22.0 million and a variable floating rate of 1.56% on approximately \$ 4.5 million.

On December 7, 2006, we entered into an unsecured loan agreement with Bank of America, N.A. (Bank of America), whereby Bank of America agreed to provide us a line of credit in the amount of \$30 million. Our outstanding borrowings on this line of credit as of December 31, 2010 and 2009 were \$0 million and \$7.0 million, respectively. Available borrowings under this line of credit as of December 31, 2009 were \$30 million. In connection with entering into the Credit Agreement, our unsecured line of credit with Bank of America was terminated on September 10, 2010.

On December 8, 2006, we entered into an unsecured loan agreement with Zions First National Bank (Zions), whereby Zions agreed to provide us a line of credit in the amount of \$1 million. The loan expired on December 1, 2009; however, it was extended for an additional three years to December 1, 2012 but terminated in March 2010. There were no outstanding borrowings on this loan agreement as of December 31, 2009.

Historically, we have incurred significant expenses in connection with new facilities, production automation, product development and the introduction of new products. Over the last two years, we spent a substantial amount of cash in connection with our acquisition of certain assets and product lines (\$96 million to acquire BioSphere in September of 2010 and \$46.2 million to acquire the assets of Alveolus and Hatch, among other transactions, during 2009). We plan to construct two new production facilities over the next two years, in South Jordan, Utah and Galway, Ireland, and a parking terrace in South Jordan, Utah, with total anticipated costs of \$52 million. In the event we pursue and complete similar transactions or acquisitions in the future, additional funds will likely be required to meet our strategic needs, which may require us to raise additional funds in the debt or equity markets. We currently believe that our existing cash balances, anticipated future cash flows from operations, sales of equity, and existing lines of credit and committed debt financing will be adequate to fund our current and currently planned future operations for the next twelve months and the foreseeable future.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical Accounting Policies

The SEC has requested that all registrants address their most critical accounting policies. The SEC has indicated that a critical accounting policy is one which is both important to the representation of the registrant's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We base our estimates on past experience and on various other assumptions our management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results will differ, and may differ materially from these estimates under different assumptions or conditions. Additionally, changes in accounting estimates could occur in the future from period to period. Our management has discussed the development and selection of our most critical financial estimates with the audit committee of our Board of Directors. The following paragraphs identify our most critical accounting policies:

Table of Contents

Inventory Obsolescence Reserve. Our management reviews on a quarterly basis inventory quantities on hand for unmarketable and/or slow-moving products that may expire prior to being sold. This review includes quantities on hand for both raw materials and finished goods. Based on this review, we provide a reserve for any slow-moving finished good products or raw materials that we believe will expire prior to being sold or used to produce a finished good and any products that are unmarketable. This review of inventory quantities for unmarketable and/or slow moving products is based on forecasted product demand prior to expiration lives.

Forecasted unit demand is derived from our historical experience of product sales and production raw material usage. If market conditions become less favorable than those projected by our management, additional inventory write-downs may be required. During the years ended December 31, 2010 and 2009, respectively, we provided on an annual basis an obsolescence reserve expense of between \$1.9 million to \$1.5 million and have written off against such reserves between \$1.1 million and \$1.3 million on an annual basis. Based on this historical trend, we believe that the amount included in our obsolescence reserve represents an accurate estimate of the unmarketable and/or slow moving products that may expire prior to being sold.

Allowance for Doubtful Accounts. A majority of our receivables are with hospitals which, over our history, have demonstrated favorable collection rates. Therefore, we have experienced relatively minimal bad debts from hospital customers. In limited circumstances, we have written off bad debts as the result of the termination of our business relationships with foreign distributors. The most significant write-offs over our history have come from U.S. packers who bundle our products in surgical trays.

We maintain allowances for doubtful accounts relating to estimated losses resulting from the inability of our customers to make required payments. The allowance is based upon historical experience and a review of individual customer balances. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Stock-Based Compensation. We measure share-based compensation cost at the grant date based on the value of the award and recognize the cost as an expense over the term of the vesting period. Judgment is required in estimating the fair value of share-based awards granted and their expected forfeiture rate. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Income Taxes. Under our accounting policies, we initially recognize a tax position in our financial statements when it becomes more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of tax positions that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authorities assuming full knowledge of the position and all relevant facts. Although we believe our provisions for unrecognized tax positions are reasonable, we can make no assurance that the final tax outcome of these matters will not be different from that which we have reflected in our income tax provisions and accruals. The tax law is subject to varied interpretations, and we have taken positions related to certain matters where the law is subject to interpretation. Such differences could have a material impact on our income tax provisions and operating results in the period(s) in which we make such determination.

Goodwill and Intangible Assets Impairment. We test our goodwill balances for impairment as of July 1 of each year, or whenever impairment indicators arise. We utilize several reporting units in evaluating goodwill for impairment. We assess the estimated fair value of reporting units based on discounted future cash flows. If the carrying amount of a reporting unit exceeds the fair value of the reporting unit, an impairment charge is recognized in an amount equal to the excess of the carrying amount of the reporting unit goodwill over implied fair value of that goodwill. This analysis requires significant judgments, including estimation of future cash flows and the length of time they will occur, which is based on internal forecasts, and a determination of a discount rate based on our weighted average cost of capital. During our annual test

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

of goodwill balances, which is completed during the third quarter of each year, we determined that our goodwill related to our endoscopy reporting unit was impaired. We determined that based on estimated future cash flows for this reporting unit, discounted back to their present value using a discount rate that reflects the risk profiles of the underlying activities, the carry value amount of this reporting unit was less than its estimated fair value. Some of the factors that influence our estimated cash flows were slower sales growth in the products acquired from our Alveolus acquisition in March of 2009, uncertainty regarding acceptance of new products and continued operating losses in our endoscopy business segment.

We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. This analysis requires similar significant judgments as those discussed above regarding goodwill, except that undiscounted cash flows are compared to the carrying amount of intangible assets to determine if impairment exists. All of our intangible assets are subject to amortization.

Table of Contents

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

Our principal market risk relates to changes in the value of the Euro and GBP relative to the value of the U.S. Dollar. Our consolidated financial statements are denominated in and our principal currency is, the U.S. Dollar. During the year ended December 31, 2010, a portion of our revenues (\$32.9 million, representing approximately 11% of total sales) was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Certain expenses are also denominated in foreign currencies, which partially offset risks associated with fluctuations of exchanges rates between foreign currencies on the one hand and the U.S. Dollar on the other hand. Because of our Euro and GBP-denominated revenues and expenses, in a year in which our Euro and GBP-denominated revenues exceed our Euro and GBP-based expenses, the value of such Euro and GBP-denominated net income increases if the value of the Euro and GBP increase relative to the value of the U.S. Dollar and decreases if the value of the Euro and GBP decrease relative to the value of the U. S. Dollar. During the year ended December 31, 2010, the exchange rate between our foreign currencies against the U.S. Dollar resulted in a decrease of our gross revenues of approximately \$936,000 and an increase of 0.2% in gross profit.

On November 30, 2010, we forecasted a net exposure for December 31, 2010 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 658,000 Euros and 222,000 GBPs. In order to partially offset such risks at December 31, 2010, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 658,000 Euros and notional amount of 222,000 GBPs. We enter into similar transactions at various times during the year to partially offset exchange rate risks we bear throughout the year. These contracts are marked to market at each month-end. During the years ended December 31, 2010, 2009 and 2008, we recorded a net gain on all forward contracts of approximately \$126,000, \$83,000 and \$52,000, respectively, which is included in other income (expense). We do not purchase or hold derivative financial instruments for speculative or trading purposes. The fair value of our open positions at December 31, 2010 and 2009 was not material.

As discussed in Note 10 to our consolidated financial statements, as of December 31, 2010, we had outstanding borrowings of approximately \$81.5 million under the Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. As part of our efforts to mitigate interest rate risk, on October 25, 2010, we entered into a LIBOR-based interest rate swap agreement that effectively fixed the interest rate on \$55 million of our current floating rate bank borrowings for a five-year period. The interest rate swap locked in our interest rate on the expected outstanding balance of \$55 million at 2.73%. This instrument is intended to reduce our exposure to interest rate fluctuations and was not entered into for speculative purposes. Excluding the \$55 million that is subject to a fixed rate under the interest rate swap, assuming the current level of borrowings remained the same, it is estimated that our interest expense and income before income taxes would change by approximately \$265,000 annually for each one percentage point change in the average interest rate under these borrowings.

In the event of an adverse change in interest rates, our management would likely take actions, in addition to the interest rate swap agreement discussed above, to mitigate our exposure. However, due to the uncertainty of the actions that would be taken and their possible effects, additional analysis is not possible at this time. Further, such analysis would not consider the effects of the change in the level of overall economic activity that could exist in such an environment.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Merit Medical Systems, Inc.:

We have audited the accompanying consolidated balance sheets of Merit Medical Systems, Inc. and subsidiaries (the Company) as of December 31, 2010 and 2009 and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2010. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2010 and 2009 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 1 to the consolidated financial statements in 2009, the Company adopted new accounting guidance related to business combinations.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2010, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2011, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah
March 15, 2011

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2010 AND 2009****(In thousands)**

	2010	2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,735	\$ 6,133
Trade receivables net of allowance for uncollectible accounts 2010 \$593 and 2009 \$541	37,362	30,954
Employee receivables	110	145
Other receivables	1,242	827
Inventories	60,597	47,170
Prepaid expenses and other assets	2,089	1,409
Prepaid income taxes	452	392
Deferred income tax assets	4,647	3,289
Income tax refund receivable	2,067	295
Total current assets	112,301	90,614
PROPERTY AND EQUIPMENT:		
Land and land improvements	12,586	9,777
Buildings	50,274	50,040
Manufacturing equipment	92,839	77,069
Furniture and fixtures	18,313	15,586
Leasehold improvements	12,121	10,280
Construction-in-progress	13,775	13,968
Total property and equipment	199,908	176,720
Less accumulated depreciation	(71,853)	(62,074)
Property and equipment net	128,055	114,646
OTHER ASSETS:		
Intangibles net of accumulated amortization 2010 \$8,996 and 2009 \$5,450	57,184	26,898
Goodwill	58,675	33,002
Deferred income tax assets	4,140	
Other assets	9,125	6,353
Total other assets	129,124	66,253
TOTAL	\$ 369,480	\$ 271,513

See notes to consolidated financial statements.

(Continued)

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2010 AND 2009****(In thousands)**

	2010	2009
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 20,092	\$ 13,352
Accrued expenses	18,890	12,196
Advances from employees	307	212
Line of credit		7,000
Income taxes payable	887	148
Total current liabilities	40,176	32,908
LONG-TERM DEBT	81,538	
DEFERRED INCOME TAX LIABILITIES	1,267	11,251
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	3,527	2,945
DEFERRED COMPENSATION PAYABLE	4,258	3,382
DEFERRED CREDITS	1,763	1,874
OTHER LONG-TERM OBLIGATIONS	1,336	344
Total liabilities	133,865	52,704
COMMITMENTS AND CONTINGENCIES (Notes 2, 7, 8, 9 and 13)		
STOCKHOLDERS EQUITY:		
Preferred stock 5,000 shares authorized as of December 31, 2010 and 2009; no shares issued		
Common stock, no par value; shares authorized 2010 and 2009 - 100,000; issued shares as of December 31, 2010 - 28,397 and December 31, 2009 - 28,181	67,091	63,690
Retained earnings	167,664	155,204
Accumulated other comprehensive income (loss)	860	(85)
Total stockholders equity	235,615	218,809
TOTAL	\$ 369,480	\$ 271,513

See notes to consolidated financial statements.

(Concluded)

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME****YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008****(In thousands except per share amounts)**

	2010	2009	2008
NET SALES	\$ 296,755	\$ 257,462	\$ 227,143
COST OF SALES	168,257	148,660	133,872
GROSS PROFIT	128,498	108,802	93,271
OPERATING EXPENSES:			
Selling, general, and administrative	87,615	64,787	53,127
Research and development	15,335	11,168	9,160
Goodwill impairment charge	8,344		
Total operating expenses	111,294	75,955	62,287
INCOME FROM OPERATIONS	17,204	32,847	30,984
OTHER INCOME (EXPENSE):			
Interest income	34	178	781
Interest expense	(596)	(28)	(17)
Other income	146	97	97
Other income (expense) net	(416)	247	861
INCOME BEFORE INCOME TAXES	16,788	33,094	31,845
INCOME TAX EXPENSE	4,328	10,564	11,118
NET INCOME	\$ 12,460	\$ 22,530	\$ 20,727
EARNINGS PER COMMON SHARE:			
Basic	\$ 0.44	\$ 0.80	\$ 0.75
Diluted	\$ 0.43	\$ 0.79	\$ 0.73
AVERAGE COMMON SHARES:			
Basic	28,232	28,011	27,769
Diluted	28,781	28,606	28,550

See notes to consolidated financial statements.

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY****YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008****(In thousands)**

	Total	Common Stock Shares	Common Stock Amount	Retained Earnings	Accumulated Other Comprehensive Income (Loss)
BALANCE January 1, 2008	\$ 164,368	27,413	\$ 52,477	\$ 111,947	\$ (56)
Comprehensive income:					
Net income	20,727			20,727	
Foreign currency translation adjustment	(2)				(2)
Total comprehensive income	20,725				
Tax benefit attributable to appreciation of common stock options exercised					
	2,044		2,044		
Stock-based compensation expense					
	962		962		
Issuance of common stock under Employee Stock Purchase Plans					
	305	19	305		
Warrants exercised					
	496	49	496		
Options exercised					
	5,405	612	5,405		
BALANCE December 31, 2008	\$ 194,305	28,093	\$ 61,689	\$ 132,674	\$ (58)
Comprehensive income:					
Net income	22,530			22,530	
Foreign currency translation adjustment	(27)				(27)
Total comprehensive income	22,503				
Tax benefit attributable to appreciation of common stock options exercised					
	987		987		
Stock-based compensation expense					
	1,182		1,182		
Issuance of common stock under Employee Stock Purchase Plans					
	353	24	353		
Warrants exercised					
	517	51	517		
Options exercised					
	1,920	308	1,920		
Stock repurchased and retired					
	(2,474)	(250)	(2,474)		
Shares surrendered in exchange for payment of payroll tax liabilities					
	(254)	(23)	(254)		
Shares surrendered in exchange for the exercise of stock options					
	(230)	(22)	(230)		
BALANCE December 31, 2009	\$ 218,809	28,181	\$ 63,690	\$ 155,204	\$ (85)
Comprehensive income:					
Net income	12,460			12,460	

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Interest rate swap, net of tax of \$451	708		708
Foreign currency translation adjustment	237		237
Total comprehensive income	13,405		
Tax benefit attributable to appreciation of common stock options exercised	399	399	
Stock-based compensation expense	1,294	1,294	
Issuance of common stock under Employee Stock Purchase Plans	378	25	378
Options exercised	1,330	191	1,330
BALANCE December 31, 2010	\$ 235,615	28,397	\$ 67,091 \$ 167,664 \$ 860

See notes to consolidated financial statements.

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008****(In thousands)**

	2010	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	\$ 12,460	\$ 22,530	\$ 20,727
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	14,856	12,271	10,240
Losses on sales and/or abandonment of property and equipment	533	271	526
Write-off of certain patents and license agreement	134	154	164
Goodwill impairment charge	8,344		
Amortization of deferred credits	(111)	(120)	(111)
Purchase of trading investments	(644)	(458)	(349)
Unrealized (gains) losses on trading investments	(382)	(561)	987
Deferred income taxes	(554)	1,791	(183)
Tax benefit attributable to appreciation of common stock options exercised	(399)	(987)	(2,044)
Stock-based compensation expense	1,294	1,182	962
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(2,088)	(2,131)	(1,464)
Employee receivables	29	(16)	10
Other receivables	223	(13)	304
Inventories	(7,614)	(6,882)	(4,036)
Prepaid expenses and other assets	(192)	(571)	301
Prepaid income taxes	(60)		
Income tax refund receivable	(1,573)	319	(93)
Other assets	(43)	(568)	5
Trade payables	5,643	296	758
Accrued expenses	3,090	1,628	554
Advances from employees	99		(57)
Current liabilities related to unrecognized tax benefits			(1,023)
Income taxes payable	1,037	825	1,692
Non-current liabilities related to unrecognized tax benefits	(372)	114	864
Deferred compensation payable	876	1,034	(715)
Other long-term obligations	174	(38)	(52)
Total adjustments	22,300	7,540	7,240
Net cash provided by operating activities	34,760	30,070	27,967
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures for:			
Property and equipment	(23,648)	(18,478)	(14,476)
Patents and trademarks	(1,083)	(1,191)	(432)

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Proceeds from the sale of marketable securities	9,673		
Proceeds from the sale of property and equipment	17	27	45
Cash paid in acquisitions, net of cash acquired	(97,785)	(46,150)	(5,112)
Net cash used in investing activities	(112,826)	(65,792)	(19,975)

See notes to consolidated financial statements.

(Continued)

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008****(In thousands)**

	2010	2009	2008
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	\$ 1,708	\$ 2,560	\$ 6,206
Proceeds from issuance of long-term debt	108,491		
Payments on long-term debt	(26,953)		
Borrowings on line of credit	1,500	19,000	
Payments on line of credit	(8,500)	(12,000)	
Excess tax benefits from stock-based compensation	399	987	2,044
Long-term debt issuance costs	(522)		
Payment of taxes related to an exchange of common stock		(254)	
Common stock repurchased and retired		(2,474)	
Net cash provided by financing activities	76,123	7,819	8,250
EFFECT OF EXCHANGE RATES ON CASH	(455)	6	214
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,398)	(27,897)	16,456
CASH AND CASH EQUIVALENTS:			
Beginning of year	6,133	34,030	17,574
End of year	\$ 3,735	\$ 6,133	\$ 34,030
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the year for (including capitalized interest of \$13, \$0 and \$0, respectively)	\$ 512	\$ 26	\$ 17
Interest			
Income taxes	\$ 6,050	\$ 8,215	\$ 9,853
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Property and equipment purchases in accounts payable	\$ 3,778	\$ 2,724	\$ 847
Acquisition of license agreement in accounts payable	\$ 250	\$ 0	\$ 0
Merit common stock surrendered (21,556 shares) in exchange for exercise of stock options	\$ 0	\$ 230	\$ 0

See notes to consolidated financial statements.

(Concluded)

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2010, 2009 and 2008

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization. Merit Medical Systems, Inc. designs, develops, manufactures and markets single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases and includes the embolotherapeutic products we acquired through our acquisition of BioSphere Medical, Inc. (BioSphere) as described in Note 2 below. Our endoscopy segment consists of gastroenterology and pulmonology medical devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

We manufacture our products in plants located in the United States, The Netherlands, Ireland and France. We export sales to dealers and have direct sales forces in the United States, Western Europe and China (see Note 12). Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The following is a summary of the more significant of such policies.

Use of Estimates in Preparing Financial Statements. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation. The consolidated financial statements include our wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated.

Cash and Cash Equivalents. For purposes of the statements of cash flows, we consider interest bearing deposits with an original maturity date of three months or less to be cash equivalents.

Receivables. The allowance for uncollectible accounts receivable is based on our historical bad debt experience and on management's evaluation of our ability to collect individual outstanding balances.

Inventories. We value our inventories at the lower of cost, determined on a first-in, first-out method, or market value. Market value for raw materials is based on replacement costs. Inventory costs include material, labor and manufacturing overhead. We review inventories on hand at least quarterly and record provisions for estimated excess, slow moving and obsolete inventory, as well as inventory with a carrying value in excess of net realizable value. The regular and systematic inventory valuation reviews include a current assessment of future product demand, historical experience and product expiration.

Goodwill and Intangible Assets. We test goodwill balances as of July 1 for impairment on an annual basis during the third quarter, or whenever impairment indicators arise. We utilize several reporting units in evaluating goodwill for impairment. We assess the estimated fair value of reporting units based on discounted future cash flows. If the carrying amount of a reporting unit exceeds the fair value of the reporting unit, an impairment charge is recognized in an amount equal to the excess of the carrying amount of the reporting unit goodwill over the implied fair value of that goodwill.

Table of Contents

We evaluate the recoverability of intangible assets periodically and take into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. All of our intangible assets are subject to amortization. Intangible assets are amortized on a straight-line basis, except for customer lists, which are generally amortized on an accelerated basis, over the following useful lives:

Customer lists and developed technology	5 - 15 years
Distribution agreements	5 - 11 years
License agreements and trademarks	5 - 15 years
Covenant not to compete	3 - 10 years
Patents	17 years
Royalty agreements	5 years

Long-Lived Assets. We periodically review the carrying amount of our long-lived assets for impairment. An asset is considered impaired when estimated future cash flows are less than the carrying amount of the asset. In the event the carrying amount of such asset is not considered recoverable, the asset is adjusted to its fair value. Fair value is generally determined based on discounted future cash flow. There were no impairments of long-lived assets during the years ended December 31, 2010, 2009 and 2008.

Property and Equipment. Property and equipment is stated at the historical cost of construction or purchase. Construction costs include payroll-related costs and interest costs capitalized during construction. Maintenance and repairs of property and equipment are charged to operations as incurred. Leasehold improvements are amortized over the lesser of the base term of the lease or estimated life of the leasehold improvements. Construction-in-process consists of various production equipment being constructed internally and externally. Assets in construction-in-process will commence depreciating once the asset has been placed in service. Depreciation and amortization are computed using the straight-line method over estimated useful lives as follows:

Buildings	40 years
Automobiles	4 - 7 years
Manufacturing equipment	5 - 20 years
Furniture and fixtures	3 - 10 years
Land improvements	10 - 20 years
Leasehold improvements	4 - 25 years

Deferred Compensation. We have a deferred compensation plan that permits certain management employees to defer a portion of their salary until the future. We established a Rabbi trust to finance obligations under the plan with corporate-owned variable life insurance contracts. The cash surrender value totaled approximately \$4.3 million and \$3.3 million at December 31, 2010 and 2009, respectively, which is included in other assets in our consolidated balance sheets. We have recorded a deferred compensation payable of approximately \$4.3 million and \$3.4 million at December 31, 2010 and 2009, respectively, to reflect the liability to our employees under this plan.

Other Assets. Other assets consist of our deferred compensation plan cash surrender value discussed above, an investment in a privately-held company accounted for at cost, deposits related to various leases, the fair value of an interest rate swap and a long-term income tax refund receivable.

Deferred Credits. Deferred credits consist of grant money received from the Irish government. Grant money is received for a percentage of expenditures on eligible property and equipment, specific research and development projects and costs of hiring and training employees. Amounts related to the acquisition of property and equipment are amortized as a reduction of depreciation expense over the lives of the corresponding property and equipment.

Revenue Recognition. We sell our single-use disposable medical products through a direct sales force in the U.S., through OEM relationships, custom packers and a combination of direct sales force and independent distributors in international markets. Revenues from these customers are recognized when all of the following have occurred: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable and (iv) the ability to collect is reasonably assured. These criteria are generally satisfied at the time of shipment when risk of loss and title passes to the customer. We have certain written agreements with group purchasing organizations to sell our products to participating hospitals. These agreements have destination shipping terms which require us to defer the recognition of a sale until the product has arrived at the participating hospitals. We reserve for sales returns of defective products (i.e. warranty liability) as a reduction in revenue, based on our historical experience. We also offer sales rebates and discounts to purchasing groups. These reserves are recorded as a reduction in revenue and are not considered material to our consolidated statements of income for the years ended December 31,

Table of Contents

2010, 2009 and 2008. In addition, we invoice our customers for taxes assessed by governmental authorities such as sales tax and value added taxes. We present these taxes on a net basis.

Shipping and Handling. We bill our customers for shipping and handling charges, which are included in total revenues for the applicable period and the corresponding shipping and handling expense is reported in cost of goods sold.

Cost of Sales. We include product costs (i.e. material, direct labor and overhead costs), shipping and handling expense, product royalty expense, developed technology expense, production-related depreciation expense and product license agreement expense in cost of goods sold.

Research and Development. Research and development costs are expensed as incurred.

Income Taxes. We utilize an asset and liability approach for financial accounting and reporting for income taxes. Deferred income taxes are provided for temporary differences in the basis of assets and liabilities as reported for financial statement and income tax purposes. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings, if any. We make estimates and judgments in determining the need for a provision for income taxes, including the estimation of our taxable income for each full fiscal year.

Earnings per Common Share. Net income per common share is computed by both the basic method, which uses the weighted average number of our common shares outstanding and the diluted method, which includes the dilutive common shares from stock options and warrants, as calculated using the treasury stock method.

Fair Value Measurements. The fair value of a financial instrument is the amount that could be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets are marked to bid prices and financial liabilities are marked to offer prices. Fair value measurements do not include transaction costs. A fair value hierarchy is used to prioritize the quality and reliability of the information used to determine fair values. Categorization within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. The fair value hierarchy is defined into the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

Stock-Based Compensation. We recognize the fair value compensation cost relating to share-based payment transactions in accordance with Accounting Standards Codification (ASC) 718, *Compensation - Stock Compensation*. Under the provisions of ASC 718, share-based

compensation cost is measured at the grant date, based on the fair value of the award and is recognized over the employee's requisite service period, which is generally the vesting period. The fair value of our stock options is estimated using a Black-Scholes option valuation model. Stock-based compensation expense for the years ended December 31, 2010, 2009 and 2008 was \$1.3 million, \$1.2 million and \$1.0 million, respectively.

Concentration of Credit Risk. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. We provide credit, in the normal course of business, primarily to hospitals and independent third-party packers and distributors. We perform ongoing credit evaluations of our customers and maintain allowances for potential credit losses. Sales to our single largest customer approximated 4%, 6% and 7% of total sales for the years ended December 31, 2010, 2009 and 2008, respectively.

Foreign Currency. The financial statements of our foreign subsidiaries are measured using local currencies as the functional currency, with the exception of Ireland which uses the U.S. Dollar as its functional currency. Assets and liabilities are translated into U.S. Dollars at year-end rates of exchange and results of operations are translated at average rates for the year. Gains and losses resulting from these translations are included in accumulated other comprehensive loss as a separate component of stockholders' equity. Foreign currency transactions denominated in a currency other than the entity's functional currency are included in determining net income for the period. Such foreign currency transaction gains and losses have not been significant for purposes of our financial reporting.

Derivatives. We use forward contracts to mitigate our exposure to volatility in foreign exchange rates, and we use an interest rate swap to hedge changes in the benchmark interest rate related to our Credit Agreement described in Note 7 below. All derivatives are recognized in the consolidated balance sheets at fair value. Classification of each

Table of Contents

hedging instrument is based upon whether the maturity of the instrument is less than or greater than 12 months. We do not purchase or hold derivative financial instruments for speculative or trading purposes. See Note 8.

Accumulated Other Comprehensive Income (Loss). Accumulated other comprehensive income (loss) consists of foreign currency translation adjustments and the effective portion of the gain on the derivatives accounted for as hedges, net of applicable taxes.

Recently Issued Financial Accounting Standards. In December 2010, the Financial Accounting Standards Board (FASB) issued authoritative guidance to address diversity in practice about pro forma revenue and earnings disclosure requirements. This guidance specifies that if a public entity presents comparative financial statements, the entity shall disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. This guidance also expands the supplemental pro forma disclosures to include a description of the nature and amount of material nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This guidance is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. We intend to apply this guidance to future business combinations.

In December 2010, the FASB issued authoritative guidance which modifies the requirements of step one of the goodwill impairment test for reporting units with zero or negative carrying amounts. This guidance modifies step one so that for those reporting units, an entity is required to perform step two of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. We do not expect the adoption of this guidance to have a material effect on our consolidated financial statements.

In January 2010, the FASB issued additional authoritative guidance on fair value disclosures. The new guidance clarifies two existing disclosure requirements and requires two new disclosures as follows: (1) a gross presentation of activities (purchases, sales, and settlements) within the Level 3 roll-forward reconciliation, which will replace the net presentation format; and (2) detailed disclosures about the transfers in and out of Level 1 and 2 measurements. This guidance is effective for the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll-forward information, which is required for annual reporting periods beginning after December 15, 2010, and for interim reporting periods within those years. We adopted the fair value disclosure guidance on January 1, 2010, except for the gross presentation of the Level 3 roll-forward information which we are not required to adopt until January 1, 2011. The adoption of this guidance did not have a material effect on our consolidated financial statements for the year ended December 31, 2010.

In October 2009, the FASB issued authoritative guidance that addresses whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. We will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. We do not expect the adoption of this guidance to have a material effect on our consolidated financial statements.

In June 2009, the FASB issued authoritative guidance that amends tests for variable interest entities to determine whether a variable interest entity must be consolidated. This guidance requires an entity to perform an analysis to determine whether an entity's variable interest or interests

give it a controlling financial interest in a variable interest entity. This guidance also requires ongoing reassessments of whether an entity is the primary beneficiary of a variable interest entity and enhanced disclosures that provide more transparent information about an entity's involvement with a variable interest entity. We adopted this guidance on January 1, 2010, the adoption of which did not have a material impact on our consolidated financial statements.

2. ACQUISITIONS

On September 10, 2010, we completed our acquisition of BioSphere in an all-cash merger transaction valued at approximately \$96 million, inclusive of all common equity and Series A Preferred preferences. BioSphere develops and markets embolotherapeutic products for the treatment of uterine fibroids, hypervascularized tumors and arteriovenous malformations. We anticipate that the acquisition of BioSphere will give us a platform technology applicable to multiple therapeutic areas with significant market potential while leveraging existing interventional radiology call points. Two immediate applications for the embolotherapy are uterine fibroids and primary liver cancer. The gross amount of trade

Table of Contents

receivables we acquired from BioSphere is approximately \$4.6 million, of which \$51,000 is expected to be uncollectible. Our consolidated financial statements for the year ended December 31, 2010 reflect sales subsequent to the acquisition date of approximately \$9.0 million related to our BioSphere acquisition. We report sales and operating expenses related to this acquisition in our cardiovascular segment. It is not practical to separately report the earnings related to this acquisition as we cannot split out sales costs related to Biosphere's products, principally because our sales representatives are selling multiple products in the cardiovascular business segment. The BioSphere purchase price was allocated as follows (in thousands):

Assets Acquired		
Marketable securities	\$	9,673
Trade receivables		4,529
Inventories		5,694
Other assets		1,340
Property and equipment		546
Deferred income tax assets		16,012
Intangibles		
Developed technology		19,000
Customer list		7,900
License agreement		380
Trademark		3,200
Goodwill		34,016
Total assets acquired		102,290
Liabilities Assumed		
Accounts payable		322
Accrued expenses		3,617
Deferred income tax liabilities		729
Liabilities related to unrecognized tax benefits		961
Other liabilities		936
Total liabilities assumed		6,565
Net assets acquired, net of cash acquired of \$274	\$	95,725

With respect to the assets we acquired from BioSphere, we are amortizing developed technology over 15 years and a license agreement over 10 years and customer lists on an accelerated basis over 10 years. While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of 15 years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 13.6 years.

In connection with our BioSphere acquisition, we paid approximately \$522,000 in long-term debt issuance costs to Wells Fargo Bank for our long-term debt (see Note 7). These costs consist of loan origination fees and legal costs that we intend to amortize over five years, which is the contract term of the Credit Agreement. We also incurred approximately \$2.5 million of acquisition-related costs during the year ended December 31, 2010, which are included in selling, general and administrative expense in the accompanying consolidated statements of income.

During the fourth quarter of 2010, we terminated several exclusive BioSphere sales distributor agreements in European countries where we already had previously established direct sales relationships. In connection with the termination of these agreements, we agreed to purchase customer lists from the terminated distributors. The total purchase price of the customer lists was approximately \$1.3 million and was allocated to customer lists. We are amortizing the customer lists on an accelerated basis over 10 years.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

On February 19, 2010, we entered into a manufacturing and technology license agreement with a medical device manufacturer for certain medical products. We made an initial payment of \$250,000 in February of 2010, a second payment of \$250,000 in May of 2010, a third payment of \$250,000 in November of 2010 and have accrued an additional \$250,000 in accrued expenses at December 31, 2010. The final payment is due upon reaching certain milestones set forth in the agreement. We believe it is probable that we will be required to make the final payment. We have included the \$1.0 million intangible asset in license agreements and are amortizing the asset over an estimated life of 10 years.

Table of Contents

The following table summarizes our unaudited consolidated results of operations for the years ended December 31, 2010 and 2009, as well as the unaudited pro forma consolidated results of operations as though the BioSphere acquisition had occurred on January 1, 2009 (in thousands, except per share amounts):

	Year Ended December 31, 2010		Year Ended December 31, 2009	
	As Reported	Pro Forma	As Reported	Pro Forma
Sales	\$ 296,755	\$ 317,382	\$ 257,462	\$ 288,589
Net income	12,460	7,258	22,530	17,000
Earnings per common share:				
Basic	\$.44	\$.26	\$.80	\$.61
Diluted	\$.43	\$.25	\$.79	\$.59

The unaudited pro forma information set forth above is for informational purposes only and should not be considered indicative of actual results that would have been achieved if BioSphere had been acquired the beginning of 2009, or results that may be obtained in any future period.

On October 21, 2009, we completed a transaction with Vysera Biomedical Limited, a medical products developer based in Galway, Ireland (Vysera). In the transaction, 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 Licensed Technology) and other intellectual property associated with the Licensed Technology and to develop and market improvements to the Licensed Technology. In the transaction, we also purchased 253,047 A Ordinary Shares of Vysera, for an aggregate price of approximately \$2.4 million. Under the License Agreement, we paid Vysera a license fee of \$1.5 million and agreed to pay royalties on products we sell that incorporate the Licensed Technology. The license fee of \$1.5 million has been allocated to developed technology and will be amortized over 15 years.

On June 2, 2009, we entered into an asset purchase agreement with Hatch Medical, L.L.C., a Georgia limited liability company (Hatch), to purchase assets associated with the EN Snare® foreign body retrieval system. We paid Hatch \$21.0 million as of December 31, 2009. Our consolidated financial statements for the year ended December 31, 2009 reflect royalty income subsequent to the acquisition date of approximately \$1.0 million and a net income of approximately \$210,000 related to our Hatch acquisition. The purchase price was allocated as follows (in thousands):

Assets Acquired	
Intangibles	
Developed technology	\$ 8,100
Customer list	590
Non-compete	240
Trademark	650
Goodwill	11,420
Total assets acquired	21,000
Liabilities Assumed	
	None
Net assets acquired	\$ 21,000

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

With respect to the assets we acquired from Hatch, we are amortizing developed technology over 11 years and a non-compete covenant over seven years. The acquired trademarks are scheduled to renew in 3.87 years (based on a weighted-average computation, from December 31, 2009 until the trademark renewal date). While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of 15 years from the acquisition date.

On March 9, 2009, we entered into an asset purchase agreement with Alveolus, Inc., a North Carolina corporation (Alveolus), to purchase their non-vascular interventional stents used for esophageal, tracheobronchial, and biliary stenting procedures. We paid Alveolus \$19.1 million in March 2009. The gross amount of trade receivables we acquired from Alveolus is approximately \$1.0 million, of which \$49,000 is expected to be uncollectible. Our consolidated financial statements for the year ended December 31, 2009 reflect sales subsequent to the acquisition date

Table of Contents

of approximately \$6.1 million and a net loss of approximately \$2.3 million related to our acquisition of the Alveolus assets. The purchase price was allocated as follows (in thousands):

Assets Acquired		
Inventories	\$	1,741
Trade receivables		974
Other assets		241
Property and equipment		547
Intangibles		
Developed technology		5,700
Trademarks		1,400
Customer lists		1,100
In-process research and development		400
Goodwill		8,028
Total assets acquired		20,131
Liabilities Assumed		
Accounts payable		467
Other liabilities		572
Total liabilities assumed		1,039
Net assets acquired	\$	19,092

With respect to the assets we acquired from Alveolus, we are amortizing the developed technology and trademarks over 15 years and customer lists on an accelerated basis over seven years. We intend to amortize the in-process research and development over 15 years, which will begin if the resulting product is successfully launched in the market. The acquired trademarks are scheduled to renew in 3.52 years (based on a weighted-average calculation, from December 31, 2009 until the trademark renewal date). While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of 15 years from the acquisition date.

Our in-process research and development (IPR&D) represents the value of in-process projects acquired in 2009 that have not yet reached technological feasibility and have no alternative future uses as of the date of acquisition. The primary basis for determining the technological feasibility of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. At the time of acquisition, we expect all acquired IPR&D will reach technological feasibility, but there can be no assurance that the commercial viability of these products will actually be achieved. Our IPR&D is currently not subject to amortization, but we anticipate that amortization will commence upon the related product launch.

On February 19, 2009, we entered into an asset purchase and supply agreement with Biosearch Medical Products, Inc., a New Jersey corporation (Biosearch), to purchase a bipolar coagulation probe and grafted biliary stents. We paid Biosearch \$1.1 million in February 2009 and paid Biosearch an additional \$500,000 in June 2009. Our consolidated financial statements for the year ended December 31, 2009 reflect sales subsequent to the acquisition date of approximately \$1.6 million and net income of approximately \$320,000 related to the Biosearch acquisition. The purchase price was allocated as follows (in thousands):

Table of Contents

Assets Acquired		
Inventories	\$	188
Property and equipment		31
Intangibles		
Developed technology		380
Customer lists		660
Non-compete		25
Goodwill		316
Total assets acquired		1,600
Liabilities Assumed		
		None
Net assets acquired	\$	1,600

With respect to the assets we acquired from Biosearch, we are amortizing developed technology over 15 years, customer lists on an accelerated basis over eight years and a non-compete covenant over seven years.

The following table summarizes our unaudited consolidated results of operations for the years ended December 31, 2009 and 2008, as well as the unaudited pro forma consolidated results of operations as though the Hatch, Alveolus and Biosearch transactions had occurred on January 1, 2008 (in thousands, except per share amounts):

	Year Ended December 31, 2009		Year Ended December 31, 2008	
	As Reported	Pro Forma	As Reported	Pro Forma
Sales	\$ 257,462	\$ 259,914	\$ 227,143	\$ 238,639
Net income	22,530	22,470	20,727	18,532
Earnings per common share:				
Basic	\$.80	\$.80	\$.75	\$.67
Diluted	\$.79	\$.79	\$.73	\$.65

The unaudited pro forma information set forth above is for informational purposes only and should not be considered indicative of actual results that would have been achieved if the Hatch, Alveolus and Biosearch transactions had been completed at the beginning of 2008, or results that may be obtained in any future period.

On December 11, 2008, we entered into an asset purchase agreement with Tran PA-C, Inc., a Florida corporation (Tran PA-C), to purchase catheter extraction products for \$1.5 million. We also accrued \$11,000 in acquisition costs. Additional payments totaling \$1.5 million have not been accrued as they are contingent upon reaching future certain sales levels. In addition, we agreed to a running royalty payment of 6% of net sales for the catheter extractor for the next 10 years. The purchase price was preliminarily allocated to inventories for \$71,228, property and equipment for \$15,436, customer lists for \$80,000, developed technology for \$85,000, a covenant not to compete for \$30,000, and goodwill for \$1.2 million. We are amortizing customer lists on an accelerated basis over 14 years, and developed technology over ten years. This product can be used to extract chronic dialysis catheters, similar to our ProGuide dialysis catheter purchased from Datascope Corporation, a New Jersey corporation (Datascope) in 2007.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

On January 29, 2008, we entered into an asset purchase and supply agreement with Micrus Endovascular Corporation, a Delaware corporation (Micrus), to purchase three catheter platforms for \$3.0 million. We also paid \$12,300 in acquisition costs. The purchase price was allocated to inventories for \$143,939, customer lists for \$270,000, developed technology for \$330,000, and goodwill for approximately \$2.3 million. We are amortizing customer lists on an accelerated basis over fourteen years, and developed technology over fifteen years.

The goodwill arising from the acquisitions discussed above consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations (see Note 4). The goodwill recognized from these acquisitions is expected to be deductible for income tax purposes, except for the goodwill recognized in connection with our stock acquisition of BioSphere.

Pro forma consolidated financial results for the acquisitions completed related to year ended December 31, 2008 have not been included in our consolidated financial results because their effects would not be material.

Table of Contents**3. INVENTORIES**

Inventories at December 31, 2010 and 2009, consisted of the following (in thousands):

	2010	2009
Finished goods	\$ 30,780	\$ 24,502
Work-in-process	7,012	5,542
Raw materials	22,805	17,126
Total	\$ 60,597	\$ 47,170

4. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the years ended December 31, 2010 and 2009, are as follows (in thousands):

	2010	2009
Goodwill balance at January 1	\$ 33,002	\$ 13,048
Impairment charge	(8,343)	
Additions as the result of acquisitions	34,016	19,954
Goodwill balance at December 31	\$ 58,675	\$ 33,002

During our annual test of goodwill balances, which is completed during the third quarter of each year, we determined that our goodwill related to our endoscopy reporting unit was impaired. We determined that, based on estimated future cash flows for this reporting unit, discounted back to their present value using a discount rate that reflects the risk profiles of the underlying activities, the carry value amount of this reporting unit was less than its estimated fair value. Some of the factors that influenced our estimated cash flows were slower sales growth in the products acquired from our Alveolus acquisition in March of 2009, uncertainty regarding acceptance of new products and continued operating losses in our endoscopy business segment. During the year ended December 31, 2010, we recorded an impairment charge of approximately \$8.3 million, which was offset by approximately \$3.2 million of deferred tax asset.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Table of Contents

Intangible assets at December 31, 2010 and 2009, consisted of the following (in thousands):

	Gross Carrying Amount	2010 Accumulated Amortization	Net Carrying Amount
Patents	\$ 4,631	\$ (1,445)	\$ 3,186
Distribution agreement	2,426	(641)	1,785
License agreements	1,833	(352)	1,481
Trademark	5,761	(636)	5,125
Developed technology	36,574	(2,301)	34,273
In-process research and development	400	0	400
Covenant not to compete	315	(67)	248
Customer lists	13,973	(3,287)	10,686
Royalty agreements	267	(267)	
Total	\$ 66,180	\$ (8,996)	\$ 57,184

	Gross Carrying Amount	2009 Accumulated Amortization	Net Carrying Amount
Patents	\$ 3,757	\$ (1,214)	\$ 2,543
Distribution agreement	2,400	(385)	2,015
License agreements	403	(287)	116
Trademark	2,538	(411)	2,127
Developed technology	17,513	(535)	16,978
In-process research and development	400	0	400
Covenant not to compete	315	(25)	290
Customer lists	4,755	(2,380)	2,375
Royalty agreements	267	(213)	54
Total	\$ 32,348	\$ (5,450)	\$ 26,898

Aggregate amortization expense for the years ended December 31, 2010, 2009 and 2008 was approximately \$3,546,000, \$2,342,000 and \$963,000, respectively.

Estimated amortization expense for the intangible assets for the next five years consists of the following as of December 31, 2010 (in thousands):

Year Ending December 31

2011	\$ 5,880
2012	5,280
2013	5,057

2014	4,658
2015	4,317

Table of Contents**5. INCOME TAXES**

For the years ended December 31, 2010, 2009 and 2008, income before income taxes is broken out between U.S. and foreign-sourced operations and consisted of the following (in thousands):

	2010		2009		2008
Domestic	\$ 10,551	\$	26,918	\$	28,184
Foreign	6,237		6,176		3,661
Total	\$ 16,788	\$	33,094	\$	31,845

The components of the provision for income taxes for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	2010		2009		2008
Current expense:					
Federal	\$ 3,547	\$	7,846	\$	9,693
State	595		689		1,008
Foreign	740		238		600
	4,882		8,773		11,301
Deferred expense (benefit):					
Federal	30		1,264		(133)
State	(545)		227		(44)
Foreign	(39)		300		(6)
	(554)		1,791		(183)
Total	\$ 4,328	\$	10,564	\$	11,118

The difference between the income tax expense reported and amounts computed by applying the statutory federal rate of 35.0% to pretax income for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	2010		2009		2008
Computed federal income tax expense at statutory rate of 35%	\$ 5,876	\$	11,583	\$	11,146
State income taxes	33		596		627
Tax credits	(530)		(670)		(271)
Production activity deduction	(355)		(215)		(114)
Income of subsidiaries recorded at foreign tax rates	(1,212)		(1,062)		(822)

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Tax-exempt interest income				(45)
Uncertain tax positions	(372)	114		66
Deferred compensation insurance investments	(133)	(196)		398
Transaction-related expenses	323			
Other including the effect of graduated rates	698	414		133
Total income tax expense	\$ 4,328	\$ 10,564	\$ 11,118	

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Table of Contents

Deferred income tax assets and liabilities at December 31, 2010 and 2009, consisted of the following temporary differences and carry-forward items (in thousands):

	Current		Long-Term	
	2010	2009	2010	2009
Deferred income tax assets:				
Allowance for uncollectible accounts receivable	\$ 242	\$ 221	\$	\$
Accrued compensation expense	1,184	750	2,046	1,436
Inventory capitalization for tax purposes	1,226	696		
Inventory reserves	570	540		
Net operating loss carry-forwards			26,273	
Deferred revenue			214	152
Intangible assets				420
Stock-based compensation expense			1,923	1,476
Uncertain tax positions	443	354	134	230
Other	1,475	1,055	211	
Total deferred income tax assets	5,140	3,616	30,801	3,714
Deferred income tax liabilities:				
Prepaid expenses	(493)	(327)		
Property and equipment			(18,103)	(13,873)
Intangible assets			(9,320)	
Other			(505)	(1,092)
Net	\$ 4,647	\$ 3,289	\$ 2,873	\$ (11,251)
Reported as:				
Deferred income tax assets	\$ 4,647	\$ 3,289	\$ 4,140	\$
Deferred income tax liabilities			(1,267)	(11,251)
Net	\$ 4,647	\$ 3,289	\$ 2,873	\$ (11,251)

The long-term deferred income tax balances are not netted as they represent deferred amounts applicable to different taxing jurisdictions. Deferred income tax balances reflect the temporary differences between the carrying amounts of assets and liabilities and their tax bases and are stated at enacted tax rates expected to be in effect when taxes are actually paid or recovered.

We have not provided U.S. deferred income taxes or foreign withholding taxes on the undistributed earnings of our foreign subsidiaries that are intended to be reinvested indefinitely in operations outside the United States. It is not practical to estimate the amount of additional taxes that might be payable on such undistributed earnings.

As of December 31, 2010 and 2009, we had U.S federal net operating loss carryforwards of approximately \$72.4 million and \$0, respectively, which were generated by BioSphere prior to our acquisition of BioSphere in September 2010. These net operating loss carryforwards, which expire at various dates through 2030, are subject to an annual limitation under Internal Revenue Code Section 382. We anticipate that we will utilize the net operating loss carryforwards over a period of seventeen years. During 2010, we utilized approximately \$2.6 million in U.S.

federal net operating loss carryforwards.

As of December 31, 2010 and 2009, we had non-U.S. net operating loss carryforwards of approximately \$2.8 million and \$0, respectively, which had no expiration date.

We are subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and recording the related assets and liabilities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. In our opinion, we have made adequate provisions for income taxes for all years subject to audit. Our federal

Table of Contents

and state income tax returns for 2007 through 2010 are open tax years. Our returns in several foreign tax jurisdictions have open tax years from 2005 through 2010.

Although we believe our estimates are reasonable, the final outcomes of these matters may be different from those which we have reflected in our historical income tax provisions and accruals. Such differences could have a material adverse effect on our income tax provision and operating results in the period in which we make such determination.

The total liability for unrecognized tax benefits at December 31, 2010 and 2009, including temporary tax differences, was approximately \$3.5 million and \$2.9 million, respectively, of which approximately \$2.9 million and \$2.4 million, respectively, would favorably impact our effective tax rate if recognized. As of December 31, 2010 and 2009, we accrued approximately \$651,000 and \$251,000, respectively, in interest and penalties related to unrecognized tax benefits. We account for interest expense and penalties for unrecognized tax benefits as part of our income tax provision. We do not anticipate that unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date.

During the year ended December 31, 2010, we added approximately \$582,000 to our liability for unrecognized tax benefits, of which approximately \$1.3 million would favorably impact our effective tax rate if recognized. Included in this amount is approximately \$400,000 for the year ended December 31, 2010 related to interest and penalties. In addition, we recorded an unrecognized tax benefit related to the lapse of applicable statutes of limitation of approximately \$825,000, of which approximately \$647,000 favorably impacted our effective tax rate.

During the year ended December 31, 2009, we added approximately \$127,000 to our liability for unrecognized tax benefits, of which approximately \$631,000 would favorably impact our effective tax rate if recognized. Included in this amount is approximately \$9,000 for the year ended December 31, 2009 related to interest expense. In addition, we recorded an unrecognized tax benefit related to the lapse of applicable statutes of limitation of approximately \$711,000, of which approximately \$610,000 favorably impacted our effective tax rate.

A reconciliation of the beginning and ending amount of liabilities associated with uncertain tax positions for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

Tabular Rollforward	2010	2009	2008
Unrecognized tax benefits, opening balance	\$ 2,790	\$ 2,668	\$ 3,611
Gross increases in tax positions taken in a prior year	518	163	257
Gross decreases in tax positions taken in a prior year	(51)	(40)	(278)
Gross increases in tax positions taken in the current year	520	710	547
Settlements with taxing authorities			(842)
Lapse of applicable statute of limitations	(825)	(711)	(627)
Unrecognized tax benefits, ending balance	\$ 2,952	\$ 2,790	\$ 2,668

The tabular roll-forward ending balance does not include interest expense (net of tax effect) and penalties related to unrecognized tax benefits. During the year ended December 31, 2008, we settled two open audits with the IRS related to certain temporary deductions. As a result of these settlements, we paid an additional \$2.2 million on our 2007 federal and state extension payments. The reversal of these temporary differences and the payment of the additional taxes did not have a material impact on our consolidated financial statements for the year ended December 31, 2008, as the income tax liabilities had already been accrued in our consolidated financial statements.

Table of Contents**6. ACCRUED EXPENSES**

Accrued expenses at December 31, 2010 and 2009 consisted of the following (in thousands):

	2010	2009
Payroll taxes	\$ 1,234	\$ 823
Payroll	3,708	1,557
Bonuses	2,387	2,072
Commissions	818	689
Vacation	3,792	2,616
Royalties	1,104	
Value-Added Tax	874	
Other accrued expenses	4,973	4,439
Total	\$ 18,890	\$ 12,196

7. REVOLVING CREDIT FACILITY AND LONG-TERM DEBT

We entered into an unsecured Credit Agreement, dated September 10, 2010 (the "Credit Agreement"), with the lenders who are or may become party thereto (collectively, the "Lenders") and Wells Fargo, as administrative agent for the lenders. Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of \$125 million. Wells Fargo has also agreed to make swingline loans from time to time through the maturity date of September 10, 2015 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate credit commitment.

On September 10, 2015, all principal, interest and other amounts outstanding under the Credit Agreement are payable in full. At any time prior to the maturity date, we may repay any amounts owing under all revolving credit loans and all swingline loans in whole or in part, without premium or penalty.

Revolving credit loans made under the Credit Agreement bear interest, at our election, at either (i) the base rate (described below) plus 0.25%, (ii) the London Inter-Bank Offered Rate ("LIBOR") Market Index Rate (as defined in the Credit Agreement) plus 1.25%, or (iii) the LIBOR Rate (as defined in the Credit Agreement) plus 1.25%. Swingline loans bear interest at the LIBOR Market Index Rate plus 1.25%. Interest on each loan featuring the base rate or the LIBOR Market Index Rate is due and payable on the last business day of each calendar month; interest on each loan featuring the LIBOR Rate is due and payable on the last day of each interest period selected by us when selecting the LIBOR Rate as the benchmark for interest calculation. For purposes of the Credit Agreement, the base rate means the highest of (i) the prime rate (as announced by Wells Fargo), (ii) the federal funds rate plus 0.50%, and (iii) LIBOR for an interest period of one month plus 1.0%.

The Credit Agreement contains covenants, representations and warranties and other terms, that are customary for revolving credit facilities of this nature. In this regard, the Credit Agreement requires us to maintain a leverage ratio and EBITDA ratio, consolidated net income and limits the amount of annual capital expenditures. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including, but not limited to, limitations respecting: the incurrence of indebtedness, the creation of liens on our property, mergers or

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

similar combinations or liquidations, asset dispositions, investments in subsidiaries, and other provisions customary in similar types of agreements. As of December 31, 2010, we were in compliance with all financial debt covenants set forth in the Credit Agreement.

As of December 31, 2010, we had outstanding borrowings of approximately \$81.5 million under the Credit Agreement, with available borrowings of approximately \$40.6 million, based on the leverage ratio in the terms of the Credit Agreement. Our principal purposes for entering into the Credit Agreement were to allow us to finance the acquisition of BioSphere and for general corporate purposes. Our interest rate as of December 31, 2010 was a fixed rate of 2.73% on \$55.0 million as a result of an interest rate swap (see Note 8), a fixed rate of 1.52% on \$22.0 million and a variable floating rate of 1.56% on approximately \$4.5 million.

On December 7, 2006, we entered into an unsecured loan agreement with Bank of America, whereby Bank of America agreed to provide us with a line of credit in the amount of \$30.0 million, which expired on December 7, 2010. The loan agreement required us to pay interest at a rate equal to the lesser of (i) the maximum lawful rate of interest permitted under applicable usury laws, or (ii) Bank of America's prime rate, plus a negative margin, as defined in the loan agreement. Alternatively, we could elect optional interest rates based on LIBOR during interest periods we agreed

Table of Contents

to with Bank of America. Our outstanding borrowings on this loan as of December 31, 2009 were \$7.0 million. Our interest rate as of December 31, 2009 was set at 1.0%. During the year ended December 31, 2010, all outstanding amounts were repaid and the loan agreement was terminated in September 2010.

On December 8, 2006, we entered into an unsecured loan agreement with Zions, whereby Zions agreed to provide us with a line of credit in the amount of \$1.0 million. The Zions loan agreement required us to pay interest at a rate of prime minus 0.35%. The loan agreement expired on December 1, 2009; however, it was extended for an additional three years to December 1, 2012, but terminated in March 2010. There were no outstanding borrowings on this loan as of December 31, 2009.

8. DERIVATIVES

General. Our earnings and cash flows are subject to fluctuations due to changes in interest rates and foreign currency exchange rates, and we seek to mitigate a portion of these risks by entering into derivative contracts. The derivatives we use are an interest rate swap and forward contracts. We recognize derivatives as either assets or liabilities at fair value in the accompanying consolidated balance sheets, regardless of whether or not hedge accounting is applied. We report cash flows arising from our hedging instruments consistent with the classification of cash flows from the underlying hedged items. Accordingly, cash flows associated with our derivative programs are classified as operating activities in the accompanying consolidated statements of cash flows.

We formally document, designate and assess the effectiveness of transactions that receive hedge accounting initially and on an ongoing basis. Changes in the fair value of derivatives that qualify for hedge accounting treatment are recorded, net of applicable taxes, in accumulated other comprehensive income (loss), a component of stockholders' equity in the accompanying consolidated balance sheets. For the ineffective portions of qualifying hedges, the change in fair value is recorded through earnings in the period of change. Changes in the fair value of derivatives not designated as cash flow hedges are recorded in earnings throughout the term of the derivative instrument.

Interest Rate Swap. A portion of our debt bears interest at variable interest rates and therefore, we are subject to variability in the cash paid for interest expense. In order to mitigate a portion of this risk, we use a hedging strategy to eliminate the variability of cash flows in the interest payments associated with the first \$55 million of the total variable-rate debt outstanding under our Credit Agreement that is solely due to changes in the benchmark interest rate. This strategy allows us to fix a portion of our interest payments.

On October 25, 2010, we entered into a \$55 million pay-fixed, receive-variable interest rate swap with Wells Fargo at a fixed interest rate of 2.73%. The variable portion of the interest rate swap is tied to the 1-Month LIBOR (the benchmark interest rate). The interest rates under both the interest rate swap and the underlying debt are reset, the swap is settled with the counterparty, and interest is paid, on a monthly basis. The interest rate swap expires September 10, 2015.

At December 31, 2010, the interest rate swap qualified as a cash flow hedge. During the year ended December 31, 2010, we recorded a net gain on this hedge of approximately \$20,000, which is included in interest expense in the accompanying consolidated statements of income. The fair value of our cash flow hedge at December 31, 2010 was approximately \$1.2 million, which was offset by approximately \$451,000 of deferred tax liability.

Foreign Currency Forward Contracts. On November 30, 2010, we forecasted a net exposure for December 31, 2010 (representing the difference between Euro and Great Britain Pound (GBP)-denominated receivables and Euro-denominated payables) of approximately 658,000 Euros and 222,000 GBPs. In order to partially offset such risks at November 30, 2010, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 658,000 Euros and notional amount of 222,000 GBPs. On November 30, 2009, we forecasted a net exposure for December 31, 2009 (representing the difference between Euro and GBP denominated receivables and Euro denominated payables) of approximately 331,000 Euros and 394,000 GBPs. In order to partially offset such risks at November 31, 2009, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 331,000 Euros and notional amount of 394,000 GBPs. We enter into similar transactions at various times during the year to partially offset exchange rate risks we bear throughout the year. These contracts are marked to market at each month-end. During the years ended December 31, 2010, 2009 and 2008, we recorded a net gain on all forward contracts of approximately \$126,000, \$83,000 and \$52,000, respectively, which is included in other expense in the accompanying consolidated statements of income. The fair value of our open positions at December 31, 2010 and 2009 was not material.

Table of Contents**9. COMMITMENTS AND CONTINGENCIES**

We are obligated under non-cancelable operating leases for manufacturing facilities, finished good distribution, office space and equipment. Total rental expense on these operating leases and on our manufacturing and office building for the years ended December 31, 2010, 2009 and 2008, approximated \$3.7 million, \$2.8 million and \$2.6 million, respectively.

The future minimum lease payments for operating leases as of December 31, 2010, consisted of the following (in thousands):

Years Ending December 31	Operating Leases
2011	\$ 3,385
2012	2,746
2013	2,396
2014	2,266
2015	2,151
Thereafter	9,539
Total minimum lease payments	\$ 22,483

Irish Government Development Agency Grants. As of December 31, 2010, we had entered into several grant agreements with the Irish Government Development Agency. We have recorded the grants related to research and development projects and costs of hiring and training employees as a reduction of operating expenses in 2010 and 2009 in the amounts of approximately \$40,000 and \$177,000, respectively. Grants related to the acquisition of property and equipment purchased in Ireland are amortized as a reduction to depreciation expense over lives corresponding to the depreciable lives of such property and equipment. The balance of deferred credits related to such grants as of December 31, 2010 and 2009, was approximately \$1,763,000 and \$1,874,000, respectively. During 2010, 2009 and 2008, approximately \$111,000, \$120,000 and \$111,000, respectively, of the deferred credit was amortized as a reduction of operating expenses.

We have committed to repay the Irish government for grants received if we were to cease production in Ireland prior to the expiration of the grant liability period. The grant liability period is usually between five and eight years from the last claim made on a grant. As of December 31, 2010, the total amount of grants that could be subject to refund was approximately \$2.9 million. Management does not believe we will ever have to repay any of these grant monies, as we have no intention of ceasing operations in Ireland.

Letter of Credit. As of December 31, 2010, we had a standby letter of credit with Wells Fargo in the amount of approximately \$88,000 which is related to the construction of a new building.

Litigation. In the ordinary course of business, we are involved in litigation and claims which management believes will not have a materially adverse effect on our financial position or results of operations.

10. EARNINGS PER COMMON SHARE (EPS)

The computation of weighted average shares outstanding and the basic and diluted earnings per common share for the following periods consisted of the following (in thousands, except per share amounts):

	Net Income	Shares	Per Share Amount
Year ended December 31, 2010:			
Basic EPS	\$ 12,460	28,232	\$ 0.44
Effect of dilutive stock options and warrants		549	
Diluted EPS	\$ 12,460	28,781	\$ 0.43
Year ended December 31, 2009:			
Basic EPS	\$ 22,530	28,011	\$ 0.80
Effect of dilutive stock options and warrants		595	
Diluted EPS	\$ 22,530	28,606	\$ 0.79
Year ended December 31, 2008:			
Basic EPS	\$ 20,727	27,769	\$ 0.75
Effect of dilutive stock options and warrants		781	
Diluted EPS	\$ 20,727	28,550	\$ 0.73

Table of Contents

For the years ended December 31, 2010, 2009 and 2008, approximately 878,000, 681,000 and 984,000, respectively, of stock options were not included in the computation of diluted earnings per share because their effect would have been anti-dilutive.

Repurchase of Our Common Stock. On April 30, 2007, our Board of Directors approved the repurchase of up to 1.4 million shares of Common Stock. During the first quarter of 2009, we repurchased a total of 250,158 shares of Common Stock for approximately \$2.5 million. We did not repurchase any shares of Common Stock during 2010.

11. EMPLOYEE STOCK PURCHASE PLAN STOCK OPTIONS AND WARRANTS.

Our stock-based compensation primarily consists of the following plans:

Stock Incentive Plan. During 1999, we adopted the Merit Medical Systems, Inc. Stock Incentive Plan (formerly the 1999 Omnibus Stock Incentive Plan), which provides for the issuance of incentive stock options, non-statutory stock options and certain corresponding stock appreciation rights (the Stock Incentive Plan). Options may be granted to directors, officers, outside consultants and key employees and may be granted upon such terms and such conditions as the Compensation Committee of our Board of Directors determines. Options typically vest 20% per year over either a four and one-half or five-year life with contractual lives of five, seven and ten years. The Stock Incentive Plan also provides for options that vest 100% upon grant with contractual lives of ten years. In no event, however, may the exercise price be less than the fair market value on the date of grant. Under a provision of our Stock Incentive Plan, participants are allowed to surrender shares of our Common Stock for the payment of the option price and minimum statutory taxes associated with the exercise of options. The shares surrendered must be shares the participant has held for more than six months. The value of the shares surrendered is based on the closing price of our Common Stock on the date of exercise by the participant. During 2009, approximately 224,000 of the remaining shares expired under this Stock Incentive Plan.

2006 Long-Term Incentive Plan. In May 2006, our Board of Directors adopted and our shareholders approved, the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan (the 2006 Incentive Plan). The 2006 Incentive Plan provides for the granting of stock options, stock appreciation rights, restricted stock, stock units (including restricted stock units) and performance awards. Options may be granted to directors, officers, outside consultants and key employees and may be granted upon such terms and such conditions as the Compensation Committee of our Board of Directors determines. Options will typically vest on an annual basis over a three to five year life (or one year if performance based) with contractual lives of seven to ten years. As of December 31, 2010, a total of approximately 1.8 million shares remained available to be issued under the 2006 Incentive Plan.

Employee Stock Purchase Plan. We have a qualified and a non-qualified Employee Stock Purchase Plan (ESPP), which will expire on June 30, 2016. As of December 31, 2010, the total number of shares of Common Stock that remained available to be issued under our qualified plan was approximately 241,000 shares and 71,000 shares for our non-qualified plan. ESPP participants purchase shares on a quarterly basis at a price equal to 95% of the market price of the Common Stock at the end of the applicable offering period.

Stock-Based Compensation Expense. The stock-based compensation expense before income tax expense for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

	2010		2009		2008	
Cost of goods sold	\$	201	\$	205	\$	101
Research and development		56		57		37
Selling, general, and administrative		1,037		920		824
Stock-based compensation expense before taxes	\$	1,294	\$	1,182	\$	962

We recognize stock-based compensation expense (net of a forfeiture rate) for those awards which are expected to vest on a straight-line basis over the requisite service period. We estimate the forfeiture rate based on our historical experience and expectations about future forfeitures. As of December 31, 2010, the total remaining unrecognized

Table of Contents

compensation cost related to non-vested stock options, net of forfeitures, was approximately \$3.3 million and is expected to be recognized over a weighted average period of 2.7 years.

In applying the Black-Scholes methodology to the option grants, the fair value of our stock-based awards granted were estimated using an expected annual dividend yield of 0% and the following assumptions for the periods indicated below:

	2010	2009	2008
Risk-free interest rate	2.24%	2.70%	3.24%-3.55%
Expected option life	6.0 years	6.0 years	4.2-6.0 years
Expected price volatility	41.4%	42.4%	38.0%-41.7%

The average risk-free interest rate is determined using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. We determine the expected term of the stock options using the historical exercise behavior of employees. The expected price volatility was determined using a weighted average of daily historical volatility of our stock price over the corresponding expected option life and implied volatility based on recent trends of the daily historical volatility. For options with a vesting period, compensation expense is recognized on a straight-line basis over the service period, which corresponds to the vesting period. Compensation expense is recognized immediately for options that are fully vested on the date of grant. During the years ended December 31, 2010, 2009 and 2008, 100,000, 140,000 and 499,000 stock-based compensation grants were made, respectively, for a total fair value of approximately \$705,000, \$1.0 million and \$2.5 million, net of estimated forfeitures, respectively.

The table below presents information related to stock option activity for the years ended December 31, 2010, 2009 and 2008 (in thousands):

	2010	2009	2008
Total intrinsic value of stock options exercised	\$ 1,928	\$ 2,757	\$ 6,150
Cash received from stock option exercises	1,330	1,690	5,405
Net income tax benefit from the exercises of stock options	399	987	2,044

Table of Contents

Changes in stock options for the years ended December 31, 2010, 2009 and 2008 consisted of the following (shares and intrinsic value in thousands):

	Number of Shares	Weighted Average Exercise Price	Remaining Contractual Term (in years)	Intrinsic Value
2008:				
Beginning balance	3,951			
Granted	499	\$ 14.41		
Exercised	(612)	8.85		
Forfeited/expired	(5)	18.84		
Outstanding at December 31	3,833	12.12	5.0	\$ 23,579
Exercisable	2,964	11.74	4.7	19,665
Ending vested and expected to vest	3,785	12.11	5.0	23,367
Weighted average fair value of options granted during year		\$ 5.32		
2009:				
Beginning balance	3,833			
Granted	140	\$ 17.28		
Exercised	(308)	6.60		
Forfeited/expired	(34)	15.39		
Outstanding at December 31	3,631	12.76	4.2	\$ 24,363
Exercisable	2,854	12.37	3.9	20,459
Ending vested and expected to vest	3,610	12.75	4.2	24,261
Weighted average fair value of options granted during year		\$ 6.86		
2010:				
Beginning balance	3,631			
Granted	100	\$ 16.45		
Exercised	(191)	6.28		
Forfeited/expired	(29)	14.85		
Outstanding at December 31	3,511	13.20	3.4	\$ 11,656
Exercisable	2,859	12.87	3.1	10,671
Ending vested and expected to vest	3,503	13.20	3.4	11,650
Weighted average fair value of options granted during year		\$ 7.05		

Table of Contents

On November 17, 2004, we acquired all of the assets and assumed certain liabilities of MedSource Packaging Concepts LLC (MedSource). In connection with this acquisition we issued 100,000 warrants to MedSource at a fair value of approximately \$323,000. Changes in these warrants for the years ended December 31, 2009 and 2008, consisted of the following (in thousands):

	Number of Shares	Weighted Average Exercise Price	Remaining Contractual Term (in Years)	Intrinsic Value
2008:				
Beginning balance	100			
Exercised	(49)	\$ 10.13		
Outstanding at December 31	51	10.13	0.9	\$ 369
Exercisable	51	10.13	0.9	369
2009:				
Beginning balance	51	\$ 10.13		
Exercised	(51)	10.13		
Outstanding at December 31	0	0.00	0.0	\$ 0
Exercisable	0	0.00	0.0	0

The following table summarizes information about stock options outstanding at December 31, 2010 (shares in thousands):

Range of Exercise Prices	Number Outstanding	Options Outstanding		Options Exercisable	
		Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$2.07 \$10.47	982	1.6	\$ 8.40	982	\$ 8.40
\$11.52 \$13.81	949	3.8	12.39	790	12.44
\$14.26 \$15.03	911	4.2	14.63	630	14.72
\$15.12 \$21.67	669	4.3	19.47	457	20.67
\$2.07 \$21.67	3,511			2,859	

Table of Contents**12. SEGMENT REPORTING AND FOREIGN OPERATIONS**

We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes the embolization devices we acquired through BioSphere. Our endoscopy segment consists of gastroenterology and pulmonology medical device products which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. During the year ended December 31, 2010, we determined our endoscopy segment met the quantitative thresholds for separate reporting. Prior period segment data has been presented to reflect this newly reportable segment. We evaluate the performance of our operating segments based on operating income (loss). Listed below are the sales by business segment for the years ended December 31, 2010, 2009 and 2008 (in thousands):

	% Change	2010	Year Ended December 31, % Change	2009	% Change	2008
Cardiovascular						
Stand-alone devices	16%	\$ 88,586	12%	\$ 76,075	9%	\$ 68,005
Custom kits and procedure trays	11%	82,799	12%	74,541	11%	66,584
Inflation devices	2%	62,495	(1)%	61,058	3%	61,656
Catheters	18%	44,824	23%	38,126	20%	30,898
Embolization devices		9,003				
Total	15%	287,707	10%	249,800	9%	227,143
Endoscopy						
Endoscopy devices	18%	9,048		7,662		
Total	15%	\$ 296,755	13%	\$ 257,462	9%	\$ 227,143

During the years ended December 31, 2010, 2009 and 2008, we had foreign sales of approximately \$95.2 million, \$86.4 million and \$72.5 million, respectively, or approximately 32%, 34% and 32%, respectively, of total sales, primarily in China, Japan, Germany, France and the United Kingdom. Foreign sales are attributed based on location of the customer receiving the product.

Our long-lived assets by geographic area at December 31, 2010 and 2009, consisted of the following (in thousands):

	2010	2009
United States	\$ 97,881	\$ 89,428
Ireland	22,203	17,148
Other foreign countries	7,971	8,070
Total	\$ 128,055	\$ 114,646

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Table of Contents

Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the years ended December 31, 2010, 2009 and 2008 are as follows (in thousands):

	2010		2009		2008
Revenues					
Cardiovascular	\$ 287,707	\$	249,800	\$	227,143
Endoscopy	9,048		7,662		
Total revenues	296,755		257,462		227,143
Operating expenses					
Cardiovascular	93,884		69,097		62,287
Endoscopy	9,066		6,858		
Total operating expenses	102,950		75,955		62,287
Goodwill impairment charge					
Cardiovascular					
Endoscopy	8,344				
Total goodwill impairment charge	8,344				
Operating income (loss)					
Cardiovascular	30,176		35,836		30,984
Endoscopy	(12,972)		(2,989)		
Total operating income (loss)	17,204		32,847		30,984
Total other income (expense) - net	(416)		247		861
Income tax expense	4,328		10,564		11,118
Net income	\$ 12,460	\$	22,530	\$	20,727

Total assets by business segment at December 31, 2010 and 2009, consisted of the following (in thousands):

	2010		2009
Cardiovascular	\$ 355,718	\$	249,726
Endoscopy	13,762		21,787
Total	\$ 369,480	\$	271,513

Total depreciation and amortization by business segment for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	2010		2009		2008
Cardiovascular	\$ 13,851	\$	11,406	\$	10,240
Endoscopy	1,005		865		
Total	\$ 14,856	\$	12,271	\$	10,240

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Total capital expenditures by business segment for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	2010	2009	2008
Cardiovascular	\$ 23,494	\$ 18,475	\$ 14,476
Endoscopy	154	3	
Total	\$ 23,648	\$ 18,478	\$ 14,476

Table of Contents

13. ROYALTY AGREEMENTS

Pursuant to a 1992 settlement agreement, we entered into a license agreement with another medical product manufacturer (the Licensor), whereby the Licensor granted to us a nonexclusive right and license to manufacture and sell products which are subject to the patents issued to the Licensor. The license agreement terminated in August 2008 upon the expiration of the last related patent. For the rights and license granted under the agreement, we paid the Licensor a nonrefundable prepaid royalty in the amount of \$600,000. In addition to the prepaid royalty, we agreed to pay the Licensor a continuing royalty of 5.75% of sales (which will not exceed \$450,000 for any calendar year) made in the United States, of products covered by the license agreement. Royalties of \$450,000 were paid or accrued for the year ended December 31, 2008.

During 2006, in connection with the purchase of the Futura® safety scalpel product line from Hypoguard USA, Inc. we acquired a license agreement with Innovative Surgical Technology, Inc. (IST) whereby IST granted to us an exclusive worldwide license to manufacture and sell products which are subject to the patents issued to IST. For the rights and license granted under the agreement, we agreed to pay the IST a royalty of 4% of net sales, with annual minimum royalty payments of \$144,000 for calendar years 2008 through 2014 and \$108,000 for 2015. During the years ended December 31, 2009 and 2008, we paid or accrued a royalty of \$108,000 and \$144,000, respectively, under this license agreement. During January 2009, we negotiated to purchase from IST the patents related to this product for \$432,000. The patent will amortize over the remaining life of the patents, which is approximately five and one-half years. In connection with the purchase of the patents, IST forgave royalties payable for the three months ended December 31, 2008 in the amount of \$36,000 and our royalty obligation for periods subsequent to December 31, 2009 was terminated.

During 2007, in connection with the purchase of the ProGuide chronic dialysis catheter from Datascope, we entered into a running royalty agreement as partial consideration of the assignment of acquired intellectual property to us. Under this agreement, we agreed to pay Datascope a royalty of 5% of net sales, with annual minimum royalty payments of \$50,000 for calendar years 2009 through 2013. During each of the years ended December 31, 2010, 2009 and 2008, we paid or accrued a royalty of \$50,000 under this agreement.

During 2010, in connection with our acquisition of BioSphere, we entered into a running royalty agreement as part of a partnership between BioSphere and L'Assistance Publique-Hôpitaux de Paris, referred to as AP-HP, pursuant to which AP-HP has granted us the exclusive license to use two United States patents and their foreign counterparts that we jointly own with AP-HP relating to microspheres. We are required to pay to AP-HP a royalty on the commercial sale of any products that incorporate technology covered by the patents. We may sublicense these exclusive rights under the agreement only with the prior written consent of AP-HP, which consent cannot be unreasonably withheld. Under the terms of the royalty agreement our exclusive license extends for the duration of both (i) the jointly owned U.S. and foreign counterpart patents which will expire in 2014 and 2012, respectively, and (ii) the products and specialties implementing the patents. On January 26, 2010, BioSphere filed patent applications which, if issued, will extend the royalty payments until approximately January 2031. The royalty rate in the agreement is 5% of net sales until the patents expire, and 2.5% of net sales thereafter as long as the product is sold. We paid or accrued approximately \$401,000 in royalty payments to AP-HP for the year ended December 31, 2010 after the BioSphere acquisition.

14. EMPLOYEE BENEFIT PLANS

We have a contributory 401(k) savings and profit sharing plan (the Plan) covering all U.S. full-time employees who are at least 18 years of age. The Plan has a 90 day minimum service requirement. We may contribute, at our discretion, matching contributions based on the employees compensation. Contributions we made to the Plan for the years ended December 31, 2010, 2009 and 2008, totaled approximately \$1.2 million, \$833,000 and \$0, respectively. We have defined contribution plans covering some of our foreign employees. We contribute between three and 36% of the employee's compensation for certain foreign non-management employees, between ten and 36% of the employee's compensation for

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

certain foreign management employees. Contributions made to these plans for the years ended December 31, 2010, 2009 and 2008, totaled approximately \$565,000, \$550,000 and \$541,000, respectively.

Table of Contents**15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

Quarterly data for the years ended December 31, 2010, 2009 and 2008, consisted of the following (in thousands, except per share amounts):

	March 31	June 30	September 30	December 31
2010				
Net sales	\$ 67,432	\$ 74,948	\$ 73,172	\$ 81,203
Gross profit	28,435	32,458	31,247	36,358
Income (loss) from operations	6,346	8,777	(3,442)	5,523
Income tax expense (benefit)	1,822	3,124	(1,539)	921
Net income (loss)	4,508	5,715	(1,973)	4,210
Basic earnings (loss) per common share	0.16	0.20	(0.07)	0.15
Diluted earnings (loss) per common share	0.16	0.20	(0.07)	0.15
2009				
Net sales	\$ 58,371	\$ 64,837	\$ 66,759	\$ 67,495
Gross profit	24,808	28,143	28,535	27,316
Income from operations	7,900	8,963	8,463	7,521
Income tax expense	2,537	3,144	2,349	2,534
Net income	5,537	5,841	6,085	5,067
Basic earnings per common share	0.20	0.21	0.22	0.18
Diluted earnings per common share	0.19	0.20	0.21	0.18
2008				
Net sales	\$ 53,553	\$ 57,441	\$ 58,153	\$ 57,996
Gross profit	21,592	24,502	23,684	23,493
Income from operations	6,604	9,009	7,169	8,202
Income tax expense	2,432	3,337	2,198	3,151
Net income	4,317	5,818	5,200	5,392
Basic earnings per common share	0.16	0.21	0.19	0.19
Diluted earnings per common share	0.15	0.21	0.18	0.19

Basic and diluted earnings (loss) per share are computed independently for each of the quarters presented. Therefore, the sum of the quarterly amounts may not equal the total computed for the year.

16. FAIR VALUE MEASUREMENTS

Our financial assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2010 consisted of the following (in thousands):

Description	Total Fair Value at December 31, 2010	Quoted prices in active markets (Level 1)	Fair Value Measurements Using	
			Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate swap (1)	\$ 1,159	\$	\$ 1,159	\$

(1) The fair value of the interest rate swap is determined based on forward yield curves.

Table of Contents

There were no financial assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2009.

During the years ended December 31, 2010, 2009 and 2008, we had losses of approximately \$8,478,000, \$154,000, \$164,000, respectively, related to the measurement of non-financial assets at fair value on a nonrecurring basis subsequent to their initial recognition. Of the total loss in 2010, approximately \$8,344,000 was related to the impairment of our goodwill related to our endoscopy reporting unit (see Note 4). The fair value of these non-financial assets was measured using Level 3 inputs. As of December 31, 2010, there was no goodwill remaining in our consolidated financial statements related to the endoscopy reporting unit.

The carrying amount of cash and cash equivalents, receivables, and trade payables approximates fair value because of the immediate, short-term maturity of these financial instruments. The carrying amount of long-term debt approximates fair value, as determined by borrowing rates estimated to be available to us for debt with similar terms and conditions.

SUPPLEMENTARY FINANCIAL DATA

The supplementary financial information required by Item 302 of Regulation S-K is contained in Note 14 to our consolidated financial statements set forth above.

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

None.

Item 9A. Controls and Procedures.

DISCLOSURE CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 as of December 31, 2010. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those written policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Merit
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles in the United States of America
- Provide reasonable assurance that our receipts and expenditures are being made only in accordance with authorization of our management and directors
- Provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of assets that could have a material effect on the consolidated financial statements

Internal control over financial reporting includes the controls themselves, monitoring and internal auditing practices and actions taken to correct deficiencies as identified. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to

Table of Contents

future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on those criteria and management's assessment, we believe that, as of December 31, 2010, our internal control over financial reporting is effective.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

During the fiscal quarter ended December 31, 2010, there has been no change in internal control over financial reporting that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

Our independent registered public accountants have also issued an audit report on our internal control over financial reporting. This report appears below.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Merit Medical Systems, Inc.

We have audited the internal control over financial reporting of Merit Medical Systems, Inc. and subsidiaries (the Company) as of December 31, 2010, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2010, of the Company and our report dated March 15, 2011 expressed an unqualified opinion on those financial statements and financial statement schedule and included an explanatory paragraph regarding the adoption of new accounting guidance.

/s/ DELOITTE & TOUCHE LLP

Salt Lake City, Utah

March 15, 2011

Table of Contents

Item 9B. Other Information.

None.

PART III

Items 10, 11, 12, 13 and 14.

These items are incorporated by reference to our definitive proxy statement relating to our Annual Meeting of Shareholders scheduled for May 27, 2011. We anticipate that our definitive proxy statement will be filed with the SEC not later than 120 days after December 31, 2010, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this Report:

(1) Financial Statements. The following consolidated financial statements and the notes thereto, and the Reports of Independent Registered Public Accounting Firm are incorporated by reference as provided in Item 8 and Item 9A of this report:

Report of Independent Registered Public Accounting Firm Internal Control

Report of Independent Registered Public Accounting Firm Financial Statements

Consolidated Balance Sheets as of December 31, 2010 and 2009

Consolidated Statements of Income for the Years Ended December 31, 2010, 2009 and 2008

Consolidated Statements of Stockholders Equity for the Years Ended December 31, 2010, 2009 and 2008

Consolidated Statements of Cash Flows for the Years Ended December 31, 2010, 2009 and 2008

Notes to Consolidated Financial Statements

Table of Contents(2) Financial Statement Schedule.

Schedule II - Valuation and qualifying accounts

YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008

(In thousands)

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses (a)	Deduction (b)	Balance at End of Year
ALLOWANCE FOR UNCOLLECTIBLE ACCOUNTS:				
2008	(497)	(139)	131	(505)
2009	(505)	(214)	178	(541)
2010	(541)	(193)	141	(593)

(a) The Company records a bad debt provision based upon historical experience and a review of individual customer balances.

(b) When an individual customer balance becomes impaired and is deemed uncollectible a deduction is made against the allowance for uncollectible accounts.

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses (c)	Deductions (d)	Balance at End of Year
RESERVE FOR INVENTORY OBSOLESCENCE:				
2008	(2,335)	(1,096)	1,170	(2,261)
2009	(2,261)	(1,469)	1,297	(2,433)
2010	(2,433)	(1,949)	1,086	(3,296)

(c) The Company writes down its inventory for estimated obsolescence for unmarketable and/or slow moving products that may expire prior to being sold.

(d) When a previously reserved for inventory item is either disposed of or sold the Company records a deduction to its reserve for obsolescence inventory.

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Table of Contents

(b) Exhibits:

The following exhibits required by Item 601 of Regulation S-K are filed herewith or have been filed previously with the SEC as indicated below:

	Description	Exhibit No.
2.1	Agreement and Plan of Merger dated May 13, 2010 by and among Merit Medical Systems, Inc., Merit BioAcquisition Co., and BioSphere Medical, Inc.*	[Form 8-K filed May 13, 2010, Exhibit 2.1]
3.1	Articles of Incorporation as amended and restated*	[Form 10-Q filed August 14, 1996, Exhibit No. 1]
3.2	Bylaws*	[Form S-18 filed October 19, 1989, Exhibit No. 2]
3.3	Amended and Restated Bylaws*	[Form 10-Q filed November 8, 2007, Exhibit No. 3.3]
4	Specimen Certificate of the Common Stock*	[Form S-18 filed October 19, 1989, Exhibit No. 10]
4.3	Articles of Amendment of the Articles of Incorporation dated May 14, 1993*	[Form S-3 filed February 14, 2005, Exhibit 4.3]
4.4	Articles of Amendment to Articles of Incorporation dated June 6, 1996*	[Form S-3 filed February 14, 2005, Exhibit 4.4]
4.5	Articles of Amendment to Articles of Incorporation dated June 12, 1997*	[Form S-3 filed February 14, 2005, Exhibit 4.5]
4.7	Articles of Amendment to the Articles of Incorporation dated May 22, 2003*	[Form S-3 filed February 14, 2005, Exhibit 4.7]
4.8	Articles of Amendment to the Articles of Incorporation dated May 23, 2008*	[Form 8-K filed May 28, 2008, Exhibit 3.1]
10.1	Merit Medical Systems, Inc. Long Term Incentive Plan (as amended and restated) dated March 25, 1996*	[Form 10-Q filed August 14, 1996, Exhibit No. 2]
10.2	Merit Medical Systems, Inc. 401(k) Profit Sharing Plan (as amended effective January 1, 1991)*	[Form S-1 filed February 14, 1992, Exhibit No. 8]
10.3	License Agreement, dated April 8, 1992 with Utah Medical Products, Inc.*	[Form S-1 filed February 14, 1992, Exhibit No. 5]
10.4	Lease Agreement dated as of June 8, 1993 for office and manufacturing facility*	[Form 10-K for year ended December 31, 1994, Exhibit No. 10.4]
10.12	Amended and Restated Deferred Compensation Plan*	[Form 10-K for year ended December 31, 2003, Exhibit No. 10.12]

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

- | | | |
|-------|--|---|
| 10.13 | Purchase Agreement dated November 17, 2004 between Merit Medical Systems, Inc. and MedSource Packaging Concepts LLC* | [Form 10-K for year ended December 31, 2004, Exhibit No. 10.13] |
| 10.17 | Unsecured Loan Agreement with Bank of America, N.A.* | [Form 8-K filed December 7, 2006, Exhibit 10.1] |

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

Table of Contents

10.18	Seventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 10-K for year ended December 31, 2006, Exhibit No. 10.18]
10.19	Stock Purchase Agreement by and between Merit Medical Systems, Inc. and Sheen Man Co. LTD, dated April 1, 2007*	[Form 10-Q filed May 9, 2007, Exhibit No. 10.19]
10.20	Eighth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.20]
10.21	Ninth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.21]
10.22	Tenth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 10-K for year ended December 31, 2007, Exhibit No. 10.22]
10.23	Merit Medical Systems, Inc. Amended and Restated Deferred Compensation Plan, effective January 1, 2008*	[Form 8-K filed December 18, 2008, Exhibit 10.1]
10.29	Eleventh Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 10-K for year ended December 31, 2008, Exhibit No. 10.29]
10.30	Twelfth Amendment to the First Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 10-K for year ended December 31, 2008, Exhibit No. 10.30]
10.31	Second Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan*	[Form 8-K filed May 27, 2009, Exhibit 10.1]
10.32	Second Restatement of the Merit Medical Systems, Inc. 401(k) Profit Sharing Plan*	[Form 8-K filed January 7, 2010, Exhibit 10.1]
10.33	Stockholder and Voting Agreement, dated as of May 13, 2010, among Merit Medical Systems, Inc., Cerberus Partners, L.P. and Cerberus International, Ltd.*	[Form 8-K/A filed May 14, 2010, Exhibit 10.1]
10.34	Amendment No. 1 to Stockholder and Voting Agreement, dated as of June 1, 2010, among Merit Medical Systems, Inc., Cerberus Partners, L.P. and Cerberus International, Ltd. *	[Form 8-K filed June 2, 2010, Exhibit 10.2]
10.35	Credit Agreement dated as of September 10, 2010 by and among Merit Medical Systems, Inc. and Wells Fargo Bank, National Association*	[Form 8-K/A filed September 16, 2010, Exhibit 10.1]

Table of Contents

10.36	Amended and Restated Employment Agreement of Fred P. Lampropoulos dated December 30, 2010	Filed herewith
10.37	Amended and Restated Employment Agreement of Kent Stanger dated December 30, 2010	Filed herewith
10.38	Amended and Restated Employment Agreement of Marty Stephens dated December 30, 2010	Filed herewith
10.39	Amended and Restated Employment Agreement of Rashelle Perry dated December 30, 2010	Filed herewith
10.40	Amended and Restated Employment Agreement of Arlin D. Nelson dated December 30, 2010	Filed herewith
21	Subsidiaries of Merit Medical Systems, Inc	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Certification of Chief Executive Officer	Filed herewith
31.2	Certification of Chief Financial Officer	Filed herewith
32.1	Certification of Chief Executive Officer	Filed herewith
32.2	Certification of Chief Financial Officer	Filed herewith

* These exhibits are incorporated herein by reference.

Indicates management contract or compensatory plan or arrangement.

(c) Schedules:

None

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on March 15, 2011.

MERIT MEDICAL SYSTEMS, INC.

By: /s/ FRED P. LAMPROPOULOS
Fred P. Lampropoulos, President and
Chief Executive Officer

ADDITIONAL SIGNATURE AND POWER OF ATTORNEY

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 15, 2011. In addition, each person whose signature to this report appears below hereby constitutes and appoints Fred P. Lampropoulos and Kent W. Stanger, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution, to sign on his behalf individually and in the capacity stated below and to perform any acts necessary to be done in order to file all amendments and post-effective amendments to this report, and any and all instruments or documents filed as part of or in connection with this report or the amendments thereto and each of the undersigned does hereby ratify and confirm all that said attorney-in-fact and agent, or his substitutes, shall do or cause to be done by virtue hereof.

Signature	Capacity in Which Signed
/s/: FRED P. LAMPROPOULOS Fred P. Lampropoulos	President, Chief Executive Officer and Director (Principal executive officer)
/s/: KENT W. STANGER Kent W. Stanger	Chief Financial Officer, Secretary, Treasurer and Director (Principal financial and accounting officer)
/s/: RICHARD W. EDELMAN Richard W. Edelman	Director
/s/: REX C. BEAN Rex C. Bean	Director
/s/: JAMES J. ELLIS James J. Ellis	Director

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-K

/s/ MICHAEL E. STILLABOWER
Michael E. Stillabower

Director

/s/ FRANKLIN J. MILLER
Franklin J. Miller

Director